

The background is a teal gradient with faint, semi-transparent images of chemical structures and laboratory glassware, including a pipette and test tubes.

COVID-19 TOOLKIT

for private life science companies

April 4, 2020

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1. Continuing Business Operations

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Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce

Federal Orders

- As of April 4, 2020, the federal government has not issued a mandatory shelter in place order.
 - However, the federal government has issued guidance on what constitutes essential services, which in large part serves as a base for the various mandatory state orders discussed below. The federal guidance can be reviewed at the following link: <https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce>.
 - Additionally, the CDC and OSHA have issued interim guidance for businesses and employers to plan and respond to COVID-19, which can be found at the following links: <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html> and <https://www.osha.gov/Publications/OSHA3990.pdf>.

Delaware Law Implications Applicable to Board Members and Officers

- Given the prevalence of shelter in place orders, board members and officers must be sure to discharge their fiduciary duties as it relates to knowing violations of such orders. It is important to remember that a director or officer engaging in a knowing violation of the law breaches his or her fiduciary duties.
- Under Delaware's Caremark standard, a board of directors has to have reasonable procedures in place to (1) prevent breaking the law and (2) ensure directors are adequately informed of the risks that a law may be broken.

Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce (continued)

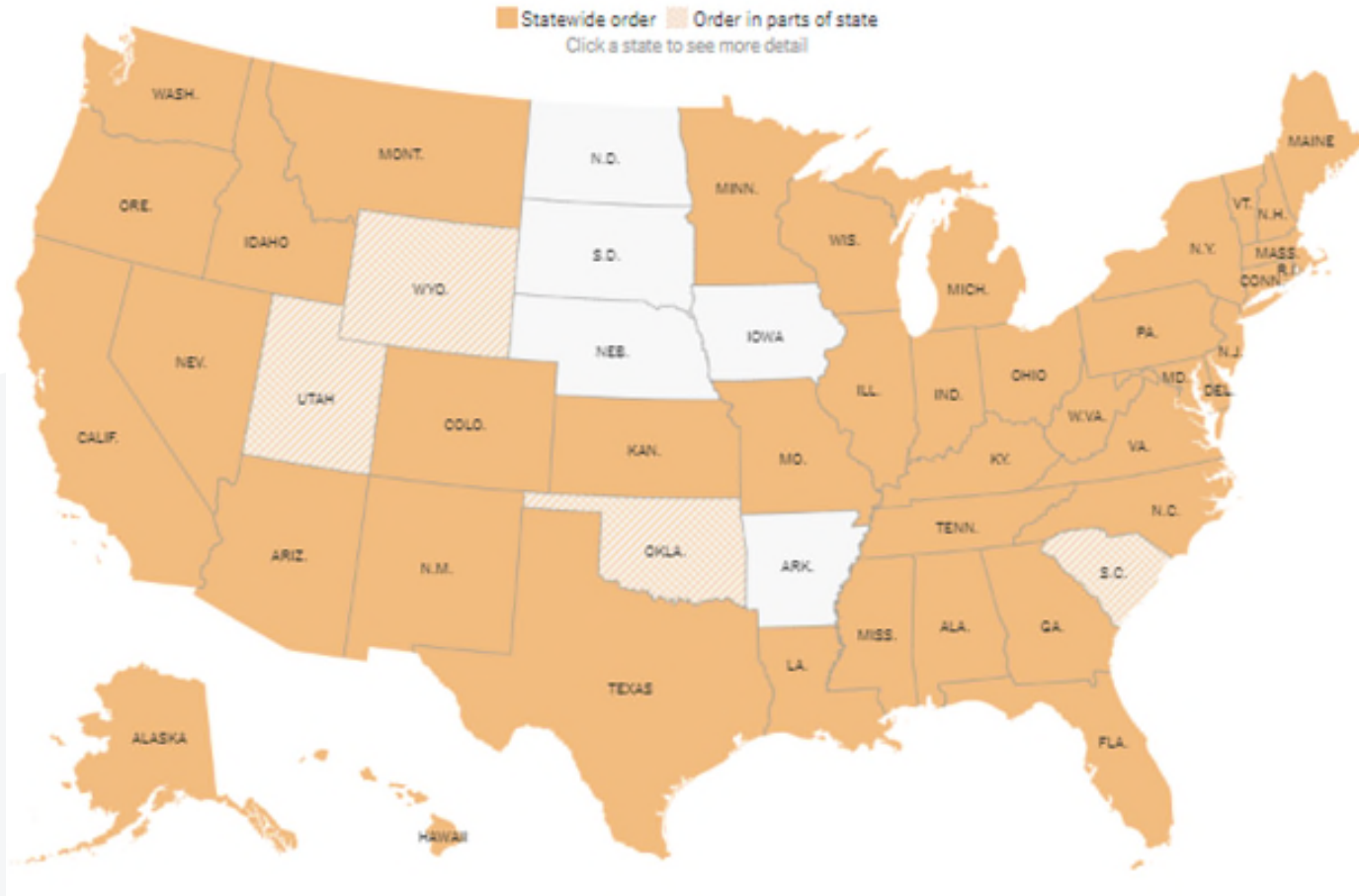
State Orders

- **California:** On March 19, 2020, California ordered all individuals to stay home or at their place of residence, except as needed to maintain continuity of operation of the federal critical infrastructure sectors.
 - Federal critical infrastructure sectors include healthcare and public health, emergency services, food and agriculture, energy, water and wastewater, transportation and logistics, communications and information technology, community-based government operations and essential functions, critical manufacturing, hazardous materials, financial services, chemical, and defense industrial base.
 - The following link provides further information on sector profiles and essential workforce:
<https://covid19.ca.gov/img/EssentialCriticalInfrastructureWorkers.pdf>.
 - Note that certain local jurisdictions have put additional orders in place which may compete with state orders. Guidance from California is to follow the most restrictive order applicable.
- **Massachusetts:** On March 23, 2020, Governor Charlie Baker issued an emergency order requiring all businesses and organizations that do not provide "COVID-19 Essential Services" to close their physical workplaces and facilities to workers, customers, and the public.
 - The list of Essential Services is based largely off the federal guidelines. The following link provides further information on Essential Services for Massachusetts: <https://www.mass.gov/doc/covid-19-essential-services/download>.
 - The Governor specifically stated that manufacturers of medical products and pharmaceutical companies developing treatments for COVID-19 and other diseases will continue to operate, and are exempt as essential business. After the order was released, Baker Administration officials clarified to that all biopharma R&D is essential and exempt.
- **New York:** On March 22, 2020, Governor Cuomo announced the “New York State on PAUSE” executive order, requiring all non-essential workers to work from home until further notice.
 - “Essential Business” means essential health care operations, infrastructure, manufacturing, retail, certain services, news media, financial institutions, providers of basic necessities to economically disadvantaged populations, construction, defense, safety and sanity operations, and vendors that provide logistics and technology support.
 - The following link provides further information on essential businesses and to request designation as such:
<https://www.governor.ny.gov/news/governor-cuomo-issues-guidance-essential-services-under-new-york-state-pause-executive-order>.

Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce

- Additionally, as of April 4, 2020, numerous other states and local jurisdictions have issued shelter in place orders.



Credit [NYTimes](#).

Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce

■ OSHA: Duty To Ensure A Safe Workplace

- OSHA covers most private sector employers and employees in the U.S.
- OSHA: Employers must furnish to each employee “employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.”
- CDC recommendations to prevent workplace exposure and planning considerations:
