## THE INTEGRATION OF HEALTH CARE POLICY IN MEDICAL EDUCATION

## APPROVED BY SUPERVISORY COMMITTEE

James M. Wagner, M.D. - Associate Dean for Student Affairs

Mary Ellen Weber, Ph.D – Vice President for Government Affairs and Policy

Lynne Kirk, M.D. – Internal Medicine Professor

## THE INTEGRATION OF HEALTH CARE POLICY IN MEDICAL EDUCATION

by

# PHUONG-KHANH JESSICA NGUYEN-TRONG

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## ABSTRACT

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## PHUONG-KHANH JESSICA NGUYEN-TRONG

The University of Texas Southwestern Medical Center at Dallas, 2009

Supervising Professor: Dr. James Wagner

Traditional medical school curriculums currently do not include introductory courses on various health care policy topics. The 2005-2006 U.T. Southwestern Congressional Health Care Fellowship activities are examined in this thesis, including Avian Influenza, the Ryan White Care Act reauthorization, and Massachusetts Health Care Reform Plan. It is predicted that the inclusion of several curriculum reforms in medical education will increase the participation from physicians in reforming our nation's healthcare system.

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#### INTRODUCTION TO THE ROLE OF HEALTH CARE POLICY IN MEDICINE

Traditionally, learning the basic science and clinical management of diseases has been the main focus in medical education. Most institutions include brief sessions to discuss a few medicolegal issues in patient care, such as ethics, mandatory state reporting for infectious diseases, and HIPAA (Health Insurance Portability and Accountability Act) laws. However, a medical student does not gain wide exposure to health care policy and its role in medicine. Topics such as coding, billing, healthcare cost, federal regulations of hospitals and physicians, the health care system organizational structure, and external factors that influence medical decision making are rarely discussed in a formal setting. Medical students only briefly become aware of the importance of these health care policy and public health topics during their third year clinical rotations as they try to navigate the healthcare system. According to a recent commentary in JAMA (The Journal of the American Medical Association), "physicians need to do what they can do to influence the larger political and policy debates regarding the social and environmental determinants of health as they interact with the biological and behavioral determinants" as public health professionals when treating chronic diseases as well as emerging epidemics.<sup>1</sup> As reforms in medical education continue in the future, an integrated curriculum which emphasizes both clinical and policy concerns will serve as the new adopted model. This would ensure that physicians are not only trained to make the best clinical decisions, but also to participate fully in shaping the healthcare environment in which they practice.

Physicians often are viewed as leaders within their individual community, but their level of participation declines sharply on the state and national levels based on professional organization membership statistics. Approximately two-thirds of 60,768 licensed physicians in the state of Texas are members of the Texas Medical Association.<sup>2</sup> However, only an estimated twenty percent of 920,000 physicians in the United States are members of the American Medical Association. It is difficult for physicians to contribute to health policy for two main reasons. First, this field has its own specialized jargon, language, and processes. Second, the demands of their profession limit the amount of time available for activities beyond clinical care. However, involvement in professional organizations is crucial as legislators believe that these organizations reflect the general opinion of physicians across the nation when crafting policy.

Physicians have expressed frustration with federal regulations that impede their workflow such as excessive paperwork and diminishing reimbursements for their services. Similarly, the regulation of medicine through health policy poses multiple challenges to legislators. First, healthcare costs have consistently risen and consumed a larger portion of the United State's gross domestic product (GDP) every year. The advent of better diagnostic tools and therapies justify their adoption with less regard for their costs by individual practitioners. Second, unlike traditional business models, human health and behaviors do not always respond or follow predictable patterns. Therefore, computerized analytical models and broad regulations fail to take into account these unique characteristics of medicine. Third, several separate systems govern the delivery of care in the United States. These include Medicare for the elderly, Medicaid for low income populations, SCHIP (State Children's Health Insurance Program) for young kids, private insurance, and uncompensated care for the uninsured. Each system has distinct problems and barriers are present when attempting to organize or increase efficiency among them. Fourth, the majority of legislators lack familiarity with the training, daily professional demands, and understanding of the complex issues surrounding medicine. Therefore, contributions from physicians to devise practical solutions to health policy dilemmas are highly valued.

In the past, physicians have not participated extensively in national politics. A study was recently published in JAMA analyzing the participation of physicians in Congress from 1960 to 2004. The most common occupations of 2196 legislators who served over this time period were 44.6 percent law, 13.6 percent business, 9.9 percent public service, 7.4 percent education, and only 1.1 percent medical. This is equivalent to 25 physicians, 23 of whom served in the House of Representative (including only one woman). There were higher number of physicians who served as congressmen from 1789 to 1889, with a corresponding 4.9 percent (252 out of 5405 congressional members).<sup>3</sup> There are now 16 physicians in the 111<sup>th</sup> Congress as listed in the table below – 2 out of 100 Senators and 14 out of 435 Representatives.<sup>4</sup> By specialty, five are obstetricians and three are family doctors.

Senate					
Name	State	Specialty			
John Barasso, R	Wyoming	orthopedic			
Tom Coburn R	Oklahoma	obstetrics			

House of Representatives					
Name	State	Specialty			
Charles Boustany, R	Louisiana	thoracic surgery			
Paul Broun, R	Georgia	family practice			
Michael Burgess, R	Texas	obstetrics			
Bill Cassidy, R	Louisiana	gastroenterology			
John Fleming, R	Louisiana	family medicine			
Phil Gingrey, R	Georgia	obstetrics			
Parker Griffith, D	Alabama	oncology			
Steve Kagen, D	Wisconsin	allergy-immunology			
Jim McDermott, D	Washington	psychiatry			
Ron Paul, R	Texas	obstetrics			
Tom Price, R	Georgia	orthopedics			
David Roe, R	Tennessee	obstetrics			
Vic Snyder, D	Arkansas	family medicine			
David Weldon, R <sup>1</sup>	Florida	internal medicine			
<sup>1</sup> retiring					

There is a clear need for more physicians to serve as public leaders and to provide input into health policy.

Table 1 – Physicians in t	the 111 <sup>th</sup> Congress	(January 2009-2011)
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#### Background to the U.T. Southwestern Health Care Policy Fellowship

U.T. Southwestern created the Congressional Fellowship program in 2005 for a student to be appointed by the Office of the President to spend six months to a year with the legislative team of Congressman Michael Burgess, M.D., in Washington, D.C. This created an opportunity for students in the health care field to become more familiar with how the United States Congress operates, build a foundation in this field, and contribute to policy during their employment and throughout their future career.

## **Congressman Burgess and Legislative Medicine**

Congressman Burgess represents the 26<sup>th</sup> district of Texas, which includes parts of Denton, Cooke, Tarrant, and Dallas counties. He worked as an obstetrician until 2002 when he was elected to Congress. He currently sits on the House Energy and Commerce Committee, including 4 subcommittees 1) Health 2) Energy 3) Oversight and Investigations and 4) Commerce, Trade and Consumer Protection.

The Energy and Commerce Committee is one of two with jurisdiction over health legislation. The second is the Ways and Means Committee. In general, the Energy and Commerce Committee reviews bills and issues related to public health, quarantine, hospital construction, food and drugs, biomedical research, and Medicaid.<sup>5</sup> On the other hand, the Ways and Means Committee oversees payments for healthcare, health insurance premiums, and health programs under the Social Security Act such as Medicare and maternal health.<sup>6</sup>

Any bill that is introduced in the House of Representatives with regards to these issues is referred to its appropriate committee. Hearings are held and the bill is subsequently reported back with proposed measures or amendments by the committee for consideration on the floor by the full House of Representatives. After debate and passage of the bill as amended, a conference committee will reconcile the different versions of the bills that were passed by the House and Senate until the same conference report is accepted by both houses to be forwarded to the President for approval. If the President signs the bill, it becomes law. This slow process ensures that adequate consideration is given to each bill with input from stakeholders and evaluation by members of Congress who have specialized knowledge on the specific issues.

## Fellowship Responsibilities within the Legislative Team

I participated in this fellowship from September 2005 to July 2006. I worked closely with the Congressman, his chief of staff, legislative director, and communications director on healthcare related issues. Daily duties included staffing congressional hearings, holding meetings with advocacy groups, outlining speeches, writing opening statements, providing website and policy updates, tracking legislation, drafting legislative language for bills and resolutions, and corresponding with federal agencies such as CMS (Centers for Medicare and Medicaid Services). Appendices A and B provide examples of remarks that a Congressman gives on the floor to bring attention to an issue he values and an opening statement provided at the beginning of a committee hearing. In addition, I specialized in three areas: avian influenza, the Ryan White Care Act, and the Massachusetts health reform plan.

