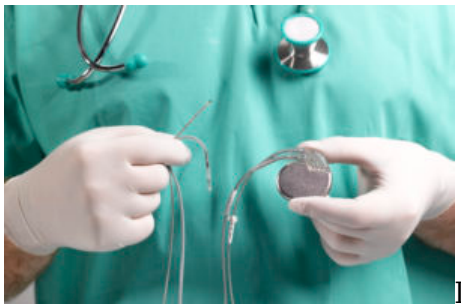
Planning For The End: Goodwin FDA attorneys Steve Tjoe and Susan Lee highlight key takeaways From FDA's draft guidances proposing transition plans for medical devices marketed under EUAs or enforcement policies during the COVID-19 Public Health Emergency

 During the COVID-19 public health emergency, the United States Food and Drug Administration (FDA) has issued hundreds of Emergency Use Authorizations (EUAs) and numerous enforcement policies to facilitate the availability of important medical devices. On December 23, 2021, FDA published two draft guidances setting forth the Agency's proposed process for transitioning the multitude of devices brought to market under these circumstances to full compliance with FDA requirements:

- Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "EUA Transition Draft Guidance"); and
- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (the "Enforcement Policies Transition Draft Guidance").

In our **recent Alert**, we summarize some key takeaways from FDA's proposed transition plan for manufacturers of devices marketed under a COVID-19 EUA ("EUA Devices") and devices marketed under one of more than 15 COVID-19 enforcement policies listed in the guidance ("Enforcement Policy Devices"). **Read More**

I want to license technology out of an academic or research institution. What kind of compensation will the institution typically look to receive?

 Academic or research institutions are at the core of early-stage innovation in the life sciences and biopharmaceutical industries. In order to gain access to the intellectual property generated or owned by those institutions, institutions typically offer to grant a license to its owned intellectual property to companies. In exchange for the license, institutions will look for consideration, which comes in a variety of forms. We can break down types of typical consideration into a few categories.

1. License Issue Fee: Institutions may ask for an upfront fee for the grant of the license. This is a one-time payment paid at the signing of the license.
2. Minimum Annual Royalties/Annual License Fees: Aside from the upfront fee, many institutions will ask for an annual "maintenance" fee. These can take the form of yearly lump sum payments, but can also sometimes be called "minimum annual royalties". If these payments are considered minimum annual royalties, then the yearly fee is creditable against any royalties owed to the institution that year.
3. Royalties: Institutions may ask for a percentage of the future sales of products that incorporate the intellectual property licensed. This comes in the form of on-going royalty payments. Typically, for most institutions, these are in the single-digits, but depend on the scope and breadth of the license.
4. Development/Commercial Milestones: Institutions may ask for lump sum payments based on the achievement of certain developmental or commercial milestones by the company. For example, if a product that incorporates the intellectual property licensed from the institution receives FDA approval, the institution may ask for a lump sum payment upon such achievement.
5. Sublicensing Income: Institutions like to ask for what we call "sublicense income". Through sublicense income, the institution is entitled to a percentage of the consideration the company receives from a sublicensee, if the company sublicenses the institutions intellectual property to a third party. The percentage varies and usually decreases over time, but is typically in the single-digits to low double-digits.
6. Patent Costs: If the company is taking an exclusive license, the institution will typically want the company to cover the costs of prosecuting any patents being licensed, those both already incurred and to be incurred in the future. In exchange, typically the company will have input in the future prosecution of the patents.
7. Equity: Depending on the relationship of the institution and the company, some institutions may request equity in the company in exchange for the license grant.

The amount and frequency of the above categories will vary from license to license, and will depend on the scope and breadth of the license (e.g., exclusive v. non-exclusive, limited geography v. worldwide, narrow field v. all fields, etc.). There also may be consideration institutions will ask for, other than the above. We recommend connecting with your Goodwin licensing or commercial counsel to discuss what might be typical for the scope of license you intend to enter into.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: Trends in Biopharma

 On Wednesday, January 15, 2020, during the J.P. Morgan Healthcare conference, Goodwin and KPMG held their initial all-day Symposium at the St. Regis hotel in San Francisco. The Symposium was composed of five separate "bursts" entitled (i) New Frontiers in Digital Diagnostics and MedTech, (ii) Europe Unleashed, (iii) Knowing the Best IPO Strategy, (iv) Trends in Biopharma and (v) Mergers and Acquisitions. Stéphane Bancel, the Chief Executive Officer of Moderna Therapeutics, provided the keynote address.

Burst Four consisted of a panel entitled "*Evaluating and Partnering New Technologies and Emerging Business Models*." This panel was moderated by **Kingsley Taft** from Goodwin, **Jeffrey Stoll** from KPMG and Nicholas Pullen from Bristol-Myers Squibb. In this panel, participants provided their insights regarding active deal sectors in biotech and issues to consider with respect to deal structure.

