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Life Sciences Playbook

Navigating Operational and Regulatory Challenges While Emerging From the COVID-19 Pandemic

How life sciences companies can position themselves to thrive as the industry prepares to deal with the new normal caused by the pandemic

By Buchanan Ingersoll & Rooney Life Sciences Attorneys

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INTRODUCTION

When SARS-CoV-2 (the novel coronavirus) and the COVID-19 pandemic came to the U.S., the life sciences industry faced a great number of challenges. Workforces were required to conduct business remotely, clinical trials were put on hold, and new policies were rapidly put into place by the Food & Drug Administration (FDA).

Yet so far, the industry has risen to the occasion and responded with great strength and resilience. Companies have rallied to create new treatments, personal protective equipment (PPE), and medical devices, and have worked expeditiously to develop and test new vaccines in an effort to protect the world from this deadly virus.

Life sciences companies will face new challenges as the industry considers life after the pandemic. The time has come to look toward the future and ask ourselves what about this industry will change, what will go back to normal, and what new opportunities will arise?

For life sciences companies looking to thrive in a post-pandemic environment, there is a lot to keep track of. Everything from regulatory shifts, supply chain changes, and new operational best practices are worth closely monitoring. At Buchanan Ingersoll & Rooney, our life sciences attorneys are keeping their finger on the pulse of the industry, including throughout these challenging times. We have turned these insights into this playbook to help organizations think about the many changes coming to this industry so you can position your company for success. The playbook provides general counsels, CEOs, compliance officers, regulatory affairs managers, and many others the information they need to thrive in this new operating landscape.

SECTION 1

EMERGING FROM THE COVID-19 PANDEMIC IN A POSITION OF STRENGTH

BY BARBARA A. BINZAK BLUMENFELD, PH.D. AND TINA HU-RODGERS

Based on the advice of public health experts, state and local officials are taking a phased approach to reopening their economies and allowing business operations to resume, in order to minimize risk to their citizens. Until data-driven conditions in each region or state are satisfied to allow them to move through the various phases of reopening, businesses including life sciences companies will be operating under a new paradigm.

As the life sciences industry at large begins to resume operations, companies will need to critically assess how this new paradigm will affect the way they engage in what has up until now been standard industry-wide business practices, and consider how to adapt to this new reality. We offer several examples of efforts that companies can take now to emerge from the pandemic in a position of relative strength.

COMPANIES SHOULD EXPLORE NEW OPTIONS FOR COMMUNICATING INFORMATION ABOUT THEIR PRODUCTS.

As business resumes, employers are considering continued employee teleworking, social distancing measures, and minimization of non-essential travel.. Larger venues may be permitted to operate, but only under limited physical distancing protocols per Centers for Disease Control and Prevention (CDC) guidelines. In practice, this means that large industry-wide conferences, speaker programs, meetings with trained healthcare professionals on how to use products, and in-office healthcare visits by sales representatives will not be feasible.

Life sciences companies that have long relied upon these avenues for educating stakeholders about their new and existing products will need to get creative and utilize other means to effectively convey information and capture the same broad audience. Promotional communications are highly regulated by FDA, and written and media communications inherently lack some of the flexibility of in-person presentations. In this age of social media, the Agency is paying particular attention to the information conveyed by companies on electronic platforms, so companies will need to be sure they are in full compliance with FDA's rules for promotional communications.

KEY TAKEAWAYS:

Industry should expect that their ability to communicate information about their products will be somewhat restricted due to continuing social distancing requirements. Traditional, in-person means to present this information will not be feasible, so companies will need to get creative with how they utilize more remote means to convey the same information and reach the same broad audience. These communication platforms may include webinars, virtual meetings, or social media outlets. At the same time, companies need to keep in mind that these new remote means will likely be more easily policed by FDA. Accordingly, companies will need to take extra precautions to ensure that their communications are compliant with the Agency's rules regarding promotional outreach.

COMPANIES WILL NEED TO MAKE CHANGES TO THEIR PRODUCT R&D AND MANUFACTURING OPERATIONS.

Social distancing restrictions will similarly impact companies' physical operations. On the product development side, traditional laboratory bench work, animal testing, and clinical trials for safety and efficacy will all likely be affected as all of these functions require close collaborations of various parties. Most of these operations have not yet been set up to allow people to continue to do work in isolation and/or off-site, and some operations simply cannot take place from home or another remote location.

Enrollment in clinical trials, many of which are conducted at hospitals, may also see a decline, as patients will likely want to limit their exposure to hospitals (which are often viewed as COVID-19 hot-spots). Similarly, on the manufacturing side, companies will need to adjust their factory operations to ensure that social distancing guidelines are being followed within the facilities. Equally important, managing the supply chains for active pharmaceutical ingredients (APIs) or other materials that may have been impacted by the pandemic will inevitably affect cost and production capabilities.

KEY TAKEAWAYS:

Industry should expect that significant changes will need to be made to their product R&D and manufacturing operations in the short term to accommodate the need for continued social distancing. Companies will need to come up with creative new ways to allow product development to progress remotely while also ensuring the integrity of data being generated from these activities. Protocols will also need to be established to ensure manufacturing and production can continue uninterrupted, to the extent possible, while also maintaining the safety of employees. Finally, companies should assess the impact of the pandemic on their normal supply chains, and consider alternative sources if needed in the short term while diversifying supply chains for the long term.

