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BDO LIFE SCIENCES LETTER



AS DRUG PRICE SCRUTINY RISES, PRESSURE BUILDS TO DEFINE VALUE

An interview between Ryan Starkes, partner and leader of the BDO Life Sciences Practice, and Dr. David Friend, Chief Transformation Officer at The BDO Center for Healthcare Excellence & Innovation

Drug pricing is one of today's most hotly debated and deeply complex topics, influencing and being influenced by the healthcare and pharmaceutical industries' paradigm shift from fee-for-service to value-based care and reimbursement.

This shift in how the system pays for drugs and patient care has enormous ramifications on business models across the entire healthcare industry, including biotech companies, big pharma and drug manufacturers. In this Q&A, Ryan Starkes sits down with his colleague Dr. David Friend, who advises both drug developers

and healthcare providers on pricing, quality measurement metrics and validation, to dig into the roots of the drug pricing issue and how the market is changing.

Mr. Starkes: *Drug companies are under attack for what is seen as exorbitant pricing on new drugs, or for raising prices dramatically on drugs that have been in the market a while. Why are we seeing this scrutiny now?*

Dr. Friend: The heart of the drug pricing debate centers on value. Warren Buffet has a favorite phrase: "Price is what you pay, and value is what you get." Looking at price in isolation doesn't give you the full story

DID YOU KNOW...

[Moody's](#) recently lowered its expectations for global pharmaceutical industry growth to 3-4 percent, adjusted down from its previously announced outlook of 4-5 percent.

In 2015, 35 percent of the 170 total IPOs were in the biotech sector, according to [Renaissance Capital](#). In January 2016, no companies went public—in any industry.

The \$160 billion deal between Allergan and Pfizer announced in November 2015 is the largest merger in the pharmaceutical sector on record, according to [Bloomberg](#).

The [U.S. Food and Drug Administration's Center for Drug Evaluation and Research](#) approved 45 novel drugs in 2015, up from 41 in 2014 and 27 in 2013. This was the highest number of approvals in 19 years.

Research from [Gartner](#) suggests that process improvements and data standards could save the life sciences industry between \$5.8 to \$6.6 billion annually.

CONTINUED FROM PAGE 1

DRUG PRICE SCRUTINY

on a drug's value. But until now, there has really been no market pressure for drug manufacturers to demonstrate their value or for physicians to prescribe medications based on value.

While it's standard practice in practically every other industry, this explicit tying of a payment to an outcome is new in healthcare, prompted in part by unsustainable costs, the Affordable Care Act and other factors. We're seeing drug manufacturers in the news as part of a much bigger conversation about healthcare pricing. And we have the added "Edward Snowden" effect of Martin Shkreli who, if inadvertently, brought attention to what has always been publicly visible, but never really discussed: How do we price? The opaque system has provided significant opportunity for many participants to maximize their profits. With as much sunlight as is now on this, organizations must understand and explain their pricing strategies much better.

That's going to have a significant impact on health businesses' earnings power going forward. So, it's incumbent upon everyone in the space who invests, who works in the companies, who has any kind of financial interest, to understand these changes in both the pricing and reimbursement landscapes.

Mr. Starkes: *How does the changing healthcare reimbursement environment relate to drug pricing?*

Dr. Friend: The healthcare system is moving more aggressively toward reimbursing healthcare providers based on their performance. The Center for Medicare & Medicaid Services (CMS), which is one of the system's biggest payers, spending trillions of dollars, is setting the tone. Their objective is to drive healthcare costs down and improve the quality of care, which is leading to more standardized care and a focus on best practices. How does this play out with prescription drugs? If there is a "best drug" for an illness, it's more likely that it will be favored by CMS and other commercial insurance payers, and less effective drugs won't be reimbursed.

This shift toward performance, or value-based payments, has an enormous impact

on pricing across the entire healthcare spectrum. Drug manufacturers must be able to justify why they are charging more than other competitors for certain drugs in order to stand up to the scrutiny coming from multiple directions. How does a drug perform against competitors? What value will payers and consumers put on that difference? How can you get a significant and fair return for shareholders? There is not going to be as much room for second best, mostly because no one ever took the time before to measure what was best and validate why.