#### POLICY AREAS OF SPECIALIZATION

In 2005, several health policy issues gained traction in Congress. First, the threat of a pandemic increased with recurrent outbreaks of fatal influenza cases in Asia. Information on this public health threat needed to be disseminated to legislators, public health officials, hospitals, health care workers, and the general public to prepare our country. Second, the Ryan White Care Act which delivers funding to communities for HIV/AIDS services needed to be reauthorized. An evaluation of the current process for grant disbursements to states and a review of the program's outcomes were necessary to modify existing law and increase this program's efficiency. Third, the state of Massachusetts had recently passed a new law creating a system designed to provide health insurance and care to all of its citizens. The feasibility of this plan generated much interest on whether this model could be applied on the national level. These three areas will be explored in further detail to highlight the relevant policy aspects.

## Avian Influenza as a Public Health Risk

The government has a duty to protect the health of its citizens and the authority to declare a state of public health emergency and quarantine individuals if necessary. A pandemic would be devastating in terms of human lives. It also has the potential to slow down the economy in terms of employee availability, trade, as well as lead to a shortage of medical supplies and personnel. There have been three pandemics in the last century. In 1918, the H1N1 Spanish flu virus killed 50 million individuals worldwide. Then, in 1957, the H2N2 Asian flu resulted in 1-2 million deaths globally. The most recent pandemic was the H3N2 Hong Kong flu with 700,000 deaths total.<sup>7</sup>

Outbreaks of avian influenza in poultry and humans have been reported since 2004, but their frequency has increased in recent years. From January to April 2006, more than 35 countries reported outbreaks which resulted in 300 million birds being culled prophylactically to prevent further spread of the disease.<sup>9</sup>

January 30	Iraq	February 18	India	March 2	Serbia-
February 8	Nigeria	February 19	France		Montenegro
February 9	Azerbaijan	February 21	Hungary	March 5	Poland
February 11	Bulgaria,		and Malaysia	March 7	Albania
-	Greece, and Italy	February 25	Slovakia	March 13	Cameroon
February 12	Slovenia		and Bosnia	March 14	Myanmar
February 13	Russia	February 27	Georgia and	March 16	Denmark
February 14	Iran, Austria,		Niger	March 17	Afghanistan
-	and Germany	February 28	Sweden	March 20	Israel
February 17	Egypt	March 1	Switzerland	March 21	Pakistan
•				March 24	Jordan

	Figure 1 –	Countries with	Cases of Avian	Influenza in early	/ 2006 (	(Januar	v-March
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According to the World Health Organization, there have been 393 confirmed cases of avian influenza in humans to date, 248 of which were fatal.<sup>10</sup> The two countries most affected have been Indonesia and Vietnam. An analysis of the epidemiologic data gathered by the World Health Organization (WHO) is presented in appendix C by geographical regions for Indonesia. It demonstrates that most disease clusters have been contained and the infected individuals lived in close contact with infected poultry. Fortunately, effective human to human transmission has not yet been achieved. However, the high fatality of avian influenza is reflected in the very short amount of time between the dates of reported symptoms, hospitalization, and death as listed.

It has been extrapolated that an H5N1 avian influenza pandemic could result in 1,903,000 deaths in the United States alone if it was as severe as the 1918 one.<sup>8</sup> Even

more devastating is that not only vulnerable populations like the elderly succumb to this disease, but that healthy adults are also at risk. A threat of this magnitude would challenge public officials in every way. Therefore, education, preparation, and improving the emergency response infrastructure have been targeted as areas that required further progress.

Education on the science behind avian influenza, vaccine preparations, likelihood of a pandemic, and preparedness strategies was devised and disseminated as a twentythree "Dear Colleague" letter series to other Members of Congress. Appendix D contains a list of the topics covered as well as three sample letters. In addition, five minute and one hour special order floor speeches were also given by the Congressman to emphasize areas that congressional committees could explore on this issue. Furthermore, an opinion-editorial titled "Zero In- A Story on Avian Flu" was published in his local district to bring awareness to his constituents (see Appendix E).

Preparation for a pandemic was supported when Congress approved \$6.1 billion in supplemental emergency appropriations for 2006. The first installment of which included \$2.654 billion for vaccine development and stockpiling, \$20 million for the Food and Drug Administration, \$96 million for international activities, \$150 million for surveillance, \$350 million to the Centers for Disease Control and Prevention (CDC) to build state and local public health capacity, and \$50 million to the CDC itself.<sup>11</sup> This demonstrates the importance of providing resources for early detection, prevention, and treatment. In addition, the Department of Health and Human Services published its 396page Pandemic Influenza Plan in November 2005 to provide further guidance on surveillance methods, diagnostic guidelines, state and local preparedness strategies,

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antiretroviral dosing, access to federal resources, and communication structure for rapid dissemination of information (see "Dear Colleague" letter 11 in Appendix D for highlights of this plan).<sup>12</sup> President George W. Bush also established the International Partnership on Avian and Pandemic Influenza to enhance global surveillance and devise ways to mitigate the potential impact of a pandemic.<sup>13</sup> In addition, economic assistance and personal protective equipment was provided to countries already having outbreaks by the U.S. Agency for International Development (USAID) to minimize further spread of the disease. Next, personal preparedness was encouraged with reminders for individuals to observe hand hygiene during sickness, online guidelines for people traveling to infected countries, and advice for families with elderly or children provided by the U.S. Department of Homeland Security.<sup>14</sup>

Emergency response during disasters can be chaotic or inadequate for the magnitude of a disaster. Testing a plan to uncover areas of weakness and ensure that each affiliate is familiar with his role is important. For example, to enhance global networks and response capabilities, 25 nations in the European Union underwent a two-day exercise in late November 2005. In the United States, the Department of Health and Human Services met with all fifty states and local officials to discuss avian influenza in December 2005. A challenge to address was the fact that volunteers and health care professionals may not show up during a pandemic due to the threat to their families and own personal health. Registering and training individuals in a volunteer-based medical reserve corps who could augment the existing healthcare workforce in advance could help alleviate this problem. Furthermore, building a network of contacts with local organizations, business partners, health providers, and public health officials would

ensure better communication and recruitment for assistance. For instance, personnel with the World Health Organization, United Nations, U.S. Department of Agriculture, Centers for Disease Control and Prevention, Health and Human Services Emergency Operations, Texas Department of State Health Services, North Texas Health Services and Texas Animal Health Commission were identified and contacted as key players to name a few. Improvements in the integration across international, national, state, and local activities are continuously ongoing to better respond to infectious diseases as they do not respect geographical boundaries. The fear that avian influenza would soon become a pandemic has diminished over the last few years as reported cases of human infections have decreased. However, this public health risk has initiated an in-depth assessment of our nation's disaster response system and brought valuable changes in our level of readiness to face such a threat.

My participation in this public health issue served to increase communication with other congressional offices and local constituents through regular updates. In addition, I conducted research on the latest available news releases and performed analyses in order to provide additional data to better prepare for such a disaster through policy reforms.

#### **Ryan White Care Act Reauthorization Process**

The Ryan White Care Act (RWCA) was first authorized in 1990 and provides federal funds for HIV/AIDS services to states, eligible metropolitan areas (EMAs) and healthcare providers. In 2008, the RWCA provided nineteen percent of the federal funding for HIV/AIDS care and is the third largest source after Medicare and Medicaid.<sup>15</sup> In general, this law is reauthorized every five years and during that process it is modified to better meet current demands. The RWCA expired on September 30, 2005, and was operating at current funding levels. On December 19, 2006, the president signed the reauthorization bill for three years.<sup>16</sup>

In 2005, the House Energy and Commerce Committee and Senate Health, Education, Labor, and Pensions Committee (HELP) joined efforts and formed a bicameral, bipartisan process to systematically review the current law, meet with stakeholders, and craft changes to existing provisions. The goal was to introduce one version of the reauthorization bill in both houses and avoid the need for a conference report. In addition, President George W. Bush outlined principles for the reauthorization which were to 1) serve the neediest first by developing a "severity of need" for core services index (SNCSI), 2) focus on life extending services with a list of core medical services and medications, 3) increase prevention efforts with additional HIV testing, 4) increase accountability of grantees with better reporting systems, and 5) increase flexibility in fund distribution.<sup>17</sup> With these principles in mind, the two committees identified several issues that needed further investigation. A few examples include whether the RWCA was fulfilling its role as payer of last resort through its interactions with other funding sources; how the system could be designed to better respond to the evolving AIDS epidemic; how to define core medical services; how to make the AIDS Drug Assistance Plan (ADAP) more portable across state lines; and how the elimination of hold harmless and double counting provisions would affect states. In the past, cities were "held harmless" from a sudden decrease in funding because the formula took into account the number of AIDS cases over the last 10 years. Therefore, cities with a new

epidemic would be eligible for a disproportionately lower level of funding. Next, double counting occurred under the existing formulas when cases were both counted in the eligible metropolitan areas (EMAs) and state when determining funding levels. To assess these policy questions, the committees met with over 30 stakeholder groups and held hearings with the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA) responsible for oversight of the program, and U.S. General Accountability Office (GAO) for analyses on the new funding amounts to states based on proposed amendments. As a result, modifications to the RWCA became incorporated and passed in the reauthorization as outlined below.