COMPANIES WILL NEED TO MANAGE THEIR EXPECTATIONS ABOUT CAPITAL INVESTMENTS AND REVISE THEIR BUDGET AND FUNDING STRATEGY ACCORDINGLY.

Life sciences companies developing new products frequently will take product development through a particular stage and then look for an exit strategy. However, as we emerge from COVID-19, product development is likely to be impacted at all stages. R&D or manufacturing difficulties can stretch out investor timelines, making investments more risky and less attractive. Additionally, in the near term, investors may be more likely to focus on investing in COVID-19-related products. Companies should therefore plan for funding challenges in the near term, and revise their budgets and revenue projections accordingly.

KEY TAKEAWAYS:

Companies should take a close look at their current budget and revenue projections, and be prepared for difficult conversations with investors, if necessary. Thinking about alternative revenue streams can help ease the impact of any negative projections.

COMPANIES SHOULD CONSIDER ALTERNATIVE REVENUE-ENHANCING PRODUCT OPPORTUNITIES.

There are other less-considered and nonconventional ways to increase company revenue that may be worth considering. For example, now might be the time to acquire a product, as many companies are highly leveraged and accretive asset acquisition may be possible. Similarly, it may be time to bring back an older discontinued product, acquire the rights to a discontinued product, or repurpose an existing product through a 505(b)(2) new drug application (NDA). Another potential opportunity is to link with telemedicine companies, testing companies, medication therapy management programs, or home monitoring companies as more and more medicine delivery and management becomes “virtual” in the wake of the pandemic.

KEY TAKEAWAYS:

Companies considering a product acquisition, bringing back an older product, or repurposing an existing product need to consider the time, cost investment, and return of such a move; prepare a plan; identify current and future roadblocks; and prepare to tell the story of how the move will bring value to the company. Companies considering alternative approaches to partnering with a telemedicine or other healthcare delivery platform should ensure that any arrangement is structured to be in compliance with the fraud and abuse laws relevant to the provision of healthcare.

MAKE YOUR VOICE HEARD BY DECISION-MAKERS.

The most successful companies are those that not only understand the regulatory process, but that also know how to accomplish their goals in Washington. Companies that can adapt to the speed of developments in Washington and that know how to present their (and their industry's) needs are more likely to be heard when decisions are made. As Congress contemplates additional COVID-19 relief measures, life sciences companies should carefully consider how they and their industry could benefit from additional Congressional relief, and make their issues known to their representatives.

KEY TAKEAWAYS:

Life sciences companies should closely monitor any new relief packages that are proposed, and reach out to federal representatives to ensure that they will receive the support needed for their business. This could be the start of a new active approach that a company takes to make sure its voice is heard by the relevant decision-makers.

Getting back to "business as usual" will be a very gradual and constantly evolving process. Life sciences companies that are cognizant of the new paradigm and take proactive steps to ensure that their business operations are flexible enough to adapt to these changing conditions will likely have the most success.

SECTION 2

ADAPTING TO THE SUNSETTING OF FDA'S COVID-19 POLICIES

BY BARBARA A. BINZAK BLUMENFELD, PH.D. AND TINA HU-RODGERS

Many corners of the life sciences industry have been impacted by FDA's issuance of temporary policies in response to the coronavirus public health emergency. Some companies are making products to address the pandemic; others have continued to operate their normal businesses under temporary Agency changes to clinical trials or the requirements of the Drug Supply Chain Security Act (DSCSA). Such modified policies will largely only be in effect during the public health emergency and will eventually sunset, though it is not clear when this will happen. How should the industry prepare for the eventual sunsetting of those policies?

Thinking and planning ahead should be priorities for any life sciences industry company. There are a number of key considerations for companies to keep in mind as they prepare to revert to pre-pandemic Agency policies in the future.

COMPANIES MARKETING PRODUCTS TO SPECIFICALLY ADDRESS COVID-19 UNDER AN EMERGENCY USE AUTHORIZATION (EUA) MUST PLAN FOR EUA EXPIRATION WHEN THE PUBLIC HEALTH EMERGENCY IS DECLARED OVER.

FDA has issued numerous EUAs that permit both approved and unapproved products to be temporarily marketed to address COVID-19. However, when the public health emergency is declared over (or if FDA decides to revoke a EUA at an earlier time, such as for chloroquine and hydroxychloroquine), any EUAs issued during the public health emergency cease to exist—as does the legal basis for marketing a product under those EUAs. FDA has made it clear that marketing a product under a EUA is merely a temporary authorization meant to address the pandemic. It is not intended to replace traditional product development pathways. Companies that want to continue marketing these temporarily authorized products after the public health emergency is declared over are expected to seek traditional approvals for their products at that time.

Examples of products currently marketed under EUAs to address COVID-19 include in vitro diagnostic tests, high-complexity molecular-based laboratory-developed tests (LDTs), and SARS-CoV-2 antibody tests. Ventilators and certain drug products are also authorized under EUAs. Finally, certain personal protective equipment (PPE) such as gowns, protective barrier enclosures, face shields, and filtering facepiece respirators are also being marketed under EUAs.

