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News: Flu vaccine makers upgrade technology—and pray for time

By Cormac Sheridan

The onset of winter in the southern hemisphere could determine whether the novel, swine-derived influenza A (H1N1) strain detected in Mexico in April will evolve into a full-fledged pandemic virus. Health authorities around the globe are by no means fully equipped to cope with a severe influenza pandemic at this stage, given the lead times and capacity constraints associated with current vaccine production processes—as was the case in 2004, when a dangerous new avian strain (H5N1) emerged in Asia. In the past five years, however, public sector laboratories and biotech companies have made considerable progress in developing modern alternatives to the cumbersome, egg-based manufacturing process that large flu vaccine producers have relied on for decades.....

“But others see universal vaccines as a long-term bet. “Our biggest concern is that the regulatory pathway for universal vaccines is not clear,” says Rahul Singhvi, CEO of Rockville, Maryland–based Novavax. The firm uses VLP technology to develop vaccines based on HA and NA and the structural protein M1. A baculovirus vector expressed in an insect cell culture system produces particles, which closely resembles the native virus. “To the immune system it appears like there’s a natural infection at the site of immunization,” says Singhvi. This approach, he says, would enable large-scale manufacturing within around 12 weeks of a pandemic strain being characterized.

The company is also offering, in conjunction with GE Healthcare, a subsidiary of Fairfield, Connecticut–based GE, a low-cost, portable, disposable manufacturing system for pandemic vaccines. “You can do this in low-infrastructure environments,” Singhvi says.....”