Plague Vaccine "Regulations": Ensuring Quality

We offer the following information for purposes of clarifying statements in the article about plague vaccine by Steve Sternberg "Bottleneck keeps existing vaccine off the market" (News & Comment, 7 Oct., p. 22). Greer Laboratories, Inc. of Lenoir, North Carolina, was licensed by the Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration on 5 October 1994 to manufacture plague vaccine.

Existing requirements specify that biological products must be safe, pure, and potent and be consistent with good manufacturing practices. In approving the Greer vaccine, CBER reviewed data demonstrating comparability with a previously approved plague vaccine manufactured by Miles, Inc., whose efficacy data were derived from the military's use during the Vietnam era; very few cases of plague occurred among U.S. soldiers immunized with this predecessor plague vaccine compared with unvaccinated Vietnamese civilians, who suffered many cases of plague. Because the incidence of plague is so low in the United States, obtaining further efficacy data through conventional clinical trials was not feasible. For this reason, the Food and Drug Administration asked Greer Laboratories to conduct a clinical trial in small numbers of volunteers to compare adverse reactions and antibody responses with the predecessor vaccine and the new vaccine.

Consistent production of biological products, particularly those that have replicating pathogens as their starting point, is difficult and demanding. This is true even for experienced manufacturers but particularly so for companies such as Greer that are new to vaccine production. Our focus therefore became ensuring that this vaccine, made in a new facility with new equipment and new staff, was comparable to the previous vaccine and was handled properly throughout a contained production process. We believe this focus was appropriate to ensure the manufacture of quality vaccine.

In review of biological products, we strive to use our best scientific judgment to responsibly apply requirements designed to protect the public health. In this situation, a committee of CBER experts worked with both Greer Laboratories and the Department of Defense to resolve the many scientific and regulatory issues involved in this application as quickly as possible.

Kathryn C. Zoon
Director,
Center for Biologics Evaluation and Research,
Food and Drug Administration,
Rockville, MD 20852–1448, USA

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Significance of $d_{x^2-y^2}$ Pairing in the Cuprates

In the News article "New clues to superconductivity" (12 Aug., p. 860), Daniel Clery notes that recent experiments suggesting that the high-temperature cuprate superconductors have a $d_{x^2-y^2}$ gap provided important clues regarding the pairing mechanism. However, P. W. Anderson (Letters, 23 Sept., p. 1789) states that "the symmetry of the gap is of little importance."

I believe the momentum dependence of the gap reflects the momentum dependence of the effective pairing interaction, just as the frequency dependence of the gap reflects the frequency dependence of the interaction. Studies of the frequency dependence of the gap in the traditional low-temperature superconductors provided detailed evidence that the exchange of phonons was responsible for pairing in these materials. In the case of the high-

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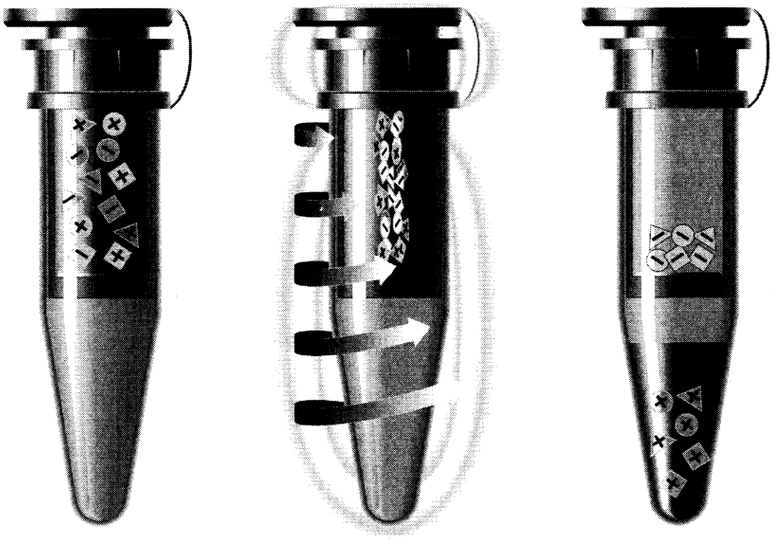

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