Key takeaways from Burst Four were as follows:

1. ***Platform technology deals in areas involving gene therapy, mRNA and immuo-oncology have been active, but some concern persists that companies in certain areas are over-valued, potentially decreasing the overall number of deals that have been made.*** Although many areas of biotech have actively been generating deals, the number large deals announced in the run-up to JP Morgan appeared to be less than in the prior year. The panelists suggested that the decreased number of deals may be a function of the high valuations that have been placed on biotech companies, noting the premium acquisition price that Roche paid for Spark as an example.
2. ***Given the complexities associated with certain platform technologies, such as gene therapy, many pharma partners prefer partnering deals as opposed to outright acquisitions for platform companies.*** Panelists suggested that pharma companies are more likely to favor a partnership structure over an acquisition structure when it comes to early-stage platform technologies in biotechnology. The reason for this is that the platform technology is likely to need a great deal of additional investment in numerous areas, including manufacturing, before the emergence of a product candidate that the pharma company is willing to develop on its own. In addition, it is very difficult for a pharma company to put a valuation on an early-platform company, but things become easier when the platform actually starts to generate potentially marketable products.

Key Takeaways from Goodwin + KPMG @ JPMorgan Symposium: New Frontiers in Digital Diagnostics and MedTech

 On Wednesday, January 15, 2020, during the J.P. Morgan Healthcare conference, Goodwin and KPMG held their initial all-day Symposium at the St. Regis hotel in San Francisco. The Symposium was composed of five separate "bursts" entitled (i) New Frontiers in Digital Diagnostics and MedTech, (ii) Europe Unleashed, (iii) Knowing the Best IPO Strategy, (iv) Trends in Biopharma and (v) Mergers and Acquisitions. Stéphane Bancel, the Chief Executive Officer of Moderna Therapeutics, provided the keynote address.

Burst One consisted of three parts. Roger Cohen from Goodwin provided an overview of the current state of the healthcare sector and regulations. During this session, Roger provided an overview of the FDA's definition of a medical device subject to FDA regulation, highlighting whether digital technologies would be encompassed within such definition. In addition, Roger reviewed other key federal and state laws of importance to companies involved in the digital healthcare space – including privacy laws such as HIPPA – and state laws regarding the corporate practice of medicine.

The second part of Burst One was a panel entitled "*New Frontiers in MedTech Space on the Global Stage: What are the Challenges in IP, Regulatory and Commercial*?" This panel was moderated by **Kristin Ciriello Pothier** from KPMG, and consisted of **Nicholas Mitrokostas** from Goodwin, Stefan Scherer from GlaxoSmithKline, Joseph Zaccaria from TrialSpark and Reena L. Pande from AbleTo. In this panel, participants provided their perspectives regarding the numerous challenges associated with bringing new medical technology to market, including as it relates to intellectual property, regulatory approvals, reimbursement and commercialization.

The final part of Burst One was a panel entitled "*Issues Facing Therapeutic Companies Using ML and AI in Drug Discovery Methods*." This panel was moderated by **Danielle Lauzon** from Goodwin and consisted of David Berry from Flagship Pioneering, and Dan Housman from Graticule and Courage Therapeutics. In this panel, participants provided their insights regarding how artificial intelligence, or AI, and machine learning, or ML, is used in the drug development process, and debated what type of input data is necessary for AI and ML to be truly useful in the drug development process.

Key takeaways from Burst One were as follows:

1. ***MedTech, digital diagnostic and health IT companies should seek guidance from experienced counsel as early on in the process as possible as laws and regulations are numerous and complicated.*** Various panel members noted that one of the biggest mistakes

that companies in the evolving medtech, digital diagnostics and health IT spaces make is failure to consider the numerous, complicated laws and regulations that may apply to their technologies. Therefore, they highly recommended obtaining experienced lawyers early in the company lifecycle to avoid potential missteps. For example, determining whether certain medical software will be regulated as a medical device by the FDA is very fact intensive and requires input from an experienced regulatory specialist as there are dire consequences for making the wrong determination. In addition, it is important to note that these laws and regulations are constantly evolving, therefore, something that may be permissible today may not be permissible in the future. Experienced counsel can keep you up-to-date on pending developments that might affect your company.

2. ***In many areas, the law has not kept pace with the speed of technological innovations; therefore, a great deal of gray space remains.*** Panelists noted that legal issues facing companies in rapidly-evolving sectors may not have a clear answer as the law has not kept pace with the speed of technological innovations. For example, in patent law, folks have had to consider whether a computer should be deemed the investor of the output from certain AI processes.
3. ***In order for new technologies in areas such as medtech, healthcare IT and digital diagnostics to become successful on a large scale, there is a need to balance the innovative mindset with the entrenched mindset and there must be an openness to collaboration both internally and externally.*** Many panelists cautioned that in order for new innovations in medtech, digital diagnostics and healthcare IT to be accepted by the current healthcare system, it will require a great deal of cooperation between the innovators and the entrenched players. Therefore, panelists advised that companies developing new technologies in these areas should seek to involve more entrenched players into their decision-making and development process as early as possible, and to seek returns on a smaller scale before seeking returns on a larger scale in order to build credibility.
4. ***AI has a great deal of promise in drug development, but questions remain regarding (i) how to obtain a sufficient amount of data for useful predictions, and (ii) the quality of the data that is used to arrive at predictions.*** Panelists noted that AI can be used throughout the drug development lifecycle, from assisting with target selection to helping predict the patient population that is most likely to respond to a product candidate. However, a panelist cautioned that the hype associated with AI should be toned down, as AI has yet to provide many of the promised benefits. Furthermore, there are many differing positions regarding the type of quality of data needed for AI to be truly useful in the drug development process.