FOLEY FORWARD

Trends

PREPARED BY THE FOLEY & LARDNER TEAM IN THE AREAS OF:

ENERGY, HEALTH CARE & LIFE SCIENCES, INNOVATIVE TECHNOLOGY, AND MANUFACTURING

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TABLE OF CONTENTS

Energy

04 | The Rapid Acceleration of Energy Convergence
06 | ESG: Staying Top of Mind in the Oil & Gas Boardroom
09 | Favorable Conditions for Onshoring in 2023

Manufacturing

11 | Antitrust: Heightening Expansion, Review, and Enforcement
14 | Three Likely Disruptors and Opportunities for Manufacturers in 2023
16 | Keeping the "S" in ESG: Human Rights & Supply Chain

Cross-Over: Energy & Manufacturing

18 | IRA Brings Energy and Manufacturing Opportunities
20 | IRA Tax Credits Benefit Energy and Manufacturing

Health Care & Life Sciences

22 | 2023 Telemedicine & Digital Health Trends
26 | The BioPharma Patent Cliff: 2023 and Beyond
28 | Growing Scrutiny of Private Equity in Health Care
30 | Considerations When Conducting Decentralized Clinical Trials

Innovative Technology

32 | 2023 M&A Outlook
35 | Where is Cloud Computing Heading in 2023?
38 | ChatGPT: Herald of Generative AI in 2023?
44 | What to Expect in 2023: Trends in Cybersecurity & Data Privacy
48 | Where is SaaS Heading in 2023?
52 | What's Next for Blockchain Tech and Crypto in 2023?"

SECTOR LEADERSHIP

Energy

Jeff Atkin
Sector Co-Chair
jatkin@foley.com
213.972.4557

Eric Blumrosen
Sector Co-Chair
eblumrosen@foley.com
713.276.5533

Heath Care & Life Sciences

Susan Pravda
Sector Chair
spravda@foley.com
617.342.4003

Innovative Technology

Pavan Agarwal
Sector Chair
pagarwal@foley.com
202.945.6162

Manufacturing

Jim McKeown
Sector Chair
jmckeown@foley.com
414.297.5530

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FOLEY FORWARD

Our clients rely on Foley & Lardner to act as their trusted business advisor. Informed by the latest sector trends and market drivers, we look beyond the law to deliver creative, practical, and effective solutions to the evolving demands you face.

Foley is pleased to provide this inaugural **Foley Forward: Trends 2023** publication, which unpacks the landscape of those evolving demands to help position you for success.

Foley Forward 2023 brings you insights from across four key sectors:

- **Energy:** convergence, ESG, and onshoring.
- **Manufacturing:** disruption, antitrust, human rights and supply chain, and the Inflation Reduction Act.
- **Health Care & Life Sciences:** telemedicine and digital health, the pending biopharma patent cliff, private equity investment, and decentralized clinical trials.
- **Innovative Technology:** cloud computing, generative artificial intelligence, cybersecurity and data privacy, software as a service, chatGPT, and blockchain.

Foley continually examines these and other topics through the eyes of our clients, and stands ready to help you see around the next curve in 2023 and beyond.

ENERGY

The Rapid Acceleration of Energy Convergence

Energy convergence is a rapidly growing macro trend within the energy sector. What is “energy convergence”? Historically, the vast majority of our energy needs have been supplied by hydrocarbons (e.g. oil & gas and coal). Now, and as we move forward, there is an accelerated shift to a more assorted supply of energy sources (e.g. solar, wind, and geothermal to name a few).

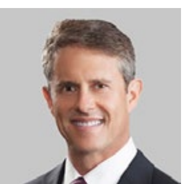
Eric Blumrosen, Danielle Osburn

As a result, businesses are focused on merging traditional forms of energy sources and business models with clean energy sources and new business strategies. The energy convergence trend at its core is centered on the global initiative to lower carbon emissions. Many businesses are participating in the energy convergence trend in an effort to (i) make energy more sustainable and affordable, (ii) appease investor and consumer demand for cleaner energy, (iii) ease geopolitical instability as countries compete for scarce resources, and (iv) participate in emerging markets with potentially attractive new revenue stream opportunities. While many energy experts have been predicting this convergence for a number of years, most did not anticipate the rapid pace at which it is occurring.

Companies in the energy sector around the world are participating in the energy convergence trend in a number of ways, but perhaps the two most obvious examples are:

- Traditional energy companies are allocating significant capital and making meaningful investments in renewables companies and/or lower carbon emitting businesses, all in an effort to reduce their carbon emissions. Additionally, traditional energy companies and financial investors view the global initiative to reduce carbon emissions as an opportunity to invest in new and emerging markets where the business models of traditional energy companies will position them well to make investments in related, lower carbon emitting businesses.
- Traditional energy companies are changing their business models. With the addition of non-traditional investments, traditional energy companies have discovered that the historical long-range planning, capital investments, and business plans of the past do not work for the more diverse energy supplies of today. Companies are attempting to process large volumes of data to help them understand how best to adjust their business planning. A result of this is the emergence of a number of joint ventures between traditional energy companies and renewable energy companies, thereby allowing traditional energy companies with the benefit of business practices and knowledge of renewables businesses.

There has never been a more exciting time within the energy sector. What is emerging is a diverse energy system where traditional hydrocarbons will continue to play a significant role, but with an accelerated emphasis on "clean" energy supplies. It is impossible to ignore the sector's increase in participation in energy convergence efforts, and Foley & Lardner LLP has the broad range of legal expertise and experience needed to help facilitate your needs to further your energy convergence efforts, or assist you in entering this dynamic market for the first time.



Eric Blumrosen
Partner
eblumrosen@foley.com
713.276.5533

Danielle Osburn
Associate
dosburn@foley.com
713.276.5471

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ENERGY

ESG: Staying Top of Mind in the Oil & Gas Boardroom

ESG is increasingly vying for airtime in oil and gas boardrooms as leaders grapple with how best to tackle environmental, social, and governance challenges. This follows a trend of ESG support throughout all sectors of the U.S. economy. A 2022 study revealed that ESG shareholder resolutions were up 22% to record levels for the year.

Scott Ellis

This article identifies (1) the key administrative reasons for the increased ESG discussion, (2) why leadership should take ESG seriously, (3) questions leaders should be asking themselves, and (4) a framework for addressing ESG challenges.

Key Administrative Reasons for Increased Focus on ESG

In 2021, the Biden Administration issued several executive orders directing federal agencies to implement ESG-related practices. Perhaps most important among these is President Biden's January 27, 2021 Executive Order, "Tackling the Climate Crisis at Home and Abroad. The Executive Order:

- Requires agencies to consider the effects of federal permitting decisions on greenhouse gas emissions and climate change;
- Initiates an agency-wide push to incorporate programs, policies, and activities to promote environmental justice; and among other things; and
- Encourages the development of renewable energy production on land and in water.

The EPA is also developing ESG-related rules that impact, or will impact, the oil and gas industry. These rules seek to:

- Reduce methane emissions from abandoned oil and gas wells.
- Reduce/eliminate the use of natural gas-driven pneumatic controllers that are widely used in the industry.
- Increase performance standards for storage tanks, pneumatic pumps, and compressors.
- Reduce emissions from existing oil and natural gas operations.
- Enhance compliance monitoring programs for new and existing well sites and compressor stations.

Reasons to Take ESG Seriously

While some oil and gas companies have been slow to react, most leaders now recognize the importance of addressing ESG. While there are many reasons to take ESG seriously, here are some of the most compelling:

- Heightened focus of investors on ESG matters. Poor ESG performance will impact access to capital.
- The public has a heightened awareness of ESG issues. Companies must take steps to ensure they are not embroiled in any negative press.
- Opportunity to demonstrate leadership by investing in new technologies that can reduce environmental impact or improve efficiency. This can lead to cost savings as well as goodwill with the public.
- ESG can help companies become more sustainable and efficient in the long term, and it is becoming an increasingly important factor to consider when selecting investments and partners in oil and gas.

Questions Leaders Should be Asking

Leadership at oil and gas companies should be asking themselves the following questions, which they must answer to stay competitive:

ENVIRONMENT

What is our company doing – and what can we do – to reduce emissions and our carbon footprint?

SOCIAL

Is our company's workplace safe? How do we measure this?

GOVERNANCE

How are our processes and procedures being managed? Are employees receiving adequate support to fulfill their role?

Best Practices to Address ESG Challenges

Oil and gas leaders should consider the following:

- Conduct diligence on what peer companies are doing with regard to climate change initiatives and reporting. Trade groups can be especially helpful with this research.
- Identify and hire an ESG consultant to assist in drafting your ESG plan and reporting framework. There are multiple consultants who work specifically with the oil and gas sector.
- Update policies and procedures to ensure they address ESG.
- Develop clear metrics to evaluate how effectively the company has executed on its ESG policies.
- Reporting throughout the company is critical. Create a cross-discipline committee to evaluate ESG initiatives. Ensure that the committee has a compliance member and a member of leadership.
- The board should receive training on frameworks for your ESG plan and related disclosure obligations.
- Establish regular board review and oversight of the planning process, the plan itself, and progress against the plan. Work with the cross-discipline committee and keep the line of communication open.
- The tone at the top matters, so be sure to get sufficient buy-in from leadership.

Scott Ellis
Partner
sellis@foley.com
713.276.5615

ENERGY

Favorable Conditions for Onshoring in 2023

As the pandemic highlighted issues in the global supply chain and as the United States intensifies its investment in clean energy, more renewable energy manufacturers than ever are considering onshoring (or nearshoring) manufacturing facilities in the United States. Domestic demand for clean energy is at an all-time high and doesn't look to be slowing.

Jeff Atkin, Becca Jordan

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Domestic production may help satisfy U.S. consumer demand for predictable delivery schedules and prices. Below we outline some of the current forces driving the move to onshore. And while onshoring is uniquely incentivized right now, it is not without challenges, requiring critical consideration of the factors we explore below.

Current Onshoring Motivators

- **Inflation Reduction Act (IRA)** – The IRA provides significant tax credits for the manufacturing of certain renewable energy components as well as the purchasing and commissioning of property to build clean energy manufacturing facilities. The IRA further provides adders for these credits where manufacturers use domestically produced components in their facilities.
- **Geopolitical Instability** – Recent years have revealed the vulnerability of the supply chain. From shutdowns and delays due to the COVID-19 pandemic, the Russia-Ukraine conflict, and labor shortages, and regulatory changes, supply chain disruptions that were once infrequent have become ordinary.
- **Antidumping Duties** – In response to antidumping duties against solar panels made in China, certain solar panel producers migrated production to other Southeast Asian countries to avoid paying the duties. The U.S. Department of Commerce recently extended the tariff orders to those countries, limiting U.S. access to solar panels.
- **Uyghur Forced Labor Act** – The forced labor law prohibiting importation of certain goods manufactured in the Xinjiang province of China has created uncertainty in the U.S. solar market, as the supply chain of some of the solar panel manufacturers extends into the prohibited region. Seized goods have skyrocketed and the near-total lack of solar import has prohibited large-scale projects from moving forward.

Key Onshoring Considerations

- **Site Selection** – Choosing the right location requires consideration of a bouquet of factors, including power and water availability, permitting and zoning requirements, and access to necessary transport hubs, raw material suppliers, and key customers.
- **Local Tax and Property Incentives** – Property and facilities costs are higher in the U.S. However, various states offer additional tax exemptions, deductions, and credits to renewable energy manufacturers and sellers.
- **Labor** – Labor costs in the U.S. are also high while access to skilled labor may be low. Additionally, employee health and safety is highly regulated by OSHA. However, increased automation in processes mitigates these costs.
- **Technology** – IP enforcement options abroad can be limited, requiring the involvement of local government actors. The U.S. offers robust IP defense and enforcement options, reducing the overall threat of IP infringement.
- **Logistics** – Shipping costs, lead times, and other delivery logistics become easier and less costly as inventory becomes geographically proximate. Particularly so for large equipment and machinery which incur significant costs when shipping on a per unit basis.

Jeff Atkin
Partner
jatkin@foley.com
213.972.4557

Becca Jordan
Associate
rjordan@foley.com
713.276.5042

MANUFACTURING

Antitrust: Heightening Expansion, Review, and Enforcement

Manufacturing companies should actively prepare for heightened antitrust scrutiny of their business practices in 2023, including practices that have not traditionally garnered the focus of the federal antitrust enforcers.