The RWCA is structured in multiple Titles and Parts, which were maintained during the reauthorization. Title I provides funding to eligible metropolitan areas (EMAs), previously defined as a population of 500,000 with 2,000 reported AIDS cases in the last five years. Now Title I has been divided into two subparts 1) EMAs redefined as a population of 50,000 and 2,000 AIDS cases in the last five years and 2) Transitional Grant Areas (TGAs) with 1,000-1,999 AIDS cases in the last five years.<sup>15</sup> In addition, funds used to be evenly distributed between grants determined by a formula and supplemental competitive grant awards. This was changed to 2/3 by formula and 1/3 by supplemental grants in 2007. Furthermore, financial support to EMAs protected by "hold harmless" provisions were to be obtained through these supplemental grants at 95 percent of the 2006 award levels for the next three years only. Finally, to reduce duplications in formula calculations, reported cases to the CDC are transitioning to patient name-based, rather than code-based submissions by states.

Title II outlines grants to states through a base amount, AIDS Drug Assistance Program (ADAP) and supplemental, and Emerging Community (EC) grants. The base amount was calculated by an 80/20 formula that added 80 percent of the state's share of estimated living AIDS cases (ELCs) in EMAs and 20 percent of the state's share of ELCs outside of EMAs. To reduce double counting, the new 75/20/5 formula now factors in 75 percent of the state's share of the nation HIV/AIDS cases, 20 percent of the state's share of HIV/AIDS cases outside of EMAs/TGAs, and 5 percent of the state's share of HIV/AIDS cases from states without EMAs/TGAs.<sup>16</sup> Next, the AIDS Drug Assistance Program provides federal funding with a state match to purchase HIV-related prescription drugs for low income people. The reauthorization eliminated the eligibility criteria that individuals had to be below 200 percent of the Federal Poverty Level (FPL) and mandated the creation of a minimum drug list on the formulary. Finally, the Emerging Community grants are now targeted to areas with 500-999 AIDS cases during the last five years as areas with higher case numbers are now included in Title I Transitional Grant Areas.

Title III mandates that 75 percent of the funds be directed to core medical services such as outpatient care, medications, dental care, early intervention services (testing), nutrition therapy, substance abuse outpatient care, etc...<sup>16</sup> Therefore, a smaller portion is available for support services such as transportation and outreach. Only minor alterations were made to the following sections. Part D focuses on family-centered care for women and children with HIV/AIDS. Then Part F supports AIDS Education and Training Centers for healthcare professionals, the Minority AIDS Initiative, and demonstration projects to test new technologies or policies. Overall, \$2.2 billion was

disbursed through the Ryan White Care Act in 2008 and the AIDS Drug Assistance Program currently has 146,000 enrollees.<sup>18</sup> This Act has played a key role in providing HIV/AIDS health services to underserved people. The reauthorization process for this important Act also illustrates how Congress amended the legislation to better incorporate the goals of the program and integrate geographical variability. Reports from grantees will be submitted in the future to the U.S. Department of Health and Human Services to demonstrate how the funding was utilized and assist in further review of this Act.

Throughout the reauthorization process, I was involved in the bicameral and bipartisan staff committee meetings that were held to implement the principles outlined by the President. I also assisted in reviewing the subsequent documents that delineated the potential impact of various proposals on this program's ability to fulfill its goal of providing health services for HIV/AIDS patients.

#### Innovation in the Massachusetts Health Care Reform Plan

There are approximately 45.7 million uninsured Americans. From state to state, the rate of uninsured varies, but nationally it is around 15.3 percent.<sup>19</sup> As the cost of health care continues to rise, state taxpayers pay an increasing share of uncompensated care. Therefore states are seeking out innovative ways to cover the uninsured, cap their charity care costs, and create incentives for individuals to take responsibility for their own health care needs. On April 12, 2006, Governor Mitt Romney signed landmark legislation to make available health coverage to every resident of the State of Massachusetts.<sup>20</sup> Proponents have praised this as a creative way to utilize existing state and federal resources to reduce levels of uninsured while opponents believe this new

program is an expansion of government and a move toward single payer, government-run health care.

Before considering which reforms to make, surveys were commissioned to better assess the composition of the uninsured population within the state. In comparison to the rest of the nation, Massachusetts has a relatively low uninsured rate of 8.3 percent. In contrast, 24.4 percent of Texans are uninsured.<sup>19</sup> With these data, input from providers, businesses, and insurance companies was also gathered to determine how to increase access and continuity of health insurance coverage for low income individuals, young adults, and non-traditional workers. In order to have affordable health insurance, legislators subsequently chose to implement market reforms, provide premium subsidies, and endorse responsibility in health care for employers and citizens. In order to design this unique model, Massachusetts then applied for a Centers for Medicare and Medicaid Services (CMS) waiver under section 1115 of the Social Security Act. This resulted in \$385 million of existing federal funds, which were now available to be redirected by the state towards premium assistance.<sup>21</sup> Another financing component of this plan was the transfer of hospitals' uncompensated care funds into subsidizing insurance premiums. Combined with the changes that are discussed in more detail below, the cost of health insurance per person was expected to decrease from \$350 to \$200-\$250 monthly.

With this plan, 460,000 uninsured in Massachusetts would gain coverage through different mechanisms based on their income. Enrollment into Medicaid would apply to 106,000 individuals who were already under 100 percent of the Federal Poverty Level (FPL). The legislation supported the development of reimbursement reforms by standardizing the fee schedule and including an allocation of \$90 million per year for the

next three years to increase payments to Medicaid providers. Next, premium assistance would be offered to the 150,000 people between 100-300 percent of the FPL through a sliding scale subsidy system. In other words, individuals would receive subsidies and pay different premiums according to their FPL. Finally, those above 300 percent of the FPL would be offered affordable health insurance for purchase.<sup>22</sup> To increase consumer choice, the Connector was created as an independent quasi-governmental entity and insurance exchange for people and businesses with 50 or fewer employees. It operates as an authority under the Massachusetts Department of Administration and Finance, but has a separate governing board. Individuals could choose health insurance from several competing plans through this system. In essence, the Connector would interface with insurance plans and deliver payments that it received from various sources – the state, individuals, or businesses. This also meant that several employers would now be able to contribute to one employee's premiums. Therefore, since access to a health plan was no longer limited to a person's place of employment, the portability of health insurance was also increased. An existing provision in the federal tax code, section 125 cafeteria plan, would also be utilized to allow employers to offer health insurance with pretax dollars.<sup>23</sup> Still, businesses could choose how much they wanted to contribute to employees' healthcare as no minimum allocation was required under this code. However, there is a possibility that this form of managed competition may not be able to decrease premiums to the levels that other plans with more free market competition would.

Several reforms were also undertaken to deregulate the health insurance market. First, fragmented insurance markets would be pooled with individual and small-group markets in July 2007. Second, HMOs would be allowed to offer high deductible plans linked to Health Savings Accounts. Third, new insurance products with less mandated benefits would be created and targeted to 19-26 year olds. Fourth, young adults would be able to remain on their parents' insurance plan for 2 years after they lose their dependent status or until they turn 25.<sup>22</sup> Combined with the option of coinsurance and directed care networks, these reforms facilitated the creation of affordable insurance products with a focus on preventive and catastrophic care.

