KING & SPALDING

CRISIS PRACTICE

Coronavirus

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FDA Regulatory Issues for Automakers Manufacturing Medical Devices

King & Spalding has an active Coronavirus Task Force assisting clients with the myriad of issues arising during this pandemic and noted the discussions this week about potentially repurposing automotive factories to manufacture badly needed medical devices such as ventilators. Lawyers in our FDA & Life Sciences group address the considerations and/or barriers there might be in quickly transforming an automotive factory into a medical device factory. These considerations include:

- Most ventilators are defined under FDA law as Class II devices. As a Class II device, there is no need for FDA approval of a change in manufacturing location. There will be, however, concern over how to maintain safety while expediting the qualification of the necessary manufacturing equipment and how to validate the manufacturing processes. We anticipate that automakers would work closely with the manufacturer that designed the ventilator to train and possibly train employees. There might also be some need to upgrade certain processes to medical grade, rather than automotive grade.

- The FDA regulatory framework for production quality systems contains specific requirements, which may differ from those in use during automotive manufacturing. Some of our Quality System experts in the medical device field also have experience in the automotive field and believe this is unlikely to be a substantial barrier.

- Typically there are registration requirements and fees in connection with the manufacture of medical devices. We anticipate that as part of the discussions with the government, many of these may be streamlined or waived. The FDA also has the right to inspect medical device production facilities. Automakers may want to have as clear an arrangement as possible with FDA up front so that the FDA can work constructively with the company while minimizing any needed production halts.

- The transition from auto manufacturing to medical device production could impact environmental and OSHA compliance as well as commercial agreements.

These are just some of the preliminary issues that are likely to arise. We know this is moving very quickly and are can counsel you in connection with any discussions you may have with government authorities.

As the legal and practical issues related to 2019 Novel Coronavirus (COVID-19) continue to evolve, King & Spalding's Crisis Practice Coronavirus Task Force brings experience and judgment to help the c-suite, legal team and the Board address mounting business and legal issues. Our clients benefit from the experience of our Crisis Practice lawyers who have deep experience leveraging the firm's resources around the globe to routinely assist clients in incident response planning and live crisis management situations. We are also able to leverage relationships with premier global duty of care and crisis communications advisors to help our clients stay in front of today's unprecedented and rapidly unfolding developments.