



*Committee on Homeland Security  
Report Prepared by the Majority Staff:*

# Getting Beyond Getting Ready for Pandemic Influenza



U.S. HOUSE OF REPRESENTATIVES  
**COMMITTEE ON HOMELAND SECURITY**  
REP. BENNIE G. THOMPSON, CHAIRMAN

## Report Documentation Page

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# EXECUTIVE SUMMARY

## OVERVIEW

Pandemic influenza is not a new phenomenon. Historically, there have been other influenza pandemics,<sup>1</sup> enough so that we now believe the planet is well overdue.<sup>2</sup> We watch avian influenza move across the world,<sup>3</sup> worry about how more than 60% of those people that contract the disease die from it,<sup>4</sup> and realize that further mutations in currently circulating strains could cause them to easily infect human beings.<sup>5</sup> If that happens, with an already high death rate,<sup>6</sup> we expect that hundreds of thousands if not millions would die,<sup>7</sup> that every country would be affected,<sup>8</sup> and that society would function poorly at best.<sup>9</sup> Expressions of culture and government – scenarios, exercises, movies, fiction, and nonfiction – have articulated our fears of an infectious disease for which we have no immediately available cure.

Work is clearly underway to prepare for such a biological event.<sup>10</sup> However, despite the fact that we are overdue for an influenza pandemic<sup>11</sup> and that we fear the consequences of such a disease spreading unchecked<sup>12</sup> – we are not prepared<sup>13</sup> as a Nation to fully withstand the impact of such a devastating widespread biological event. Pandemic influenza would destroy the security of our Nation and homeland.<sup>14</sup> It is for this reason that the House Committee on Homeland Security has made oversight of pandemic preparedness a priority, and why this study was undertaken.

When Peter Ginaitt, Director for Emergency Preparedness for the Lifespan Hospital Network in Rhode Island, was explaining to staff of the House Committee on Homeland Security the challenges the hospitals in his State were facing – how he was having to scrounge for extra supplies to stockpile in or near the hospitals, how he was having to fight for the small amounts of funding that could be spared for preparedness efforts, and how regional meetings were resulting in little more than checking the box for the Department of Homeland Security (DHS) and the rest of the Federal government – he was very clear that, “we need to get beyond getting ready.”<sup>15</sup> Representative Jim Langevin, Chairman of the Subcommittee on Emerging Threats,

Cybersecurity, and Science and Technology for the House Committee on Homeland Security agreed and said that, “we have to get beyond getting ready and, “...actually be ready.”<sup>16</sup> This is not about semantics – getting ready versus being ready. Representative Bennie G. Thompson, Chairman of the House Committee on Homeland Security believes that this is about ensuring that the Nation is ready to address such a biological event from a position of strength.<sup>17</sup>

## CHARGE TO THE STAFF

Recognizing the devastating impact an influenza pandemic would have on our Homeland<sup>18</sup> and National Security,<sup>19</sup> and the need to be ready to handle the pandemic when it occurs, Chairman Thompson and Subcommittee Chairman Langevin directed the Majority Staff to:

- Conduct oversight regarding the pandemic influenza preparedness activities of DHS and other members of the Executive Branch;
- Gather information through hearings, briefings, and meetings to determine the status of National efforts to prepare for pandemic influenza;
- Identify weaknesses in our National preparedness for pandemic influenza; and
- Determine what specific actions could strengthen such efforts and help the Nation achieve readiness for pandemic influenza.

## APPROACH

Hearings were held during the 110<sup>th</sup> Congress on September 26, 2007 in Washington, DC (*Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*)<sup>20</sup> and July 22, 2008 in Providence, RI (*Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*).<sup>21</sup> A member briefing was held on September 23, 2008 in Washington, DC.<sup>22</sup> Members and staff met with a number of public and private sector entities from May 2007 through October 2008. The National Strategy for Pandemic Influenza<sup>23</sup> and its Implementation Plan<sup>24</sup> were examined in their entirety. Information systems, such as Pandemicflu.gov<sup>25</sup> and the Lessons Learned Information Sharing



system (LLIS.gov)<sup>26</sup> were utilized to the extent they were kept updated.

