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Automakers' Shift To Med Supplies Comes With Legal Hazards

By **Linda Chiem**

Law360 (March 25, 2020, 9:19 PM EDT) -- Auto companies volunteering to make critical medical supplies such as respirators and ventilators to stem the COVID-19 outbreak must carefully navigate product liability and intellectual property concerns that could end up thwarting their efforts to aid first responders in the public health crisis, experts say.

With American auto manufacturing on pause amid the pandemic, Ford, General Motors and Fiat Chrysler's respective plans to **retool certain production lines** to manufacture face shields, masks, respirators and ventilators for health care workers and other emergency personnel have been hailed as a notable example of big industry stepping up to fight COVID-19.

So there's growing buzz that "the government and its regulatory bodies will work with the carmakers to help support this effort by validating and approving necessary changes to their facilities and processes on a very fast track," said Ann Marie Uetz, a partner and trial attorney with Foley & Lardner LLP who represents suppliers in the automotive and defense industries.

But there are a number of regulatory and legal issues automakers must take into account before they mass produce critical medical supplies, signaling that there may not be as quick a turnaround for more complex equipment like ventilators, experts say.

Here, Law360 examines a few key issues that automakers will have to navigate.

FDA Requirements

The U.S. Food and Drug Administration on Sunday eased some of its restrictions for making ventilators and respirators to let medical device makers more easily change existing products and allow automakers to repurpose idled factory lines to meet skyrocketing demand for the devices.

The FDA's new guidance gives manufacturers "maximum regulatory flexibility" to source materials, modify software and hardware and other components, and gives companies that don't typically make medical supplies some leeway under the FDA's Emergency Use Authorization to get approval for their products.

Even with the extraordinary moves the FDA is making to address the COVID-19 emergency, companies that are willing to step into the medical equipment manufacturing world have to be aware of what they're getting into and whether they can deliver as promised, experts say.

"Even though the FDA has shown an extraordinary willingness to bend over backwards, it doesn't mean the basics are not still in place," Chuck Jolly, of counsel at Baker Donelson Bearman Caldwell & Berkowitz PC, told Law360.

Jolly, who specializes in FDA regulation, said one way to ensure that newly made products are safe, efficient and conform to FDA regulations is for automakers to partner with a sophisticated FDA-regulated company that can properly guide them on requirements related to ongoing reporting and quality manufacturing standards.

"However, that is not carte blanche," Jolly said. "Make sure you partner with someone who understands what the FDA mindset is [because] there are different constructs, differences in our compliance profile that's atypical in the rest of the manufacturing industry."

And it's something that the automakers are clearly mindful of, experts say. Ford Motor Co. said this week that it will team up with 3M to produce a new design of a powered air-purifying respirator that uses parts from both companies. It also said it would work with GE Healthcare to produce more ventilators. General Motors, meanwhile, has said it will work with Ventec Life Systems to boost production of Ventec's ventilators and other respiratory care products.

Thomas C. Regan, a products liability partner with Lewis Brisbois Bisgaard & Smith LLP, told Law360 that the FDA's latest guidance helps "speed [the] process" and might even insulate companies from having to adhere to things like reporting requirements.

"What that does is it allows manufacturers who are not in the business of manufacturing [medical equipment] to have that kind of recruitment to get into the business without what's called a 510(k) filing or without a formalized [risk evaluation and mitigation strategy]," Regan said.

A 510(K) is a premarket filing that a manufacturer gives to the FDA stating the device it wants to market is at least as safe and effective as a device that's already legally on the market.

Intellectual Property Concerns

In addition to questions of liability that can cascade throughout a manufacturer's production line and supply chain, automakers making the leap into medical equipment manufacturing will also contend with intellectual property concerns.

For one thing, they'll have to be aware of who owns the designs for products and whether they need to get licenses for those designs.

"Ventilators are a crowded IP space," said Ravi Mohan, an IP partner with Rutan & Tucker LLP. "It's possible that you would be stepping on someone's toes from an IP standpoint, so it's unclear if companies are going maverick or collaborating with someone."

It's therefore important for any of these companies trying to promulgate technology that's not their core competency to not rush a product to market, and to spell out rights and liabilities in their joint venture and other agreements.

"You can say we pivoted this auto chassis line to ventilators within two weeks and that sounds great, but if you put a product in the marketplace and if something goes sideways, the risk is really high," Mohan said.

Regan of Lewis Brisbois pointed out that the collaborative spirit in times of crisis can devolve into something more adversarial in times of normalcy if companies don't do their due diligence early on.

"There are going to be IP protections, NDAs and corporate documents and that becomes an issue if you have foreign manufacturers in Asia, Europe or wherever decide that they believe their product has been reverse engineered by any of these companies. Then you could see some litigation over that," Regan said.

President Donald Trump on March 18 signed an **executive order** invoking the Defense Production Act of 1950 to make the federal government the top priority for receiving medical equipment to combat the outbreak. But Trump has so far resisted calls to officially order private companies to expedite the production of medical equipment, saying many companies are already volunteering to do so on their own.

Patrick Keane, an IP attorney with Buchanan Ingersoll & Rooney PC, described the president's move of invoking the wartime law as an "eminent domain-like authorization" to mobilize manufacturers who are interested in building highly complex equipment like ventilators. And it might provide some cover for companies running up against IP issues, he said.

"A significant concern with other industries, such as auto manufacturers, veering into ventilator production is the possibility of patent right infringement," Keane said. "However, with President Trump activating the DPA, it could provide auto manufacturers the right to produce these ventilators with potential for the U.S. government to accept responsibility for any related patent infringement."

"The bottom line is, as long as competitors are careful to work with the government and patent rights holders, the situation can be effectively and efficiently implemented in the interest of promoting health needs of all," Keane said.

--Editing by Aaron Pelc and Emily Kokoll.

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