 - Perform frequent environmental cleaning
 - Support good hygiene practices (i.e., hand washing and respiratory etiquette)
 - Implement social distancing (see below)
 - Emphasize staying home when sick
 - Discourage use of others’ equipment and workspaces.
 - Be prepared to implement Workplace Emergency Readiness Plan

■ Social Distancing

- Social Distancing means reducing the frequency, proximity, and duration of contact between people (both employees and customers) to reduce the chances of spreading the virus from person to person
 - Use videoconferencing and email to reduce in-person, non-essential meetings
 - Reduce or restrict social gatherings
 - Cease non-essential visits from non-employees at the offices
 - Implement telecommuting where possible
 - Staggered shifts for employees coming into the worksite

Continuing Business Operations

Complying with Federal and State Guidelines Regarding Telecommuting Policies

■ Telecommuting

- Considerations for employers who decide to encourage or require telecommuting to minimize the risks of employees contracting COVID-19:
 - Keeping track of hours worked by non-exempt employees and ensuring compliance with wage and hour laws, such as overtime and meal and rest breaks
 - Employee accessibility and productivity
 - Protecting company confidential information
 - Employee’s use of home computers and other personal devices
 - Network safety – VPN or other encrypted link to home office
 - Recovering company property and information when employees resume working at the office or if employment terminates
 - Are employees responsible for injuries occurring at home?
 - Do federal, state, or local leave laws apply?
- If an employee asks to telecommute, does an employer have to permit employees to telecommute?
 - Review your policies & use common sense
 - The federal Americans with Disability Act requires employers to provide reasonable accommodations to a qualified individual with a disability to enable the individual to perform the essential functions of the job
 - A “disability” is “a physical or mental impairment that substantially limits one or more major life activities”
 - Employees who contract COVID-19 may or may not be seriously ill long enough to substantially limit a major life activity
 - A sick employee may claim that an employer regarded him or her as having a disability, which may form the basis for a discrimination claim under the ADA (although no accommodation requirement)
 - A serious case of COVID-19 could be covered under more expansive state or local laws, such as in New York and California

2. Employee Matters

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Employee Matters

Family and Sick Leave

■ Emergency Family Medical Leave (EFMLA)

- Employers with fewer than 500 employees must provide eligible employees with up to 12 weeks of leave:
 - If the employee is unable to work (or telework) due to the need to care for the employee's son or daughter under 18 years of age if the child's school or place of care has been closed, or the child care provider is unavailable due to COVID-19.
 - Employees are eligible for leave if they have worked at least 30 days for their employer.
- The first 10 days of leave are unpaid, but employees may elect to substitute any of their accrued vacation, personal, medical, or sick leave for such time.
 - The remaining EFMLA days shall be paid by the employer (who may be entitled to receive corresponding tax credits).
 - Employees are entitled to payment that is at least two-thirds of an employee's regular rate of pay for the number of hours the employee would otherwise be normally scheduled to work. The payments are capped at \$200 per day and \$10,000 in the aggregate.
- Employers are generally required to restore eligible employees to the position they previously held (or its equivalent) following their return from leave. There are specific exceptions for employers with fewer than 25 employees.

■ Emergency Paid Sick Leave Act

- Employers with fewer than 500 employees must provide eligible employees 10 days of paid sick leave if the employee is quarantined due to COVID-19 or caring for someone quarantined due to COVID-19, the employee is experiencing symptoms of COVID-19 and is seeking medical diagnosis, or the employee is caring for a child, if the child's school or child care facility has been closed or the child's care provider is unavailable because of COVID-19 precautions.
- Pay for employees taking leave due to their own medical condition is calculated based on the employee's regular rate, but capped at \$511 per day and \$5,110 total. Pay for employees acting as a caregiver for a family member is calculated based on two-thirds of the employee's regular rate, but capped at \$200 per day and \$2,000 total.
- The Act also prohibits employers from discharging, disciplining, or otherwise discriminating against any employee who takes sick leave, or has filed any complaint relating to the Act (or participates in any such proceeding).