Elizabeth A. N. Haas, Kate E. Gehl

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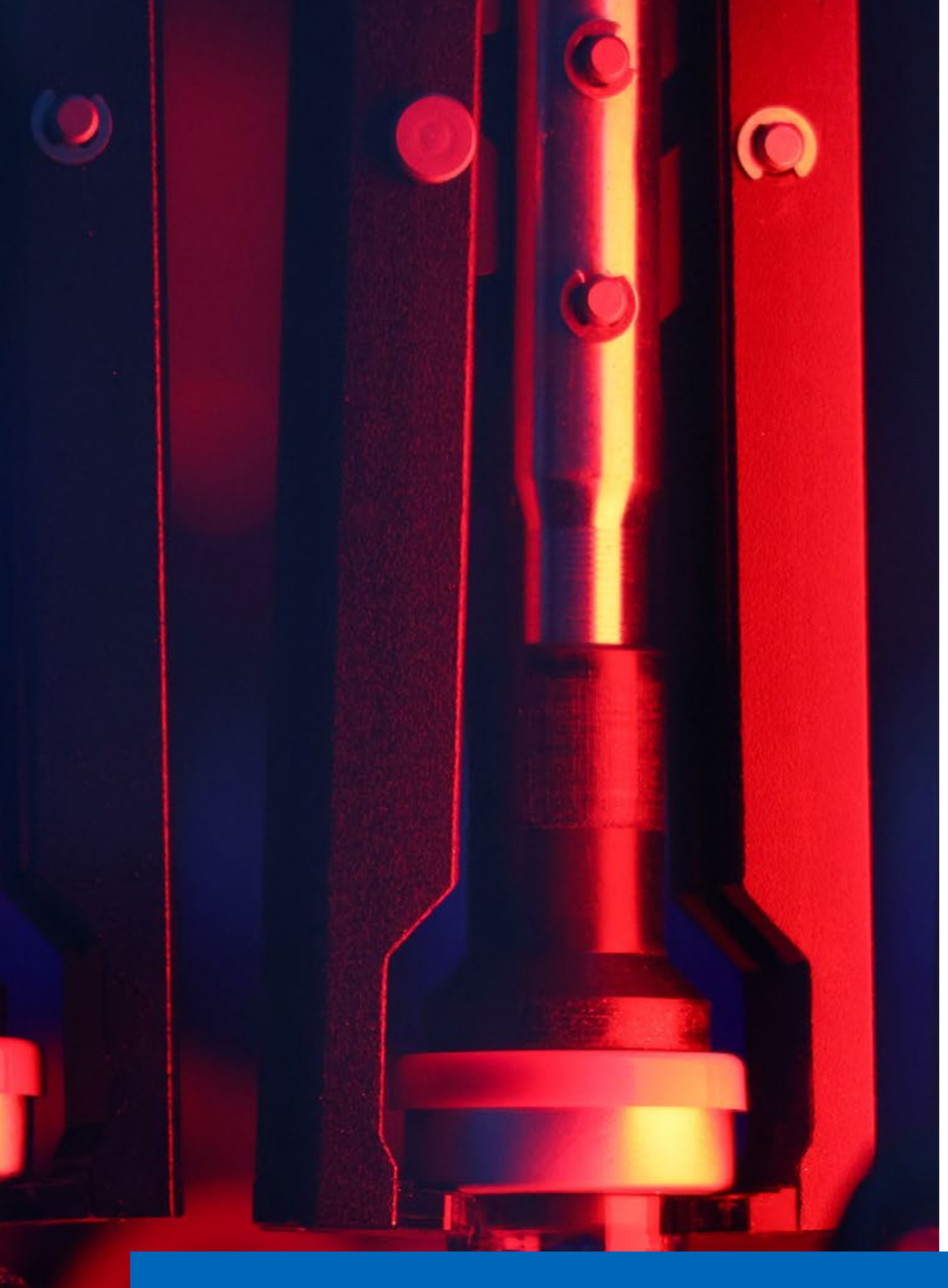

Employee noncompetes have recently come under fire from the Federal Trade Commission (FTC). In the first week of 2023, the FTC announced a proposed regulation that would implement a sweeping ban on employee noncompete clauses across the United States with only a few exceptions. The proposed regulation would apply to noncompetes with all types of employees and retroactively to existing noncompete agreements. The FTC is soliciting feedback to its proposed rule through its formal comment process. Manufacturers should evaluate whether to submit comments to the FTC if the proposed ban causes harm to their legitimate business. Manufacturers should also take steps now to evaluate how they are protecting their businesses, and whether other types of agreements, such as a non-disclosure agreement, may make sense now given the proposed ban.

In November 2022, the FTC announced its expanded view of what constitutes an "unfair method of competition" under Section 5 of the FTC Act. In a Policy Statement, the FTC indicated its intent to investigate and challenge business practices that have not historically raised antitrust concerns or that do not otherwise constitute violations of the federal antitrust laws as insidious "unfair methods of competition" in need of redress.

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Manufacturers should also be prepared for the FTC and the U.S. Department of Justice Antitrust Division (DOJ) to continue aggressive antitrust merger enforcement in 2023, particularly in those industries experiencing supply chain consolidation. After withdrawing the 2020 Vertical Merger Guidelines in Fall 2021, the FTC and DOJ are expected to issue updated vertical and horizontal guidelines early this year. The revised guidelines are likely to feature a combined analysis of transactions involving both horizontal and vertical impacts and will likely utilize non-traditional methods of analysis – for example, looking beyond the efficiencies of a transaction to evaluate competitive harms. The agencies seem primed to challenge more vertical mergers (i.e., mergers between companies involved in different stages of the supply chain) than ever before.

Finally, on February 3, 2023, the DOJ announced its withdrawal of three antitrust policy statements: Department of Justice and FTC Antitrust Enforcement Policy Statements in the Health Care Area (Sept. 15, 1993); Statements of Antitrust Enforcement Policy in Health Care (Aug. 1, 1996); and Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Oct. 20, 2011). While these statements were originally intended for healthcare markets, they have been applied more broadly over time to other sectors to provide guidance on acceptable practices and safe harbors relating to a host of commercial behavior including joint ventures, joint purchasing arrangements, and information sharing among actual or potential competitors. In its formal Withdrawal Statement, DOJ characterized these guidelines as "outdated enforcement policy statements" that are "overly permissible on certain topics, such as information sharing." DOJ did not indicate any intent to update the guidelines, but instead supports a case-by-case enforcement approach. Many manufacturers engage in information exchanges under the safe harbors in these guidelines, but DOJ cautions that some of these exchanges – particularly with the greater use of algorithms, the speed of data and the ability to de-anonymize sensitive information – can enable price and wage fixing, and other forms of illegal conduct, which warrants this new scrutiny to reflect existing market realities. DOJ also warned that merging companies with a history of sharing competitively sensitive information will face heightened review during the merger clearance process as well.

Elizabeth A. N. Haas
Partner
ehaas@foley.com
414.297.5083

Kate E. Gehl
Senior Counsel
kgehl@foley.com
414.297.5279

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MANUFACTURING

Three Likely Disruptors and Opportunities for Manufacturers in 2023

The ever-resilient manufacturing sector has been bruised (and some might say battered) in recent years, through the pandemic, raw material shortages, increased labor costs, rising interest rates, and Russia's war against Ukraine.

Nick Ellis, Michael Small, Ann Marie Uetz

Below are the three likely disruptors manufacturers face at the outset of 2023, and tips for surviving (or even thriving) in the face of what Foley and Lardner's manufacturing sector attorneys see coming down the road:

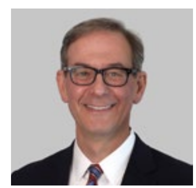
1. **More manufacturers will suffer financial distress, but there will be possible opportunities for growth through acquisition.** Lenders, many of whom previously provided extensions of credit and forbearance on defaults, are increasingly asserting their rights and remedies in the case of new or ongoing defaults. Variable interest rate facilities have become more burdensome. The cash flow and credit issues that borrower companies face may result in opportunities for other companies to purchase them (or their lenders' debt) at depressed valuations. While these deals may appear hard to come by, shrewd investors will be well served by considering both out-of-court and bankruptcy acquisitions of the distressed companies under pressure due to the current environment. For more information, click here.

2. **More manufacturers will face continued increased costs, but there are possible opportunities for cost-recovery.** While manufacturing costs continue to rise, suppliers who seek cost recovery from their customers and who support their request with transparent and thorough data are more likely to achieve support from their customers. This can be in the form of increased prices, a lump sum payment, or more profitable go-forward business. These negotiations can strengthen long-term relationships within the supply chain.

3. **Some manufacturers may be disrupted by the transition from internal combustion engine (ICE) vehicles to electrical vehicles, but there will be opportunities for growth in the new frontier.** Perhaps not since the introduction of the Ford Model T has there been a more exciting and transformative time in the automotive industry. Countless opportunities exist for startup and early-stage companies seeking to supply new components required for electric vehicles, with many still in the development phase. Federal grants to support this nascent industry are increasingly in play, such as those awarded by the Department of Energy in 2023 to support the manufacture of batteries for electric vehicles in the U.S. For more information, click here.

Foley's manufacturing sector attorneys who focus on financially distressed suppliers can help identify and maximize opportunities in a challenging market.

Nick Ellis
Partner
nellis@foley.com
313.234.7168



Michael Small
Partner
msmall@foley.com
312.832.5832

Ann Marie Uetz
Partner
auetz@foley.com
313.234.7114

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MANUFACTURING

Keeping the "S" in ESG: Human Rights & Supply Chain

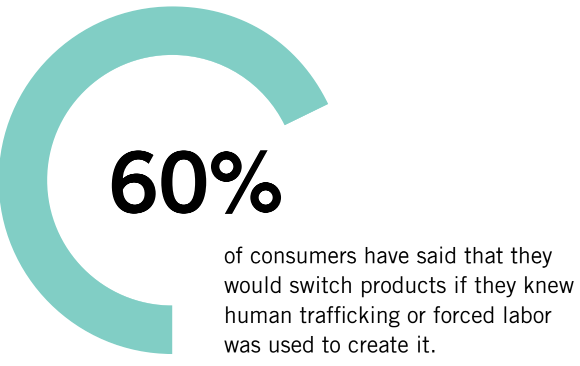
Companies in the manufacturing industry must continue to keep a close eye on the "S" in ESG. One key aspect of the "social" component of ESG involves respecting human rights in supply chains.

David Simon, Olivia Singelmann, David Wenthold

Indeed, manufacturers are facing heightened expectations—from government enforcement agencies, consumers, and other stakeholders—to ensure that their supply chains don't include any products made using forced or child labor. This trend is accelerating and forward-thinking manufacturers should be focused on this issue.

Compliance and Reputational Risks

Both enforcement agencies and consumers are increasingly focused on manufacturers' supply chains. Manufacturers must understand that human-rights-enforcement frameworks increasingly have real teeth. As we've detailed here, both the United States and the European Union either have or in the process of adopting real enforcement mechanisms to protect against the importation of goods made using forced labor. In 2023, we expect heightened enforcement in the U.S. of the Uyghur Forced Labor Prevention Act. As a sign of things to come, Germany's Supply Chain Due Diligence Act and Norway's recent Transparency Act impose affirmative human-rights-due-diligence obligations on companies and create an enforcement structure with severe penalties for non-compliance.



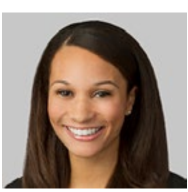
As important, manufacturers will face tangible reputational risks if forced-labor issues are exposed in their supply chains. When Joe Rogan is talking about forced labor in supply chains, you can bet the subject has become of mainstream significance. As transparency in supply chains increases and issues are exposed (whether by government seizures, consumer-focused-compliance-assessment tools, or media exposure), media and consumers have more data at their fingertips. And, according to one recent survey, that information matters: 60% of consumers have said that they would switch products if they knew human trafficking or forced labor was used to create it. So the consumer base—and, hence, the bottom line—will become more acutely at risk for manufacturers who fail to properly assess their supply chains.

Managing Risk in Your Supply Chain

These paradigms highlight an important fact: It's not good enough to just check the compliance boxes to show stakeholders that your company is socially responsible. So what should manufacturers do to address this risk? It's important to start with an understanding of your supply chain and an assessment of its human-rights risks. You are expected to know what goes into your products and where it comes from. And for components sourced in high-risk countries and that emerge from high-risk industries, you are expected to take reasonable steps to ensure that you have vetted your suppliers (and their suppliers and their suppliers' suppliers and so on . . .), that you have made sure they understand your compliance expectations and are contractually obligated to comply, and that you monitor and audit them to ensure they are in compliance

Tools like our International Compliance and Mitigation Heat Map and our framework for a basic forced-labor/supply-chain risk assessment, like we have outlined here, provide a useful starting point.

David W. Simon
Partner
dsimon@foley.com
414.297.5519



Olivia S. Singelmann
Partner
osingelmann@foley.com
202.295.4146

David Wenthold
Associate
dwenthold@foley.com
414.297.4985

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MANUFACTURING & ENERGY

IRA Brings Energy and Manufacturing Opportunities

President Biden has repeatedly discussed the need to onshore or re-shore U.S. manufacturing to improve national security and competitiveness. The war in Ukraine and worldwide supply chain issues created by the COVID-19 pandemic have underscored the need to reduce U.S. dependence on foreign manufacturing.

Bill Ball, Dennis Cardoza, Kate Kros

In response to these calls for action, Congress recently passed the **"Inflation Reduction Act" (IRA)**, which attempts to build on the **"White House Strategy for Advanced Manufacturing."** This article will provide a high level outline of these two initiatives and their relevance and opportunities for our clients.