Finally, an individual mandate and employer responsibility were established. The function of the individual mandate is to encourage individuals who can afford health insurance to buy coverage. Massachusetts citizens had to obtain health insurance by July 1, 2007, and show proof on their state income tax forms. If no coverage was indicated, the penalty for tax year 2007 was the loss of one's personal tax exemption. The noncompliance penalty for subsequent tax years would have been 50 percent of the price for an affordable insurance product in the Connector.<sup>22</sup> In general, it still remains to be determined whether these rules will give enough of an incentive for people to buy health insurance. Some young and healthy individuals might decide to accept the penalties if they still do not perceive health care insurance as a necessity. In addition, every citizen does not currently submit an income tax return form. Enforcing these penalties with individuals who do not have a permanent place of residence or illegal immigrants could prove to be challenging. Next, the new legislation included provisions to engage employers to fulfill their "fair share." A \$295 annual, per-worker fee on businesses with more than 10 workers was applied if they did not offer and contribute enough to employee insurance. It was estimated that \$50 million would be generated by this mechanism. In addition, a free rider surcharge was applicable to businesses with 11 or

more employees if they did not provide health benefits and utilized more than \$50,000 in uncompensated care in one year. This surcharge would be waived if the company offered a section 125 plan.<sup>23</sup>

Several new entities, such as a Health Care Quality and Cost Council, Health Safety Net Office, and Health Disparities Council, were also created. The data gathered for the Health Care Quality and Cost Council would be posted on its website.<sup>24</sup> Since individuals could select from health plans with various deductible levels on the Connector, this online information would be a useful tool for patients to decide where to receive their health care services. However, these councils denote an expansion of government and there are concerns over the resources that they would require.

Overall, the Massachusetts health care reform plan decreases barriers of entry into the health insurance market for individuals. In addition, flexibility for employers and insurance providers is enhanced. Whereas the state previously focused on payments to providers as the preferred financing method, the new law refocused these payments at the point of purchase by ensuring some form of insurance for every person. The new program was mainly funded by redistributing existing funds such as federal Medicaid funds, the uncompensated care pool, and state revenues allocated to health into premium subsidies. New revenue streams would include employer assessments and individual contributions toward the purchase of health insurance. On the other hand, it has yet to be determined whether these reforms will produce the desired results, especially substantial decreases in the price of monthly insurance premiums. A burden will be placed on the state to determine whether employers and citizens are complying with the health reform mandates. In addition, Massachusetts has a small uninsured population. Therefore, it would be significantly more difficult and costly for states with higher rates of uninsured to subsidize premiums. Each state's business infrastructure and uncompensated care pool size also largely influences whether these measures could successfully be replicated across the nation.

By evaluating this new law, I gained a deeper understanding of the relation between the insurance market, budgetary constraints, and the current system for healthcare delivery. Examining the various components of this plan subsequently led to novel approaches to address health coverage for the uninsured. Comprehensive healthcare reform bills are now being debated in the current Congressional session.

#### **RECOMMENDATIONS FOR CURRICULUM CHANGES**

The medical school curriculum at U.T. Southwestern currently offers few lectures on health policy and public health. At the beginning of first year, one and a half hours are allocated to professionalism and wellness. Then ethic topics, such as scholastic integrity, genetic testing, and disclosure, are introduced in small group sessions. During the second year, clinical ethics with conflict of interest, advance directives, informed consent, medical errors, and confidentiality are covered in four and a half hours. Finally, the completion of two healthcare finance modules is mandatory during the fourth year. One is interactive online to highlight the problem of the uninsured and difficulties in access to care. The second module focuses on the general structure of our country's healthcare system and each student finds a health policy article for discussion following one lecture. Additionally, students may choose to participate in optional electives. These are offered as ten-hour courses on subjects such as Global Health, Economics and Finance, Medical Finance, Medical Law, and Public Health. Only a small portion of students enroll in these courses every semester as the enrollment is often capped to foster student participation.

I will suggest several modifications to increase medical students' exposure to healthcare policy and its impact on medicine. First, membership in the Dallas County Medical Society and Texas Medical Association should be encouraged when students matriculate into medical school. It is free and brings the student into a community of physician leaders. In addition, joining a national professional organization should be customary. A student membership in the American Medical Association (AMA) costs \$68 for four years. Several state societies - Connecticut, South Carolina, New Mexico, and the Dakotas - sponsor all their medical students to the AMA.<sup>25</sup> Second, participation in the Texas Medical Association Lobby Day in Austin or one state medical conference should be strongly promoted. These conferences take place three times a year and are held in Houston, Austin, Dallas, or San Antonio. Registration is free for student members and funding is available through the Southwestern chapter for a limited number of people to attend these events. These conferences would expose students to the state's legislative agenda and health policy issues through seminars on leadership, managed care, patient-physician communications, updates in specialty specific approach to clinical care, etc... For example, the administration at Texas A&M Health Science Center arranged bus transportation and brought hundreds of their medical students to the medical student Lobby Day in 2005. Third, U.T. Southwestern could offer a monthly calendar of grand rounds on health policy issues. First and second year students could be required to attend three sessions per year. Fourth, two health policy sessions per semester could be incorporated into each year's curriculum to discuss current trends with the latest Health Affairs policy journal articles or Institute of Medicine report findings. Fifth, another option would be to require the incorporation of bimonthly one-hour lectures on policy topics pertinent to the corresponding clinical rotation during the third and fourth year. For example, the internal medicine rotation could educate students on the Medicare reimbursement system for primary care services or epidemiologic research principles to decrease infectious disease outbreaks in the hospital setting. For instance, Texas A&M Health Science Center offered a new ten-hour elective, titled "The Economics of Health Care," at lunch in 2005. It was attended by 120 students and addressed "economics of health insurance, physician services, hospitals, pharmaceuticals and government

intervention (including details on Medicare/Medicaid), as well as comparative health care systems.<sup>26</sup> Sixth, summer internship opportunities with the Texas Department of State Health Services, Dallas County Department of Health and Human Services, or health media with the Dallas Morning Newspaper could be fostered by U.T. Southwestern in adjunct to the Congressional Fellowship.

A commitment from U.T. Southwestern to incorporate health policy in medical education by implementing one or several of recommendations listed above would lead to the training of excellent physicians as well as public leaders. Dr. Daniel Podolsky, President of U.T. Southwestern, has recently identified the development of programs in health policy as one of seven strategic priorities as well. In the long term, familiarizing students with the basics in health economics and policy would prepare them to better function as physicians and advocate for their patients within the healthcare system. Furthermore, if policy becomes integrated across the nation in the medical curriculum, an unprecedented era could begin when medical professionals would finally become major contributors in reforming our nation's healthcare system. APPENDIX A

Extension of Remarks<sup>\*</sup> on National Osteoporosis Awareness Month





United States of America

proceedings and debates of the  $109^{th}$  congress, second session

# House of Representatives

# The Honorable Michael C. Burgess (TX-26)

Tuesday, May 23, 2006 Extension of Remarks

#### 2006 National Osteoporosis Awareness and Prevention Month

Mr. Speaker, I rise today to recognize that the 2006 National Osteoporosis Awareness and Prevention Month will be observed this May.

There are currently 44 million Americans, age 50 or older, who have osteoporosis. In addition, an estimated 1.5 million fractures are attributed to this disease every year. Although this disease has commonly been associated with women, it is prevalent in men as well. Nearly two million men currently live with osteoporosis, millions of others are at risk, and one in eight men older than 50 years will have an osteoporotic fracture.

Furthermore, the risk for osteoporosis does increase with age. However, it is important to adopt a good diet with calcium and vitamin D during childhood and adolescence to prevent a person from being diagnosed with low bone mass later on.

As we observe the National Osteoporosis Awareness Month, I would like to urge providers and individuals to discuss osteoporosis and carry out bone mineral density diagnostic tests when necessary.

In addition, I would like to commend the National Osteoporosis Foundation for bringing awareness to this debilitating disease, providing educational material on this issue, and supporting a search for a cure since 1984. They have entitled this year's campaign "Osteoporosis...it matters" and will be hosting events throughout the nation.

Mr. Speaker, it is with great honor that I stand here today to promote the National Osteoporosis Awareness Month and honor the National Osteoporosis Foundation staff for all of their hard work.

\* A Member of Congress can ask for permission to include Extension of Remarks in the Congressional Record, which is published daily and is the official record of the proceedings in the United States Congress.