Employee Matters

Sick Leave Continued

■ New York Paid Sick Leave

- New York State recently expanded the state's Paid Sick Leave Law to provide job protection and pay for New Yorkers quarantined as a result of the COVID-19.
- The following provisions took effect as of March 18 and apply to all private employers:
 - Employers with 100 or more employees as of January 1, 2020: Must provide at least fourteen (14) days of paid sick leave for employees who are subject to a mandatory or precautionary order of quarantine or isolation due to COVID-19 issued by the state of New York, the department of health, local board of health, or any governmental entity duly authorized to issue such order ("Quarantined Employees").
 - Employers with 11 to 99 employees as of January 1, 2020: Must provide at least five days of paid sick leave for Quarantined Employees. After the five days of paid sick leave, Quarantined Employees are eligible to receive paid family leave and disability benefits starting as of the first full day of the unpaid period of a mandatory quarantine. An employee may collect up to \$840.70 in paid family leave and \$2,043.92 in disability benefits per week during the period of unpaid leave.
 - Employers with ten or fewer employees as of January 1, 2020 (> \$1,000,000 in net income): Must provide the same benefits as those described directly above for employers with 11 to 99 employees. For purposes of this statute, an employer's net income is measured based on the previous tax year.
 - Employers with ten or fewer employees as of January 1, 2020 (< \$1,000,000 in net income): Must provide unpaid sick leave for Quarantined Employees. The Quarantined Employees are eligible to receive paid family leave and disability benefits starting as of the first full day of the unpaid period of a mandatory quarantine. An employee may collect up to \$840.70 in paid family leave and \$2,043.92 in disability benefits per week during the period of unpaid leave.
- **Right to Reinstatement:** Upon return to work, Quarantined Employees must be restored to the position they held prior to any leave taken under this law. No employer may discharge, threaten, penalize, or in any other manner discriminate or retaliate against an employee for taking this leave.

Employee Matters

Salary Reduction Considerations

- **Many companies are considering decreasing salaries to preserve cash. This raises some important considerations:**
 - **Is the arrangement a deferral of salary or a temporary salary reduction? What's the difference?**
 - A deferral of compensation provides an employee (usually limited to executives) with the opportunity to be paid their earned salary (and sometimes bonus) at a later date. This amount is treated as a liability that the company would be required to pay in the future.
 - A temporary salary reduction involves an employee (usually an executive or other highly paid employees) foregoing some portion of their base salary. These amounts are not earned and there is no contractual right for the employee to be paid these amounts in the future.

- **Are salary deferrals more difficult to implement than a temporary salary reduction?**
 - If the arrangement is a salary deferral, then care must be taken to defer the salary in compliance with Section 409A. Failure to do so would result in negative tax consequences to the employee (a 20% federal penalty tax, a 5% penalty tax for employees subject to taxation in California, and penalties and interest on top of the employee's regular taxes).
 - Compliance with Section 409A can be restrictive and substantially increase the administration of the arrangement.

- **Due to the complexities of Section 409A, we expect most companies to choose to avoid structuring the arrangement as deferred compensation. Accordingly, the remainder of the considerations discussed on the following slides assume that the arrangement would be structured to be a temporary salary reduction and not a deferral of compensation**

Employee Matters

Salary Reduction Considerations (continued)

■ Will anything be provided in exchange for the salary reduction?

- Companies often want to provide some sort of alternative compensation for reducing salaries. For instance, we often see companies provide for an opportunity to earn a bonus or grant a stock option or other equity award in recognition of the reduced salary
- Any additional arrangement should be structured to comply with tax laws, in particular Section 409A
 - For instance, if the company wanted to continue the salary reduction through a qualified financing event and pay a bonus to the employee upon completion of the financing, the employee should be required to continue employment through the financing event in order to earn the bonus, with the bonus paid shortly after that.
 - For a stock option grant, consider the following:
 - How will the number of shares be calculated? Will it be based on aggregate base salary reduction/FMV or some other formula?
 - Will the stock option be subject to vesting? If so, what will be the vesting schedule?
 - The exercise price should be no less than FMV on the grant date. Consider whether the valuation is current and can continue to be relied upon to establish the FMV of the common stock.

■ Will the salary reduction be forced or elective?

- Employers generally can adjust the compensation of at-will employees on a go-forward basis without their consent, subject to certain exceptions under applicable laws and contractual rights on behalf of the employees.
- If the reduction is to be elective, then the company must consider the tax consequences of doing so. In particular, this election process could result in constructive receipt of the forgone compensation and could potentially trigger penalty taxes under Section 409A.
- As a result, the general preference is that these arrangements be structured as being mandated by the company and not providing a true election opportunity for the employee.

Employee Matters

Salary Reduction Considerations (continued)

■ Additional Considerations

- Confirm whether approval of the Board of Directors and/or Compensation Committee would be required
 - We would expect the Board of Directors and/or the Compensation Committee to approve any arrangement for executives officers even if not technically required.
- Confirm the salary reduction does not require consent under an employee’s employment agreement or applicable law.
- Review “Good Reason” rights and obtain a waiver from each employee if needed to avoid triggering a right to resign and receive severance benefits.
- Confirm whether the intent is for the reduced salary to apply when calculating annual bonus and severance amounts.
- If known, be clear as to when the base salary will resume (and at what amount).
- Depending on the amount of the salary reduction, confirm that the employees will be eligible to participate in the company’s benefit plans and will continue to receive compensation to make any contributions.
- Assess whether reduced salaries violate minimum wage laws.