Mr. Starkes: *How are organizations attempting to measure value?*

Dr. Friend: There's no scale that says what's best, or what's value. It's still a debate up for grabs. We think there's a lot of opportunity for organizations to think about the value propositions they bring. Value is determined by a variety of players—consumers, institutions that manage and produce care, drug manufacturers, investors—and their points of view are constantly evolving.

One of the many ways to think about value is through outcomes. Consider hepatitis medications, which have come under scrutiny for their expense. Let's say a patient is charged \$100,000. That's an extremely high price, but what if the pill permanently cures hepatitis? Society might otherwise spend \$1 million or more for that patient's treatment over their lifetime. In that context, is \$100,000 a good value?

What about the value of a drug that minimizes side effects, or is easier to administer? The FDA already has a very involved process to validate drug effectiveness and safety. How will drug manufacturers further validate that their product has greater value than another product to justify its price?

It's a challenge to everybody along the healthcare supply chain because you have to get it right. Your premise for your price is becoming contingent on what you're saying the outcome is, and those outcomes can be looked at retrospectively by authorities. If you say, "Our drug should command a higher price because the readmission rate is lower," someone will be able to verify that and

hold you to it. We're seeing more and more enterprises demanding specific performance guarantees from their vendors and penalizing them when they're not met.

Organizations are going to have to continuously monitor performance to prove their value as new competitors enter the market, and to justify their costs as regulators and others compare their performance claims with outcomes. Measurement will have to be built into the core business and into the economics of pricing. The finance group will likely be tasked with not only measuring and monitoring financial data, but clinical data as well. As dollar payments become explicitly linked to clinical reported outcomes, there will also be a need for someone within organizations to verify the accuracy of the clinical data.

And measurement, again, takes us directly back to business value. If your product creates a lot of value and you can demonstrate that, you should be thinking about how to get a significant and fair return for your shareholders. That may mean that your prices should in fact increase. On the other hand, if your product is really not as good as your competitor's, it may not be enough to lower the price. You may be excluded entirely from the network. If I make the cheapest jet engines out there but they catch fire every couple of hours, Boeing is never going to put my product on their plane.

Mr. Starkes: *Many drug providers attribute costs to research and development. How will these new pricing factors impact drug innovation?*

Dr. Friend: We are really in a golden age of science as far as our ability to create new medications, but it's extremely expensive to do so, and we believe that roughly 9 out of 10 products that are attempted, fail. Investors need to be able to get a sufficient return to absorb nine failures for that one success.

Pricing, then, is also a function of how much innovation we want as a society. The more the market is willing to pay for drugs, the more money there is to put toward taking risks to innovate. U.S. citizens are paying higher prices than anyone else in the world for medications because we're paying for

CONTINUED FROM PAGE 2

DRUG PRICE SCRUTINY

innovation that benefits the rest of the world. How much are we willing to pay? How do companies recoup the investment they made across 10 products to get one successful one? One lever we can pull is price; another is patent length.

Mr. Starkes: *Are investors comfortable with such a high level of risk taking, given the current environment?*

Dr. Friend: There is still tremendous opportunity in healthcare and life sciences. However, it's absolutely critical for investors to understand what's happening with pricing and reimbursement, because they are central to driving earnings. Over the next 10 years, there will be around \$10 trillion of value created in healthcare, but \$4 trillion will also be destroyed. Investors on the winning end will be those with a much better handle on pricing.

Smart investors have to evaluate the value proposition that a company brings. If a company can generate superior outcomes, it needs to be able to tell that story in an economic way and in a clinical way to justify their price and generate shareholder returns. On the other hand, there must be an understanding of how companies respond to having products lower down the value-chain profile—will the price of the drug be lowered? Will the company only charge people for whom the drug was effective?

New questions will be introduced in healthcare and life sciences in coming years that are common in other industries but which haven't been asked of these sectors before.

This Q&A originally appeared in the BDO Knows Healthcare blog. The original post can be viewed [here](#).



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THE FIGHT AGAINST BRIBERY IN PHARMA: WHAT YOU NEED TO KNOW NOW

By Ryan Starkes, Glenn Pomerantz and Nina Gross



Over the past several years, the pharmaceutical industry has become subject to heightened attention in the face of the U.S. government's prosecution against global bribery and corruption.

Under the Foreign Corrupt Practices Act (FCPA), U.S. authorities have investigated and subsequently charged some of the largest multinational pharmaceutical companies with international bribery violations, including Pfizer, Eli Lilly and Johnson & Johnson, to name a few. Just last month, SciClone Pharmaceuticals agreed to pay \$12 million to settle FCPA charges.