KEY TAKEAWAYS:

Companies must ensure that they have an alternative legal basis to continue to market a product when a EUA is revoked or terminated, such as an investigational new drug application (IND), new drug application (NDA), investigational device exemption (IDE), premarket notification (510(k)), or premarket application (PMA). Companies should begin considering now whether they intend to continue marketing a EUA-authorized product post-pandemic and, if so, should start formulating a development strategy.

COMPANIES SHOULD STAY APPRISED OF CHANGES TO FDA'S TEMPORARY MARKETING POLICIES AND THINK BEYOND THEIR TERMINATION DATE.

In addition to products under EUAs, companies are bringing other COVID-19-related products to market under temporary FDA policies. When the pandemic is over, FDA largely intends to revert back to policies that were in place prior to the public health emergency.

Examples of such products being marketed under temporary Agency "enforcement discretion" policies for the duration of the public health emergency include patient examination gloves and surgical gloves, as well as alcohol-based hand sanitizers. FDA also has temporary policies for drug compounding, including compounding of specific drugs by outsourcing facilities for hospitalized patients, and compounding of specific drugs for hospitalized patients by pharmacy compounders that are not registered as outsourcing facilities.

KEY TAKEAWAYS:

Companies should stay apprised of changes to FDA's temporary marketing policies and think beyond their termination date. These policies are being regularly revised. Furthermore, like the termination of a EUA, companies marketing products under temporary policies should think about whether they are interested in long-term marketing beyond the pandemic and, if so, what their FDA regulatory strategy will be.

COMPANIES THAT WERE NOT MARKETING COVID-19-RELATED PRODUCTS MAY NONETHELESS HAVE BEEN IMPACTED BY OTHER TEMPORARY FDA POLICIES THAT WILL EXPIRE WITH THE PUBLIC HEALTH EMERGENCY, AND MUST PREPARE ACCORDINGLY.

Even if a company has not been producing products to address COVID-19, it may have been impacted by temporary policies that enabled it to take (or refrain from taking) certain measures intended to ease regulatory burdens on both industry and FDA. Some examples include the following:

- **CLINICAL TRIALS GUIDANCES**

  FDA has issued a number of new clinical trial guidance documents directed toward both COVID-19 and non-COVID-19 products. Those directed towards COVID-19 include pre-IND meetings and general development considerations. Those directed towards all clinical trials more generally include, for example, information for sponsors about clinical trial subject safety, compliance with good clinical practices, and minimizing clinical trial risk.

- **DSCSA GUIDANCE**

  When a public health emergency is declared, certain activities related to prescription drugs are excluded from DSCSA requirements. For example, product distribution for emergency medical reasons is exempted from the definition of a "transaction" and excluded from the definition of "wholesale distribution" under the law. Accordingly, certain DSCSA provisions will not apply in particular situations during the pandemic.

- **ADVERSE EVENT REPORTING**

  During a public health emergency, FDA recognizes that neither companies nor FDA may be operating at full capacity, and job functions may have shifted. Furthermore, there may be increased adverse event reporting due to COVID-19-related products. The Agency has therefore provided guidance that can help industry comply with its normal adverse event reporting requirements during the pandemic. The policy indicates when certain reports for drugs, devices, dietary supplements, blood and blood components, source plasma, and human cells, tissues, and cellular and tissue-based products (HCT/Ps) must be submitted and when they can be held for later reporting.