## **WEAKNESSES TO BE STRENGTHENED**

To date, a large number of actions to prepare for pandemic influenza have been undertaken and completed.<sup>27</sup> Accomplishments are listed in other places, including Pandemicflu.gov.<sup>28</sup> Yet, many organizations either lack the sense of urgency and/or funds<sup>29</sup> to continue preparing, or they are stuck endlessly preparing and are not yet ready.<sup>30</sup> Majority staff identified the following weaknesses in the current approach to get ready for pandemic influenza:

- **Early Warning And Detection Inadequate**
  - Information used to inform US decisions not uniformly collected or derived;
  - Biosurveillance early warning unsatisfactory; and
  - Biosurveillance integration insufficient.
- **Execution Of Key Planning Activities Incomplete**
  - Key stakeholders not consulted during strategy development;
  - Synergy with other National strategies not identified;
  - Planning guidance to the States and Territories inadequate;
  - Evidence of pandemic influenza planning for the Federal Departments and agencies scant; and
  - Private sector continuity of operations plans lacking.
- **Challenges Posed By Key Medical Response Requirements Partially Addressed**
  - Difficult issues left unaddressed by the Bush Administration;
  - Hospital resource and priority management problematic;
  - Pharmaceutical interventions limited; and
  - Recommendations for non-pharmaceutical interventions lacking.
- **Levels Of Preparedness For Pandemic Influenza Unclear**
  - Measurement of and reporting by the Executive Branch unsuitable;
  - Reporting under the Bush Administration inconsistent;
  - Federal priority on pandemic influenza preparedness lowered; and
  - Example set by Executive Branch Departments and agencies working together poor.

## **WHAT SHOULD BE DONE**

The change in Presidential leadership presents a new opportunity to establish National readiness for pandemic influenza.<sup>31</sup> Below are key recommendations to become ready:

- **Establish Effective Management And Coordination**
  - Restore White House leadership of National efforts to get ready for pandemic influenza;
  - Report on a consistent basis; and
  - Set better example at the Federal level for public health, safety, and security coordination.
- **Address And Meet Key Medical Requirements**
  - Discuss the most difficult topics regarding life and death medical decisions and their consequences;
  - Reorient approach to health care delivery in the case of very limited resources; and
  - Identify and activate fast and dependable domestic capacity to produce needed pharmaceuticals.
- **Evaluate And Update Plans**
  - Update and modify the National Strategy for Pandemic Influenza<sup>32</sup> and its Implementation Plan;<sup>33</sup>
  - Identify and include necessary stakeholders in the evaluation and updating of the Implementation Plan;<sup>34</sup>
  - Analyze and comprehend how the National Strategies interact;
  - Understand how a pandemic could be taken advantage of by terrorists and plan accordingly;
  - Fill the gap in Federal planning;
  - Generate more than grant guidance for the non-Federal government; and
  - Require continuity of operations plans to qualify for Federal funds.



- **Improve Early Warning And Detection**
  - Implement an effective public awareness campaign to help citizens; and
  - Implement a uniform global biological surveillance program to provide biological warning of incidents and suspicious events.

## **CONCLUSION**

It is possible that the next influenza pandemic will result in hundreds of thousands to millions of deaths even here in the US.<sup>35</sup> Clearly, there is cause for concern. Leaders throughout the public and private sectors share the responsibility<sup>36</sup> for addressing this threat without delay.<sup>37</sup> Indications have been received that the Obama Administration will make this a priority.<sup>38</sup> The House Committee on Homeland Security looks forward to working with them to achieve readiness for an influenza pandemic.

We are not incapable. As a Nation we are resourceful and creative. Culturally, we are willing and able to take a step back, assess the state of our affairs, admit mistakes and failures, and redirect our efforts. Doing so will require renewed commitment and greater confidence in our ability to deal with what we think we cannot. We must get beyond getting ready.<sup>39</sup> We can get beyond getting ready. The will to meet and overcome this disease is as great a mission as any on the global battlefield.<sup>40</sup> Our success depends on keeping up the fight<sup>41</sup> until pandemic influenza is overcome.