- See [Wilson Sonsini’s SixFifty COVID tools](#), which serve as an additional resource to organize and solve employment related issues arising from the COVID-19 pandemic.

3. Contracts and Transactions

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Contracts and Transactional Matters

Force Majeure Clauses

- The uncertainty given the spread of COVID-19 extends to existing contractual relationships, and one question which may arise is whether this unprecedented disruption excuse delays or non-performance under a contractual force majeure clause. The answer will turn on, among other factors, the following three factors.
 - Purpose & Triggering Terms: Many clauses set out specific triggering events, which tend to vary by contract. The following triggering events, if listed, may be implicated by COVID-19 and current events: epidemic / pandemic / viral or communicable disease outbreak, quarantines, lack of or inability to obtain fuel, power, components, or materials, disruption of supply chains, disruption of transportation systems, disruption of labor force, national emergency, act, order, or requirement of any governmental authority, "Act of God", or a "catch-all" phrase such as "or other similar causes beyond the control of such party".
 - Jurisdictional Differences: While courts in different jurisdictions generally consider the same factors in their analysis, they apply these factors differently, often in ways that can prove case-dispositive.
 - COVID-19 and Fact Specific Issues: In evaluating the impact of COVID-19 on existing contractual relationships, it is important to evaluate the triggering event impacting performance, whether the triggering event is encompassed by the language of the clause, governing law, foreseeability, affect on performance and whether performance is still possible or impracticable, steps to mitigate, remedies provided by the force majeure clause or otherwise under the contract and steps required to exercise rights under the contract.
- Successful invocation of a force majeure clause is a fact specific analysis. Moreover, as events change and continue to unfold, businesses should closely monitor how shifting dynamics may implicate the express triggering events listed and the effect on performance. Many businesses will no doubt find themselves on both sides of this issue, as both promisor and promisee, depending on the circumstances and context. We advise businesses to keep these factors in mind when entering into new contracts for which there is a risk of COVID-19 impacting future performance. For additional information, see the full Wilson Sonsini alert [here](#).

Contracts and Transactional Matters

Expedited Procedure to Obtain Antitrust Advisory Opinions

- On March 24, 2020, the FTC and DOJ announced an expedited procedure to provide antitrust guidance to business collaborations responding to the COVID-19 pandemic. Effective immediately, the agencies will respond to all COVID-19 related requests, and resolve those addressing public health and safety, within seven calendar days of receiving all information necessary to fully analyze the proposed arrangements.
- What Type of Arrangements Are Covered by the Expedited Procedure?: The procedure is geared to collaborative activities that need to be implemented immediately to address the health and safety issues created by the pandemic. Examples include joint efforts of limited duration that are necessary to assist patients, consumers and communities affected by COVID-19 and its aftermath, joint research and development related to COVID-19, joint healthcare purchasing arrangements and federal government enlisted assistance from private companies to address the crisis, such as through the Defense Production Act and the Pandemic and All-Hazards Preparedness Act.
- How will the Expedited Procedure Work?: The agencies will accept requests for expedited staff advisory opinions related to the COVID-19 crisis. The request must be in writing and provide as much information and documentary support as the parties can reasonably provide. The agencies will be able to request additional information to support the proposal and any issued opinion will be effective for one year after it is issued. If more than one year is required to respond to the COVID-19 crisis and its aftermath, parties will be able to subsequently request an extension utilizing the expedited procedure.

Contracts and Transactional Matters

The Impact of COVID-19 on Merger Reviews: Practical Considerations for the United States

- As of March 17, 2020, given the unprecedented challenges for merging parties and enforcement agencies, the Department of Justice (DOJ) and Federal Trade Commission (FTC) altered longstanding merger review processes. Although both agencies remain open, continue to accept pre-merger filings, and are actively conducting merger review, changes have been implemented for new filings and transactions currently under review given the majority of staff is working remotely.
- The DOJ and FTC have implemented a temporary electronic pre-merger filing system for submissions under the Hart-Scott-Rodino Act. However, parties will temporarily no longer be able to request early termination and will need to wait out the statutory 30-day initial waiting period.
- Transactions currently under review can expect delays, and parties should be prepared to quickly respond to any requests from the agency to be best positioned to avoid delays. While we do not expect changes to the rigor of review, current circumstances will make it more difficult for the agency to finish review during the statutory waiting period.
- Parties involved in a transaction should assess deal timetables realistically and engage with the antitrust agencies as early as possible – even during deal negotiations. Anticipate delays and resource limitations when assessing the companies' ability to meet deadlines for submissions and communicate these limitations up front with the agency to avoid procedural sanctions. For additional information, see the full Wilson Sonsini alert [here](#).

Contracts and Transactional Matters

Breach Related to Compliance with Law Representations and Warranties

- Given the changing and rapidly evolving legal landscape, heightened attention should be given to representations and warranties made, or in the process of being negotiated, in which the company reps that it is in compliance with all applicable laws and regulations.
- The following areas of law are examples that may be implicated by COVID-19 and the related orders put in place to combat the virus:
 - Employment and Labor
 - Privacy and Information Security
 - Employee Benefits and Executive Compensation
 - Antitrust & International Trade
 - Tax laws and regulations
 - SEC Disclosure, Securities Laws and other corporate governance measures
 - FDA regulations and guidelines
- Representations should be reviewed and proactively managed to ensure compliance and prevent breaches.
- Consider any necessary amendments to existing agreements, as well as additional disclosures and carve-outs relating to any impact, existing or potential, arising from the COVID-19 pandemic.