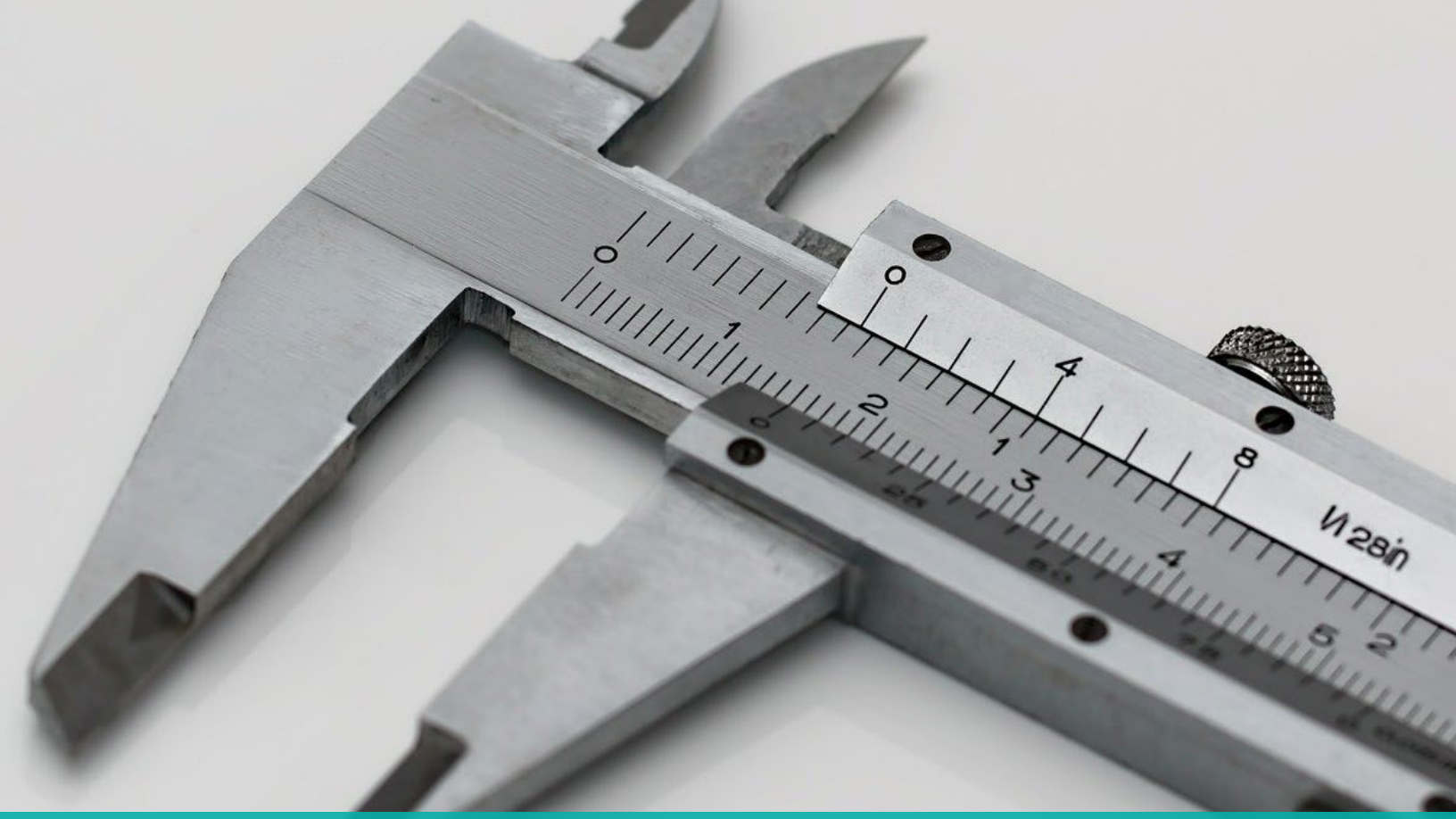
- **COMPLIANCE WITH CERTAIN RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS**

  In the case of certain drug products subject to REMS, the Agency has stated that it will not take enforcement actions against drug companies or others if accommodations are made during a public health emergency for laboratory testing or imaging study requirements that would otherwise be required. These accommodations should be made based on a health care professional's judgment, and the accommodations that are made for patient access to such drugs should be described in the next REMS assessment report.

KEY TAKEAWAYS:

Companies that have been operating under a temporary FDA policy during the public health emergency should make certain they are aware of any updates and changes to those policies while they are still operational. Companies should also be thinking about how to transition back to normal pre-pandemic FDA policies, such as how and when the company will report to FDA any clinical trial changes instituted to protect enrolled subjects during the pandemic, and how those temporary changes will impact the overall clinical development program.

FDA's efforts to both enhance production of COVID-19-related products and to accommodate normal industry operations and product development during the public health emergency have resulted in its issuance of many temporary policies. Not only must companies be aware of the fact that these policies are rapidly changing while we are still in the pandemic, they must also be aware that these policies will largely sunset when the public health emergency is declared over. Despite the continued uncertainties, well-prepared companies will begin to think now about how they will transition their operations and regulatory activities to policies that existed before the pandemic.



SECTION 3

PRIORITIZING RISK: RECALIBRATING LIFE SCIENCES COMPLIANCE PROGRAMS TO RISE FROM COVID-19

BY JOHN P. CUNNINGHAM AND TERRY M. BROWN, JR.

The spread of COVID-19 disrupted business operations at companies of all sizes (and in most industry sectors), with life sciences corporations experiencing among the more severe impacts. Legal and compliance officers at life sciences companies are grappling with newer compliance issues and program monitoring challenges, primarily those generated by the measured reopening of the economy. Maintaining compliance functionality, ethics and integrity standards, and program oversight as conditions continue to change are key issues compliance professionals are now confronting.

Sustaining compliance program functionality during the throes of a widespread global pandemic presented unique challenges for life sciences entities, many of which are highly regulated and beholden to a litany of government requirements. While it was impossible to predict the various obstacles that would make compliance program monitoring increasingly difficult, successful compliance teams quickly learned that the key was to focus on risk management. By consistently monitoring risk and bringing steady attention to the core principles of compliance, life sciences companies have been able to preserve program robustness and uphold regulatory responsibilities and reporting requirements during the various phases of the pandemic.

THE CHALLENGE

With many employees working remotely during the height of the pandemic, it was more difficult to monitor their actions, including activities that could present severe compliance risk to life sciences companies. Even with modern oversight, monitoring, and auditing technology, the workforce separation created gaps in communication and invited greater potential for aberrant (and even illegal) activity. Legal and compliance officers and their teams did not have as many opportunities for in-person communications and regular updates from various group leaders. Moreover, with so much new information surfacing daily as a result of COVID-19, it was exasperating for many compliance professionals to decide how to focus both their compliance resources and attention.

A PROACTIVE APPROACH

Despite such hurdles, we saw devoted and steadfast compliance units effectively preserve (and even enhance) compliance program robustness while also minimizing issues with (or negative attention from) relevant agencies and regulators at the height of the COVID-19 crisis. This required a proactive, communicative, and risk-adjusted approach—particularly in the life sciences sector, where considerable attention is concentrated by the government, and where compliance, therefore, is particularly vital.