# INTRODUCTION

Over the past thirty years, the potentially devastating impact that an influenza pandemic could have on the Nation has been recognized and steps have been taken to try and address the problem. In 1977, the Carter Administration's Department of Health, Education, and Welfare initiated the creation of a National strategy for pandemic influenza.<sup>42</sup> When the Department of Health and Human Services (HHS) was created in 1980,<sup>43</sup> it retained responsibility for the strategy. The draft strategy remained in a consensus-gaining process for the next 27 years.<sup>44</sup>

Although the disease itself certainly falls under the purview of HHS, all members of the Executive Branch must deal with the impact any pandemic would have on society.<sup>45</sup> HHS did not have the authority to compel the other Federal Departments and agencies to take actions to prepare for, respond to, or recover from an influenza pandemic – let alone make them provide speedy review and relevant commentary on the draft strategy. Clearly, the consensus-gaining process utilized by HHS was also very time-consuming.

More recently, the Bush Administration determined that such a multiagency effort should be lead by the White House.<sup>46</sup> In turn, the Office of Health and Biodefense in the Homeland Security Council (HSC) developed the National Strategy for Pandemic Influenza in 2005.<sup>47</sup> Thereafter, the HSC Office of Health and Biodefense lead a group of Federal agency representatives to determine how best to execute the National Strategy,<sup>48</sup> and released the more robust Implementation Plan for the National Strategy for Pandemic Influenza in 2006.<sup>49</sup>

The Bush Administration did recognize that the National Strategy for Pandemic Influenza<sup>50</sup> could no longer wait for the seemingly endless iterations of the consensus process being utilized by HHS to produce it to be completed.<sup>51</sup> However, action was not taken to remedy the situation until five years into the Administration. Regardless, in producing the Strategy<sup>52</sup> and its Implementation Plan,<sup>53</sup> the HSC provided a much needed framework for increasing National pandemic

influenza preparedness. Although most Federal activities listed in the Implementation Plan<sup>54</sup> are reported complete,<sup>55</sup> much more progress is necessary throughout the public and private sectors in order to attain National pandemic readiness.<sup>56</sup>

Peter Ginaitt, Director for Emergency Preparedness for the Lifespan Hospital Network in Rhode Island has explained the challenges that the hospital community in his State has been facing – including how he had to scrounge for extra supplies to stockpile in or near the hospitals and to fight for resources that could be spared for preparedness efforts.<sup>57</sup> He felt that regional meetings were resulting in little more than a “checking the box” exercise for DHS and others in the Federal government.<sup>58</sup> Dr. Ginaitt was very clear that, “we need to get beyond getting ready.”<sup>59</sup>

Representative Jim Langevin, Chairman of the Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology for the Committee on Homeland Security agreed and said that we have to get beyond getting ready and, “...actually be ready.”<sup>60</sup> Representative Bennie G. Thompson, Chairman of the House Committee on Homeland Security believes that we need to ensure that the Nation is ready at any moment to address such a biological event from a position of strength.<sup>61</sup>



# WEAKNESSES TO BE STRENGTHENED

## EARLY WARNING AND DETECTION LACKING

### Information used to inform US decisions not uniformly collected or derived

Many public and private sector health reporting and surveillance efforts are currently underway for a wide variety of diseases and medical conditions.<sup>62</sup> Unfortunately, these systems have not often been compatible, able to communicate easily with each other, or interoperable. In some cases, systems are specific to particular diseases. In others, systems report information on a number of diseases. Exacerbating the situation are the different requirements for reporting the occurrence of diseases and health conditions by the States and Territories. The result has been a surveillance patchwork in which there is overlap in some places and holes in others.

### Biosurveillance Early Warning Unsatisfactory

The current state of disease surveillance by public health and health care delivery organizations does not allow for adequate early warning.<sup>63</sup> There are different thresholds for reporting (meaning that different organizations define how many cases compose an outbreak in their opinion). Additionally, health care professionals receive varying amounts of training regarding the need to and process for reporting. Poor initial reporting of cases of Severe Acute Respiratory Syndrome (SARS)<sup>64</sup> in 2002 and 2003 exemplifies this problem.<sup>65</sup> China certainly differed in its approach to reporting the syndrome as compared many other countries, including the United States (US) and Canada.<sup>66</sup> Although avian influenza is worrisome due to its mortality rate (greater than 60% as of September 2008),<sup>67</sup> and is currently moving slowly across the globe,<sup>68</sup> should a new pandemic variant arise with different characteristics<sup>69</sup> (allowing for faster transmission rates, among other things) it will be necessary to have adequate biosurveillance already in place to allow for the earliest warning possible.<sup>70</sup> Waiting for high numbers of people to become ill – or worse, die – is unacceptable.