It isn't just the U.S. government cracking down on big pharma, however. Under the Bribery Act of 2010, the U.K.'s Serious Fraud Office (SFO) has initiated actions against the pharmaceutical sector. For example, in May 2014, the SFO launched a formal criminal investigation into the commercial practices of GlaxoSmithKline following cases of alleged bribery in other jurisdictions, including China. Chinese authorities, too, have escalated

their anti-corruption probes of multinational pharmaceutical giants, also targeting AstraZeneca and Novartis, among others. The recent success of cross-border investigations will likely lead to even greater cross-border cooperation and information sharing by regulatory authorities.

In the United States, both the Department of Justice (DOJ) and Securities and Exchange Commission (SEC) have made clear their intentions to target FCPA violations in the pharmaceutical industry. Most recently, the SEC outlined its intentions to aggressively pursue pharma FCPA violations in a [March 2015 speech](#), highlighting three areas of misconduct that most frequently arise in bribery investigations. The SEC is zeroing in on "pay-to-prescribe" bribes, in which informal payments are made to healthcare professionals of government or state-owned companies in exchange for their recommendation of a specific medication or medical device. A second form of bribery that commonly arises is incentives to include a company's products on a formulary or approved device list. The third and final form of bribery the SEC cited is paying bribes

CONTINUED FROM PAGE 3

BRIBERY IN PHARMA

under the guise of charitable giving. The lesson, according to the SEC, "...is that bribes come in many shapes and sizes."

The DOJ has indicated its intent to probe the pharmaceutical industry for possible FCPA violations as far back as 2009. At the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, DOJ Assistant Attorney General Lanny A. Breuer stated that, "One area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead [is] the application of the Foreign Corrupt Practices Act...to the pharmaceutical industry," citing, among other things, the significant overseas sales generated in countries with government-operated health systems.

SINGLING OUT PHARMA

Why are U.S. and international regulators singling out pharma? Historically, once the SEC successfully brings an enforcement action against a company, it can apply a similar approach when prosecuting other targets in the same industry to expedite a favorable outcome. The SEC netted multibillion dollar settlements for bribery charges against Pfizer and Eli Lilly in 2012, and pharma has remained in its crosshairs since then.

Secondly, the growing concern around international bribery allegations is an indication that more companies in the sector have expanded their operations in emerging markets. As pharmaceutical companies grow their international business, they confront less established regulatory environments and different rules for how business interactions are conducted and reported. These inconsistencies from market to market create confusion over what constitutes a bribe, resulting in both accidental and purposeful misconduct.

Pharma, perhaps more than any other industry, is at risk of FCPA bribery charges stemming from sales to foreign government officials. As stated by the DOJ, "Nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning

of the FCPA." The industry is built on close interactions with third parties such as physicians, nurses, hospital administrators and even pharmacists, who are considered government employees under the FCPA and most other anti-bribery laws. These third parties are typically less knowledgeable of—and in many cases, completely blind to—their anti-bribery compliance obligations. Combining rapid growth in emerging markets with the extent of third-party interactions, the pharmaceutical industry only increases its risk of exposure to corrupt behavior. For example, SciClone Pharmaceuticals was found in violation of the FCPA for providing money and gifts to Chinese officials (including employees of state-owned hospitals) in order to boost sales.

The fines and penalties levied against a company found in violation of anti-bribery laws can be severe, wreaking havoc on the company's finances and ability to continue to do business in those countries. In addition, the legal, forensic accounting and compliance fees associated with a bribery investigation, and subsequent third-party monitoring in some cases, can often exceed the costs of the actual bribe. Finally, the long-term reputational costs may be the most damaging. The initial financial penalty doesn't fully account for the loss of consumer trust and the negative view toward the company and its leadership, nor does it account for the potential for shareholder lawsuits.

Pharma is not the only industry facing increased scrutiny, as the SEC expands into other life sciences arenas. In 2012, Biomet, a medical device company headquartered in the United States and operating globally, entered into a Deferred Prosecution Agreement (DPA) with the DOJ and SEC. Biomet was charged with paying bribes to government doctors in Argentina, Brazil and China. Biomet agreed to pay a \$17.28 million criminal penalty to the DOJ and disgorgement of profits totaling \$5.4 million. Additionally, Biomet was required to have a compliance monitor in place for a three-year term. In March 2015, the DOJ extended Biomet's DPA and required monitoring for an additional year after uncovering misconduct in additional countries.