The Administration fused its two national imperatives – conversion from a fossil fuel economy to combat Climate Change and development of an advanced manufacturing economy – into a strategic plan for the new economy. The action plan has three goals: 1) A 30 percent reduction in greenhouse gases (GHG) by 2030, and a reduction to net zero by 2050; 2) Acceleration of domestic manufacturing of microelectronics, semiconductors, and support for bio-manufacturing advancement; and 3) Development of new materials and processing technologies. In order to accomplish these goals the Administration also wants to expand the human resource base and improve work force training in order to man the new economy. It is estimated there will be a shortage of 2.1 million skilled workers if nothing is done to enhance STEM education,

It is estimated there will be a shortage of

2.1 million skilled workers if nothing is done to enhance STEM education, particularly among disadvantaged populations where education opportunities lag.

particularly among disadvantaged populations where education opportunities lag. In early December, the Administration presented "BUILDING A CLEAN ENERGY ECONOMY: A GUIDEBOOK TO THE INFLATION REDUCTION ACT'S INVESTMENTS IN CLEAN ENERGY AND CLIMATE ACTION." The 183-page document begins to lay the roadmap of manufacturing support funding to advance and to de-carbonize the economy. The executive summary of this document describes and highlights the strategy with the following statement:

> *"The Inflation Reduction Act will deliver results through a combination of grants, loans, rebates, incentives, and other investments to support the President's whole of-government economic plan. The Inflation Reduction Act includes some two dozen tax provisions that will save families money on their energy bills and accelerate the deployment of clean energy, clean vehicles, clean buildings, and clean manufacturing. Many of the clean energy tax provisions offer bonus credits to projects that are located in low-income communities or energy communities, pay prevailing wages and use registered apprentices, or meet certain domestic content requirements—all with the goal of creating good-paying, high quality jobs and shared economic growth that will last well beyond the Biden-Harris Administration. The Inflation Reduction Act also provides billions of dollars in grant and loan programs and other investments for clean energy and climate action. As with the tax provisions, Congress and President Biden designed these programs to benefit working families and parts of the United States that are too often overlooked and underserved. The law advances President Biden's Justice40 Initiative, which commits to delivering 40 percent of the overall benefits of climate, clean energy, infrastructure, and other investments to disadvantaged communities, including Tribes, communities with environmental justice concerns, rural areas, and energy communities."*

The Guidebook represents a good start to providing a path on how companies can access IRA funding, but as of late December 2022 much of the regulatory structure to deliver funds has either yet to be developed by the relevant agencies, or will be left to the discretion of the states. In the meantime, companies may want to engage in the regulatory process in order to help shape ongoing funding priorities, including the $1.7 trillion funding appropriation package approved just before Christmas. We have already helped clients secure tax credits and training reimbursement opportunities in excess of $3 billion dollars.

In 2023, we expect that the new Republican majority in the House of Representatives will work to shape these initiatives more to their liking. Investigative hearings will try to highlight waste or inefficiencies in the new programs. Unspent funds and projects that require further congressional direction for funding will receive particular close scrutiny in the appropriations process. Companies that wish to protect sources of future funding will want to pay particularly close attention the budget process as it unfolds.

Bill Ball
Director, Public Affairs
wball@foley.com
202.295.4067

Dennis Cardoza
Director, Public Affairs
dcardoza@foley.com
202.295.4015

Kate Kros
Public Affairs Advisor
kkros@foley.com
202.295.4063

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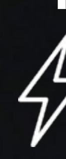
MANUFACTURING & ENERGY



IRA Tax Credits Benefit Energy and Manufacturing

The passage of the Inflation Reduction Act (IRA) in August of last year saw the introduction of a number of new and expanded tax credits aimed at boosting onshore American manufacturing. These incentives represent opportunities for manufacturing within critical industries, in particular those industries that are key players in the administration's goal to address climate change.

Adam Schurle

The incentives range from tax credits available directly to manufacturers of certain equipment, to incentives for taxpayers to purchase equipment from American manufacturers.

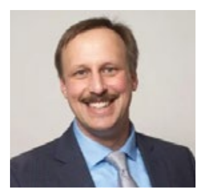
A new production tax credit, the Section 45X Advanced Manufacturing Tax Credit, is a credit available to manufacturers of eligible components produced within the United States and sold to an unrelated party. Eligible components include components included in wind, solar, and battery projects, such as PV cells, PV wafers, solar modules, blades, nacelles, inverters, and battery cells and modules, among many others. Credits are available on an annual basis through 2032, and credit rates vary depending on the component.

The IRA also expanded a tax credit that provides incentives for solar manufacturers, among other clean energy equipment manufacturers, for purchasing and commissioning property to build a manufacturing facility before January 1, 2025. The credit was expanded under the IRA and includes additional types of qualified investments, for up to $10 billion in total credits. The credit amount is up to 30% on investments into manufacturing facilities, and is available for certain expansions and re-equipping of existing facilities.

Another significant manufacturing-related change under the IRA incentivizes renewable energy project developers to buy equipment from U.S. manufacturers. Both the investment tax credit (Section 48 of the Code) and the production tax credit (Section 45 of the Code), which provide taxpayers with credits for certain renewable energy facilities and the production of electricity from such facilities, now include tax credit add-ons if (i) 100% of any steel or iron that is a component of the facility was produced in the United States, and (ii) 40% of manufactured products that are components of the facility were produced in the United States.

The IRA also enacted several provisions that, in certain cases, permit direct cash payments from the government and permit the sale of tax credits.

As we look ahead to 2023, we anticipate that Treasury will continue to develop guidance relating to these tax credits (many of which went into effect on January 1, 2023). We expect industry participants to be involved in that process, and to continue exploring opportunities to take advantage of these new incentives.



Adam Schurle
Partner
aschurle@foley.com
414.297.5158

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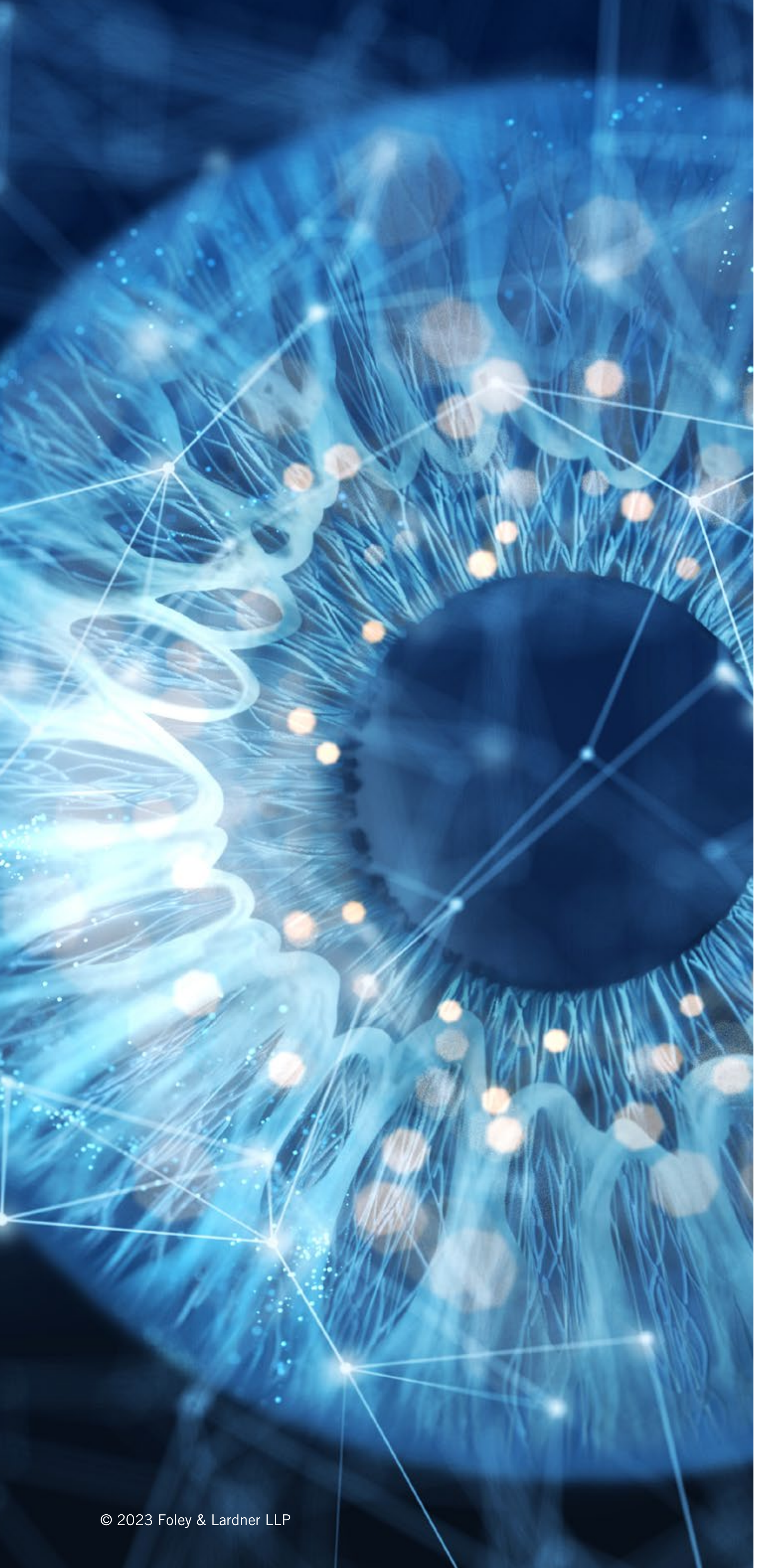
HEALTH CARE & LIFE SCIENCES

2023 Telemedicine & Digital Health Trends

TJ Ferrante, Rachel Goodman, Jennifer Hennessy, Jacqueline Acosta, Sunny Levine, Aaron Maguregui, Sarah Iacomini, Kristen Murphy



Medicare telehealth post-Public Health Emergency (PHE)

With the COVID-19 PHE concluding on May 11, 2023, many of the telehealth flexibilities the Centers for Medicare & Medicaid Services (CMS) implemented during the PHE will sunset at varying times. For example: CMS will continue paying for telephone Evaluation and Management (E/M) visits (via CPT codes 99441–99443) at the same rate as in-person visits through October 9, 2023; while other flexibilities (such as billing for telehealth services regardless of patient location; audio-only telehealth services; and an expanded list of eligible telehealth providers) will be available through December 31, 2024. Though such flexibilities are unlikely to be available during the same period in hospital outpatient departments. As a result, providers and facilities who have relied on Medicare's telehealth flexibilities as a key component of their care model these past three years must now re-assess their offerings and adjust operations to comply with the post-PHE landscape.

Prescribing controlled substances

In 2023, telemedicine prescribing of controlled substances will drastically change when the COVID-19 PHE expires on May 11, 2023. Since the start of the PHE in March 2020, the Drug Enforcement Administration (DEA) has waived the federal Ryan Haight Act's in-person requirement, allowing practitioners

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After passing telehealth statutes and rules in response to the pandemic, we anticipate states will hone in on modifications to telehealth modalities required for appropriate standards of care in 2023.

to prescribe controlled substances via real-time audio-video telemedicine. DEA also issued a separate waiver that allowed practitioners to prescribe buprenorphine, a schedule III controlled substance, via telemedicine (including audio-only telemedicine) for the treatment of opioid use disorder (OUD) without a prior in-person exam. To further increase access to buprenorphine treatment, the DATA-2000 waiver (or X-waiver), which was previously required to prescribe buprenorphine, was removed in December 2022. DEA has recently released two proposed rules interpreting the Ryan Haight Act, but if enacted as drafted, the rules would require some sort of in-person interaction to prescribe controlled substances via telemedicine (although not necessarily a prior in-person interaction).

Online ad trackers

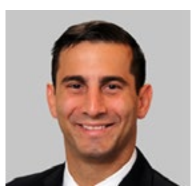
In light of heightened scrutiny related to use of online tracking technologies in the health care space, including recent Health and Human Services (HHS) guidance and Federal Trade Commission (FTC) enforcement action, digital health companies will need to carefully consider (i) how the data derived from analytic and tracking technologies via its website or mobile application is regulated; and (ii) the legal requirements the company must comply with before using such technologies to process data which may be considered HIPAA protected health information or otherwise personally identifiable.

State law practice standards and modalities

After passing telehealth statutes and rules in response to the pandemic, we anticipate states will hone in on modifications to telehealth modalities required for appropriate standards of care in 2023. For the most part, we anticipate further adoption of store-and-forward communication – as recently demonstrated by New Hampshire, which now allows use of asynchronous modalities, provided that the physician meets certain enumerated requirements (e.g., confirming the patient's identity). Some states may also clarify that internet prescribing prohibitions do not extend to dynamic/adaptive questionnaires by using language like the telehealth laws of Maine and New Jersey, which limit the states' internet prescribing prohibitions to "static" questionnaires. Overall, look for changes on the horizon of allowable telehealth modalities.

Regulatory changes impacting remote monitoring services

While Medicare reimbursement for remote physiologic monitoring and remote therapeutic monitoring has served as a catalyst for the industry's growth, a number of policy changes around the corner in 2023 will impact the industry. For example, Medicare Administrative Contractors (MACs) are considering publishing a local coverage determination (LCD) which could place restrictions and parameters around reimbursement; after May 11, providers can no longer extend blanket waivers of co-pays and must start collecting them from patients receiving remote physiologic monitoring (RPM) or remote therapeutic monitoring (RTM) services and RPM services will once again be limited to established patients; and the 2024 proposed physician fee schedule, to be released in July, likely will contain additional changes to RPM and/or RTM from CMS. Thus, continue to monitor for regulatory and legislative changes that affect or improve remote monitoring services.



