Cautious industry welcome for US flu vaccine plan

The US government's recent raft of preemptive measures in favor of flu vaccine R&D and stockpiling in the wake of the October announcement of the creation of a new R&D funding agency to support biodefense research, funded by Project BioShield, may seem like a new window of opportunity for the biotech industry. The new procurement, if approved, could help catalyze a rebound of an industry that remains in flux. But although such initiatives would be good for the industry's bottom line, they won't necessarily foster innovative vaccines.

On November 1, increasing concerns about an Asian flu pandemic prompted US President George W. Bush to announce his national strategy for pandemic influenza that will include $7.1 billion to combat the threat, including $2.8 billion support the development of cell-culture based vaccines .

In parallel, the biodefense and Pandemic Vaccine and Drug Development Act of 2005, introduced in October to the US senate would introduce liability coverage that

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An infectious and political time bomb: As Asia vaccinates poultry in an attempt to contain avian flu, the US government is making available more funds for vaccine research.

could be an important incentive for the industry. Liability is a key issue because vaccine production is traditionally a low-margin business, and expensive settlements—for claims like the measles-mumps-rubella (MMR) vaccine causing autism in some children—can quickly make it unprofitable. 'That's why a lot of companies got out of the [influenza vaccine] field," says Rahul Singhvi, president and CEO of Malvern, Pennsylvania-based Novavax. "Having some sort of indemnification from the government would be an important incentive."

The act also contains some potential good news for innovation. Among other measures, the bill would establish the Biomedical Advanced Research and Development Agency (BARDA), which would support and coordinate countermeasures against epidemic or pandemic diseases and biological, chemical or nuclear agents, including funding of R&D in industry. The agency would have an annual budget of over $1 billion. Funding for the first year would be drawn from the $5.6 billion (over ten years) pot created by last year's BioShield legislation, whereas future years would come from an-as-yet undetermined source, according to the *Wall Street Journal*. US Senator Richard Burr, who sponsored one of two versions of the bill, also supports milestone payments for companies reaching development goals, shielding companies from some of the risk of failing to land a supply contract.

Still, some are skeptical. According to Elaine Cheung, senior manager of business development at Brisbane, California-based VaxGen—which was awarded the first contract under the auspices of Project BioShield, to supply the US government with anthrax vaccine—the rationale behind BARDA stems from the fact that since 9/11, the administration has shifted its vaccine focus away from just military use to include the civilian population. That has spread funding and responsibilities through multiple agencies, creating an unwieldy bureaucracy.

Will BARDA help? Cheung isn't sure. "The effort is commendable, but to work, there needs to be more predictability and transparency in what they want from the private sector. If it's successful, it's a good idea that could make the whole process more efficient. If it's not well designed, it'll [add another layer of bureaucracy and] make it even worse," she says.

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President Bush has also proposed using some of the $5.6 billion from this year's BioShield legislation for nonbiodefense applications, including pandemic flu research, which could prompt companies to enter the field. "It shows a clear intent to buy," Cheung says.

Like BioShield, the National Strategy for Pandemic Influenza provides an immediate guaranteed market for pandemic flu vaccines. But the money isn't guaranteed to attract companies. Depending on government procurement for something like pandemic flu, which has no viable commercial market, "is a risky proposition. It may not justify development unless there's a backup strategy," says Rahul Singhvi, president and CEO of Malvern, Pennsylvania-based Novavax. With pandemic flu, that strategy is seasonal flu. "With the pandemic flu, the same strategy can be used to make a seasonal vaccine. If you can do fewer experiments or clinical trials by leveraging the work done on pandemic flu, then (pursuing a pandemic flu vaccine) is a reasonable risk to take."

The National Strategy for Pandemic Influenza and BARDA represent the latest in a trend, says Cheung. "There has been a fundamental shift in the vaccine industry and government policy from a focus on prevention of childhood diseases to preparedness for diseases that are emerging or that are bioterror threats," she says. Vaccines for adult diseases are also getting more consideration, such as Merck's Gardisil (a recombinant vaccine comprising four human papilloma virus subtypes), which made headlines in early October when it proved 100% effective in preventing cervical precancer and noninvasive cervical cancer in a phase 3 trial. That means the need for innovative vaccines might be better recognized, but they won't necessarily get funded by the new government plans.

Although the policy shift could bolster the vaccine industry, sustainability of the effort remains a concern. "Recent developments are encouraging, says Brian Currie, who is vice president and senior medical director at Albert Einstein College of Medicine's Montefiore Medical Center, but cautions "something like West Nile virus comes up and a lot of money gets thrown at it, and then it dries up. Then another problem emerges [and the pattern repeats]. We went from one episode to another without a coherent plan." The President's plan calls for at least the beginning of an infrastructure. "To me, that was reassuring."

Still, most would like to see more. "[Bush's plan] probably isn't enough, but it's certainly a starting point," says Dino Dina, president and CEO of Berkeley-based Dynavax, which is developing immunostimulatory sequences as adjuvants to a conventional flu vaccine. Others are optimistic, including Michael J. Shuster, who is an attorney with Silicon Valley, California-based law firm Fenwick & West. "I do think that for political reasons—for fear of a pandemic and fear of the political repercussions for not having done everything possible to [stave one off]—there is a lot of political will right now to get something done."

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