The cost of violation of anti-bribery laws is not only significant for companies, but can also have severe consequences for company officers, directors and employees. In September 2015, the DOJ issued the "Yates Memo," calling for increased focus on individual accountability in both criminal and civil corporate wrongdoing. Although most FCPA enforcement actions have not resulted in charges against company employees, the Yates Memo serves as a reminder to executives and employees that compliance is both a company issue and an individual responsibility. Additionally, it sets the stage for the more aggressive prosecution of individual perpetrators, encouraging broader civil enforcement and raising the threshold on what constitutes cooperation credit when negotiating a DPA. Continuing the theme of the Yates memo, in February 2016, the DOJ announced that as part of entering into settlement agreements, companies will be required to sign certifications stating they have disclosed all information about individuals involved in wrongdoing.

BUILDING A COMPLIANT ORGANIZATION

In this environment, compliance can't be an afterthought; it needs to be viewed as a key business driver and an integral piece of strategy and risk management. Companies that establish a culture of compliance from the top down will be in the best position to mitigate risk. Without active participation and leadership from management as well as the board, compliance programs won't permeate the DNA of the organization, and violations may occur. Management needs to design, implement and test company policies and procedures, as well as ensure the right controls and compliance resources are in place to prevent, deter and detect fraud and corruption. The process should start with a fraud and corruption risk assessment either as a standalone or as part of an Enterprise Risk Management (ERM) process, culminating in timely monitoring of adherence to policies, procedures and the compliance program in general. The board's oversight responsibility cannot be overstated. Directors should understand the fraud and corruption risks, confirm that appropriate risk assessments have been conducted, know the gaps and remediation plan and be confident that

CONTINUED FROM PAGE 4

BRIBERY IN PHARMA

an appropriate monitoring mechanism is in place.

Companies must also be vigilant in conducting due diligence for their acquisition targets. In an extremely competitive market such as pharmaceuticals, M&A is frequently used for strategic advantage but may also lead to inheriting legal and regulatory problems after the deal closes. Acquiring a company means acquiring its potential fraud and corruption problems. Organizations should conduct extensive, risk-based anti-corruption due diligence before finalizing an acquisition and factor the risk of fraud and corruption into the purchase price and indemnities. Additionally, after a deal is completed the acquirer should take steps to integrate its compliance culture and ensure all parties are operating on the same wavelength.

Unfortunately, compliance is not a one-size-fits-all solution. Every company — big or small, public or private — needs to identify and measure its unique fraud and corruption risks, link those risks to existing controls, identify gaps, perform cost-benefit analysis on possible remediation measures, remediate and monitor.

As bribery and corruption investigations continue to rock the pharmaceutical industry, all of healthcare has been placed under a microscope. The Department of Justice is extending its focus beyond drug companies to medical devices, clinical trials and a number of other health-related industries. Expect authorities in the U.S. and abroad to leverage their insights from prosecuting Big Pharma to target the broader healthcare ecosystem.



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FDA ISSUES NEW CYBERSECURITY GUIDELINES FOR MEDICAL DEVICE MANUFACTURERS

By Shahryar Shaghghi and Ryan Starkes

Following a spate of major data breaches—resulting in over 112 million compromised health records in 2015 alone—healthcare is the latest industry to face heightened regulatory scrutiny of its cyber preparedness.

The U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) are both moving forward with initiatives this year aimed at improving cybersecurity efforts within the healthcare industry.

HHS is more broadly focused on the healthcare industry at large. The Cybersecurity Act of 2015, a provision of the omnibus spending bill passed in December, requires HHS to submit a report to Congress assessing the preparedness of the healthcare industry in responding to cyber threats within the next year, with the goal of establishing a “single, voluntary, national, health-specific cybersecurity framework.” A cybersecurity task force comprised of regulatory agencies, industry stakeholders and cyber experts will help to inform their recommendations on developing a centralized intelligence-sharing system on cybersecurity threats and protections for networked medical devices and electronic health records.

The FDA is focusing its attention on medical device manufacturers and, in January 2016, issued new post-market guidance for the management of cybersecurity in medical devices.