Proactive legal and compliance departments at life sciences companies managed the various elements of their programs in the face of the pandemic primarily by adhering to core principles—namely leadership, communication, risk assessment, policies and controls, training, and oversight. Preservation of this commitment to functionality and core principles are the keys for life sciences compliance teams to lead their companies beyond COVID-19 with clarity, risk awareness, focus, and program robustness.

ATTENDING TO CORE PROGRAM COMPONENTS AS THE CRISIS EVOLVES

LEADERSHIP

Chief Executive Officers, Chief Financial Officers, General Counsels, Chief Compliance Officers, and other members of the C-Suite in the corporate leadership group, in coordination with the board (where one exists), should take the lead in reinforcing the critical importance of compliance at life sciences entities as the COVID-19 pandemic evolves. Messaging that reinforces adherence to compliance requirements must come from the top and align with the compliance department's priorities and goals.

Indeed, in times like these, one of the most valuable practices life sciences leadership can adopt is to ensure that they keep abreast of real-time developments with respect to the pandemic, and likewise adapt company culture to the changing industry landscape. This can be demanding because, among other things, information is evolving in real time. Ultimately, in order to protect the company, leadership must be aware of germane new legislation, executive orders, ordinances, and guidance proposed and implemented at the federal, state, and local levels to evaluate risk and craft tailored risk mitigation plans.

Compliance officers in particular should stay attuned, for example, to the Department of Health and Human Services (HHS) and its agencies, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). These and other pertinent agencies are disseminating important information to ensure that key stakeholders and managers have the most current compliance information to provide to employees as many return to workplaces that will have integrated novel safety and health requirements.

COMMUNICATION

With significant disruptions to supply chains during the crisis, reduced workforce communications, delayed project management guidance, technological issues affecting employees who still may be operating from home, diminished access to information and materials, and other changes to the work environment, life sciences employees have been looking to corporate leadership to keep them engaged and informed.

> ***Compliance directors should continue to manage inquiries from employees relating to an evolving work situation by making themselves readily available to answer questions and assuage concerns.***

Moreover, as necessary, modern technology assimilated during the pandemic, including vast improvements in video conferencing, can continue to facilitate the regular intake of employee and management inquiries, particularly for those who are still working remotely. This will help ensure that consistent messaging on compliance strategy and faithful program observance continues across the organization, wherever employees are located.

RISK ASSESSMENT

For most life sciences companies, risk assessment is the most critical of the core compliance program components both during a global or economic crisis and also in times of peace and prosperity. In light of this, legal and compliance officers should continue evaluating evolving risk on a proactive, regular basis and reallocate resources accordingly. Indeed, compliance professionals should take the time to assess the most pertinent risks on a daily basis and aptly distribute resources. Typically, this type of assessment may be initiated on a less frequent basis. But considering the evolving nature of the pandemic, compliance teams need real-time information, and must work together to triage their compliance efforts, particularly for concerns exacerbated by COVID-19.

For example, with many employees still working remotely, companies are facing additional security threats from home networks, along with cybersecurity risks and a greater potential for deviant conduct with (or to) company equipment.

> ***Compliance departments should, among other things, collaborate with IT leaders to ensure that all corporate-related connections are secure. This is especially important for life sciences companies, where confidential and proprietary information is often a prominent part of the business enterprise and can be more easily compromised on an employee's home network.***

Further, it is important to minimize supply chain interruptions and update contingency plans to curtail corporate disruptions as the economy improves. For instance, China produces roughly 90 percent of pharmaceutical ingredients used by the life sciences industry. The impact of COVID-19 on China created a domino effect of sorts, disturbing supply chains worldwide. The actualized impact of any potential supply chain disruption may not be felt until the coming months, making it vital for life sciences companies to evaluate their current supply chain and have procedures in place to allay any interruptions or shortages.

Recently FDA updated its policies to address medical and drug supply shortages during the COVID-19 pandemic. In an effort to combat drug shortages, for example, the FDA revised its list of extended-use dates, allowing some products to be used beyond certain labeled expirations. Consequently, by closely monitoring the risk of supply chain issues during the crisis, many life sciences companies positioned themselves to adeptly alert the FDA of anticipated shortages. Because compliance professionals are skillful at evaluating risk, many of them have been able to make reasonable efforts to ensure that vital corporate concerns, such as product supplies, were not compromised during the crisis. These efforts can help companies avoid being hamstrung by debilitating deficiencies as they move beyond the pandemic.

POLICIES AND CONTROLS

Given the magnitude of the COVID-19 calamity, many life sciences compliance teams also wisely took time to locate, organize, and make existing policies and procedures more conspicuous. Managers and employees have needed access to guidance quickly, and having policies and procedures at arm's length helped save time and eliminated ambiguity when making decisions. Now is a good time for compliance departments to reevaluate by setting forth new guidance and updated policies and controls to reflect the evolving COVID-19 environment.

> ***Fresh policies and procedures can help outmaneuver the negative consequences of COVID-19, such as sick leave issues, employee safety, and novel employment-related rules promulgated by federal and state lawmakers.***

Finally, any new policies or procedures—even if temporary—must be properly disseminated to all applicable employees and departments.

