

Homeland Security – Law Firms

Meeting The Challenge Of Avian Flu – A Blueprint For Global Pandemics?

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McKenna Long & Aldridge LLP (MLA) has had the privilege over the past few years of taking a leading role in the development of a market for vaccines, detection devices, diagnostics, information technology, and other countermeasures to be used against infectious diseases. This market has steadily grown as the reality of potential bioterrorism or the spread of pandemic diseases has been brought to light. In this article, we present a brief review of avian flu and discuss ongoing measures meant to reduce the danger of this potential pandemic.

The terms avian flu, pandemic, H5N1, mortality rates, and mutations have recently become part of the vernacular in the United States as the government, businesses, and families try to make sense of the buzz surrounding the next potential global threat. However, while these important public health and scientific terms are used with a certain ease, the interchangeability of terminology that has accompanied much of the discussion indicates that while the language is readily and freely used, often it is employed inappropriately and without real understanding. The development of meaningful preparation and preparedness against avian flu relies upon understanding the nature of the threat, integrating initiatives and complementary resources, and developing proactive strategies that can be implemented fearlessly and seamlessly if and when a pandemic develops. These are requisite activities whether on a federal, local, corporate, or individual level.

“H5N1” flu is a strain of influenza virus that naturally circulates among birds, most often without infecting humans, and thus is dubbed an “avian flu.” That said, all influenza – including the flu that occurs every year – begins in birds. Unlike the annual flu, the typical avian flu transmission cycle only occurs in birds, with infections of other animals, including humans becoming infected only by accident and do not contribute significantly to the lifecycle of the pathogen. This type of accidental transmission to humans or other animals is most often due to close proximity with infected birds, but this is not the transmission that is going to directly ignite a pandemic. The worry associated with avian flu is the potential for the virus to mutate in such a fashion that would allow for direct human to human transmission of the virus, without the need for contact with an infected bird. H5N1 is a specific

strain of avian flu which has a high potential for such an adaptation to humans.

Human to human transmission of the H5N1 strain of avian flu is currently not taking place, outside of a very small number of transmissions traced to very close contact. According to the World Health Organization (WHO), as of June 6, 2006 there have been 225 cases of H5N1, of which 128 cases were fatal. All of the 225 cases of H5N1 that have occurred in humans since 2003 have been a result of close contact with infected birds, and none of the cases have been confirmed to be the result of human to human transmission. There have been at least seven cases that appear to be human-to-human transmission, however, in each of these instances, it appears there were very close contact that likely included direct exchange of bodily fluids (such as a mother caring for a sick child). Most recently, a “cluster” of cases in Indonesia has sparked significant concern that human-to-human transmission may be more possible than previously understood. Significant concern arises as more cases are reported because human to human transmission of H5N1 could occur should a specific set of mutations or reassortments occur within the H5N1 viral genome.

It is important to understand that all viruses mutate very easily, and there will be many changes which occur that do not have any effect on the ability of the virus to circulate among humans. At the same time, because viruses do mutate easily, it is possible that one of these mutations will lead to the ability for the virus to be transmitted among humans. While this may make us all feel somewhat powerless against an ever-changing pathogen, significant biomedical research has been conducted on previous influenza pandemics and on other important human viral infections which has led to the identification of the factors that may likely be important for the emergence of a pandemic. Scientists feel confident that they know which mutations will be important for meaningful human to human transmission to occur. Consequently, much of the work being done globally involves the collection of viral samples from infected birds and humans to determine what mutations have occurred and if the mutations pose a significant threat to the health of humans. Therefore, viral surveillance is a key first step in the protection of humans because if scientists are able to identify an important mutation before significant movement of infected individuals occurs, then preparations can be put into place to minimize spread and contact with these important viral strains and infectious carriers.