Elements of Successful Cybersecurity Management in Medical Devices

The FDA guidance encourages a proactive risk-based approach to managing post-market cybersecurity vulnerabilities. Ongoing risk assessment and monitoring, routine device cyber maintenance and implementation of necessary actions to mitigate device

functionality and patient safety risks are key to “good cyber hygiene.” The agency is also promoting information and intelligence sharing (a key provision of the Cybersecurity Act of 2015) within the medical device community. “Voluntary” participation in an Information Sharing Analysis Organization (ISAO) is considered a critical component of a manufacturer’s proactive cyber strategy and is considered a mitigating circumstance when an issue arises.

The FDA calls for manufacturers to adopt a comprehensive cybersecurity risk management program and documented process for identifying hazardous cyber vulnerabilities in line with the National Institute of Standards and Technology Framework for Improving Critical Infrastructure Cybersecurity, which includes the core principles of “Identify, Protect, Detect, Respond and Recover.” Such a program should include:

- ▶ Monitoring cybersecurity information sources for identification and detection of cybersecurity vulnerabilities and risk
- ▶ Understanding, assessing and detecting presence and impact of a vulnerability
- ▶ Establishing and communicating processes for vulnerability intake and handling
- ▶ Clearly defining essential clinical performance to develop mitigations that protect, respond and recover from the cybersecurity risk
- ▶ Adopting a coordinated vulnerability disclosure policy and practice
- ▶ Deploying mitigations that address cybersecurity risk early and prior to exploitation

Manufacturers should assess potential cyber risks tied to the device’s “essential clinical performance,” evaluating the exploitability of the cybersecurity vulnerability and the severity of the potential health impact to patients.

CONTINUED FROM PAGE 5

CYBERSECURITY GUIDELINES

In instances where the “essential clinical performance” of a device could be compromised, the manufacturer is required to notify the agency. Reporting requirements are not enforced if the following circumstances are met:

- ▶ No known serious adverse effects or deaths associated with the vulnerability;
- ▶ The manufacturer sufficiently remediates the issue within 30 days of learning of the vulnerability; and
- ▶ The manufacturer is a participant of an ISAO.

A device with an unacceptable level of risk to its essential clinical performance may be considered in violation of the Federal Food, Drug & Cosmetics Act and subject to enforcement actions.

PROTECTING THE LARGER ECOSYSTEM

Medical device manufacturers are only the first line of defense in managing cybersecurity threats. The FDA stresses that medical device cybersecurity is a shared responsibility between all healthcare stakeholders including healthcare facilities, patients and providers.

While manufacturers are ultimately responsible for identifying and remediating potential cyber vulnerabilities associated with their medical devices, hospitals and healthcare systems must safeguard their networks from potential breaches of security via medical devices.

The domino effect of a healthcare data breach sheds light on the importance of information sharing, a growing area of focus in cyber strategy and policy. The Cybersecurity Information Sharing Act (CISA), also part of the omnibus spending bill, offers prescriptive advice on furthering collaboration between the government and private sector, as well as industry collaboration within the private sector. While we will likely see an uptick in threat intelligence sharing across all industries, concerns about protecting competitive information and privacy risk have yet to be addressed. The level of sharing remains to be seen and will dictate the effectiveness of ISAOs and other information sharing systems

in mitigating cyber risk. Participation in ISAOs or Information Sharing and Analysis Centers (ISACs) will likely remain voluntary in the near term; however, as exemplified by the FDA, regulatory entities will increasingly consider participation when assessing cyber preparedness.

Cybersecurity threats will continue to evolve and become more sophisticated, and the stakes will grow higher for device manufacturers that are unprepared. Establishing a solid cybersecurity management framework and an ongoing process for evaluating emerging threats is not only critical as a protective measure but as a requirement for business growth.

CYBER PREPAREDNESS

What can medical device manufacturers do to prepare?

Start at the drawing board: Make sure to incorporate cybersecurity considerations throughout the product lifecycle, including the design and development phases. The extent to which the device is connected to the Internet or other electronic data interfaces determines its vulnerability to potential attack. Security functionalities should include limited access and multi-authentication factors, as well as a system to detect and respond to intrusions. However, manufacturers need to carefully balance implementing the necessary security controls and safeguards with device usability.