4. Debt & Credit Considerations

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Debt and Credit Considerations

Companies with Existing Loan Facilities

- In times like these, cash is king, and a company's debt financing is critical to managing cash flows.
- Borrowers can proactively review terms in their existing debt facilities for ways to reduce pressure on company cash flows and to identify possible amendments, postponements or waivers, even if only temporary and in the near term:
 - Principal and interest payment dates and amounts
 - Interest rates, if based on financial ratios
 - Consider using PIK (paid in kind) interest, though the cost of PIK interest should be weighed carefully
 - Prepayment triggers and premiums
 - Financial covenants, if any
 - Excess cash flow sweeps, if any
 - Conditions to drawing down additional funds
 - Other covenants that may require more time in order for a company to comply
 - Milestone dates and conditions

Debt and Credit Considerations

Companies with Existing Loan Facilities (continued)

- Borrowers should proactively review Events of Default and covenant triggers in their existing debt facilities to take stock of potential upcoming default and compliance risks and timing:
 - Reporting or other time deadlines that the Company may miss due to audit delays, supply chain disruptions, regulatory changes, and the Covid-19 situation generally
 - “Bright line” triggers such as payment defaults or financial covenant breaches
 - Other covenant compliance risks
 - Mandatory prepayment triggers and premiums
 - Especially for biotech companies -- Milestone dates and conditions which may be delayed due to regulatory authority (FDA, etc) or other delays
 - Biotech companies whose businesses are ***not*** related to Covid-19 or related essential businesses may experience regulatory or other delays, as priority is given to Covid-19 or related essential businesses.

- Consider possible amendments, postponements, waivers and forbearances to proactively reduce or mitigate near-term default risks

Debt and Credit Considerations

Companies with Existing Loan Facilities (continued)

If the Company Has:

- Unused credit available, or the capacity to ask its lender to increase available credit

- Any deadlines, such as reporting covenants, delivery of financial statements, payment dates, milestones, dates by which credit availability ends, etc.

Consider:

- Whether to draw down additional loan(s) or to approach the lender to increase available credit
 - Are there any Material Adverse Effect, Material Adverse Change, or Investor Support conditions, and if so, can they be met?
 - Whether representations and warranties would be materially true and correct at the time of such drawdown?
 - Financial covenant and other financial effects

- Amending deadline dates, such as:
 - Date by which any upcoming financial statements are due, as most auditors will be delayed generally
 - Interest payment dates – pushing out and/or consider using paid-in-kind interest (vs. cash pay interest) for the next few months, to help conserve cash in the near term; however, cost of PIK interest should be carefully evaluated

Debt and Credit Considerations

New Loan Facilities in the time of COVID-19

Key Terms To Review:

- All drawdown and credit availability conditions and dates
- All payment terms and timing
- Interest provisions – payment dates, cash vs. PIK interest, if tied to any financial covenants
- Any mandatory prepayment terms
- Any other deadlines, such as reporting covenants, delivery of financial statements, milestones, etc.
- Any financial covenants, and any other terms tied to a financial ratio or measure
- Operational covenants in light of the Covid-19 situation
- Events of Default – ability to cure

Consider:

- Are there any Material Adverse Effect, Material Adverse Change, or Investor Support conditions, and if so, can they be met?
- Effects on any financial or liquidity covenants
- Other terms which may be tied to financial measures or ratios (such as pricing, excess cash flow sweeps, reserve accounts, etc.)
- Adding sufficient flexibility to representations and warranties that must be true and correct at the time of closing and funding
- Negotiating sufficient operational flexibility in the covenants
- Ways to mitigate default risk by lengthening cure periods, adding opportunities to cure, materiality qualifications, etc.

Debt and Credit Considerations

Your Company May Also Be a Creditor: Supplier, Customer and Counterparty Risk

- A company may also be (or become) a creditor, if suppliers, vendors, customers and other counterparties start having their own cash flow difficulties and do not (or cannot) pay the company on time
 - Monitor and identify credit risks
 - UCC and lien searches are a quick and easy way to see if a counterparty has secured creditors in the US
 - In some cases, a company may be able to use purchase money liens to improve its position
 - In some cases, a company may wish to consider asking for some kind of credit and/or guaranty support, or some kind of security, from a counterparty

5. Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

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CARES Act

Potential Sources of Capital Under the CARES Act and Limitations

- On March 27, 2020, President Trump signed into law the CARES Act, a stimulus package providing emergency assistance and health care response for individuals, families and businesses affected by COVID-19 (CARES Act). Brief highlights of the various sources of capital are summarized below. **For a full summary chart breakdown of the application requirements, process, timing and loan details, please see [Wilson Sonsini's CARES Act Loan Summary Chart](#).**
- The CARES Act contains three new loan assistance programs designed to help offset economic pain caused by COVID-19.
 - Expanded SBA Economic Injury Disaster Loan (EIDL): The CARES Act expanded the existing SBA EIDL program. Under the expanded program, the SBA may provide qualifying businesses both loans and emergency grants.
 - Paycheck Protection Program (PPP): The CARES Act created \$349 billion program providing for SBA-guaranteed loans made by SBA lenders to eligible recipients. Loan amounts are based on an applicant's monthly payroll costs, capped at \$10 million per loan, and are forgivable provided a company retains its existing employees at or near current salary levels. Applicants must make a good faith certification¹ that the proceeds are necessary to support ongoing operations. **Note that recipients are precluded from receiving funding under both the PPP and the EIDL program for the same purpose.**
 - Treasury Mid-Size Business Lending Facility: For businesses between 500-10,000 employees, the Treasury will construct a lending facility to provide direct financing to banks and other lenders that make direct loans to companies between 500-10,000 employees. These loans will have rates capped at 2% and required 6 month grace period before repayment.
- SBA and Affiliation Rules: In determining the size of a business, and its eligibility for federal programs, the SBA will include in the analysis the applicant's affiliates in certain instances where the affiliate has the power to control such company. The controls given to investors may in certain instances trigger the affiliation rules, and disqualify startups from obtaining access to programs under the SBA. See the following slide for a summary of the affiliation rules as applied to the Paycheck Protection Program.

¹ The board of directors should consider all relevant factors in discharging their fiduciary duties and making a determination that the funding is a necessity. This decision-making process should be documented to support the company's good faith determination. See slide 4 for a primer on fiduciary duties.

CARES Act

Paycheck Protection Program

- While the CARES Act did not provide any waiver or amendment to the affiliation rules, on April 2, 2020, the Treasury released an Interim Final Rule on affiliation, followed by additional guidance released April 3, 2020 by the SBA, in each case regarding the application of the affiliation rules for the Paycheck Protection Program, which be found [here](#) and [here](#), respectively.
- Generally, if an equity investor owns more than 50% of the voting equity of an applicant, the SBA will aggregate the applicant's employees with the employees of each other company that such equity investor controls.
 - If no single investor owns 50% of the business, control may still be found, and therefore found to be an affiliate, if a minority investor has the ability to prevent a quorum or otherwise block action by the board of directors or shareholders.
 - Additionally, the guidance released on April 3, 2020 made the following changes to the affiliation rules: (i) removed the totality of circumstances review standard; (ii) clarified that spinouts are no longer aggregated with their original parent company; (iii) removed rules relating to the aggregation of foreign affiliates; and (iv) removed the 'common investment' basis for finding affiliation between investors that commonly co-invest together.
 - While owners of at least 20% of the applicant are no longer required to provide direct certifications, applicants still need to certify in good faith the following regarding such 20% owners:
 - Whether they, or any business owned or controlled by them, has obtained a direct/guaranteed loan from the SBA or any Federal Agency that is delinquent or has defaulted in the last 7 years.
 - List of all businesses for which they are an “owner”
 - Whether they are suspended or debarred, or have certain criminal matters
- The affiliation rules remain a fact intensive analysis, and the ownership structure, type of securities held, contractual and other negative control rights, convertible securities and options and agreements to combine should all be carefully analyzed by your advisors prior to submission of an application.
- For additional information and up to date alerts, please see the following resources:
 - [Wilson Sonsini's COVID-19 Client Advisory Resource](#)
 - [National Venture Capital Association COVID Resource](#)
 - [SBA Disaster Loan Assistance](#)
 - [Treasury CARES Act](#)
 - [SBA Paycheck Protection](#)

CARES Act

Summary of Additional Individual Benefits

- Direct Payment: The CARES Act includes a one-time direct payment of \$1,200 per adult or \$2,400 for married couples filing jointly (and an additional \$500 per child) in the form of tax credits. The payment amount will phaseout as an individual's earnings increase above \$75,000, and \$150,000 for joint returns. Individuals with adjusted gross income above \$99,000 as a single filer and \$198,000 as a married couple filing jointly (in each case, with no children) will be phased out completely and receive zero funds.
- Public Health and Social Services Emergency Fund: The CARES Act includes approximately \$150 billion in investment in the healthcare system and allocates \$100 billion to a "Public Health and Social Services Emergency Fund," to reimburse eligible healthcare providers for healthcare related expenses or lost revenues attributed to COVID-19. It also invests billions more in medical research and medical equipment and infrastructure, including protective equipment, testing supplies, and increased workforce and training. Additional funding is also available to delivering Medicare payment increases to hospitals and health care providers.
- Pandemic Unemployment Assistance: The CARES Act creates a new program that would provide unemployment benefits to individuals who do not qualify for regular unemployment compensation and are unable to work because of the COVID-19 pandemic for a number of different scenarios, including business closure, losing access to transportation to work, or is otherwise unable or unavailable to work. Assistance under this provision is capped at 39 weeks and is calculated in accordance with state law, and increased per the Emergency Increase in Unemployment Compensation provision (discussed below).
- Emergency Increase in Unemployment Compensation: The CARES Act provides an additional \$600 in Federal Pandemic Unemployment Compensation to every weekly unemployment benefit, effective until July 31, 2020. This \$600 benefit will be taxable (like regular unemployment benefits), but will be disregarded in determining Medicaid or CHIP eligibility.

6. Tax Relief

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Tax Relief

Recent legislation regarding tax benefits

- On March 18, 2020, the “Families First Coronavirus Response Act” was signed into law, making emergency supplemental appropriations to address the COVID-19 emergency and enact payroll tax credits for certain smaller businesses. Since these tax credits apply to payroll, not income, tax, a wide range of businesses are expected to benefit. Employers may retain certain payroll tax deposits in the amount of the tax credits, and the IRS will implement expedited refund procedures. The new payroll tax credits include credits for paid sick leave and paid family leave. For additional information, see the full Wilson Sonsini alert [here](#).