TJ Ferrante
Partner
tferrante@foley.com
813.225.4148

Sunny Levine
Senior Counsel
sjlevine@foley.com
813.462.7712

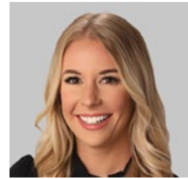
Rachel Goodman
Partner
rgoodman@foley.com
813.225.4158

Aaron Maguregui
Senior Counsel
amaguregui@foley.com
813.225.4129

Jennifer Hennessy
Partner
jhennessy@foley.com
608.250.7420

Sarah Iacomini
Associate
siacomini@foley.com
813.225.4100

Jacqueline Acosta
Special Counsel
jacosta@foley.com
813.225.4104



Kristen Murphy
Associate
kmurphy@foley.com
813.462.7700

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HEALTH CARE & LIFE SCIENCES

The BioPharma Patent Cliff: 2023 and Beyond

A "patent cliff" refers to the end of IP protection for a drug that has enjoyed market exclusivity since its launch. Various types of regulatory exclusivity can occasionally lengthen the protection for drugs, but generally when a drug loses patent protection we begin seeing generic competitors on the market.

Jason N. Mock

Of course, the expected term of exclusivity for a drug can be unexpectedly lengthened or shortened based on the outcome of patent litigation, Patent & Trademark Office patent reviews, and delayed biosimilar or generic launches.

Between now and 2030, the biopharma sector is expected to be rocked by a number of high-profile patent cliffs that are likely to reshape the market in potentially unpredictable ways. For example, many estimates suggest that the largest biopharma companies—such as Bristol Myers Squibb, Pfizer, and Amgen—will see significant percentages of their revenues absorbed by competitors launching copycat products.

Throughout the remainder of this decade, patent cliffs will open the market to competition for numerous brand new drugs like Humira (AbbVie), Stelara (Johnson & Johnson), Xeljanz (Pfizer), Pomalyst (BMS), Revlimid (BMS), Trulicity (Lilly), Keytruda (Merck), and Opdivo (BMS), just to name a few.

Understandably, companies and investors want to know how soon this will affect them and the scale to which it will. For their part, brand name companies can attempt to minimize the impact of price erosion following a patent cliff (i) through innovation and development of newer products still enjoying market exclusivity, (ii) through transactions, strategic partnerships, and other alliances between companies, and (iii) strategic IP life-cycle management to extend protection to the extent possible.

In 2023, several top drugs are set to lose U.S. exclusivity as patents expire or settlements allow for generic entry.

Of the impending patent cliffs in 2023, the most talked about is likely that of Humira. AbbVie's Humira is the world's most successful drug in terms of sales, bringing in more than $20 billion in revenue in 2021. While Humira is facing a cliff of sorts, this loss of exclusivity is related to settlements rather than a conventional patent cliff. Richard Gonzalez, CEO of AbbVie, claims that Humira has patent coverage out to 2034, and this coverage via a so-called "patent thicket" has sparked criticism and litigation, with the latter resulting in AbbVie inking multiple biosimilar deals with competitors.

Starting in January 2023, Amgen will be the first competitor to produce a biosimilar of Humira thanks to a settlement reached between the parties in 2017, but this settlement is only the first. AbbVie has made deals with at least eight competitors, including Boehringer Ingelheim, Pfizer, Samsung Bioepis, Mylan, Sandoz, and others, which will allow these companies to follow closely on the heels of Amgen.

The entry of multiple Humira competitors to the market is expected to allow Merck's Keytruda to dethrone Humira as the world's most successful drug, and with at least five years left on the term of key patents protecting Keytruda, Merck may maintain the top spot for years to come. However, the details of the settlements between AbbVie and the companies poised to produce Humira biosimilars are unclear, but the terms will likely provide AbbVie with a softer landing than companies facing a more conventional patent cliff.

Both Johnson & Johnson (J&J) and Merck will also face patent cliffs in 2023. J&J's Stelara, which is used to treat psoriasis, psoriatic arthritis, and Crohn's disease, and Merck's Type 2 diabetes drugs Januvia and Janumet will both lose IP protection this year, and the impact of this loss of exclusivity is difficult to predict. In general, small molecule drugs like Januvia and Janumet typically erode quickly following a generic entry, while biologic drugs usually retain a greater amount of market share even after a biosimilar hits the market. This is likely because biosimilars are difficult to make and, as a result, there are usually fewer competitors. Indeed, despite facing a patent cliff for its anti-TNFα antibody, Remicade, back in 2016, J&J was able to maintain the vast majority of market share (so much so that Pfizer sued J&J for anticompetitive deal making).

Other notable patent cliffs for 2023 include those for Takeda's ADHD drug Vyvanse and Novo Nordisk's Type 2 diabetes drug Victoza. Although Victoza will lose its primary patent protection in 2023, generics are not likely to launch until June 2024 according to Novo's Securities and Exchange Commission (SEC) filings.

As a result of the patent cliffs in 2023 and beyond, there will be an increasing pressure on large biopharma companies to replenish their pipelines, regardless of whether that comes from in-house R&D or new partnerships and acquisitions. Although current estimates suggest that more sales are at risk from upcoming patent expirations than are expected to be generated from new products, large biopharma companies may still be able to offset some of the resulting shortfalls and price erosion. In particular, the remainder of the decade is likely to see an uptick in new business development, strategic transactions, and a pursuit of new indications for existing drugs.

Jason N. Mock
jmock@foley.com
Senior Counsel
202.295.4775

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Growing Scrutiny of Private Equity in Health Care

The presence of private equity (PE) investment has exploded in recent years in all areas of the health care sector. PE in health care is a good thing when done right: It can pave the way for much needed innovation, efficiency, and nontraditional care delivery models.

Lori Rubin, Michelle Freeman, Samantha Robbins Jamali

However, government regulators, media journalists, some health care practitioners, and private parties are watching PE investment with growing suspicion that profit-driven goals may conflict with the quality of care for patients. Indeed, PE firms often do not have the luxury of long time horizons for their investments and often have investors that expect relatively quick financial returns. News outlets have added fuel to concerns by publishing reports alleging decreases in quality care when PE firms acquire health care businesses. Additionally, PE firms do not always appreciate the complex regulatory environment in which health care operates — an environment where a regulatory misstep can become a major fraud and abuse issue. That is drawing the focus of government enforcers. Meanwhile, PE investment is capturing the attention of antitrust regulators concerned about industry roll-ups and the lessening of competition.

The Biden Administration has made several pronouncements of its stance against what it calls Wall Street's "takeover" of health care. In accordance with this policy, anti-fraud and abuse government enforcers are becoming increasingly hostile to PE. Enforcers are looking beyond target companies to include the companies that invest in and manage them. In the last three years, PE firms have paid millions of dollars to settle government allegations that they knew of the allegedly improper practices of companies they backed, including a PE firm that allegedly knew of a scheme to pay purported kickbacks to marketers; a PE firm that allegedly learned of a purported unlawful scheme to submit false claims during due diligence of a company it invested in but did not put an end to the practice after investing; and a PE firm that held the majority of seats on the board of directors of a company that allegedly submitted claims for Medicaid reimbursement for unlicensed, unqualified, and inappropriately supervised patient care.

PE companies are also facing increased scrutiny by antitrust regulators. The Department of Justice's (DOJ) Antitrust Division has identified as among its enforcement priorities the cumulative competitive impact of PE-backed roll-ups, particularly smaller transactions that do not require Hart-Scott-Rodino Act (HSR) reporting which may over time reduce competition; market distortions stemming from PE prioritizing short-term financial gains and cost cutting over innovation and quality; and interlocking directorates which violate Section 8 of the Clayton Act (Section 8 prohibits directors and officers from serving simultaneously on the boards of competing corporations subject to limited exceptions because of the potential for anti-competitive effects such as facilitating collusion – e.g. pricing fixing and market allocation). This prioritized targeting of PE by DOJ, coupled with escalating rhetoric from antitrust enforcement leadership at DOJ and the Federal Trade Commission (FTC), suggests increased investigations and enforcement actions are forthcoming. One area where we see these priorities in action is that DOJ appears poised to proactively scrutinize interlocks as part of standalone investigations and enforcement actions (rather than only during merger or transaction reviews). DOJ can rely largely on publicly available information and filings to do so. In October 2022, DOJ announced the resignation of seven directors from the corporate boards of five companies after DOJ sent letters to multiple companies, including PE firms, expressing concerns that their board composition constituted unlawful interlocks in violation of Section 8 and warning that enforcement actions might be coming. While historically PE companies have not been the target of aggressive antitrust enforcement, they should be prepared for a different experience moving forward.

Private plaintiffs have gotten in on the action against PE firms as well, bringing lawsuits against PE-backed companies and their investors for violations of state corporate practice of medicine laws. Corporate practice of medicine laws prohibit corporations from practicing medicine or otherwise exercising undue influence on physicians and their medical care choices.

Despite their laudable contributions to innovation, efficiency, and influx of cash investment into the health care sector, PE firms do not always get a good rap, and we anticipate the unflattering buzz surrounding PE in health care continuing in 2023. Well-intentioned investors may not always be aware of the regulatory hurdles facing health care companies; downstream consequences to patient care of certain practices; or the evolving priorities and concerns of enforcers. Investors should seek to appreciate the complex regulatory scheme, including fraud and abuse, antitrust, and corporate practice of medicine risks, and the priorities and philosophies of enforcers, so that they can take proactive steps to manage risk.

Lori Rubin
Partner
larubin@foley.com
202.295.4760

Michelle Freeman
Senior Counsel
mfreeman@foley.com
313.234.7136

Samantha Robbins Jamali
Associate
sjamali@foley.com
213.972.4592

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Considerations When Conducting Decentralized Clinical Trials

Although use of telehealth in clinical trials is not new, the modality was not popularized until social distancing efforts brought about by COVID-19 forced the issue.

Kyle Faget

Companies interested in providing clinical trial services via telehealth have to deal with whether the carrying out the clinical aspects of a clinical trial is part of the practice of medicine. Some argue that clinical aspects of a trial is not the same as the practice of medicine. Others argue that there is clinical care required in case of an adverse event.

There exists evidence under state law that performance of clinical research constitutes the practice of medicine. Under Tex. Admin. Code § 177.1(2) (emphasis added), Texas defines actively engaged in the practice of medicine as follows:

> "The physician on a full-time basis is engaged in diagnosing, treating or offering to treat any mental or physical disease or disorder or any physical deformity or injury or performing such actions with respect to individual patients for compensation and shall include clinical medical research, the practice of clinical investigative medicine, the supervision and training of medical students or residents in a teaching facility or program approved by the Liaison Committee on Medical Education of the American Medical Association, the American Osteopathic Association or the Accreditation Council for Graduate Medical Education, and professional managerial, administrative, or supervisory activities related to the practice of medicine or the delivery of health care services. The term "full-time basis," for purposes of this section, shall mean at least 20 hours per week for 40 weeks duration during a given year."

Texas, therefore, explicitly includes *"clinical medical research"* in its definition of the practice of medicine, as well as "professional managerial, administrative, or supervisory activities related to the practice of medicine or the delivery of health care services." Although a number of states are silent on this issue, silence does not necessarily mean that research services are not considered clinical care subject to a state's practice standards. An argument exists that clinical research is not clinical care per se because the clinicians are typically following an Institutional Review Board (IRB) approved protocol and any regular care, even when provided in an emergency context, will be provided by a local, licensed clinician. Nonetheless, the fact that there exists states such as Texas that explicitly include clinical medical research in the definition of *engaging in the practice of medicine* means that entities entering the clinical research support services space must consider this issue when thinking about discerning applicable practice standards.

Where clinical research is considered the practice of licensed profession (such as medicine in Texas), the relevant legal requirements applicable to the practice of medicine will apply. For example, generally, healthcare providers must be licensed in the state in which a study subject is located unless an applicable exception applies. Moreover, applicable telehealth standards of care must be considered and adhered to when interacting with study subjects.

Issues such as compliant creation of the physician-patient relationship, modality requirements when creating and then maintaining the physician-patient relationship, remote prescribing requirements, (if applicable) controlled substance prescribing requirements, (if applicable) medical record requirements for telehealth practice, telehealth identity verification and disclosure requirements, and any emergency or follow-up care plan requirements.

One requirement bears unique consideration in the context of decentralized clinical trials. In addition to the standard IRB-approved informed consent accompanying a clinical trial, a number of states have specific consent requirements when utilizing telehealth that concern the treatment methods, risks, and limitations of using such a platform. Sponsors and sites will want to consider whether a telehealth informed consent must be used in addition to consents required for subjects participating in a clinical trial.

Each practice standard requirement and compliance thereto requires a state-by-state analysis where clinical research is considered the practice of medicine or is arguably considered the practice of medicine. Failure to adhere to such standards could subject study sites, investigators, and staff to unwanted enforcement. Study sponsors will want to think carefully about the representations and warranties in the applicable clinical trial agreement and how use of telehealth may or may not affect protocol development.

Kyle Faget
Partner
kfaget@foley.com
617.502.3292

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INNOVATIVE TECHNOLOGY

2023 M&A Outlook

There was great speculation that the decreased valuations of 2022 would lead to a surge in M&A activity; however, activity last year was lower than anticipated. Worldwide, deal value for M&A fell by 37% in 2022 compared with the prior year. 2022 saw the largest year-over-year percentage decline in deal volume since 2001. Inflation, unrest abroad, volatile capital markets, and rising interest rates are just a few of the factors causing the decline.

