

## **Bush's Smallpox Vaccine Compensation Plan May Have 'Safe Needle' Measure**

The Bush administration may include a "sheathed needle" provision in its smallpox vaccination compensation plan, but it likely will not include a liability indemnification provision for companies manufacturing biodefense products, according to a high-ranking federal health official. The administration may propose its legislative plan for compensating health care workers injured by the smallpox vaccine as early as this week.

Speaking at a National Governors Association meeting Monday (Feb. 24), Joseph Henderson, the director of the Centers for Disease Control and Prevention's Terrorism Preparedness and Response Program, said he expects the legislative proposal to seek additional funds to help the states carry out the smallpox vaccination program. Henderson said he did not know how much funding the administration would propose, saying only that the vaccination program could cost states anywhere between \$150 million and \$845 million.

Henderson said the White House is working out the details of the plan with the Office of Management and Budget (OMB).

The plan will focus on compensating health care workers for injuries incurred by taking the vaccine, including the cost of missing work, Henderson said. He also said that he expects the administration to include a provision similar to Rep. Henry Waxman's (D-CA) "safer needles" plan. Earlier this month Waxman introduced a smallpox vaccination compensation bill, H.R. 865, which included a measure requiring states to provide FDA-approved sheathed, bifurcated needles for administering the vaccine.

FDA approved the Wyeth smallpox vaccine in kits of 100 doses that included 100 bifurcated needles made by the medical device company Precision. However, Waxman's legislation calls for requiring that states also offer what some say are safer needles, which are bifurcated needles mounted in a sheath to protect health care workers from inadvertently sticking themselves.

As of Feb. 20 the states had bought about 2,800 of Wyeth's kits, a little over half of the kits needed to inoculate the approximate 500,000 health care workers in the first phase of the smallpox vaccination plan, according to CDC's website. Up to 10 million health care workers and first responders could be offered the vaccine during the second phase of the vaccination plan. An FDA spokesperson says that to include the sheathed needles in future kits, Wyeth would need to submit a supplemental application.

Henderson said he did not know of any liability indemnification provision in the administration's plan. Republicans in Congress have been pushing for a provision that would protect companies making biodefense products against class-action lawsuits. However, Senate Republicans have decided to work with the White House on compensation legislation before negotiating with Democrats on liability protection (see FDA Week, Feb. 14, p1), indicating that Republicans may push for liability indemnification legislation elsewhere. -- John Wilkerson