DRUG DEVELOPMENT COURSE 2006

GROUP PROJECT #3.

One of the most serious threats to global health is the possibility of a virulent avian influenza virus crossing over into humans and causing a world-wide pandemic, as occurred during the catastrophic influenza epidemic of 1918-1919. You are employed by one of the largest American pharmaceutical companies, in their vaccines division. Your company already markets vaccines for hepatitis A and B, polio, and influenza A and B.

IN 2005, an avian influenza outbreak occurred in Southeast Asia, which crossed over into about 100 poultry farmers and their household contacts with a mortality rate of 50%. You have been approached by the Centers for Disease Control and the World Health Organization requesting your assistance and expertise in developing and rapidly deploying a human vaccine effective against the virus that has been isolated from this Southeast Asian outbreak.

The Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) have offered modest financial assistance (about $20 million) for the laboratory research and development and initial manufacturing of this product, but they are expecting your company to foot the bill for human testing and expect that you, in turn, will sell this vaccine for a profit in the developed world, while offering it for cost to the developing world. You have confirmed that this virus can be grown in the same culture system you normally use to grow the virus for the killed human influenza A and B vaccines you currently manufacture, and your assumption is that this vaccine is likely to be as efficacious as the influenza vaccines you already market.

ADDRESS THE FOLLOWING:

1. What are the risks and benefits to the company in taking on this project?

2. How will you assess efficacy of this vaccine?

3. Propose a course of development for this vaccine that would make it “approvable” by the FDA and other regulatory bodies.