Eric Chow, Brandee L. Diamond, Louis Lehot

What does the M&A forecast look like for 2023? Will we see an uptick in activity, or will we continue to see a much more cautious approach from buyers and targets? Below are some of the predictions making headlines.

A Return to Normal

Many analysts have been predicting that we may see a return to pre-2021 activity. While we saw a precipitous drop in deal value and volume for 2022, this is due, in large part, to the incredible uptick we saw in M&A in 2021. 2021 was a blockbuster year for M&A with a historic number of transactions. That kind of activity is challenging to duplicate and exceed year after year. Leaving out the anomaly that was 2021, activity in 2022 was comparable to 2020. So, we may simply be experiencing a return to a more normalized M&A activity level as we move into 2023.

There Could Be a Spike in Some Areas

In 2022, tech deals accounted for approximately 20% of the value of all deals. In 2023, many expect tech to continue to drive M&A. In an interview with *The Information*, Goldman Sachs bankers told the outlet that consolidation among private tech firms could pick up this year. This could be particularly true for those startups who had to alter their IPO plans. These companies are likely exploring alternative exit strategies, and decreased valuations will make acquisitions in this space more attractive.

There is also some speculation that the FinTech industry could see higher levels in 2023. This has been an area that has seen steep drops in valuations and a roller coaster year in 2022. With valuations down, FinTech investors with a lot of dry powder will be more likely to deploy this capital in 2023. Many are also predicting market consolidation in the FinTech industry which may drive increased M&A for FinTech companies.

2021 was a blockbuster year for M&A with a historic number of transactions. That kind of activity is challenging to duplicate and exceed year after year.

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Ernst & Young is also predicting that an appetite for tech deals will return in 2023, citing a recent EY study that found "72% of tech CEO respondents plan to pursue M&A in the next 12 months, compared with 59% of CEO respondents across all industries." Acquisition potential could be especially true for the more innovative technology startups as companies look to take advantage of lower valuations and expand into new, highly innovative areas.

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Interest Rates vs. Dry Powder

Borrowing money is considerably more expensive due to multiple spikes in interest rates. Gone are the days of virtually free money. We have yet to determine what the Federal Reserve has in store for the remainder of the year, but markets view interest rate increases over the next few months to be probable. That means that it will continue to be expensive to borrow moving forward. However, the Federal Reserve may hit the top of its interest rate cycle and rates could level off for the second half of the year.

While the higher cost of taking on debt makes acquisitions more challenging, private equity firms have an unprecedented amount of dry powder in their reserves. These buyers can also use accruing, participating, and pay-in-kind dividends with a senior liquidation preference to structure around the interest. They will be looking to use their dry powder as valuations become more attractive. In addition, strategic buyers have strong balance sheets relative to prior recessionary periods, and will also be looking to take advantage of attractive valuations. The combination of these factors has the potential to bolster activity this year.

Due Diligence Will Continue to Be a High Priority

Due diligence will continue to be a higher priority for buyers as they look more closely than ever into their targets. In 2022, buyers took more time to conduct diligence on their targets, and this lengthening of time for the due diligence process will likely continue through 2023. As the market swings to favor buyers, we can expect them to use this leverage to understand the impacts of interest rates and other market factors as well as its ability to implement a growth strategy and any anticipated business synergies. Target companies will need to be prepared on their end, with financials and operations ready to face greater scrutiny.

It is difficult to predict with certainty the level of M&A activity in 2023, as market conditions and other factors can change rapidly. However, if the economy remains stable and valuations remain attractive, it is possible that we could see an increase in activity in M&A for 2023.

Eric Chow
Partner
echow@foley.com
650.251.1120

Brandee L. Diamond
Partner
bdiamond@foley.com
415.438.6401

Louis Lehot
Partner
llehot@foley.com
650.251.1222

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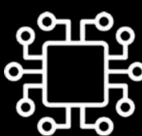

Where is Cloud Computing Heading in 2023?

The cloud computing market has grown at a rapid rate and is expected to continue that trajectory for years to come. With this increasing demand, it is important to stay up to date on the latest trends and technologies so you can make the most of the opportunities available. Here are some of the trends in cloud computing that you should look out for in 2023:

Chris McKenna

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The Popularity of Edge Computing is Growing

Edge computing is quickly gaining traction due to its ability to process data closer to where it is being generated. As more devices become connected, edge computing allows for the processing of an increased amount of data without having to send it to the cloud. This reduces latency and improves performance, making it an invaluable tool for any business.

As a side effect, edge computing allows for enhanced cybersecurity as data never needs to leave the device, providing an extra layer of security for businesses. Furthermore, it also provides cost savings for businesses as data processing can be done locally without the need for expensive cloud infrastructure.

Security Has Been and Will Continue to be a Focus

Cloud computing has become an integral part of organizations in the modern digital world, with an unparalleled ability to provide scalability and flexibility to businesses. However, security has increasingly become a key focus of organizations utilizing the technology. Security is and will always be an essential component of cloud computing, and organizations must take steps to ensure that their cloud environment is secure. Security is critically important because it ensures that confidential data is kept safe from malicious actors, and it also helps protect cloud infrastructure from cyber threats.

In the cloud computing environment, organizations must ensure that access to their services and data is secure and that all data is encrypted and stored securely. Organizations must also ensure that their cloud infrastructure is regularly monitored and updated to protect against potential security breaches. Companies need to continue to invest in advanced security technologies as well as to develop policies and procedures to protect data and ensure that their cloud environment is compliant with relevant regulations and industry standards.

Machine Learning and Artificial Intelligence Will be Widely Used

The importance of artificial intelligence and machine learning is rising in the field of cloud computing. Companies are now starting to leverage these potent technologies in ways that were previously impractical, thanks in particular to cloud computing. At a fraction of the cost of conventional computing systems, cloud computing offers access to enormous datasets, potent processing resources, and complex algorithms. With the ability to base judgments on the data they have obtained, this has enabled businesses to develop more accurate and effective models. Task automation, increased effectiveness, and cost savings are all now within reach. As cloud computing becomes more accessible and affordable, machine learning and artificial intelligence will become increasingly prevalent in many industries. In 2023, we can expect to see more companies using these technologies in combination with cloud computing to gain a competitive edge in the market.

Increasingly Common Cloud-Native Applications

Applications that are cloud-native are created to benefit from the scalability, adaptability, and affordability of cloud computing. These tools can subsequently be used to build solutions that are specifically tailored to an organization's needs. Cloud-native applications are rising in popularity as businesses turn away from on-premises technology and toward cloud-based solutions. Businesses can swiftly provision the resources required to run their applications as well as scale up and down as appropriate. Additionally, distributed computing's power is harnessed by cloud-native programs, resulting in better resource usage, performance, and availability. These advantages make cloud-native apps a tempting option for businesses wishing to maximize cloud computing.

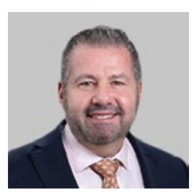
Serverless Computing Will Continue to Gain Traction

The way that companies and developers access computing resources is changing thanks to the innovative technology known as serverless computing. Simply said, serverless computing enables companies to execute apps without having to manage any infrastructure or servers. This allows businesses to concentrate on developing their applications rather than worrying about managing the underlying infrastructure. As a result, it is an appealing option for businesses seeking an easier approach to deliver apps.

Over the coming years, serverless computing will continue to gain in popularity as businesses look for more affordable and efficient ways to deploy programs. As a result, there will be less of a need for server provisioning and management, which can be an expensive and time-consuming necessity. Complementary to its other advantages, serverless computing also provides greater security because organizations are relieved of the responsibility of maintaining the underlying infrastructure.

Looking Forward

We expect to see companies taking advantage of the synergistic combination of serverless computing, edge computing, artificial intelligence, and machine learning to further drive efficiencies, experience, and performance. While edge computing enables local processing of data, serverless computing enables users to access their data from anywhere. In order to increase the speed, accuracy, and scalability of these applications, artificial intelligence and machine learning will benefit from leveraging both serverless and edge computing. This will lead to quicker decision-making and optimized performance.



Chris McKenna
Partner
cmckenna@foley.com
617.342.4057

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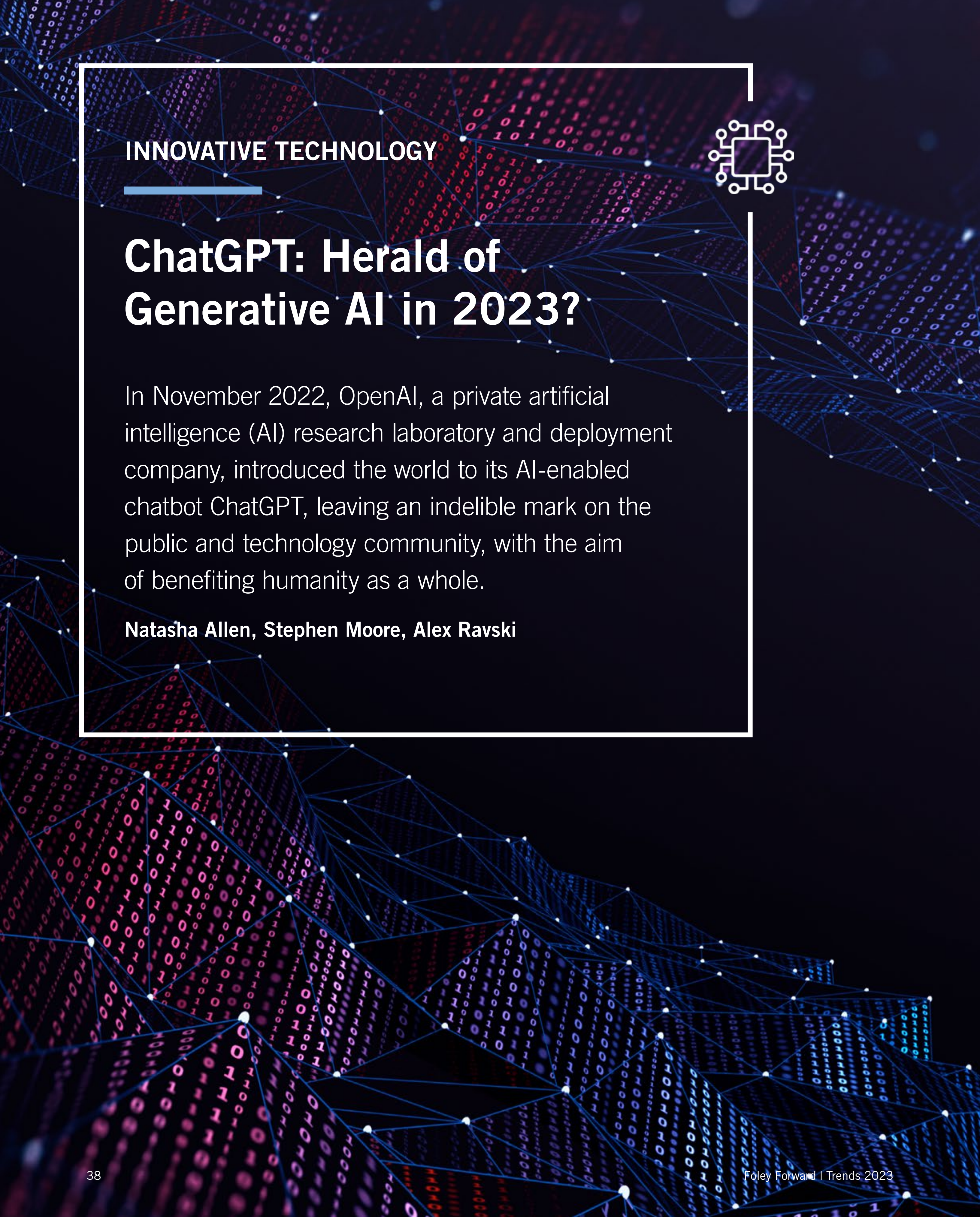

INNOVATIVE TECHNOLOGY

ChatGPT: Herald of Generative AI in 2023?

In November 2022, OpenAI, a private artificial intelligence (AI) research laboratory and deployment company, introduced the world to its AI-enabled chatbot ChatGPT, leaving an indelible mark on the public and technology community, with the aim of benefiting humanity as a whole.

Natasha Allen, Stephen Moore, Alex Ravski

It hit the world like a storm. Within five days of the platform's initial release, the company drew more than one million daily users,[1] and generated quite the buzz. Besides the publicity and energy behind the launch, what ChatGPT did was send shockwaves throughout the tech community and re-energized the belief in AI's real-world applications.

With this release, OpenAI has garnered widespread attention both in the news and from the investor community. In late January, Microsoft, which has already invested US$3 billion into OpenAI, confirmed its commitment to continue its investment in the company with estimates of an additional US$10 billion investment to come,[2] placing OpenAI's valuation at US$30 billion.[3]

What is ChatGPT?