Implement early detection protocols:

A variety of systems and technologies, including artificial intelligence, machine learning and probabilistic mathematics, are already in use in other industries to identify malware and intrusions that have gained access to IT systems. Device manufacturers can contain these infiltrators by identifying them early on and preventing them from accessing what they want to access.

Identify your sensitive data: As medical devices are increasingly networked to facilitate patient care, a breach of data could compromise device functionality and inadvertently cause patient injury or even death. When evaluating the risk to essential clinical performance, manufacturers should



assess both the exploitability of the cyber vulnerability and the severity impact to health. A binary assessment of the degree of risk posed by a vulnerability is critical to prioritization and establishing effective compensating controls.

If you do get attacked:

- ▶ Isolate the affected systems before the point of no return.
- ▶ Inform your customer base and other parties in your network. Hackers may be using medical devices as a gateway to attacking another healthcare player in the system.
- ▶ Protect patient financial data as well as their medical data from future cyber attacks.
- ▶ If the attack has serious adverse health consequences, remediate the vulnerabilities to reduce risk to an acceptable level. If an official fix is not immediately feasible, provide a workaround or temporary fix in the interim.
- ▶ Work to identify the source of the issues and learn from potential and actual breaches.



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PErerspective in LIFE SCIENCES

By Lee Duran and Aftab Jamil



While biotech stocks took a hit at the end of last year, 2015 was an all-

time record year for pharmaceutical and biotech M&A following a strong 2014.

Some 166 deals were announced, compared with 137 in 2014, with a total deal value of over \$300 billion, up from \$250 billion in 2014, according to The Pharma Letter. There were 30 deals valued at over \$1 billion, up from 26 in 2014 and 20 in 2013.

Despite the feeding frenzy, PE firms have tended to stay clear of pharmaceutical and biotech companies, with the exception of established generic drug makers, which offer a more reliable source of revenue. Fundamentals in the industry remain strong, but intense scrutiny around the rising costs of prescription drugs has made some investors skittish about even the biggest pharmaceutical giants. Early-stage biotech companies—while appealing to strategic investors that need to boost their drugs offerings as older patents run out—are too risky for many PE investors, who are less willing to place bets on pre-revenue companies in a volatile market.

Instead, pharmaceutical outsourcing services providers, supply chain management services providers, and contract research organizations have been profitable areas of focus for PE firms. Great Point Partners recently sold Cyto Vance—a manufacturer of proteins and antibodies to be used in clinical trials—for \$205.7 million, representing

a return of 7.4 times the original investment, The Wall Street Journal reports. The over-the-counter segment, which includes vitamins, minerals and supplements, is also attractive for PE investors, thanks to its low reimbursement risk, according to a Bain Capital report.

During the first three quarters of last year, the biotech IPO market was also booming, with over 200 launches since 2011, and 127 in the three-year period from 2013 to 2015, according to Dealogic and Dow Jones VentureSource. In the second half of last year, a glut of early-stage companies with no commercially-approved products receiving high valuations pointed toward a bubble—which some say burst last July. Additionally, the drug pricing controversy that erupted in September prompted a months-long sell-off of biotech stocks. The Nasdaq Biotechnology Index dropped more than 20 percent by the end of 2015 amid the broader bear market, and the decline has persisted into the new year.

As a result, the funding environment seems to be cooling, with only four biotech launches so far this year—a sharp reduction, according to The Wall Street Journal. A number of biotech firms are scheduled to go public this year, but many may not make it due to poor earnings and the ongoing stock market selloff, the Financial Times reports.

The first launches of the year were seen as a litmus test of the sector's current fund-raising abilities, according to the Financial Times. Chinese biotech company BeiGene, a developer of novel cancer treatments, listed on Nasdaq in early February, raising \$158 million, and saw its shares jump 17 percent to value the company at \$854 million. But

other stocks have fared poorly, due in part to drug failures. The fact that many biotech firms have products still under development makes it very difficult for investors to determine the potential success of a given firm. Pricing issues are further stressing investors, raising new questions about how companies can justify the cost of their drugs and the value they offer to the marketplace.