## APPENDIX B Pulmonary Hypertension Hearing Opening Statement<sup>\*\*</sup>

Opening Statement Congressman Michael C. Burgess, M.D. Hearing on Pulmonary Hypertension and Chronic Pain December 8, 2005

I would like to thank Chairman Deal for holding this hearing on two often overlooked medical conditions – pulmonary hypertension and chronic pain.

The number of diagnosed pulmonary hypertension cases has steadily been increasing over the years and it is estimated that more than one hundred thousand Americans are affected. However, the understanding of this disease is still primitive and diagnosis is often made at a late stage. Pulmonary hypertension is also found comorbid with other diseases such as sickle cell anemia or chronic liver disease. Only a few drugs are currently available to treat this condition and the treatment protocols are burdensome. Therefore, research targeted to enhance our knowledge of this silent killer will help in ensuring early diagnosis and designing better treatments for pulmonary hypertension.

Chronic pain is another condition that unfortunately is not adequately dealt with. The quality of life of patients with chronic pain is strongly diminished as the suffering of these individuals is frequently overlooked. Misconceptions and lack of awareness about the breadth of treatments that can be offered to them need to be dispelled. The fear of pain medicine, especially the unfounded belief that these drugs are addicting, prevents patients from asking for help. Furthermore, the issue of chronic pain is complex. Research in neuroscience as well as how to relieve chronic pain has to be enhanced.

I look forward to today's testimony and would like to thank the witnesses for taking the time to be here. This hearing can give Congress some insight as we move to reauthorize the National Institutes of Health (NIH). An emphasis on cross-disciplinary research should be placed to address solutions to these two complex conditions. I hope that in the future a routine check-up for pulmonary hypertension will be available and incorporated into the practice of medicine and that individuals no longer have to experience chronic pain on a daily basis.

<sup>&</sup>lt;sup>\*\*</sup>Members of Congress give opening statements at the beginning of a Congressional Committee hearing to state their opinion and direct the witnesses to topics they would like to gather information on. An opening statement can be waived in exchange for additional time to question the witnesses.

## **APPENDIX C** Analysis of the WHO Epidemiologic Data on the Avian Flu Cases in Indonesia

The World Health Organization publishes online situation reports that describe the surrounding circumstances of new avian flu cases and whether confirmatory testing has been received. This data was analyzed and aggregated in table format by geographical region.

#### INDONESIA (cumulative total 51 cases, of which 39 fatalities) - update as of 6/21/06 - investigated WHO cases with more details

Patient	Age	Status H5N1 conf. unless	Suspected Source of Infection	Symptoms	Hosp.	Death	Case #
		otherwise stated					

NORTH SUMATRA - Kubu Simbelang Village, Karo District Family Cluster, (7cases, 6 fatalities)

Index woman	37	deceased - no specimen	3 of her backyard chickens died, she kept them indoors at	24-Apr	2-May	4-May	1
		prior to burial for H5N1	night				
		confirmation testing					
her son	15	deceased	spent night with sick index patient April 29	~5-May		9-May	3
her second son	17	deceased	spent night with sick index patient April 29	~5-May		12-May	3
her visiting brother	25	surviving	spent night with sick index patient April 29	~5-May			3
her sister	28	deceased	took personal care of sick index pt (neighboring house)			10-May	3
her sister's baby	18 month	deceased	took personal care of sick index pt (neighboring house)			14-May	3
son of second brother	10	deceased	often visited index patient and was there April 29			13-May	4
second brother	32	deceased	took care of sick son in hospital May 9-13	15-May		22-May	4

NOTE: 54 surviving family members still under home quarantine, surveillance in 400 households, close monitoring to undergo until ~ June 13 No evidence of genetic reassortment with human or pig influenza viruses nor significant mutations. No mutations for increased resistance to Tamiflu WHO pandemic alert phase remains at 3 (i.e. very limited human to human transmission) and will not be raised to phase 4 (increased human to human transmission) because hosptial workers and community are not getting infected.

WEST SUMATRA (	1 case, 0 fatalit	v)					
girl	15	hospitalized	under investigation	17-May			46
WEST JAKARTA (	1 case, 1 fatality	0					_
man	39	deceased	cleaned pigeon feces from blocked roof gutters	9-May	16-May	19-May	45
girl	20 month	deceased	dead chickens near her home one week prior to on set -	17-Mar	22-Mar	23-Mar	
			unconfirmed cause of death				30
man	35	deceased	under investigation	6-Nov-05	9-Nov-05	19-Nov-05	14
SOUTH JAKARTA	(1 case, 0 fatali	ty)					
man	43	recovered	under investigation	6-May			44
boy	13	deceased	helped grandfather slaughter family diseased chickens, grandfather remains healthy	9-Jun	13-Jun	14-Jun	51
GREATER JAKAR	ГА						
man	30	deceased	under investigation - lived near animal/poultry pens	17-Apr	21-Apr	26-Apr	33
man	24	deceased	under investigation	29-Mar	5-Apr	8-Apr	32
EAST JAKARTA				-			
boy	12	deceased	under investigation		7-May	13-May	41
man	23	deceased	egg seller at wet market	5-Feb	7-Feb	10-Feb	26
man	39	deceased	under investigation	9-Dec-05	11-Dec-05	12-Dec-05	16
Patient	Age	Status H5N1 conf. unless	Suspected Source of Infection	Symptoms 5 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Hosp.	Death	Case
		otherwise stated					
JAKARTA - report i	not location spe	ecific					
woman	29	deceased	dead neighborhood chickens 2 wks prior to onset, bought	31-Dec-05	1-Jan	11-Jan	
			market slaughtered chickens, midwife in hospital - unlikely to				17
			be from occupational exposure				
woman	20	deceased	under investigation	5-Nov-05	9-Nov-05	12-Nov-05	11
girl	16	deceased	under investigation	4-Nov-05	6-Nov-05	8-Nov-05	10
woman	27	deceased	dead family chickens prior to onset	17-Sep-05	19-Sep-05	26-Sep-05	4
woman	37	deceased	under investigation	31-Aug-05	6-Sep-05	10-Sep-05	2

CENTRAL JAKARTA							
boy	8	deceased	under investigation	8-Dec-05	13-Dec-05 15-D	)ec-05	15