TRAINING

Significantly, with the constantly evolving nature of COVID-19, it may be tempting to allow existing life sciences training programs to fall by the wayside. Compliance leaders, however, must find ways to keep employees engaged in training. Many companies today, for instance, have adopted e-learning programs that employees can complete remotely, which is helpful for personnel still working at home. Using such technology not only facilitates ongoing and essential training for remote management and employees, it also serves as a communication vessel for compliance leaders to remind employees that, despite COVID-19, regulators expect training programs to continue. Meanwhile, this is a keen time to re-assimilate standard training programs back into the regular compliance regimen for those returning to the office. The shrewd combination of remote technology learning and in-person training can be a challenge to implement at first, but will grease the skids for the methodical return to a fulsome, best-practice training program when the emergency diminishes.

MONITORING AND OVERSIGHT

Monitoring employee activity has been difficult while most of the workforce was geographically fragmented, requiring life sciences compliance teams to be more vigilant in their compliance program oversight efforts during COVID-19. However, perceptive legal and/or compliance officers did not shy away from checking in with the board, leadership, and employees regularly as COVID-19 swept through the country. Instead, they used secure email, audio, and video technology to create regular touchpoints to confirm that stakeholders, from the board room to the mail room, were adhering to company policies and continuing to follow compliance program expectations.

As the country begins to prepare for life beyond the pandemic, and lines of communication become less static, compliance leadership should align with internal audit professionals and leaders from other business areas of the corporation to examine monitoring efficacy and plan any needed modifications or enhancements to prepare for a return to more predictable work days and risks.

MANAGING CURRENT CORPORATE INTEGRITY AGREEMENTS OR RELATED REQUIREMENTS

Adding to the above demands on compliance officers, life sciences companies beholden to Corporate Integrity Agreements (CIAs) from HHS, or enhanced compliance program obligations from other agencies have been, for the most part, expected by such agencies to maintain those responsibilities during COVID-19. Some compliance programs that are now confronting financial, resourcing, or related challenges as a result of the pandemic may find certain heightened requirements either impractical or, perhaps, impossible. Legal and compliance leaders are responsible for proactively notifying the appropriate government entities to request, through suitable channels, a temporary relaxing of such obligations.

MAINTAINING PROGRAM ROBUSTNESS AS WE PLAN FOR THE PANDEMIC TO ABATE

While uncertainty continues, compliance teams at life sciences companies must be prepared for the murkiness that lies ahead for business operations and program devotion, while also planning vigorously to segue into a less traumatic period in the wake of COVID-19. While these are challenging times, maintaining compliance program efficacy is achievable. Compliance teams can also take advantage of the pandemic-related complications to evaluate what strategies worked, which will help to enhance their programs in a post-COVID-19 world.

Ultimately, life sciences companies that are successfully navigating this unprecedented landscape are those that proactively attended to the essential compliance program components discussed above, prioritized pressing risks for timely consideration, and strategically allocated limited resources. Continued adherence to certain best practices derived from compliance program fundamentals—but tailored to the demands of a national emergency—will serve as a guiding light for the road ahead:

1. Develop a plan to provide cohesive and consistent messaging to leadership and employees relating to both the upkeep of, and any necessary adjustments to, your compliance program during and after the COVID-19 outbreak.
2. Stay proactively apprised of the continuous changes to relevant federal and state laws, regulations, legislation, and executive orders resulting from the pandemic.
3. Reassess pertinent operational, business, and compliance risks on a more frequent (preferably daily) basis, and reallocate compliance program resources accordingly.
4. As a compliance professional, be accessible and available to answer employee and corporate leadership inquiries by leveraging audio and video technology.
5. Use lessons learned during the crisis to develop longer-term compliance program improvements to help ensure that the compromising of vital business practices will be mitigated in the event of a future national emergency.
6. Ensure that all relevant policies, procedures, and controls are readily accessible so that employees both working remotely and returning to the office can quickly access guidance.
7. Continue to require that employees remain active in the company's training program, so existing training regimens do not lapse.
8. Plan and facilitate regular touch points with executives, the board, and employees using secure email, audio, and video technology to monitor compliance program adherence and remind leaders of needed compliance resources, particularly as the crisis evolves.
9. Skillfully team with internal audit professionals and trusted leaders from other business units to assist in recalibrating the compliance program to move beyond COVID-19.
10. Continue to observe CIA obligations, or enhanced compliance program requirements from other government bodies; if compliance becomes unmanageable due to COVID-19 complications, then promptly notify the proper authorities.

SECTION 4

WHAT THE INDUSTRY CAN EXPECT AS FDA EASES INTO "BUSINESS AS USUAL"

BY BARBARA A. BINZAK BLUMENFELD, PH.D. AND TINA HU-RODGERS

FDA is still intensely focused on responding to the COVID-19 pandemic. What began as an Agency effort that provided rapid-fire, although somewhat disjointed, information to industry and the public has evolved into a streamlined FDA operation to inform industry decisions through the use of dedicated FDA resources. FDA's "Coronavirus Disease 2019" landing page includes a wealth of information for companies interested in aiding the COVID-19 efforts through the development of diagnostic tests, therapeutics, medical devices, convalescent plasma, vaccines, and other products.

