



## Summary and Comment: "Flu Speed Ahead for Vaccines Market"

### The RPM Report October 2006

This report examines the article, "Flu Speed Ahead for Vaccines Market," written by Cole Werble for the October 2006 *RPM Report*. The article explores the current US flu vaccine market, particularly how and why the size of the market has grown so dramatically and what this means for the future. The author asserts the explosion of interest in flu vaccines is in response to a multi-front campaign by the US Government (USG) to create a revitalized market, specifically using direct incentives to rebuild the vaccine sector. The main point to keep in mind while thinking about this growing potential flu market and the flood of new producers is the potential for oversupply.

### The Flu Vaccine Market On the Rise

- The increasing market size for vaccines and government funding associated with preparations for a potential pandemic flu outbreak are contributing to a surging vaccines business. Companies which have been laboring with little notoriety in the vaccine industry are now making strong pitches to the financial markets.
- Since the beginning of 2005, GlaxoSmithKline has committed almost \$2 billion to acquisitions and capital projects in the flu area.
  - Acquisitions in 2005
    - \$400 million for Corixa Corp.
    - \$1.4 billion for ID Biomedical Corp. (Canada)
    - more than \$100 million for the acquisition and refurbishing of Wyeth's Marietta, PA vaccine facility
  - Entering into the flu market in a big way jumping from an emergency delivery of 1.2 million doses to the USG in 2004 to a projected 25 to 30 million doses in 2006.
- Novartis has invested \$6.4 billion, more than tripling GSK's investment.
  - Quickly took control of Chiron, \$5.7 billion purchase of the 58% of Chiron shares it did not already own.
  - Announced a commitment of \$600 million to \$700 million to a four-year project to build and license a plant in North Carolina to produce cell culture-derived flu vaccines.
  - They maintain the vaccine field will outperform the traditional pharma business in the next three years. Overall growth rate should be three times as high as traditional pharma through 2009.
- The total flu vaccine supply for this year (2006) will be between 100 million and 120 million doses. This represents a huge increase over the last peak production year in 2002 when 95 million doses were produced.
  - Producers:
    - 30 million doses from GSK companies (ID Biomedical included)
    - 50 million doses from Sanofi-Aventis
    - 35 million doses from Novartis
    - 3-4 million doses from MedImmune Inc.
  - CDC expects three new companies to receive FDA licensure during the 2006-2007 and 2007-2008 season, presumably:

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### US Government Involvement and the Burgeoning Flu Vaccine Market

- A broad political consensus has translated into large grants to the flu vaccine manufacturers for clinical development, research on new dosage forms, and subsidies for plant construction. It is believed the overriding goal of the government is to build a new, broad infrastructure of flu vaccine manufacturers.
- It is predicted that USG will be willing to put as much as \$2 billion more into the flu field, for vaccines and other preparedness measures, in the next two fiscal years through the use of remaining funds from the original pandemic flu preparedness subsidy and from a new \$1 billion commitment for FY08.
- The USG is partaking in “push” strategies to get products to market and “pull” incentives to ensure larger market sizes.
  - “Push” -- The Australian company CSL Ltd. is getting significant help from the NIH/National Institute of Allergy and Infectious Diseases to get through the clinical trials for its application to the FDA (a similar effort was taken to get GSK’s Fluarix to market quickly).
  - “Push” -- HHS has committed over \$1.1 billion to six companies to advance cell culture production.
    - GSK ~\$275 million
    - Novartis ~\$221 million
    - Solva SA ~\$299 million
    - MedImmune ~\$170 million
    - Sanofi-Aventis ~ \$97 million
    - DynPort ~ \$40.97 million
  - “Pull” -- The government is creating a growth market by building the target population for the inoculations and accepting an increase in price for the flu vaccines.
    - CDC has expanded the recommended population to receive flu shots. Recent changes have added vaccinations for children at preschool age. The recommendations now include approximately 218 million people for 2006-2007, up from about 180 million two years ago.
  - “Pull” -- HHS supports a strong communication effort, funded at \$900,000 per year. There has been a move to expand this effort by shifting unused funds from pandemic preparedness to increasing awareness of general flu immunization effort.

### The Future and Flu Vaccine Markets

- It can be argued the USG is stimulating a big development effort for manufacturing techniques and capacity for the general flu vaccine in preparation for a pandemic event and the vaccines that will be needed. HHS expects to have manufacturers to have the manufacturing capacity for pandemic flu vaccines to provide for 600 million courses of treatment by the end of 2011.
- The big challenge for this year and those to come, is that the incentives to produce vaccines may be working too well. This year, shortages are not a concern, instead a potential oversupply could threaten revival of the flu vaccine market in the long run, and ruin the USG’s goal of building broad infrastructure of flu vaccine manufacturers.
- The author noted that universal flu vaccination recommendations are just around the corner. There are signs of pressures, especially, within the vaccine community to move towards efforts of universal vaccination of the US population. Programs such as this are already in place in Ontario, Canada and are frequently looked to as a precedent. It seems that with the annual incremental CDC recommendations, it may be easier to move on to a universal recommendation.

To conclude, this article offers some information that can be used to target the growing flu vaccine marketplace. Specifically, the willingness of the USG to give money directly to companies, both foreign and domestic, for new vaccine development as well as expanding the target vaccine population. These efforts are more than likely in preparation for a pandemic. This sustained support for the field is promising for flu vaccine manufacturers.

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