## Analysis of the WHO Epidemiologic Data on the Avian Flu Cases in Indonesia (continued)

	- sinaleu exposure to inite				
10	deceased	contact with sick/dying chickens at home in week prior to	16-May	22-May	23-May
		onset			
18	deceased	contact with sick/dying chickens at home in week prior to	16-May	22-May	23-May
		onset			
15	deceased	dead family chickens 1 wk prior to onset	24-May	26-May	30-May
23	recovered	poultry worker - dead chickens 2 wks prior to his farm visit	20-Mar		
27	deceased	dead neighborhood chickens 4 days prior to onset	13-Feb		20-Feb
27	deceased	dead neighborhood chickens 4 days prior to onset	31-Jan		10-Feb
22	deceased	neighborhood and market chickens being tested	25-Jan		10-Feb
15	deceased	dead neighborhood chickens in week prior to onset			1-Feb
22	deceased	dead neighborhood chickens prior to onset			26-Jan
9	recovered	dead village chickens prior to onset		19-Jan	
16	stable	dead family chickens 2 wks prior to onset being tested, 2	6-Nov-05	16-Nov-05	
		brothers, 7 and 20, died of suspected typhoid Nov. 3 and 11 -			
		no specimen prior to burial for testing			
23	deceased	exposure to infected poultry		28-Sep-05	30-Sep-05
fatality)					
18	recovering	dead chickens in home in week prior to onset	6-May	17-May	
38	deceased		2-May	7-May	12-May
	10 18 15 23 27 27 27 27 27 15 22 9 16 fatality) 18 38	2 ratatics)  state exposure to me    10  deceased    18  deceased    23  recovered    27  deceased    27  deceased    27  deceased    27  deceased    27  deceased    22  deceased    15  deceased    22  deceased    9  recovered    16  stable    23  deceased    16  stable    18  recovering    38  deceased	10    deceased    contact with sick/dying chickens at home in week prior to onset      18    deceased    contact with sick/dying chickens at home in week prior to onset      15    deceased    contact with sick/dying chickens at home in week prior to onset      23    recovered    poultry worker - dead chickens 2 wks prior to his farm visit      27    deceased    dead neighborhood chickens 4 days prior to onset      22    deceased    dead neighborhood chickens at home in week prior to onset      22    deceased    dead neighborhood chickens in week prior to onset      22    deceased    dead neighborhood chickens prior to onset      22    deceased    dead neighborhood chickens prior to onset      28    deceased    dead neighborhood chickens prior to onset      29    recovered    dead neighborhood chickens prior to onset      16    stable    dead family chickens 2 wks prior to onset being tested, 2 brothers, 7 and 20, died of suspected typhoid Nov. 3 and 11 - no specimen prior to burial for testing      23    deceased    exposure to infected poultry      fatality)    18    recovering    dead chickens in home in week prior to onset      38    deceased    dead chickens in home in week prior to onset    deceased </td <td>2 relaties)    Strated exposure to infection for furthal to an sinission      10    deceased    contact with sick/dying chickens at home in week prior to onset    16-May      18    deceased    contact with sick/dying chickens at home in week prior to onset    16-May      15    deceased    dead family chickens 1 wk prior to onset    24-May      23    recovered    poultry worker - dead chickens 2 wks prior to his farm visit    20-Mar      27    deceased    dead neighborhood chickens 4 days prior to onset    13-Feb      27    deceased    dead neighborhood chickens 4 days prior to onset    31-Jan      22    deceased    dead neighborhood chickens in week prior to onset    25-Jan      15    deceased    dead neighborhood chickens prior to onset    25-Jan      16    stable    dead neighborhood chickens prior to onset    16-Nov-05      9    recovered    dead neighborhood chickens prior to onset    6-Nov-05      16    stable    dead family chickens 2 wks prior to onset    2      23    deceased    exposure to infected poultry    6-Nov-05      16    stable    dead family chickens 2 wks prior to onset    6-Nov-05      23<td>10    deceased    contact with sick/dying chickens at home in week prior to onset    16-May    22-May      18    deceased    contact with sick/dying chickens at home in week prior to onset    16-May    22-May      15    deceased    dead family chickens 1 wk prior to onset    24-May    26-May      23    recovered    poultry worker - 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dead chickens 2 wks prior to his farm visit    20-Mar      27    deceased    dead neighborhood chickens 4 days prior to onset    13-Feb      27    deceased    dead neighborhood chickens 4 days prior to onset    31-Jan      22    deceased    dead neighborhood chickens in week prior to onset    31-Jan      22    deceased    dead neighborhood chickens in week prior to onset    25-Jan      15    deceased    dead neighborhood chickens prior to onset    16-Nov-05      15    deceased    dead neighborhood chickens prior to onset    19-Jan      16    stable    dead family chickens 2 wks prior to onset    10-Nov-05      16    stable    dead family chickens 2 wks prior to onset    19-Jan      16    stable    dead family chickens 2 wks prior to onset    28-Sep-05      fatality)    23</td>	10    deceased    contact with sick/dying chickens at home in week prior to onset    16-May    22-May      18    deceased    contact with sick/dying chickens at home in week prior to onset    16-May    22-May      15    deceased    dead family chickens 1 wk prior to onset    24-May    26-May      23    recovered    poultry worker - dead chickens 2 wks prior to his farm visit    20-Mar      27    deceased    dead neighborhood chickens 4 days prior to onset    13-Feb      27    deceased    dead neighborhood chickens 4 days prior to onset    31-Jan      22    deceased    dead neighborhood chickens in week prior to onset    31-Jan      22    deceased    dead neighborhood chickens in week prior to onset    25-Jan      15    deceased    dead neighborhood chickens prior to onset    16-Nov-05      15    deceased    dead neighborhood chickens prior to onset    19-Jan      16    stable    dead family chickens 2 wks prior to onset    10-Nov-05      16    stable    dead family chickens 2 wks prior to onset    19-Jan      16    stable    dead family chickens 2 wks prior to onset    28-Sep-05      fatality)    23

#### WEST JAVA (2 cases, 2 fatalities) - shared exposure to infection not human to human transmission

CENTRAL JAVA							
girl	12	deceased	household chickens died days prior to onset -H5 confirmed	19-Feb	23-Feb	1-Mar	29
her brother	10	deceased -no H5N1 testing	sympt. assoc. w/dengue hemorrhagic fever or flu	19-Feb		28-Feb	
boy	4	deceased	dead neighborhood chickens prior to onset	10-Feb		28-Feb	28

Patient	Age	Status H5N1 conf. unless
		otherwise stated

Suspected Source of Infection

Symptoms Hosp.

<u>Death</u> Case #

#### LAMPUNG PROVINCE

		recovered -retrospective				20
boy	5	conf. by Ab levels	infected slaughtered chickens	Oct		20
		recovered -inconclusive				ĺ
his brother	20	initial diag. test	infected slaughtered chickens	Sept		
boy	4	recovered	nephew of case below, same neighborhood, human to human	4-Oct-05		-
			transmission unlikely			
man	21	hospitalized/stable	dead family chickens prior to onset	20-Sep-05	24-Sep-05	5

#### JABOTABEK REGION - Tangerang

UNDU INDERNEOION	rungerun	9					
woman	25	deceased	sick poultry in neighborhood being tested	17-Nov-05	23-Nov-05	25-Nov-05	13
woman	19	deceased	visited brother - see below	19-Oct-05	26-Oct-05	28-Oct-05	8
her brother	8	hospitalized/stable	sick and dying neighborhood chickens	25-Oct-05			9
			sick and dying family and neighborhood chickens, 10 yo				
girl	7	deceased	brother died May 29 of resp. dis. but no specimen tested	26-May	30-May	1-Jun	50

#### LOCATION NOT STATED - family cluster

	iaiiiiy	0140101					
girl	13		dead family chickens 3 days prior to onset	6-Jan	12-Jan	14-Jan	18
her brother	4		dead family chickens 3 days prior to onset	8-Jan	14-Jan	17-Jan	19
her sister	14	hosp. with resp symp	dead family chickens 3 days prior to onset		14-Jan		
		samples being tested					
her father	43	hosp. with resp symp	dead family chickens 3 days prior to onset		17-Jan		
		samples being tested					

#### LOCATION NOT STATED

boy	8	hospitalized		5-Sep		
man	38	deceased	family cluster of 3 dead ppl - lab tests for 2 daughters did not			
			meet criteria for acute H5N1 infections, unable to locate			
			source of infection			

## APPENDIX D "Dear Colleague" Letter Series on Avian Influenza Examples

These letters are sent from one Member of Congress to another in order to urge his colleague to cosponsor one of his bills or inform him about a policy topic that he values. This table lists the topics that were addressed in Congressman Burgess' letter series on avian influenza. Three sample letters are also included in this appendix.

	Topic Outline
1	science of influenza
2	antivirals vs. vaccines
3	regular vs. universal vaccines
4	eating poultry is safe
5	genetic shift vs. drift
6	vaccine production*
7	local containment
8	diagnostic tests and prepositioning
9	medical workforce and volunteers
10	global health
11	national plan highlights*
12	Texas state plan highlights
13	personal preparedness
14	links and resourves
15	2006 situation update
16	modes of transmission
17	evoluation of the virus
18	outline of the progression of SARS
19	how SARS was stopped
20	economic impact of SARS
21	airborne transmission*
22	how antivirals work
23	safety of Tamiflu in pediatrics

\* letters included as samples

## "Dear Colleague" Letter 6

MICHAEL C. BURGESS, M.D. 26th District, Texas

WASHINGTON OFFICE: 1721 LONGWORTH HOUSE OFFICE BUILDING WASHINGTON, DC 20515 (202) 225-7772

DISTRICT OFFICES: 1660 SOUTH STEMMONS FREEWAY SUITE 230

Lewisville, TX 75067 (972) 434-9700 1100 Circle Drive

SUITE 200 Fort Worth, TX 76119 (817) 531–8454

www.house.gov/burgess

Congress of the United States House of Representatives Washington, DC 20515–4326

Medical Focus - Avian Flu Essentials

November 29, 2005

COMMITTEE: ENERGY AND COMMERCE SUBCOMMITTEES. HEALTH ENERGY AND AIR QUALITY OVERSIGHT AND INVESTIGATIONS

HOUSE REPUBLICAN POLICY COMMITTEE

CHAIRMAN: MEDICARE AND MEDICAID SUBCOMMITTEE

"Few things help an individual more than to place responsibility upon him, and to let him know that you trust him." – Booker T. Washington

Dear Colleague:

In the sixth letter in the Avian Flu Essentials series, I will delve into production issues involving vaccine and antiviral treatments.