- On March 20, 2020, the IRS outlined certain relief from tax deadlines to Americans and their businesses adversely affected by the COVID-19 emergency. Notably, tax filing and payment deadlines have been postponed until July 15, 2020 and there is no cap on the amount of tax that any taxpayer may postpone. Note that this change only applies to U.S. federal income tax filings and payments, as deadlines for filing any other U.S. federal tax or information returns remain unchanged. For additional information, see the full Wilson Sonsini alert [here](#).

- The CARES Act provides additional tax relief to businesses, a few highlights of which are below. Other relief measures not described below include, among others, more favorable net operating loss rules. For additional information, see Wilson Sonsini’s [COVID-19 Client Advisory Resource](#).
 - [Refundable Employee Retention Credit](#): If a company is subject to closure due to COVID-19 orders or experiences a significant decline in gross receipts, there is a refundable tax credit in the amount of 50% of up to \$10,000 of wages paid to an employee after March 12, 2020 and before January 1, 2021.
 - Closure means either fully or partially suspended operations due to a government order. A significant decline in gross receipts means a drop to less than 50% of gross receipts for the same quarter in the prior year. Companies with more than 100 employees are eligible for the credit for wages paid with respect to employees who are not providing services due to closure or significant decline in receipts. Companies with 100 or fewer employees are eligible for the credit for all employees.
 - [Employer Payroll Tax Payments](#): Timing for employer Social Security payroll tax payments has been extended, allowing a delay of employer payroll tax payments otherwise due for the remainder of 2020. Half of such employer payroll tax payments must be paid by the end of 2021, and the other half must be paid by the end of 2022.
 - Note that companies receiving SBA loans under the Paycheck Protection Program discussed above generally are not eligible for either the Employee Retention Credit or the payroll tax deferral.

7. FDA Actions and Guidance

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FDA Actions and Guidance

Recent FDA Regulatory Policies to Address the COVID-19 Threat

- [FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections](#): On March 18, 2020, the FDA announced that it has temporarily postponed all domestic routine surveillance facility inspections. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical. The FDA is evaluating additional ways to conduct for-cause inspections including, among other things, evaluating records in lieu of conducting an onsite inspection.
- [FDA Issues Guidance for Conducting Clinical Trials](#): On March 18, 2020, the FDA issued a guidance for industry, investigators, and institutional review boards conducting clinical trials during the COVID-19 pandemic. The guidance outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. Considerations recommended include, among others, sponsors evaluating alternative methods for assessments, like phone contacts or virtual visits and offering additional safety monitoring for those trial participants who may no longer have access to investigational product or the investigational site.
- [FDA Issues Temporary Policy for FSMA Onsite Audit Requirements](#): On March 17, 2020, to help prevent disruptions in the food supply-chain during the COVID-19 pandemic, the FDA issued a temporary policy for Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements.
- [FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics](#): On March 16, 2020, the FDA issued a guidance that provides recommendations for test developers who wish to develop serological tests; puts forth a policy for states to take responsibility for tests developed and used by laboratories in their states; and announces enforcement discretion towards commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an emergency use authorization, under certain circumstances.
- [FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19](#): On March 9, 2020, the FDA and the FTC issued warning letters to seven companies for selling fraudulent COVID-19 products. The products were considered unapproved drugs that pose significant risks to patient health and violate federal law. Rather than affording the usual 15 days for company responses, the warning letters requested companies respond in 48 hours describing the specific steps they have taken to correct the violations.

FDA Actions and Guidance

Recent FDA Regulatory Policies to Address the COVID-19 Threat (continued)

- [Supply Chain Update](#): On February 27, 2020, the FDA announced initiatives to help curb potential disruptions to supply or shortages of medical products in the U.S. Certain manufacturers of medical products have been asked to evaluate their supply chain as communicating potential disruptions can help work with companies to help identify interventions to mitigate potential shortages. The announcement also advocated four specific proposals included in the President's budget that the FDA believes help prevent or mitigate medical product shortages: lengthen expiration dates to mitigate critical human drug shortages, improve critical infrastructure by requiring risk management plans, improve critical infrastructure through improved data sharing and require more accurate supply chain information, and establish reporting requirements for device manufacturers.

FDA Actions and Guidance

Questions Regarding Regulatory Aspects of COVID-19

■ Below is a high-level list of certain questions we've been fielding as it relates to the regulatory response to COVID-19. For up to date alerts and advisories, be sure to follow Wilson Sonsini's [COVID-19 Client Advisory Resource](#).

- What should I consider when importing respiratory masks and PPE into the US?
- Do all N-95 respiratory masks and other PPE need FDA approval or clearance?
- Are companies that manufacture supplies/components for a medical device company considered an "essential business"?
- Can field-activities be performed by medical device and pharma sales staff?
- Has FDA issued guidance that will help companies and laboratories develop and commercialize COVID-19 diagnostic tests?
- Can companies and laboratories commercialize COVID-19 tests while an Emergency Use Application is pending?
- Do I need a doctor's prescription to get tested for COVID-19?
- Do shelter in place orders require employees of pharmaceutical, biotech, and medical device companies who are in the R&D phase (and without any commercial products) to stay at home?
- Have HIPAA security rules been waived so that employees can work from home on unsecure networks?
- Has FDA relaxed any regulatory restrictions regarding the manufacture and distribution of hand sanitizers?

8. Patent Filings

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Patent Filings

Strategic Delay: What if you foresee a budget shortfall, and need to act now?

- Prioritize patent families into those that cover your current product, those that may cover a future product, and those that do not cover either category (e.g., terminated programs, design-arounds, etc)

- For those that cover your current product:
 - Take maximum extensions in the less-major markets, usually such costs are much less than putting together a response.