## Biosurveillance Integration Insufficient

Entities within HHS have been trying to solve the problem of comprehensive and global biosurveillance for many years, with some notable efforts undertaken by the Centers for Disease Control and Prevention (CDC), including BioSense<sup>71</sup> and BioPHusion.<sup>72</sup> Biosurveillance data from a number of the Federal Departments and agencies is also supposed to be funneled to, combined, and analyzed by the DHS National Biosurveillance Integration System (NBIS)<sup>73</sup> at the National Biosurveillance Integration Center (NBIC). NBIC has met with limited success due to the inability of the DHS Office of Health Affairs to manage the system and Center properly<sup>74</sup> and the lack of data coming into the Center from the 12 agencies that were envisioned by Congress to provide the data.<sup>75</sup>

Eight memoranda of understanding (MOUs) have been established,<sup>76</sup> with one interagency security agreement (ISA)<sup>77</sup> one interagency agreement (IAA),<sup>78</sup> and one commitment to provide personnel to the NBIC.<sup>79</sup> The NBIC exists to integrate biosurveillance information from organizations that feed their data to the Center. This cannot occur if MOUs and other agreements are not put into place and information sent, recombined and analyzed. This does not bode well for being able to quickly ascertain when an influenza pandemic occurs anywhere in the world.

The DHS Office of Health Affairs also faces the challenge of managing NBIC with limited resources and a constrained mission. The NBIC cannot and should not track every disease (including the large variety of influenza variants) on the planet. That would be too costly and not all of these diseases could affect homeland security. On the other hand, waiting to track diseases until they become serious outbreaks and pandemics is also not acceptable.



## **EXECUTION OF KEY PLANNING ACTIVITIES INCOMPLETE**

### **Key Stakeholders Not Consulted During Strategy Development**

Notably absent from the White House process to develop the Implementation Plan<sup>80</sup> were a number of key stakeholders, including representatives from the States, Territories, Tribes, and localities,<sup>81</sup> as well as the private sector and the international community. Although the Implementation Plan<sup>82</sup> was briefed to some of these stakeholders (or their representatives) shortly after its release,<sup>83</sup> they were not afforded the opportunity to participate in the process to develop the Plan in the first place.<sup>84</sup> As a result, the Executive Branch did not have their buy-in or support.

### **Synergy with Other National Strategies Not Identified**

The Bush Administration neglected to determine how the National Strategy for Pandemic Influenza<sup>85</sup> would work with other National strategies with which synergy might or should exist. For example, although an influenza pandemic is generally thought to be a naturally-occurring disease event, it is possible that it could be deliberately generated (such as through the introduction of a purposely genetically-modified influenza variant).<sup>86</sup> This would be considered the intentional distribution of a biological agent – an act of biological terrorism.<sup>87</sup> Therefore, quite a few National strategies would apply in this context, including but not limited to the National Strategy for Combating Terrorism,<sup>88</sup> the National Strategy for Homeland Security,<sup>89</sup> the National Strategy for the Physical Protection of Critical Infrastructure and Key Assets,<sup>90</sup> and the National Strategy for Information Sharing.<sup>91</sup>

There appears to have been an effort to deconflict these National Strategies. However, there is no evidence to indicate that the Bush Administration determined which strategy should take priority and under what circumstances, or the impact that executing numerous and possibly conflicting National strategies would have. Strategy documents serve to provide direction for additional planning efforts.<sup>92</sup> In generating another National strategy that did not clearly

address other National strategies that could be applicable, the Bush Administration created the potential for greater Federal inefficiency.<sup>93</sup>

### **Guidance Given by Executive Branch to Non-Federal Government Insufficient**

There is limited discussion of the needs of and guidance to the non-Federal public and private sectors in the National Strategy<sup>94</sup> and its Implementation Plan.<sup>95</sup> Other high-level homeland security documents, such as Homeland Security Presidential Directive 10 (Biodefense for the 21<sup>st</sup> Century, which lacks significant discussion of preparedness)<sup>96</sup> and Homeland Security Presidential Directive 21 (Public Health and Medical Preparedness, which identifies problems to be addressed but does not provide direction on how they should be addressed by the non-Federal government)<sup>97</sup> are also oriented towards the Federal government.