Egg-based H5N1 vaccines are manufactured utilizing extremely lengthy techniques. Eleven day old fertilized chicken eggs are injected with the reference viral strain that has been modified to be less virulent. Other components are then added to help the viruses grow. Next, the viruses are harvested, purified, and inactivated so that the vaccine can be made. This process takes at least six months and relies on a continuous egg supply.

On the other hand, the seed strain can be injected directly into cell cultures using the cell based vaccine method. The viruses would still need to be harvested, purified and inactivated. The potential advantage is a faster ability to increase production. In addition, allergies to egg albumin could be prevented with this technique. However, finding a proper cell line to grow the virus in and adequately monitoring rapidly growing cell lines can prove to be a challenge.

In order to encourage vaccine research and more rapid production techniques, additional funding is needed, along with liability reform. Laws need to be in place to shield manufacturers from scientifically unfounded injury claims. There are existing programs to monitor for adverse reactions such as the CDC Vaccine Safety Datalink that help ensure the safety of new vaccines.

If a pandemic occurs, antiviral treatments can serve as a first line of defense. Additional studies on their effectiveness and support for antiviral production capacity will enhance our preparedness. Promoting licensing agreements can allow other manufacturing companies to produce this treatment with proper institutional expertise. Simply breaching a company's intellectual property rights would actually provide a disincentive for research. Furthermore, adequate facilities would not be in place to rapidly accomplish these manufacturing processes.

An article excerpt on the reverse side of this letter describes active research and careful exploration of new vaccines. For that reason, incentives need to be in place so that the United States can develop vaccine and antiviral manufacturing capacities by having the proper infrastructure at hand.

Sincerely, (Back Page of Sixth Letter)

Excerpt from The Cincinnati Enquirer, Children's Hospital tests bird flu vaccine Medical center one of four U.S. study sites, November 10, 2005: Michael C. Burgess, M.D. Member of Congress

## "Dear Colleague" Letter 6 (continued)

AVONDALE - Cincinnati Children's Hospital Medical Center is one of four sites in the United States testing a vaccine that could protect millions against a bird flu pandemic.

The vaccine, manufactured by sanofi pasteur, based in Swiftwater, Pa., is being administered locally to about 60 healthy older adults and 60 healthy children, said Dr. David Bernstein, director of infectious diseases at Cincinnati Children's.

Nationally, 450 children and adults will be recruited for the trial. Sanofi pasteur was awarded a \$100 million contract by the U.S. Department of Health and Human Services this year to produce bulk vaccine against bird flu.

Cincinnati Children's began giving out the vaccine Oct. 31.

No vaccine exists for bird flu, although at least two are being tested.

Sanofi pasteur is also conducting studies of its vaccine in France and Australia.

"If there is a pandemic from this bird flu, the estimates are in the millions for lives that could be lost," Bernstein said.

"It would easily overwhelm the medical system."

It's almost impossible to give a time frame on when the vaccine could be on the market.

"There are so many variables to consider," John Abrams, a spokesman for sanofi pasteur, said.

Those variables include possible health complications, licensing by the U.S. Food and Drug Administration and manufacturing capacity. And it's possible that H5N1, the virus the vaccine is based on, will never become a widespread threat. Viruses mutate, and another form of avian flu could evolve to become a threat.

But if it does, the vaccine will be used.

"If we had to use it tomorrow, we would use it," said Bill Hall, a Washington-based spokesman for the U.S. Department of Health and Human Services.

If the vaccine is approved and a need for it is identified, Bernstein said, the vaccine could be available within three months after that point.

Double-blind study

At Cincinnati Children's, the trial is a placebo-controlled, double-blind study, meaning that volunteers don't know whether they received the bird flu vaccine or a placebo.

None of the volunteers has complained of ill effects, said Vicki Smith, a registered nurse and study coordinator. Volunteers are being recruited from previous vaccine trials and are being paid \$40 a visit to cover time and travel costs. If they complete the trial, each will receive another \$100.

Each volunteer receives a primary vaccination and two boosters over a six-month period. They will be tracked for one year for signs of health problems, such as immune disorders or allergic reactions.

A previous trial of the vaccine at other centers showed it to be safe in healthy adults, Bernstein said. The current trial examines the vaccine's safety and how long it might provide protection against bird flu in those most at risk for complications: seniors and young children.

MICHAEL C. BURGESS, M.D. 26th District, Texas

WASHINGTON OFFICE: 1721 LONGWORTH HOUSE OFFICE BUILDING WASHINGTON, DC 20515 (202) 225–7772

> DISTRICT OFFICES: 1660 SOUTH STEMMONS FREEWAY SUITE 230 LEWISVILLE, TX 75067 (972) 434-9700

> > 1100 CIRCLE DRIVE SUITE 200 FORT WORTH, TX 76119 (817) 531–8454 www.house.gov/burgess

# Congress of the United States House of Representatives

"Dear Colleague" Letter 11

Washington, DC 20515–4326

#### Medical Focus - Avian Flu Essentials

December 13, 2005

"The price of greatness is responsibility." - Winston Churchill

#### Dear Colleague:

In the eleventh letter in the Avian Flu Essentials series, I would like to highlight some sections in the Department of Health and Human Services Pandemic Influenza Plan. Many of the elements that are intrinsic to rapidly contain an outbreak have been discussed in the last several letters. The overview presented below will give an introduction and tie in those elements to the national preparedness plan, which is a 396 page manual subdivided into two parts. Part 1 presents the HHS Strategic Plan and Part 2 gives Public Health Guidance on various topics including surveillance, communication, and clinical guidelines.

First, the planning assumptions and what the country should expect in term of illnesses, hospitalizations, and deaths with a moderate or severe pandemic can be found in Part I pages 18-19. The federal role during a pandemic is also described with the specific duties of various HHS officials and agencies in Table 3 (starting on page 27). In addition, the intensity of the nation's response will be guided by classifying the different pandemic phases according to the World Health Organization (WHO) system (appendix C). Then, the distribution of vaccines and antiviral drugs can be targeted according to the priority groups determined in appendix D (tables on pages 13 and 21).

Second, Part 2 is the most relevant section to state officials as it presents clear recommendations. Surveillance is discussed in Supplement 1. The various components that compose the surveillance system and how health departments should categorize the amount of influenza-likeillness in a state will serve to alert the nation and monitor the development of a pandemic should one occur (on pages S1-10 and S1-13).

Third, knowing which situations call for samples to be sent to designated labs or the CDC for viral strain determination is important. Supplement 2 in Part 2 of the HHS Pandemic Influenza Plan gives laboratory diagnostic guidelines. The types of viruses that are endemic to poultry and humans can be better understood by looking at page S2-11. As researchers confirm whether samples contain the pandemic flu virus, the false positive testing rates for scientists to bear in mind depend on the prevalence of the disease (see pages S2-25 and S2-26).

Fourth, states' preparedness plans should integrate Healthcare Planning guidelines (Supplement 3 in Part 2). Consideration should also be given to modify current state and local laws and procedures necessary to facilitate a rapid response (see Appendix 1 on I-13 in Part 2).

Fifth, health care providers should be provided with the flow charts that show how to test and treat patients with influenza and pneumonia during a pandemic (Supplement 5, pages 16-19 and 34-35). Based on this assessment, health care workers can refer to a table that establishes viral drug dosages based on an individual's age (Supplement 7 page 18).

Sixth, Supplement 10 addresses public health communication. Informing and educating the general public prior to the occurrence of a global threat will help allay people's fears and allow them to make better decisions when faced with a disaster. Regular updates from a person an individual trusts during a pandemic will also help prevent panic.

The brief overview presented in this letter is not inclusive of every segment in the HHS Pandemic Influenza Plan and public officials should take the time to familiarize themselves with the whole plan. Our ability to handle a pandemic can only be strengthened if pandemic preparedness plans are implemented. On the reverse of this letter, President Bush's strategy for pandemic influenza is outlined. Active steps to deal with this global health threat in a timely way must be taken and a source of funding is necessary to take action.

Michael C. Burgess, M Member of Congress

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## "Dear Colleague" Letter 21

MICHAEL C. BURGESS, M.D. 26th District, Texas

WASHINGTON OFFICE: 1721 LONGWORTH HOUSE OFFICE BUILDING WASHINGTON, DC 20515 (202) 225-7772 www.house.gov/burgess

## Congress of the United States House of Representatives Washington, DC 20515–4326

Medical Focus - Avian Flu Essentials

April 7, 2006

#### Spotlight on SARS and Lessons Learned

Dear Colleague:

In the twenty-first letter of the Avian Flu Essentials series, I will discuss some of the research findings about the transmission of SARS-associated coronaviruses and how the effectiveness of various disease control measures depend on these characteristics.