Venture capital investment in the life sciences sector is second only to the software industry. U.S. biotech venture funding reached a record \$8.7 billion in 2015, up from \$7.06 billion in 2014, according to data from Evaluate Pharma. Average rounds rose to \$24.1 million, with the top 10 percent accounting for 19 percent of total funds raised. However, deal numbers were down, with capital flowing to a smaller number of firms that barely beat the all-time low, according to FierceBiotech. For now, VC interest in the sector remains strong, but 2016 may see a reduction in crossover deals as non-traditional investors pull back following the stock market slide, FierceBiotech reports.

PErerspective in Life Sciences is a feature examining private equity investment in the life sciences and biotechnology sector.

Sources: The Pharma Letter, Wall Street Journal, Bain Capital, Financial Times, FierceBiotech, Dealogic, Dow Jones VentureSource, MarketWatch, BioPharmaDive, MoneyShow.com



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CHANGES TO R&D TAX CREDIT CREATE MORE OPPORTUNITIES TO SAVE THAN EVER BEFORE

By Chris Bard, Chai Hoang, & Nina Medina

Recent changes to the research and development (R&D) tax credit create new opportunities—regardless of whether a business is currently paying regular income tax or the alternative minimum tax (AMT). The Protecting Americans from Tax Hikes Act of 2015 (PATH Act), signed into law in December, included three significant benefits for life sciences businesses of all sizes.

PERMANENT R&D TAX CREDIT – effective Jan. 1, 2015

The federal research credit is intended to encourage businesses to invest more in U.S. development activity. For the same reason, more than 35 other countries provide similar, sometimes even more generous, benefits, e.g., Japan. Not surprisingly, then, many businesses tend to locate and remain in these innovation-friendly countries: 75 percent of the companies listed on the Thomson Reuters 2015 Top 100 Global Innovators [list](#) are based in either the U.S. or Japan.

Time will tell if the PATH Act will increase the U.S.'s share of global innovators, but its conversion of the R&D credit from a temporary provision of the Internal Revenue Code to a permanent one should help. For the first time since 1981, when the credit was enacted, businesses can take the positive financial benefit of the credit into greater account when planning and budgeting for future years' growth and spending. The new permanency of the credit strengthens its initial intent — to foster innovation and economic growth. The permanent extension of the credit provides a particular advantage to life sciences companies, which often face significant financial uncertainty and instability, as their stock performance and revenues often depend on the unpredictable outcome of drug development. It further helps mitigate the financial risks involved in new drug discovery and development, providing a reliable tax benefit that makes



financial forecasting more simple, more stable and more predictable.

Newer and smaller life sciences companies, in particular, will also benefit from the certainty that the R&D credit will be available once they become taxable—a potentially critical factor for reinvestment in development activities and continued growth. And until they do become taxable, the PATH Act provides two additional benefits for such companies.

CREDIT ALLOWED AGAINST AMT FOR ELIGIBLE SMALL BUSINESSES – effective Jan. 1, 2016

Many small businesses—especially early-stage pharmas and biotechs—find themselves subject to the AMT. Generally though, prior to the passage of the PATH Act, the R&D credit could not be used to offset AMT. As a result, many of the exact type of companies the credit was intended to incentivize were often not able to use it.

The PATH Act changes that. **Eligible small businesses** can now claim the credit against AMT, a game changer for these companies, as well as for their pass-through shareholders who had often been unable to use their share of R&D credits due to AMT limitations.

“Eligible small businesses” include corporations that are not publicly traded, partnerships and sole proprietorships where the average annual gross receipts for three taxable years preceding the tax year in which the credit is being claimed do not exceed \$50 million.

Permitting the use of the research credit against AMT creates a new opportunity for taxpayers to take the sting out of AMT by enabling them to use it offset their tax liability.

TREATMENT OF R&D CREDIT FOR CERTAIN STARTUP COMPANIES – effective Jan. 1, 2016

The R&D credit is also now more beneficial for many startup companies that previously generated credits but couldn't use them because they weren't paying regular income tax.

Under the PATH Act, **qualified small businesses** can now offset up to \$250,000 of their federal payroll taxes for up to five years. “Qualified small businesses” are generally businesses with (1) gross receipts in the taxable year of less than \$5 million and (2) no gross receipts prior to the five taxable years ending in the taxable year.

CONTINUED FROM PAGE 7

CHANGES TO R&D TAX CREDIT

This enhancement to the credit can be an important cash boost to startups—keeping doors open for some of the sector's most disruptive players, and incentivizing further investment in innovation.