ChatGPT stands for Chat "Generative Pre-trained Transformer" (GPT) which is an AI large language model (LLM) that deploys deep learning and autoregressive (AR) modeling. AR modeling is simply a model that predicts a future outcome in a series or body of text based on previously observed outcomes of that sequence. The model uses prior learned outcomes to identify patterns in LLM datasets, and repeatedly predicts the next word in a set of text based on those patterns and groupings identified. The prior learning of the model is the result of the AI training method known as Reinforcement Learning from Human Feedback (RLHF). RLHF relies on frequent human supervision and training to reinforce and reward the most accurate conclusions of the models. Below is an infographic visualizing the process:

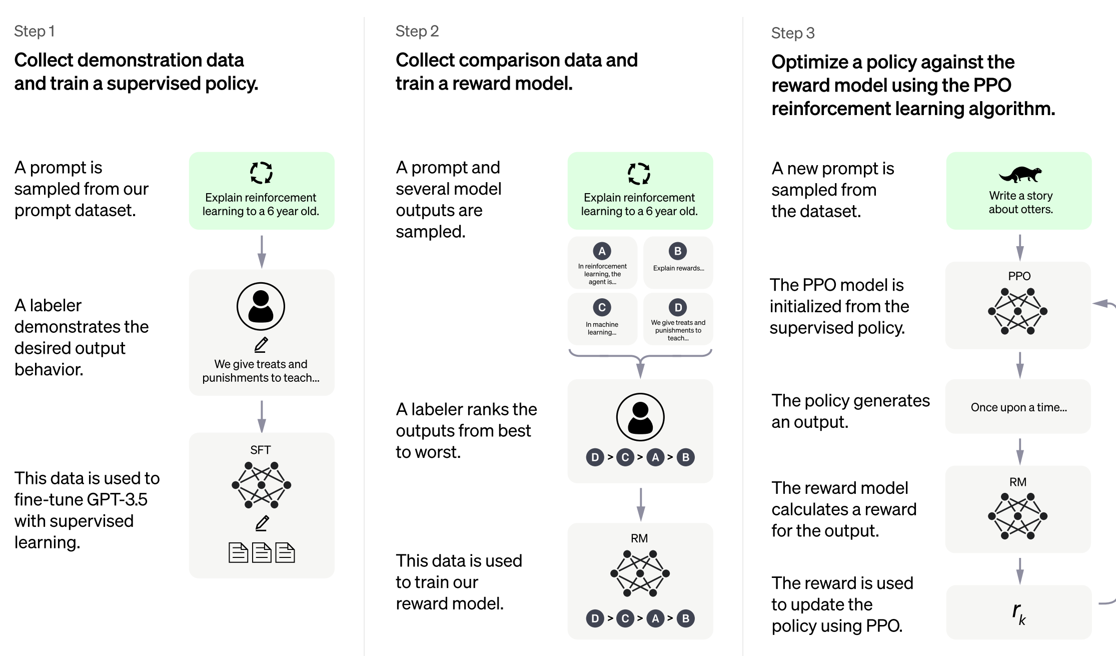

Image Source: "ChatGPT: Optimizing Language Models for Dialogue" OpenAI.

1 Helms, Shawn and Krieser, Jason. "ChatGPT Will Unleash Copyright Chaos" *Barron's,* 27 January 2023.

2 "Microsoft and OpenAI extend partnership" *Microsoft*, 23 January 2023.

3 Robbins, Jacob. "After Microsoft's OpenAI play, a feast at the generative AI buffet" *Pitchbook*, 30 January 2023.

While the public often associates LLMs with various iterations of the GPT, LLMs can be trained using a range of architectures, and are not limited to transformer-based models.[4] LLMs can process and produce various forms of sequential data, including assembly language, protein sequences, and chess games, extending beyond natural language applications alone.

It is important to recognize that the ChatGPT chatbot does not actually "know" anything. Rather, it applies a finely tuned model to identify patterns, group words, and quickly predict outcomes based on a library of information, with the caveat that the information stored on the ChatGPT server is limited to knowledge of events through 2021. Even ChatGPT tells us that it has limited knowledge of the world and events after 2021.

It is important to recognize that the ChatGPT chatbot does not actually "know" anything.

A prompt of "what is your knowledge based from?" yields the following generated response: "as an AI language model, my knowledge is based on a large dataset of text from the internet, books and other sources." Note, the training is constantly updated to ensure that ChatGPT has the most current information available.

For example, if you ask ChatGPT how many times Argentina has won the FIFA World Cup, you will get an answer of "two", in 1978 and 1986. It does not account for Argentina's recent World Cup win in 2022 in Qatar.

ChatGPT is not a new technology in many respects. It was built on the GPT models, specifically on top of OpenAI's GPT-3.5 and GPT-4 families of LLM. GPT is a type of neural network that uses a transformer-based architecture to generate text. Further, GPT-3.5 is a model variant of GPT-3, which is a highly advanced language model developed by OpenAI. Each new iteration tends to be more efficient and cost-effective than its predecessor, while still providing a high level of language understanding and generation capabilities.

GPT-4, the latest milestone in OpenAI's effort in scaling up deep learning, was released on March 14, 2023[5], and is made available via API and for premium ChatGPT users. GPT-4 is a large multimodal model, which allows it to accept image and text inputs, emitting text outputs, providing for a more interactive and immersive experience for the user.

A Panoply of Opportunity

ChatGPT is being heralded for the numerous applications and panoply of opportunities in a variety of industries and sectors. While this does raise concerns for those who fear AI job replacement,[6] it is more likely (at least for now) that its application will lead to new collaborative work streams for AI-enabled human work.[7] With just a few words typed into the prompt, ChatGPT can generate coherent text that feels authentically human in many cases, which means it can conceivably revolutionize many of the customer service chatbots in use today. It can also be used in a variety of research contexts to aid in the analysis and synthesis of thousands of texts in mere seconds. There is also a budding area of AI-as-creator opportunities with ChatGPT's capabilities in artistic endeavors such as poetry, screenplay drafting, storytelling, and even journalism.

To date, the chatbot has shown promise in passing various standardized and master's degree level tests in fields of medicine,[8] law,[9] and others, with limitations.[10]

4 Devlin, J., Chang, M.-W., Lee, K., and Toutanova, K. (2019). Bert: Pre-training of deep bidirectional transformers for language understanding. ArXiv, abs/1810.04805.

5 OpenAI. GPT-4 Release Announcement. 14 March 2023

6 Cerullo, Megan. "AI ChatGPT is helping CEOs think. Will it also take your job?" CBS News, 24 January 2023.

7 Book, Joakim. "ChatGPT Isn't Coming for Your Job (Yet)" Reason, 24 January 2023.

8 Kung, Tiffany et al. "Performance of ChatGPT on USMLE: Potential for AI-Assisted Medical Education Using Large Language Models" medRxiv, 21 December, 2022.

9 Sloan, Karen. "ChatGPT passes law school exams despite 'mediocre' performance" Reuters, 25 January 2023. and Choi, Jonathan et al. "ChatGPT Goes to Law School" SSRN, 25 January 2023.

10 Kung, Tiffany et al. "Performance of ChatGPT on USMLE: Potential for AI-Assisted Medical Education Using Large Language Models" medRxiv, 21 December, 2022.

Model capabilities are progressing rapidly. Consider the chart below that reflects the jump in exam performance between GPT-3.5 and GPT-4[11].

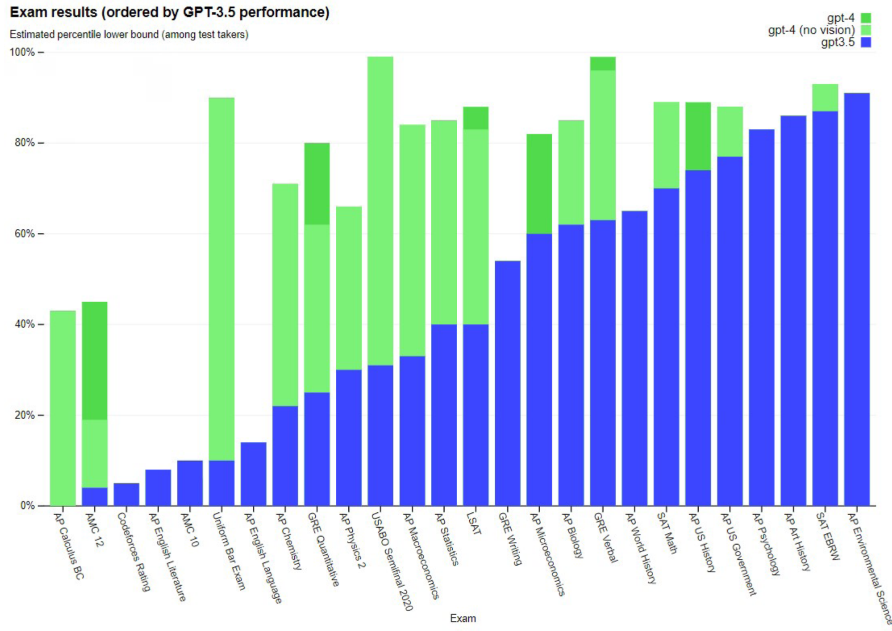

Image Source: "Exam results (ordered by GPT-3.5 performance)" OpenAI.

That being said, the program still has some ways to go, performing at the level of mediocre student in most of these examinations and oftentimes arriving at the correct answer for incorrect reasons. Additionally, the chatbot still has difficulty answering very basic questions in certain fields like math,[12] basic logical reasoning,[13] and computer programming.[14]

Limitations, Risks, and Ethics

ChatGPT is far from perfect in generating outputs, facing a number of concerning limitations that create risks for users. The chatbot has been shown on numerous occasions to write "plausible sounding, but incorrect or nonsensical answers."[15] In a recent study, it drafted fake scientific abstracts and papers that fooled reviewers nearly a third of the time.[16] Others have highlighted its proclivity for manufacturing made up sources to cite when answering technical questions, with the bot going as far as

ChatGPT is far from perfect in generating outputs, facing a number of concerning limitations that create risks for users.

11 GPT-4 technical report. Technical report, OpenAI

12 Von Hippel, Paul. "ChatGPT Is Not Ready to Teach Geometry (Yet)" Education Next, 4 January 2023.

13 Ansari, Tasmia. "Freaky ChatGPT Fails That Caught Our Eyes!" Analytics India Magazine, 7 December 2023.

14 Rose, Janus. "Stack Overflow Bans ChatGPT For Constantly Giving Wrong Answers" Vice, 5 December 2023.

15 "ChatGPT: Optimizing Language Models for Dialogue" OpenAI, Accessed 10 March, 2023.

16 Bushard, Brian. "Fake Scientific Abstracts Written By ChatGPT Fooled Scientists, Study Finds" Forbes, 10 January 2023.

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to use real authors' names associated with fabricated articles that do not exist.[17] These "hallucinations" are common for chatbots and create a risk with fidelity to the truth and reliability of the information derived from their use.

ChatGPT is also limited by the common AI issues of bias and unknowable data inputs and outputs commonly referred to as the "black box problem." The limited data through 2021 used by ChatGPT does not provide for a way to know whether the information relied on contains inherent biases. The potential of bias in AI is well documented and a point of contention when considering whether to use the technology, with critics of ChatGPT pointing to a potential political bias in the chatbots' outputs.[18] The issue of bias in the data is compounded by developers' inability to understand what information is being relied upon and how the AI-informed decision making actually occurs. This is due to the large corpus of data, the speed of neural networks, and the reinforced learning (AI vs. AI) algorithms these systems operate on, resulting in a "black box" machine that users and developers are unable to truly comprehend. This inability to audit the data and understand the purpose behind the machine's decisions poses a risk to users.

Additional ethical concerns have been raised in connection with how ChatGPT and chatbots will affect students. GPT is affecting how people learn. Educators around the world are raising concerns about the potential for these tools to undermine student learning and testing as many students are already admitting to using chatbots during coursework.[19] The concern of chatbot-generated plagiarism may be short lived though, as AI-generated text detection tools like GPTZero are being developed with incredible speed and efficiency.[20]

Finally, the issue of copyright and IP ownership is also at the forefront of the debate. The library of information that ChatGPT queries when deriving answers is often copyrighted and owned materials, begging the question of who or what intellectual property rights are attributed to the chatbot's output. This issue of AI authorship is not unique to ChatGPT, with other AI products like OpenAI's DALL-E 2, an image generator, raising similar concerns about artistic creatorship and ownership.[21]

> 2023 seems to be the year of AI. Human capacity will be pushed to new realms, we will interact with each other differently, ideas and efficiencies will be developed and implemented.

Just the Beginning

Despite their limitations, LLMs are becoming more and more popular and integrated into specialized applications in areas like writing assistance, coding, and legal researching, paving the way for businesses and individuals to adopt GPTs more widely and regularly.

The tech community is using ChatGPT to write web and mobile applications and to audit code. Creative users are even claiming that ChatGPT has built them businesses that make money.

17 "ChatGPT produces made-up nonexistent references" [Discussion Post], Y Combinator Hacker News, 3 December 2022.

18 Johnson, Arianna. "Is ChatGPT Partisan? Poems About Trump And Biden Raise Questions About The AI Bot's Bias—Here's What Experts Think" Forbes, 3 February 2023.

19 Westfall, Chris. "Educators Battle Plagiarism As 89% Of Students Admit To Using OpenAI's ChatGPT For Homework" Forbes, 28 January 2023.