FDA's efforts to combat the novel coronavirus has come at the cost of "business as usual" for both the Agency and industry. Until we can safely say that COVID-19 is in our rearview mirror, FDA will continue to manage both its COVID-19 and routine activities. Therefore, as companies think about their own operations through the end of 2020, it is imperative that they consider how to adapt to FDA's divided efforts. We offer several ways for them to do so.

FDA'S COVID-19 RESPONSE WILL CONTINUE TO REQUIRE DEDICATED CENTER RESOURCES FOR THE FORESEEABLE FUTURE.

Virtually every FDA Center has committed resources to this public health response, often by rededicating staff to COVID-19 projects. These efforts continue and are unlikely to abate anytime soon. COVID-19 will continue to siphon resources from the Agency's normal work priorities, and the most successful companies will learn how to adapt to this shift.

KEY TAKEAWAYS:

Industry should expect that COVID-19 activities will continue to impact FDA's normal operations, including site inspections and company meetings. Accounting for these shifts and modifying company timelines accordingly will accommodate these changes and will help manage company and investor relations and expectations.

FDA'S ABILITY TO MEET USER FEE GOALS WILL BE CHALLENGED.

Early in the public health emergency, FDA noted that its drug user fee goals were still being met. However, the Agency also made clear that these goals could be jeopardized the longer the pandemic continued or if drug shortage or supply chain issues emerged. Meeting user fee goals is in all parties' best interests and remain critical—pandemic or not—for priority review products or first-to-file generic drugs when exclusivity is at stake.

KEY TAKEAWAYS:

Industry should expect user fee goals to be met, but should also be prepared that they will not be. Ongoing communication with the appropriate review division will be essential so that scale-up manufacturing, product launches, partnerships with distributors, and product launch campaigns can be revisited and accommodated, if necessary.

CONTINUE TO EXPECT VIRTUAL COMPANY-FDA MEETINGS.

The Agency has shifted to virtual company meetings held by teleconference or videoconference. This change inevitably impacts the normal meeting dynamic. Both FDA staff and companies must approach meeting preparation differently when attendees are not in the same workplace. Critically, companies that are used to in-person meetings must consider how to "read the room" when that room is spread over various worksites. Even as FDA staff begin to return to their offices, it is safe to say that virtual meetings will be the trend in the immediate future.

KEY TAKEAWAYS:

Rehearsing a meeting in a virtual format will give all company participants a better sense of what to expect during the actual FDA meeting. Individuals can role-play FDA so that everyone is comfortable with Agency responses over the phone or by video. Making sure that all company attendees have a clear understanding of their roles during the meeting—whether presenting, leading discussion, summarizing feedback, or taking careful notes—will also help smooth the actual meeting process.

THE LOGISTICS OF ADVISORY COMMITTEE MEETINGS WILL CONTINUE TO REMAIN IN FLUX.

Although FDA initially cancelled or postponed a number of advisory committee meetings, FDA intends to resume videoconferenced committee meetings imminently for two pending drug applications. As FDA continues to gain experience with virtual committee meetings, this format may become the new normal for some time to come. However, any difficulties with scheduling or execution of these videoconferences have the potential to jeopardize critical user fee goal dates and product approval timelines. Also the virtual meetings reduce the personal interactions among the committee members, FDA staff and other presenters, which are often vital to approval decisions.

KEY TAKEAWAYS:

Maintaining dialogue with FDA about meeting schedules will be critical. Determine as early as possible if an advisory committee meeting will be required for your product, as well as how your product fits into any FDA priorities for conducting meetings. Companies should also strategically prepare for various meeting scenarios, and consider whether it makes sense to have certain attendees in the same location. A virtual advisory committee meeting could be beneficial, as it may allow company attendees to communicate with each other off-line during the meeting to better coordinate responses.

EXPECT A BACKLOG OF FDA INSPECTIONS ONCE THEY RESUME.

Early in the pandemic, FDA eliminated routine domestic and foreign facility inspections. This change occurred in parallel with the Agency's work from home directive and social quarantine efforts. As a result, there is likely to be a large backlog of inspections both here and abroad that will need to be prioritized and conducted when safe to do so. FDA's goal is to resume pre-announced, on-site priority domestic inspections during the week of July 20.

However, state and local rules and guidelines governing business operations will impact FDA's inspection operations in those locations. Further, this efforts highlights the discrepancy and disadvantage that domestic manufacturers as the Congress and the Administration look to repatriate manufacturing to the United States.

KEY TAKEAWAYS:

Expect FDA to prioritize critical inspections, such as pre-approval inspections that are required to meet a user fee goal or to advance a priority-review product through the approval process. If a company is expecting an inspection in the near future, it should work with FDA to determine the Agency's timeline and how the inspection can be accomplished smoothly when it does occur.

TEMPORARY POLICIES AND GUIDANCE DOCUMENTS WILL SUNSET WHEN THE PUBLIC HEALTH EMERGENCY ENDS.

Many of the policies and guidance documents that FDA has issued during the public health emergency will no longer be effective once the pandemic is over. FDA has stated that they will only remain in effect for the duration of the COVID-19 public health emergency declared by DHHS in January 2020 (including any renewals). Therefore, companies that are relying on these temporary policies or guidance documents must plan ahead accordingly.