The federal government is spearhead-

ing much of the movement for research and development into pandemic vaccines, surveillance, and biomedical equipment. In the area of biodefense, current activities in Congress will help scientists and biomedical industries through the arduous and expensive product development process. Passage of legislation introduced by Senator Richard Burr (R-NC), with co-sponsorship by Senator Judd Gregg (R-NH) and others, creating the Biopharmaceutical Advanced Development Research Agency (BARDA), and the commitment by the President in his FY 2007 budget to fund such an effort with nearly \$200 million, is a very positive development. Passage of the creation of BARDA will go a long way to address the “valley of death” in biodefense countermeasure development. This concern was first identified by Senators Joe Lieberman and Orrin Hatch in 2002, and merits the strong support of industry for passage this year. In addition, the Department of Health and Human Services (HHS) Deputy Secretary Alex Azar recently announced that he and Secretary Leavitt are about to complete a revised implementation strategy for Project BioShield to eliminate many of the delays that have been observed in the BioShield program. Given the substantial talents of Deputy Secretary Azar, his personal involvement in this effort is welcome and encouraging.

Supplementing legislative action is the ongoing significant funding in research and development for pandemic vaccines. On May 4, 2006, Secretary Leavitt announced the award of almost \$1 billion in advance development contracts for cell-culture influenza vaccines. These cell-culture based vaccines are critical in order for the U.S. to rapidly scale up production in order to deliver enough vaccine to immunize a significant proportion of the population. We should also take heart in the size and diversity of the companies which have been awarded cell-culture contracts. Both traditional pharmaceutical companies like Glaxo-SmithKline and biotechnology companies like MedImmune, which developed the first licensed innovation in flu vaccine technology in over 50 years with the Flu-Mist vaccine, have been welcomed by HHS. Given the recent challenges HHS has faced with delays in delivery of an experimental anthrax vaccine under BioShield, it is clear that HHS understands the need to diversify its influenza research portfolio.

Additionally, HHS is now moving forward with development of adjuvant technology to improve the disappointing effectiveness of the H5N1 vaccine purchased last year, as well as to continue development of exciting new vaccine technologies such as DNA-based vaccines and novel antivirals. At the same time, HHS has recognized the need to accelerate the development of critical rapid diagnostics, and has announced plans to move forward with an advance development program for such technology in the coming weeks.

The government alone will not be able to thwart a global pandemic. While pandemic preparedness is first and foremost an issue of public health, it is also an issue

of ensuring American competitiveness in the global markets. If we are less prepared than the rest of the World, not only will our Nation’s health suffer more, but so will our economy and our path to recovery from such an event. Companies must plan now for the possibility that 40% or more of their work force may not be able to show up to work during a pandemic, including, according to a recent study, up to 67% of back office health care workers providing technical support, payroll and payment processing, and other administrative functions. Public companies, of course, have an even greater obligation to implement internal controls to address such an event to protect shareholder assets.

In addition, we must examine the supply chain for delivery of critical countermeasures that must be deployed during a pandemic, but also for delivery of goods and services, as a whole, during a state of emergency caused by a pandemic. Most certainly, some, if not all, borders will close, thereby crippling food distribution and delivery of goods and component parts made outside of the United States. For critical countermeasures, the federal government should deal now with policies to ensure protection from counterfeiting and theft of vaccine supplies, implementation of workable, non-burdensome tracking mechanisms, and protection of data and other information needed to allow the supply chain to function.

Because timing is essential, the federal government should rely on resources available through private sector experts for developing and executing mission-critical functions like supply chain management and inventory control, and implement commercially tested systems including those already in place in key parts of the health care infrastructure, that can be quickly and easily operable. Effective supply chain management solutions for the strategic stockpiles must be proven and reliable, and can link thousands of stakeholders including pharmaceutical and medical supply companies, health care providers, distributors, shippers, security and customs organizations, and private and public local, state, federal and international health care agencies. Effective supply chain management may also require significant automation, since significant numbers of personnel throughout the supply chain may be sick or fail to show up for work. Information, to the greatest degree possible, needs to be readily accessible yet secure among multiple jurisdictions, interoperable with multiple existing systems using different levels of technical standards and training of operating personnel.

While the resources needed to prepare us for a possible pandemic are extensive, it is important to note that the challenges faced during this preparation phase open up unprecedented market opportunities for the biotech industry as a whole. Additionally, given the renewed understanding of the constant threat of emerging infectious diseases, the demand for novel medical countermeasures and technologies will lead to much needed research and development throughout both the private and public sectors.

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