FDA Approves First Cell Culture Influenza Vaccine

On November 20, 2012, the FDA announced the approval of Flucelvax, the first seasonal influenza vaccine licensed in the United States produced by animal cells instead of fertilized chicken eggs. This marks a significant turning point for the influenza vaccine manufacturing process, in that production turn-around for future lots of influenza vaccine in the United States is hoped to be much more rapid in the event of a pandemic similar to what occurred during the 2009 H1N1 influenza outbreak. At that time, development and production of a vaccine against H1N1 was slowed by the antiquated chicken egg technique. Due to poor financial incentive to find new methods for production, this method had remained in place for over 70 years.

The 2012 guidelines published by the Centers for Disease Control recommend that patients 6 months of age and older be vaccinated annually to prevent infection from a variety of influenza strains. However, Flucelyax is only approved currently for the vaccination of patients 18 years of age and older.

References:

- Press Announcements. FDA approves first seasonal influenza vaccine manufactured using cell culture technology. FDA. Available at: http://www.fda.gov/NewsEvents/Newsroom/ PressAnnouncements/ucm328982.htm
- Hatz C, Cramer JP, Vertruyen A, Schwarz TF, von Sonnenburg F, et al. A randomised, single-blind, dose-range study to assess the immunogenicity and safety of a cell-culture-derived A/H1N1 influenza vaccine in adult and elderly populations. Vaccine. 2012 Jul 6;30(32):4820-7.
- Flucelvax [package insert draft]. Cambridge, MA: Novartis Vaccines and Diagnostics, Inc.; 2012.
- Centers for Disease Control and Prevention (CDC). Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP)— United States, 2012-13 influenza season. MMWR Morb Mortal Wkly Rep. 2012 Aug 17;61(32):613-8.

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