20 Bowman, Emma. "A college student created an app that can tell whether AI wrote an essay" NPR, 9 January 2023.

21 Ellison, Steven. "Who Owns DALL-E Images?" FindLaw, 29 August 2023.

2023 seems to be the year of AI. Human capacity will be pushed to new realms, we will interact with each other differently, ideas and efficiencies will be developed and implemented. Perhaps this is the start, or progression of, another revolution, as the previous tech revolutions that came before it. While we are in early stages of AI, already there have been demonstrated use cases of AI in marketing and sales, creating personalized marketing literature and commentary, operations, providing for efficient task lists, IT and development, and other areas where complex answers are answered.

The AI revolution is here.

AI can use AI algorithms to create unique and original pieces of art (with legal implications of ownership, of course). AI can be used to generate new musical compositions, analyze fashion trends, create more realistic game characters, create recipes and perhaps even help do your homework! Of course, there are ethical and plagiarism concerns associated with some of the use cases. ChatGPT is further limited and is not designed to do the following:

- Physical tasks
- Make or provide moral or ethical judgments
- Provide medical treatment or diagnosis
- Provide legal advice
- Predict the future
- Provide comments on subjective topics
- Counsel or provide emotional support
- Engage in hateful, malicious, racial or harassing behavior or speech, or illegal activities

ChatGPT may have taken the world by storm since its re-release on March 14, 2023, but its unaccompanied rise was just the beginning. Numerous chatbot competitors are entering the marketplace with Google's Bard, Meta's LLaMA,[22] and Microsoft's improved Bing search being just a few of the LLMs launched or announced in 2023.[23] What will be the impact of ChatGPT and similar large language models? According to ChatGPT:

> "Chatbots like ChatGPT will significantly improve the efficiency and accessibility of customer service and support, while also automating repetitive tasks in various industries, such as education, healthcare, and business, freeing up employees to focus on more complex work. Their impact has the potential to revolutionize the way we interact with technology, making information and services more accessible to a wider range of people."

Natasha Allen
Partner
nallen@foley.com
650.251.1112

Stephen Moore
Associate
smmoore@foley.com
720.437.2029

Alex Ravski
Associate
aravski@foley.com
415.438.6414

22 Sundar, Sindhu. "Mark Zuckerberg just announced a new AI model 'LLaMA,' designed to help researchers make chatbots less 'toxic'" Business Insider, 24 February 2023.

23 Shakir, Umar. "Bing, Bard, and ChatGPT: AI chatbots are rewriting the internet" The Verge, Accessed 9 March 2023.

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INNOVATIVE TECHNOLOGY

What to Expect in 2023: Trends in Cybersecurity & Data Privacy

The New Year is in full swing and it's time to consider the top trends in cybersecurity & data privacy our team expects to see throughout 2023. It will be an exciting year due to the myriad of new laws coming into effect, and organizations will need to update their global cybersecurity & data privacy programs accordingly.

Kim Klinsport, Jennifer Urban, Lauren Hudon

Whether at a state, federal, or international level, these developments are likely to impact businesses in every industry over the coming months:

State Consumer Privacy Laws

California, Virginia, Colorado, Connecticut, and Utah are the five states that have enacted comprehensive consumer privacy laws. The California Privacy Rights Act (CPRA) and the Virginia Consumer Data Protection Act (VCDPA) went into effect **January 1**, and Colorado, Connecticut, and Utah go into effect later this year.

Although the CPRA is already in effect, the initial set of its regulations are not set to be finalized until April 2023. Further, the current regulations do not include regulations related to artificial intelligence (AI), cybersecurity audits, or privacy risk assessments, and the California Privacy Protection Agency (CPPA) recently commenced the rulemaking process on these topics. Additionally, the CPRA is currently the only law that applies to employment and business-to-business information as the CPPA has not indicated that it plans to extend the partial and temporary exception from the California Consumer Privacy Act (CCPA).

Colorado is the only other state to issue regulations related to its consumer privacy law. The Colorado Attorney General recently issued proposed regulations on the Consumer Privacy Act (CPA) and will begin holding stakeholder sessions in 2023. Although the CPA does not go into effect until July 1, organizations should begin assessing how the CPA and the proposed regulations will affect their overall privacy program.

Many other states are also considering adopting comprehensive consumer privacy laws so organizations will need to continually adapt their data privacy programs. Namely, organizations should map out what personal data they use, how they collect it, who has access to it, and where it is stored. In particular, organizations will need to assess if their use of data and advertising practices meet these new requirements. Organizations should also review privacy policies and related notice at collection to ensure the necessary information is disclosed to consumers, employees/applicants, and business-to-business contacts, if applicable. Due to the fact the laws are in flux, organizations should also monitor developments in state legislatures and other applicable global jurisdictions.

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Regulations Related to AI and Automated Processing

In 2023, organizations will be subject to new AI and automated processing related obligations under four new state consumer privacy laws. While organizations subject to the General Data Protection Regulation (GDPR) are likely familiar with the law's requirements related to AI and automated processing, the regulatory landscape in the U.S. remains uncertain and it is unclear whether there will be meaningful overlap between GDPR and state privacy laws. New consumer privacy laws in California, Colorado, Connecticut, and Virginia have AI/automated processing-related requirements, such as impact assessments on high-risk processing and opt-out rights, but questions remain on how states will address consumer harms and right to delete requests, and what type of information organizations should provide to consumers related to automated processing. Over the course of the year, organizations that use AI or automated processing technology should be mindful that new requirements are likely to emerge as California's rulemaking process is in progress and Colorado has issued proposed regulations.

Children's Privacy

The government remains focused on children's privacy. California recently enacted the California Age-Appropriate Design Code Act (CAADCA), which takes effect July 1, 2024. The CAADCA intends to protect the wellbeing, data, and privacy of children using online platforms and is modeled after the Age Appropriate Design Code recently enacted in the United Kingdom. On the federal level, the Federal Trade Commission (FTC) continues to aggressively enforce the Children's Online Privacy Protection Act (COPPA) by issuing hefty fines. Companies with online services directed to children or that have reason to know that children under the age of 13 use their services should ensure compliance with COPPA and state laws.

EU-U.S. Data Privacy Framework

The EU and the U.S. agreed on a data transfer regime last year and the EU recently issued its draft adequacy decision on the EU-U.S. Data Privacy Framework (DPF). The draft adequacy decision, if adopted, establishes that the U.S. offers appropriate safeguards to EU consumers and ensures the adequate level of protection for personal data transferred from the EU to organizations in the U.S. Although the DPF has been praised by EU and U.S. officials, EU regulators are already planning a challenge as they believe it falls short of the level of protection required by the GDPR.

Escalated Enforcement Actions and Litigation

2022 marked the first enforcement of the California Consumer Privacy Act (CCPA), and the expectation is that both domestic and international regulators will be increasing their efforts to identify and bring enforcement actions against entities they perceive as violating data privacy and security laws.

At the same time, the EU Advocate General provided guidance that data subjects are not automatically owed compensation for technical violations of the GDPR without material or non-material damage, and instead can only be compensated for actual harm. This may reduce private claims under the GDPR.

> According to the Verizon Data Breach Investigation Report, ransomware attacks increased 13% last year and will likely increase in 2023.

Cybersecurity Programs and Incident Response Plans

Cybersecurity remains a top priority for organizations as cyberattacks, including ransomware and cyber extortion, continue to increase year-over-year. According to the Verizon Data Breach Investigation Report, ransomware attacks increased 13% last year and will likely increase in 2023. Even the largest, most sophisticated organizations can be victims of data breaches as a result of cyberattacks. As such, organizations should proactively monitor risks and update their cybersecurity programs and incident response plans to defend against and efficiently respond to cyberattacks.

There is a myriad of new proposed laws on the horizon for this year, such as the New York Department of Financial Services (NYDFS) cybersecurity regulation, the Securities and Exchange Commission (SEC) cybersecurity disclosure requirements for public companies, and the Cybersecurity Incident Reporting for Critical Infrastructure Act (CISA) that could come into effect. As such, organizations should keep their eyes on these developments as they build their cybersecurity programs and incident response plans.

State Data Breach Notification Laws

In addition, state data breach notification laws are continually evolving with new and different requirements. Organizations must make it a priority to monitor these changes to understand their obligations in the event of a data breach and update their incident response plans accordingly. To learn more about state data breach notification laws and developments, please access Foley's state data breach notification chart here.

For more information about complying with cybersecurity & data privacy laws and building an effective program, please contact any Partner or Senior Counsel in Foley's Cybersecurity and Data Privacy Team.

Kim Klinsport
Partner
kklinsport@foley.com
213.972.4741

Jennifer Urban
Partner
jurban@foley.com
414.297.5864

Lauren Hudon
Law Clerk
lhudon@foley.com
414.319.7212

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INNOVATIVE TECHNOLOGY

Where is SaaS Heading in 2023?

As we look toward the future of Software as a Service (SaaS), it's clear that the landscape is changing rapidly. From artificial intelligence (AI) to data analytics, the industry is undergoing a rapid transformation that is shaping the way businesses operate and interact with customers. In this article, we'll discuss some of the trends that are expected to shape the SaaS industry in 2023 and beyond.

Chris McKenna

Artificial Intelligence and Automation

The SaaS sector will continue to be significantly impacted by AI and automation, which enables businesses to optimize their operations and deliver more individualized and effective client experiences. Companies can analyze client data, pinpoint issues, and provide solutions more quickly and precisely than ever before with the aid of AI-powered technologies:

- **Targeting:** AI will be used to evaluate customer data, enabling businesses to pinpoint client wants and provide tailored solutions.
- **Customer Service:** Companies will be able to quickly detect and resolve client issues with the use of AI-powered solutions, including chatbots that can be utilized to communicate with clients and provide prompt responses to questions. This will free up time for customer service workers and allow businesses to offer a more effective resolution of complex issues.
- **Preemptive Troubleshooting:** Companies will be able to identify client demands and provide answers before they are even asked thanks to AI-based predictive analytics. This can be used to enhance client segmentation accuracy and provide more tailored customer experiences.

Related to (and overlapping significantly with) AI, automation will be utilized to build and maintain customer databases, balancing customer service while lowering customer churn. This process will help companies automate mundane tasks, freeing up more time and resources for higher-value activities. We foresee these trends continuing in 2023 and beyond.

Data Analytics

Data analytics will be crucial for SaaS organizations in 2023 as the world continues to digitize. Companies offering services can watch and evaluate user interactions with their software thanks to data analytics, which enables them to decide how to improve offerings. They can subsequently use these techniques to learn more about the tastes and behavior of their customers, e.g. determining which features clients use the most, the least, and at what times of day. The user experience can then be enhanced, pricing and packaging can be optimized, and client segmentation can be made clearer with the use of this data.

Data analytics can also assist SaaS businesses in spotting trends, such as which features are gaining traction. As a result, they may be able to create new features or services in response to customer demand. Additionally, data analytics can aid in the identification of future issues with current products or services, enabling SaaS providers to fix them before consumer friction rises. In 2023, SaaS businesses will also need to focus on data analytics due to the growing use of AI, which can assist in automating difficult processes like customer segmentation, product recommendations, and data collection.

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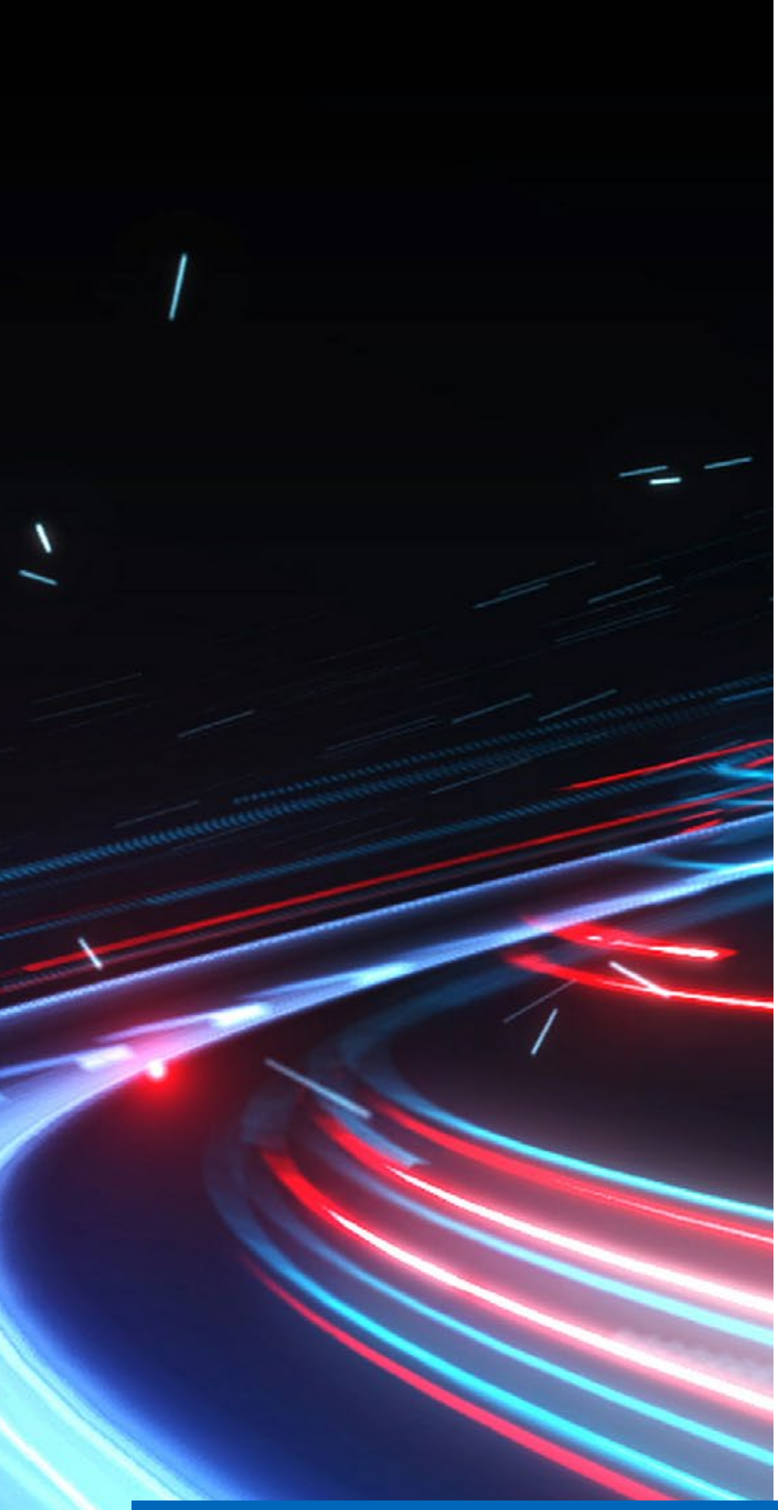