KEY TAKEAWAYS:

Confirm whether your development program or product has been impacted by a COVID-19-related policy or guidance document, and take note of whether and when that policy or document expires. Companies should plan for a transition period during which they begin to adhere to policies or guidance documents that were in effect before the public health emergency, such as clinical trials guidance.

FDA's resumption of business as usual will be a gradual transition as conditions continue to change. Companies that look beyond the present into an uncertain future will be the most prepared to stay on track with their 2020 goals.

SECTION 5

ASSESSING THE LIFE SCIENCES MANUFACTURING AND SUPPLY CHAIN AMID COVID-19

BY MATTHEW L. FEDOWITZ AND MATTHEW S. PISCITELLI

As businesses begin to restart operations, life sciences companies need to heed FDA regulations on top of those imposed by their state and local governments. FDA's ability to enforce its regulations has been hampered in recent months, and drug and medical device manufacturers should take stock of the current regulatory landscape and FDA's proposed steps moving forward.

FACILITY AND PRODUCT INSPECTIONS

The FDA suspended domestic routine surveillance facility inspections on March 18, 2020. This followed an announcement on March 10, 2020 that FDA would postpone most foreign inspections. Both of these announcements left open the possibility that mission-critical inspections would still be considered on a case-by-case basis. In order to do so, FDA stated that it would rely on additional tools and approaches to ensure safety and compliance with regulations in the interim. In addition, FDA stated that postponed inspections would take place after the restrictions were lifted. FDA's goal is to resume pre-announced, on-site priority domestic inspections during the week of July 20, depending upon state and local rules and guidelines related to the pandemic.

With the inability to inspect facilities abroad, FDA focused on the safety of imported products at their points of entry into the U.S. These efforts have taken the form of a renewed focus on denying entry for unsafe and inferior quality products, and FDA is using prior inspection records and partnerships with foreign agencies to determine which imported products warrant the most comprehensive inspection and follow-up.

FDA is also partnering with agencies like the Centers for Disease Control and Prevention (CDC) to ensure imported products comply with the recently relaxed standards. For example, the CDC's National Institute for Occupational Safety and Health (NIOSH) and National Personal Protective Technology Laboratory (NPPTL) are testing respirators for proper fit and filtration. This testing revealed that some respirators filtered only a fraction of the particles that they claimed. Accordingly, FDA issued a modified Emergency Use Authorization (EUA) on May 7, 2020 which excluded a number of respirators previously imported from China.

MANUFACTURING AND SUPPLY CHAIN CONSIDERATIONS

Manufacturers should consider shifting production to larger facilities, spreading production to multiple facilities, and shifting production to jurisdictions with less restrictive work regulations or lower infection rates. Additionally, some companies may be introducing new products to market, either as a response to the COVID-19 pandemic or as part of drug or device development predating the public health emergency. These production changes or introductions to market would normally need to be reflected in a drug or device application or supplement, and FDA has not changed these requirements. FDA will, however, give priority review to manufacturers of drugs that are related to treatment of COVID-19 patients or drugs on the FDA's drug shortage list.

> ***The uncertainty regarding on-site inspections poses a significant barrier for firms that require an inspection approval prior to marketing. For some companies, the opportunity for mission-critical inspections still exists, and FDA is most likely to exercise its discretion to conduct such inspections when COVID-19 treatments are involved.***

FDA's evolving inspection priorities may require companies that are anticipating a pre-approval inspection to approach FDA with viable alternatives to in-person inspections. The agency, through recent guidance, has demonstrated flexibility with pre-market inspection requirements for Humanitarian Device Exemptions (HDE) and device Premarket Approvals (PMA).

This relaxed enforcement discretion largely relies on companies demonstrating risk minimization strategies while making deviations from previously approved production locations and methods. Companies that are introducing drugs or devices to market but are stuck due to a postponed inspection should consider discussing alternatives with FDA, such as implementing interim risk minimization strategies.

CLINICAL TRIAL SITE INSPECTIONS

Clinical trial sites have largely been relocated across the United States for a variety of reasons related to the COVID-19 pandemic. FDA acknowledged these challenges, and issued a guidance document addressing clinical trial conduct during the pandemic. In this guidance, FDA stated that, when inspections resume, it will require documentation for reasons why planned on-site subject monitoring visits were not possible. Trial sponsors will be expected to justify missed visits and deviations from the study's protocols, and FDA expects accurate, specific documentation for each deviation.

> ***The COVID-19 pandemic has shifted the priorities of many life sciences companies, but compliance with good manufacturing and good clinical practices must remain at the forefront.***

While FDA appears to understand the challenges the pandemic presents, FDA will still expect sponsors to maintain proper documentation for the pandemic period. This documentation must be ready when FDA inspections resume. Additionally, while the FDA is not inspecting foreign facilities for the time being, importers will still face scrutiny at ports of entry and CDC laboratories.

CONCLUSION

As life sciences companies continue to deal with a changing operating and regulatory environment, we are confident in the industry's continued ability to adapt and thrive under new conditions. However, emerging successfully into a post-pandemic world will require a prudent eye on evolving laws, regulations, operational best practices, and safety and compliance guidelines. At Buchanan, our attorneys and government relations professionals have decades of experience offering counsel on each of these matters, and can keep any life sciences company prepared to react, adapt, and thrive as the landscape continues to change.

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