The length of the incubation period for communicable viruses like SARS or influenza is useful to determine, because it gives health officials information on how long a patient should be isolated from others and who might have become infected from that patient by contact. The incubation period in essence describes how long it takes for a person to manifest symptoms after exposure to a pathogen. The maximum incubation period for SARS-CoV is ten days. On the other hand, the incubation period for avian flu is shorter from two to five days on average.

In addition, the viral load in infected SARS patients peaks during the second week. Therefore, transmission has mainly occurred with symptomatic SARS patients. This facilitates outbreak investigations and control. For example, airplane passengers were not infected by non-symptomatic SARS travelers. The challenge and concern with avian flu is the possibility of transmission prior to the appearance of symptoms.

The ability of airborne transmission by SARS-CoV was suggested from the analysis of the SARS outbreak at the Amoy Gardens housing complex in Hong Kong. In March 2003, the index patient visited and used the restroom in Building E. An outbreak of 321 cases ensued and lead to the hospitalization of hundreds of residents. Contamination was attributed to the design of the building and air flow. Close to half of the cases were traced back to Building E. The clustered appearance of cases a few days later supported the theory that a common source of infection was responsible for the spread of the virus, rather than personal contacts. Further investigation and study revealed that aerosols were spread from toilet flushing and the direction of air flow within Building E and other complexes correlated with the distribution of cases. Diagrams on the reverse of this letter illustrate this.

In addition, data was gathered on SARS cases with airplane passengers to look at the risk of infection from traveling. This revealed that individuals seated within three rows of the index patient were most at risk, but that several other people further away on the plane were also infected. Therefore, airborne transmission played a role as well and should be taken into consideration.

Controlling a disease that is airborne is more complex because the potential exposure to a pathogen is over greater distances. The amount of virus load in airborne transmission varies with different pathogens as well, which determines how effectively this mode is in spreading a disease. Therefore, ventilation systems in public buildings can affect the spread of airborne diseases. This reinforces the need for isolation wards and stronger air sanitation measures. Furthermore, it is important to minimize infectious disease exposure of individuals in hospital waiting rooms. Influenza is generally spread through respiratory droplets by coughing and sneezing. A better understanding of the viral modes of transmission for avian influenza will be necessary should human-to-human transmission become more widespread.

Sincerely, Aichael C. Burgess, M Member of Congress

DISTRICT OFFICE: 1100 CIRCLE DRIVE SUITE 200 FORT WORTH, TX 76119 (817) 531–8454

COMMITTEE: ENERGY AND COMMERCE

> SUBCOMMITTEES: HEALTH

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HOUSE REPUBLICAN

CHAIRMAN: MEDICARE AND MEDICAID SUBCOMMITTEE

POLICY COMMITTEE

DISTRICT OFFICE: 1660 South Stemmons Freeway Suite 230 Lewisville, TX 75067 (972) 434–9700

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#### **APPENDIX E**

**Opinion-Editorial on Avian Influenza in the Star Community Papers, Texas** 

## Zero In – A Story on Avian Flu

WASHINGTON, DC, Nov 2

By: Phuong-Khanh Jessica Nguyen-Trong Congressional Health Care Fellow in the Office of U.S. Representative Michael C. Burgess (Texas-26)

Not a newscast airs today that does not talk about the spread of avian flu. Is that attention warranted or has the threat been over-hyped?

Attention devoted to this issue has certainly brought this virus to the forefront of everyone's thoughts. It is significant to note that avian flu refers to viruses that only infect birds. In this particular instance, the virus is H5N1. As humans become infected, it no longer is characterized as strictly an "avian flu." However, with the strong possibility that H5N1 could cross species – from birds to humans – decisive action must take place.

Worldwide pandemics are not all together rare occurrences. Less than a century ago, the 1918 flu pandemic claimed 50 million lives. More recently, the world rallied against the 1957 Asian and 1968 Hong Kong influenza.

So will H5N1 represent a threat comparable to these historical outbreaks? Yes. But it is important to remember that a new pandemic has not yet bloomed and may not be as severe as previous ones. But the threat alone means we must be prepared.

Through technological inventions, humans have broken down geographical barriers. Today, instant communication and travel entwine in our everyday lives. With the increasing appearance of H5N1 in several Asian and European countries, many leaders are considering methods to isolate nations from each other, which at this point in history is no simple task.

Already, the modern world has some perspective on dealing with pervasive infectious diseases such as with SARS, a 2003 respiratory virus epidemic. According to the World Health Organization (WHO), by the end of the SARS outbreak, over 8,000 people were infected with nearly 800 deaths. SARS was a dangerous disease, but not nearly as fatal as avian flu. As of October 10, 2005, over 100 human cases of H5N1 have been reported with over half of these cases resulting in death. Thus, this high mortality rate has led to caution among the scientific community and compounds the challenges of the 2003 SARS outbreak.

In the modern age, information and data are highly prized. Our current research capacity gives us the gifts of time and foresight. A global, united front to face this potential threat is critical to protect the health and safety of humankind.

U.S. Human and Health Services Secretary Michael Leavitt took a bold step in gathering knowledge about avian flu through his trip in Asia. Understanding the conditions of these regions where the outbreak is occurring is essential. Secretary Leavitt's firsthand account

of the situation in Asia is immeasurably more beneficial than what is captured by reading a report. His findings will be shared with Congress in the final version of the Pandemic Influenza Response and Preparedness Plan. This plan will be invaluable to federal, state and local leaders who should analyze the plan and build on it to adequately prepare to handle a pandemic.

How do we begin to combat this potential crisis? The best way to prevent a pandemic is containment. Streamlined relief efforts help squelch an outbreak before it travels further. At the local level, mandatory and self-quarantines need definition, including how to react to the increased need for health care and how to prevent the spread of the virus. This might include a temporary stop in mail delivery or addressing work absenteeism.

Health care workers must define the best way to provide antiviral drugs and vaccines to people. Currently, antiviral drugs need to be administered within two days of an infection – a short but vital timeframe. New drug designs should not be limited by this window. Additionally, a rapid screening test should be developed to classify an infection as H5N1 prior to administering its treatment.

Another necessary aspect of containment is accurate communication to prevent panic. The general public needs to be educated to recognize symptoms of H5N1, including practical steps to minimize the dispersion of the virus. The efficacy of protective equipment should be examined and may need to be in every household. Furthermore, cities need to designate a hospital or large clinic as the primary treatment manager for a pandemic if one is to occur.

Every individual also needs to be responsible and plan ahead. If a person suspects infection, they should know how to protect others while making a straight route to the designated hospital. Personnel at these treatment sites will be better trained and equipped to treat the virus. In addition, diverting patients with weakened immune systems to non-designated hospitals will decrease their exposure to H5N1.

Because a virus must be destroyed to hinder it from growing into a pandemic, containment begins at the local level. Practical and concise preparedness plans need not only be outlined but also implemented. Because in the words of Goethe, "Knowing is not enough, we must apply. Willing is not enough, we must do."

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#### VITAE

Phuong-Khanh Jessica Nguyen-Trong was born in Toulouse, France, on March 17, 1983, and is the daughter of Hai Nguyen-Trong and Phuong-Chi Nguyen. After completing her work at Klein High School, Spring, Texas in 2000, she entered Texas A&M University in College Station. She received the degree of Bachelor of Science with a major in Biology and a minor in Business in May 2004. She then entered medical school at the University of Texas Southwestern Medical Center at Dallas in August 2004.

During her undergraduate years, she developed an interest in foreign policy and attended several conferences at the Bush School of Government and Public Service on the Texas A&M campus. She subsequently became an active member of the Texas and American Medical Associations (TMA and AMA) during her first year of medical school. She discovered that she enjoys organized medicine and the ability to shape the environment in which physicians practice. Between her first and second year, she decided to take a one year leave of absence and was employed as the first Congressional Fellow in Health Care Policy in the office of Congressman Michael Burgess, M.D., in Washington, D.C.

Upon her return to medical school, she went on to serve two terms on the AMA Council on Legislation. She has been inducted in the Alpha Omega Alpha National Medical Honor Society and was a recipient of the 2006 AMA Foundation Leadership Award. She will be awarded her degree in medicine in June 2009 and is pursuing a residency in Internal Medicine at Johns Hopkins.

Permanent Address: 13301 Presidio Place Tustin, CA 92782