Cloud Computing

SaaS has been undergoing a revolution thanks to cloud computing, and this trend is only projected to intensify in the years to come. As a key component of SaaS infrastructure in 2023, cloud-based solutions will be the standard option for many companies for the following reasons:

- **Scalability:** The capacity to scale quickly and easily is the main benefit. With cloud computing, companies may access resources on-demand to accommodate demand spikes, enabling them to swiftly and effectively meet consumer needs.
- **Subscriptions:** SaaS businesses can now offer their services on a subscription basis so that users only pay for what they really use thanks to cloud computing. Customers find this business model appealing since it enables them to pay for the services they require when they require them. Additionally, it gives companies a more predictable pricing structure so they may better manage budgets.
- **Platform Agnostic:** SaaS vendors can more easily deploy their services across several platforms thanks to cloud computing. This means that users of various devices, such as PCs, phones, and tablets, can access the same services. As a result, SaaS companies can access a larger market.

SaaS and cloud computing go hand in hand, and we will see more SaaS applications being developed, deployed, and used in 2023 to drive the overall cloud computing market.

SaaS and cloud computing go hand in hand, and we will see more SaaS applications being developed, deployed, and used in 2023 to drive the overall cloud computing market.

Security

As mentioned above, there has been exponential growth in the cloud computing market with SaaS solutions gaining popularity among businesses of all kinds. At the same time, organizations are well aware of the possible repercussions of a security breach. SaaS providers and their customers are keeping cybersecurity in mind within the context of the growing, dynamic world of threats. SaaS solution providers must not only safeguard their data to keep a competitive edge in the market, but they also need to handle the difficulties presented by a more complicated security environment as the industry expands. As such, the adoption of cutting-edge security measures to stay ahead of the curve will continue.

Additionally, businesses must make sure their solutions comply with a variety of industry rules, such as the General Data Protection Regulation (GDPR), various state, federal, and international privacy laws, and application-specific data laws such as the Health Insurance Portability and Accountability Act (HIPAA). Security will be a top priority and integral aspect of SaaS and cloud computing in 2023 and for years to come.

Mobility

Finally, the incorporation of mobile applications will be crucial to the growth of the SaaS market in 2023. Providers will need to make sure their services are adapted for mobile platforms as more customers transition to mobile devices. These users will want a smooth experience across all devices in the future, making mobility a critical component of the success of any SaaS program:

- **User Interface:** The user interface is one of the most crucial components of a successful mobile application. Companies should concentrate on developing interfaces that are simple to use and comprehend. This is essential since clients who aren't technology knowledgeable require an easily utilized user interface to help them navigate the application.

- **Responsive Design:** Complementary to the success of an interface is responsive design, meaning the program can adapt to the size of the device it is being used on. Customers need to be able to quickly navigate the application on any device thanks to a consistent appearance across all devices.

- **Loading Times:** Last but not least, businesses need to make sure their applications load rapidly. Customers are impatient and frequently switch to another application if they have to wait too long for the application to load. Businesses should concentrate on mobile device optimization so that the application loads quickly even with sluggish connections.

In conclusion, the integration of mobile applications will be crucial for the SaaS market in 2023. To make sure their applications are mobile platform optimized, businesses should concentrate on developing user interfaces with easy controls, responsive design, and quick loading times. Customers will get a consistent experience across all devices thanks to this, which will also help businesses stay competitive in the SaaS market.

Looking Forward

The combination of mobility, artificial intelligence, and data analytics will be crucial elements of effective SaaS applications in 2023. Customers may access their applications anywhere, at any time, which enables them to remain connected and productive from any place. Businesses can gain real-time insights from AI and data analytics into customer behavior and preferences, which will enable them to better understand needs and tailor service offerings. By having a well-designed strategy to utilize a combination of these technologies, SaaS businesses can make sure they maintain their competitiveness in a market that is constantly evolving.

These are just a few of the trends that we can expect to see in the SaaS industry in 2023 and beyond. With the right strategies and solutions in place, companies can capitalize on these and create more efficient and effective customer experiences.

Chris McKenna
Partner
cmckenna@foley.com
617.342.4057

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INNOVATIVE TECHNOLOGY

What's Next for Blockchain Tech and Crypto in 2023?

Following the recent closures of Silicon Valley Bank, Signature Bank, and Silvergate Bank and Credit Suisse's takeover by Swiss-based rival UBS, ramifications for blockchain tech and crypto-based assets and deals are unavoidable.

Patrick Daugherty, Louis Lehot, Alex Ravski

The banking crisis arose less than six months after the crypto industry suffered the loss of billions of U.S. dollars upon the failure of FTX. While some proclaim the beginning of the end of crypto assets and Web3 technologies, we continue to see a multi-trillion-dollar asset class and technologies with applications and utility far beyond your wallet. Bitcoin, the leading indicator for the crypto asset class, which first tumbled to ~$16K/BTC from ~$46K, has recently seen an increase to ~$27K as of this writing.

With a new Congress in 2023 and a first-ever Subcommittee on Digital Assets, the road has been paved for thoughtful legislation and effective oversight of federal financial agencies charged with establishing a regulatory framework beyond enforcement. Simultaneously, the community can expect auditors, investigators, and bankruptcy courts to illuminate what went wrong inside some of the centralized financial institutions supporting the dynamic decentralized crypto ecosystem.

How Did We Get Here?

Seven key events and paradigm shifts occurred in 2022 that had a direct impact on the crypto industry outlook for 2023. As summarized in CB Insights' recently released State of Blockchain 2022 Report:

1. **Blockchain venture funding and deals hit new highs in 2022** US$26.8 billion worldwide
2. **The FTX failure and bankruptcy, and a drop-off in blockchain tech funding hit hard in Q4' 2022** With only US$3.2 billion raised, there was a 64% drop in funding in Q4'22 vs Q4'21. The FTX bankruptcy in November 2022 led to a crash in crypto asset prices, a loss of consumer trust, and a web of affected counterparties that will take years to unravel.
3. **The average blockchain tech deal size fell from US$21.2m in 2021 to US$16.2m in 2022** This was driven by a sharp drop in US$100 million+ mega-rounds throughout the year. Investors gained more power over deal sizes, as less capital chased fewer deals.
4. **Blockchain unicorn count stalled out at 79 at the end of 2022** Only two new unicorns entered the market in Q4'22 -- Uniswap Labs, the leading decentralized exchange, and Celestia, a Layer-1 blockchain network.
5. **Over half of global blockchain tech funding in 2022 went to U.S.-based companies** U.S-based blockchain companies raised US$15.3bn, while Asia-based blockchain companies raised a record US$4.7bn in 2022, up from US$3.2bn in 2021.
6. **US$15.1bn in funding went to Web3 startups** Dollars flowed away from centralized exchanges (including wallets) from US$6.9bn in 2021 to only US$3.6bn in 2022, and instead concentrated in differentiated verticals like Web3 and blockchain infrastructure.
7. **Blockchain tech infrastructure and development had a record year for funding** This signals investor confidence in blockchain tech's future irrespective of crypto asset price volatility. In the second half, VCs pulled back on making deals as institutional demand for crypto waned.

What to Expect in 2023 and Beyond?

Q4'22 reflected a significant downturn in VC investment into and activity within the crypto market. That said, despite the downturn, 2022 reflected significant amounts of invested capital and deals.

In Pitchbook's recently released Q4 2022 Emerging Tech Research – Crypto Report, recent VC trends and emerging opportunities were highlighted and are summarized below.

Practical Use of Crypto Assets

While the crypto market has grown exponentially in the past decade, the practical benefits of crypto assets remain elusive in most cases, as many projects and companies are still in the experimental phase. We believe that retail adoption is unlikely to grow significantly again in the United States until a workable regulatory framework is adopted. The crypto industry also needs payment rails, which U.S. banking regulators were curtailing even before the failures of Silvergate, SVB, and Signature Bank (each of which held significant fiat deposits on behalf of crypto-industry pillars). Meanwhile, crypto asset adoption continues to grow outside the United States, especially in regions such as Latin America.

Securities Tokens, NFTs, and the Real-World Asset Tokenization Phenomenon

Related to digitally native crypto assets such as Bitcoin and Ether, but with demonstrable real-world value, are securities tokens, NFTs, and other tokenized assets (such as tokenized real estate). The development and launch of these products continues apace and in our view is benefiting from the headwinds faced by the rest of the crypto industry. Well-designed NFTs are not securities. Millions of them exist and more are coming on line all the time.

Not only real estate, but indeed any kind of asset, can be tokenized and sold, then resold, in Securities and Exchange Commission (SEC)-authorized markets and on off-shore platforms. Foley obtained the first SEC and Financial Industry Regulatory Authority (FINRA) approvals for such a market and we are presently advising other old and new market participants and advised on the first sale of real property via non-fungible token. According to survey results release by BNY Mellon, 91% of institutional investors are interested in owning tokenized products. We expect to continue to see and help lead the rapid growth in this sector.

Emerging Technologies

Key developments to watch out for:

1. **Blockchain networks**
2. **Infrastructure and developer tools**
3. **Access**
4. **Web3**
5. **Decentralized Finance (DeFi)**
6. **Real World Asset Tokenization**
7. **Staking providers**

Network Effects Are Kicking In

Metcalfe's law posits that the value of a network increases exponentially as the network itself grows linearly. We are seeing Metcalfe's law at work in U.S. and global crypto adoption. More than 50 million U.S. citizens and residents have bought crypto assets. More than 400 million people worldwide own crypto assets. At this point, crypto assets are here to stay.

At the recent ETHDenver conference, politicians were in attendance, hoping to cement the mutual sentiment between government and the crypto industry in favor of cooperation. The creation of the Digital Assets Subcommittee of the House Financial Services Committee certainly is a favorable development, likely to lead to thoughtful legislation.

Further showcasing adoption, the M&A sector continues to document the use of digital assets by transaction parties. Law and business schools teach digital assets, NFTs are on the rise again, and, as noted, real world asset tokenization is growing.

Regulations and Enforcement

We expect the Department of Justice (DOJ), SEC, Federal Bureau of Investigation, and Treasury Department to continue to crack down on bad actors in the cryptocurrency space and address criminality in the dark web. For example, on January 18, 2023, the DOJ, together with the Treasury Department, and French law enforcement authorities disrupted Bitzlato, a China-based cryptocurrency exchange alleged to be the broker of choice for criminal proceeds from the dark net. In light of geopolitical developments elsewhere, the Treasury Department has heightened scrutiny of transactions with Russian interests, through which dark net activity is alleged to be conducted.

Separately, on March 10, 2023, Ether, the native cryptocurrency for Ethereum, fell to its lowest market price in two months when the New York attorney general asserted that it is a security, bracketing it with assets such as stocks and bonds and fueling fears of a wider regulatory crackdown. We are seeing continued monitoring, regulation and enforcement in the crypto asset markets on multiple levels, including a significant tightening of state-by-state money transmission regulation, which is redefining the regulatory framework for the digital asset marketplace.

Despite financial instability, regulatory crackdown, devaluation of crypto assets and the behavior by some participants in the centralized sector of the crypto industry, crypto assets are here to stay in one form or another.

Additional Thoughts About 2023[1]

1. Market success for centralized crypto players will depend upon re-establishing trust
2. There will be more enforcement activity until Congress legislates
3. Bipartisan work on legislation to regulate stablecoins is moving ahead
4. TradFi will continue to lean into permissioned blockchain tech while opposing crypto
5. Web3 will make a bigger splash
6. NFTs are growing again
7. Real-world utility will be a major focus

Despite financial instability, regulatory crackdown, devaluation of crypto assets and the behavior by some participants in the centralized sector of the crypto industry, crypto assets are here to stay in one form or another. Decentralization aligns with the yearning of the human spirit for freedom and self-governance. We don't see that changing, despite recent setbacks.

Patrick Daugherty
Partner
pdaugherty@foley.com
312.832.5178

Louis Lehot
Partner
llehot@foley.com
650.251.1222

Alex Ravski
Associate
aravski@foley.com
415.438.6414

1 PwC. "5 crypto and NFT trends that matter right now" Accessed 24 March 2023.

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