- For inventions covering a future product:
 - Understand the competitive landscape, and make an educated guess if you need to act now, or can wait several months or a year. Perhaps your current filings can give you some protection. Make sure no public disclosures.

- For terminated programs: consider abandoning the patent families.

- For design-arounds: combine maximum extensions and filing continuation/divisionals to push costs down the road.

Patent Filings

Basic USPTO operations currently continue without interruption.

- Patent and trademark application deadlines and other deadlines are not extended. They are not granting any waivers or extensions of dates or requirements set by statute.
- Restoration: The USPTO is waiving petition fees in certain situations for customers impacted by COVID-19. This means if an application goes abandoned because the applicant was unable to timely reply due to the effects of the pandemic, the USPTO will waive the revival petition fee. The petition must be filed no later than two months of the issue date of the notice of abandonment.
- There will be no in-person interviews, but video or telephone interviews remain available. Examiner and examining attorney interviews, Patent Trial and Appeal Board (PTAB) and Trademark Trial and Appeal Board (TTAB) oral hearings, and other similar in-person meetings with parties and stakeholders scheduled to take place at USPTO offices will be conducted remotely by video or telephone.
- See the following link for up to date alerts from the [USPTO](#).

Patent Filings

European Deadline Extensions Available and Patent Office Remains Active

- **Automatic Extension:** The EPO announced that certain deadlines expiring after March 15, 2020 are extended to April 17, 2020. These deadlines include the deadline to respond to search reports, and the deadline to enter the European national stage.
 - The EPO's extension of certain deadlines is not a blanket extension. It excludes deadlines to pay renewal fees, and to file divisional applications (divisional applications must still be filed prior to publication of the grant of a patent).
 - Importantly, the EPO's deadline extension does not create a grace period to file a patent application following a public disclosure.
 - If you were not able to meet a deadline prior to March 15, 2020 because of disruptions due to the COVID-19 pandemic, certain remedies will be available.

- All oral proceedings in examination and opposition proceedings scheduled until April 17, 2020 have been postponed, unless they have already been confirmed to take place by means of videoconferencing.

- If the COVID-19 pandemic continues to disrupt operations at the EPO after April 17, 2020, the EPO may issue further extensions and delays for various deadlines. Consider PACE request to avoid upcoming glut of cases that used extension.

- See the following link for up to date alerts from the [EPO](#).

Patent Filings

Chinese and Japanese Patent Offices

■ China

- Plan to have filings ready at least one or two days ahead of the deadline.
- Similar to the USPTO, the Chinese Patent Office provided that a restoration of right based on this uncontrollable event may be available if a deadline is not met due to the pandemic and the applicant can provide evidences such as local government declaration or announces of emergency rules, evidences showing the applicant being quarantined, or diagnosis of infection. It is unclear whether/how this applies to applicants outside China, but it may be helpful to keep it in mind as a last resort.
- When interviews are needed, there might be a chance the examiner may not be reachable. There are some uncertainties when needing to schedule phone interviews with the examiners, particularly based on which division and location of the Chinese Patent Office the examiner works. Many examiners are working from home and there are chances of unavailability due to telecommunication issues.
- See the following link for up to date alerts from the [CNIPA](#).

■ Japan

- The Japanese Patent Office is open and functioning normally.
- No extensions of time or special provisions are currently provided.
- Generally, plan to send filings several weeks in advance to allow for translation delays.

9. Patent Post-Grant Proceedings

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Patent Post-Grant Proceedings

Proceedings Continue Despite COVID-19 Disruptions

- As of March 28, 2020, the Patent Trial and Appeal Board (PTAB) and the United States Court of Appeals for the Federal Circuit (CAFC) have made adjustments in their practices to accommodate the new realities of COVID-19 and social distancing, but remain open for business.
 - Parties before either body should continue to meet set deadlines. Importantly, United States Patent and Trademark Office (USPTO) has stressed that it [cannot waive statutory deadlines](#).
- Adjustments at the PTAB
 - The USPTO has closed its physical offices to the public, including PTAB hearing rooms, until further notice but is otherwise continuing its operations.
 - The PTAB will provide parties with notice in each affected case regarding options for video or telephonic hearings.
 - Thus far the PTAB has not needed to exercise its ability to extend cases solely due to COVID-19 related issues. We have seen evidence that the PTAB is more liberally employing other extension mechanisms, such as extensions in joinder cases.
- Adjustments for Parties at the PTAB
 - While much of the work parties do during the course of a PTAB trial can occur remotely, depositions pose a particular challenge.
 - Travel for client, co-counsel, and witness meetings is restricted.
 - When actual papers are served (typically just the petition and accompanying exhibits), parties should consider providing courtesy copies by email when possible to reduce COVID-19 related excuses, such as delay in receiving service.
- Adjustments at the CAFC
 - The CAFC, which historically has been generous in granting oral argument, will be more selective in the cases it hears and will decide more cases solely on the briefs.
 - All arguments scheduled for April will be conducted by telephone; no in-person hearings will be held. The parties in scheduled cases will receive updated notices in their cases.
 - Filing of paper copies (now required once briefing has been completed) is suspended until further notice unless the initial filing can only be made in paper.
 - Call volume has forced the CAFC to curtail telephone assistance from the Clerk's Office; questions should be directed to one of two email addresses for case-specific and general questions, respectively.

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*For up to date alerts
and advisories, see
the Wilson Sonsini's
COVID-19 Client
Advisory Resource.*