CONCLUSION

R&D is at the heart of the life sciences industry and critical to its continued growth. The bread-and-butter activities that take place during attempts to develop new or improved drugs or techniques or other components are prime targets for the R&D tax credit, but they're hardly the only activities that qualify. Life sciences companies attempting to develop or even just to improve existing products or production processes may also be eligible for R&D tax credits. The cost of supplies used in these processes can qualify as well, including lab supplies, prototypes and experimental production lots. And of course, costs related to many types of clinical and other testing—e.g., for product safety—can qualify as well.

For life sciences companies that have been claiming the R&D credit for years, now is a great time to make sure nothing is left on the table, e.g., because people burdened with other commitments default to SALY—same-as-last-year—procedures. And for startups and small businesses, the new credit modifications offer opportunities that can provide significant value. To take full advantage of these new and expanded opportunities and comply with all of the sundry legal requirements not outlined above, please consult with a tax advisor with experience in R&D credits.



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INVESTORS ANXIOUS, BUT FUNDAMENTALS STILL STRONG



Insights from J.P. Morgan Healthcare Conference

A sharp decline in the stock market in the first month of the year following a turbulent 2015 largely dominated the discussion at this year's J.P. Morgan Healthcare conference in San Francisco, traditionally viewed as the biggest healthcare investing event of the year.

Drug pricing was an inescapable focal point both inside and outside of the conference, with many biotech companies on the defensive about the complexities driving up costs and the negative impact that lower prices can have on research and development (R&D).

A 3.4 percent drop in the Nasdaq Biotechnology Index—its worst performance for the first day of the conference since 2001—tempered much of the customary exuberance exhibited by company executives. Some analysts said the negative tone reflected apathy among investors who weren't seeing companies issue many market-moving announcements leading up to the event, but the general consensus is that while fundamentals remain strong, perhaps valuations had become a bit stretched.

The latest [BDO Biotech Briefing](#) reports a similar story, with many of the driving forces for industry growth in recent years expected to continue. R&D expenditures have been rising and are projected to increase in the year ahead; FDA approvals of new drugs were also strong in 2015.

While biotech stocks were off to a volatile start in 2016, slowing deals, there are indications that merger & acquisition activity will pick up

again soon. In early February, Abbott Laboratories announced plans to acquire diagnostic group Alere for \$5.8 billion. Stryker also revealed its plans to buy medical supplier Sage for \$2.8 billion.

But the real action this year may be found in partnerships. A number of big life sciences players at the conference appeared reluctant to pull the trigger on deals, instead pointing to the benefits of partnering with companies on drug development. Johnson & Johnson's CEO Alex Gorsky made statements shrugging off the idea of a large M&A deal, stating a preference to [partner with companies to find the next blockbuster drug](#). Genentech's global head of partnering issued similar comments about the firm's focus on "partnering" with like-minded people to discover new medicines.

Tough headlines may dominate the sector currently, but there still exists a strong and promising environment for drug development. While equity markets may have cooled, biotechs looking to fundraise this year are likely to find success in partnerships and acquisitions to fuel their pipeline.

MARK YOUR CALENDAR...

The following is a list of upcoming conferences and seminars from the leading technology associations and business bureaus:

MARCH 2016

March 14-17

BioProcess International Conference & Exposition

Oakland Marriott City Center
Oakland, Calif.

March 15-16

13th Annual BIO Asia International Conference

Grand Hyatt Tokyo
Tokyo, Japan

March 16-17

CBI Global Anti-Corruption and FCPA Compliance Congress

Doubletree Center
Philadelphia

APRIL 2016

April 5-7

Bio-IT World Conference & Expo

Seaport World Trade Center
Boston

April 15

Crain's 'Business of' Series: Life Sciences

John Jay College of Criminal Justice
New York

April 20-22

Advances in Process Analytics and Control Technology (APACT) 2016

Crowne Plaza Hotel
Chester, United Kingdom

April 25-27

BioTrinity

Hotel Novotel London West,
London, United Kingdom

MAY 2016

May 5-6

Drug Development Immersion Course

The Conference Center at Mercer
West Windsor, N.J.

May 16-19

Biopharmaceutical Development & Production Week

Grand Hyatt

JUNE 2016

June 6-9

2016 BIO International

Moscone Center
San Francisco
Shanghai, China

May 31-June 1

Boston CEO Conference

Four Seasons
Boston

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