

Bird Flu and the FDA's Expedited Approval Processes: Is There Cause for Concern?

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It often takes the U.S. Food and Drug Administration ("FDA") years to approve medical products, but using an expedited review process the FDA in only two weeks approved a device intended to be used to diagnose the avian flu. If the FDA's standard approval process does not produce safe drugs and/or devices (as most recently evidenced with the problems with Vioxx), how can the FDA even begin to confirm the safety and effectiveness of products that are on the approval "fast-track" for use in the diagnosis and treatment of the avian flu?

From December 1, 2003, through February 3, 2006, the World Health Organization reported 161 confirmed human cases of avian influenza A (H5N1). Of these, 86 (53%) were fatal. The infections occurred in Cambodia, China, Indonesia, Iraq, Thailand, Turkey, and Vietnam. No infections with avian influenza A/H5 (Asian lineage) have been reported in animals or humans in North America.¹

On February 3, 2006, the FDA announced clearance of a medical device designed to detect the avian influenza viruses associated with recent laboratory-confirmed infections of avian influenza in humans. Through use of an expedited review process, the FDA completed the review and approval of the new device, from the Centers for Disease Control and Prevention ("CDC"), within *two weeks* of the time CDC submitted its application – an extraordinarily short timeline. According to acting FDA Commissioner Dr. Andrew von Eschenbach, "preparing for a possible flu pandemic is a top priority for our nation, and FDA acted quickly to evaluate and expedite CDC's request for approval of this test." In announcing the approval, Dr. Eschenbach also explained that, "[u]sing flexible regulatory authorities, FDA was able to prioritize this expedited approval based on the clear critical need without compromising the quality or integrity of the FDA review process."²

In 2004, the median approval time for a medical device (with no prior comparable device) was close to six months.³ Medical devices are typically subject to the "general controls" of the Federal Food Drug & Cosmetic Act. These controls are the baseline requirements that apply to all medical devices and control marketing, proper labeling and monitoring a device's performance once the device is on the market. Medical devices must go through an approval process to confirm the device's safety and effectiveness. The process begins with applications to the FDA to begin clinical studies. Once

¹ U.S. Department of Health and Human Services, *News Release: FDA Approves New Laboratory Test To Detect Human Infections With Avian Influenza A/H5 Viruses* (Feb. 3, 2006), available at <http://www.hhs.gov/news/press/2006pres/20060203.html> (last visited May 6, 2006).

² *Id.*

³ U.S. Food and Drug Administration, *Approval Times* (June 19, 2005), available at <http://www.fda.gov/cber/products/apprtime.htm> (last visited May 6, 2006).

approved, the studies must meet stringent patient consent, labeling, monitoring and recording requirements. Finally, the manufacturer submits data from the clinical studies to support the manufacture and marketing of the medical device.

In contrast, the newly approved avian flu detection test was evaluated under a less stringent process provided by Congress in the 1997 Food, Drug, and Modernization Act (FDAMA), despite the absence of the required “precedent device” mandated in FDAMA. The process of evaluation under the FDAMA allows the FDA to use less burdensome regulatory procedures in establishing the safety and effectiveness of a proposed device and permits early interaction between the FDA and the manufacturer/applicant seeking approval for a device. This interaction often begins with a “determination meeting,” during which the FDA can provide the manufacturer with the agency’s determination of what valid scientific evidence will be necessary to demonstrate that the device is effective for its intended use. The FDAMA expedited process then allows the FDA to determine whether clinical studies are needed to establish effectiveness and, in consultation with the applicant, determine the least burdensome way of evaluating effectiveness of a device that has a reasonable likelihood of success.

In further expansion of the perceived need for more expeditious review of products related to avian flu preparation, Congress gave the Secretary of the U.S. Department of Health and Human Services (“HHS”) the authority to declare when products are necessary “countermeasures” in a public health emergency. In addition, Congress also granted “sweeping liability protection” to the companies manufacturing and distributing these products. HHS Secretary Mike Leavitt announced on February 13, 2006, that the Bush administration plans to contract with companies to develop avian flu vaccines, rapid-detection tests and technology to stretch the vaccine supply.⁴ Secretary Leavitt also said the administration will “deal with the issue of liability.” Specifically, he observed, that “[i]f you’re a vaccine manufacturer, you’re not likely going to want” to conduct clinical trials on new flu-related products “unless you’ve got adequate liability protection.” Under this liability protection, people injured by related products would have to prove willful misconduct in order to claim damages, essentially barring all lawsuits in the name of public protection.

Even when medical devices and drugs are subject to the standard approval process, there remain an alarming number of product recalls due to safety concerns and/or defects with such products. In January 2006 alone, the FDA announced recalls of more than 200 previously approved products.⁵ In the case of the early avian flu detection test, a problem has already appeared. Apparently, test results provide only a presumptive positive, meaning that further testing and “careful interpretation” would still have to be conducted by the CDC.⁶

⁴ Kevin Freking, *Bird-flu vaccine makers to get protection*, FORT WAYNE J. GAZETTE, Feb. 13, 2006, available at <http://www.fortwayne.com/mld/journalgazette/13863497.htm> (last visited May 6, 2006).

⁵ U.S. Food and Drug Administration, *Enforcement Report*, available at <http://www.fda.gov/po/enforceindex/2006enforce.html> (last visited May 6, 2006).

⁶ Amanda Gardner, *New Test Quickly Spots Bird Flu in People*, HEALTHDAY NEWS, Feb. 3, 2006, available at <http://health.msn.com/healthnews/ArticlePage.aspx?cp-documentid=100124052> (last visited May 6, 2006).

If the FDA determines whether clinical studies are needed to establish effectiveness, if the FDA has “flexible” regulatory authority, if the FDA determines the least burdensome way of evaluating effectiveness of a device that has a reasonable likelihood of success, if the FDA has control over which products are allowed to be produced and marketed, and if the FDA determines when products are entitled to sweeping liability protections, how can we trust the safety and effectiveness of the products given the FDA’s seal of approval? Add this to the ongoing controversies over pharmaceutical industry control of medical research and hidden biases within the regulatory process, and we are left with very little faith in “approved” avian flu products.

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