Guidance to the non-Federal government was released in 2008,<sup>98</sup> long after many States, Territories, Tribes, and localities had already developed plans to address pandemic influenza without much input from the Executive Branch.<sup>99</sup> In some cases, existing grant guidance from DHS,<sup>100</sup> HHS,<sup>101</sup> and other Federal agencies was the only guidance available to the States, Territories, Tribes, and localities – but it changed frequently enough to cause the non-Federal government to have to shift program priorities and to deal with the resulting increased inefficiency.<sup>102</sup>

Non-Federal entities – those in both the public and private sectors – need to know what they can expect from the Federal government, before, during, and after an influenza pandemic has occurred. This is almost impossible without clear information regarding what can be expected from the members of the Executive Branch. Additionally, non-Federal entities need to know how what the Federal government is suggesting in the way of priorities so that the States, Territories, Tribes, and localities are not working at cross-purposes to the Federal government and without adequate funding.

Despite this initial and continuing lack of sufficient guidance,<sup>103</sup> all States and Territories, as well as some Tribes and localities, produced plans well in advance of many of the Federal Departments and



agencies.<sup>104</sup> Almost two and a half years after the release of the National Strategy for Pandemic Influenza<sup>105</sup> and its Implementation Plan,<sup>106</sup> most Federal Departments and agencies (including DHS) appear not to have developed their own strategies and implementation plans for dealing with pandemic influenza or if they have, their plans have not been posted on Pandemicflu.gov. Those that have [Department of Defense (DOD), HHS (specifically, the Administration on Aging, the CDC and the Food and Drug Administration), and the Veterans Administration]<sup>107</sup> should be commended for planning in advance and recognizing the need for public communication and transparency. It is of particular concern that DHS has not produced and posted its own plan. As with DOD and National security, without a plan for DHS, homeland security will be compromised during an influenza pandemic.

### **Planning Guidance to States Inadequate**

The States, Territories, and some localities have produced their own plans for addressing pandemic influenza.<sup>108</sup> As expected, due to the lack of guidance they have received from different members of the Federal government, these plans vary in quality, depth, importance placed on different activities, and responsiveness to the grant guidance originally issued by HHS.<sup>109</sup> This guidance (originally issued in December 2005) was confusing and difficult to utilize, especially in the form of the checklist provided by HHS.<sup>110</sup> Subsequently, DHS, HHS, and other members of the Federal government developed clearer and more comprehensive grant guidance and issued it in March 2008.<sup>111</sup> Utilizing this much improved guidance, the States, Territories, and localities were recently required to update their plans and submit them back to HHS for review by a number of Federal agencies (including DHS) in June 2008.<sup>112</sup> Information is not yet available regarding how well and to what extent these plans were revised.

The greatest amount of guidance regarding these plans and what they should address is found in the HHS grant guidance.<sup>113</sup> Beyond that, grant applicants and recipients can look at other documents that have either been given to the Departments and agencies themselves (such as the National Strategy<sup>114</sup> and its Implementation Plan<sup>115</sup>) or to the few other documents that the

Departments and agencies have generated in addition to this grant guidance,<sup>116</sup> such as information regarding the applicability of Homeland Security grant funding.<sup>117</sup>

### **Evidence of Pandemic Influenza Planning for the Federal Departments and Agencies Scant**

Relatively comprehensive plans have been developed by the HSC,<sup>118</sup> and by the States, Territories, and localities to address pandemic influenza.<sup>119</sup> However, far fewer appear to have been developed by the Federal Departments and agencies themselves.<sup>120</sup> As a result, the monitoring, measurement, and evaluation of the Federal entities in-between the White House and the States and Territories can only be done incompletely, if at all. This is a glaring weakness at the level of the Federal Departments and agencies.<sup>121</sup>

Recent events have shown that the Federal government has learned from past mistakes, developed comprehensive plans after various events, and pulled its elements together to better respond.<sup>122</sup> However, the Nation will not be given the opportunity to respond to and recover from one pandemic, learn from what it did well and poorly, plan, and then respond again to another pandemic occurring soon after the first. Once an influenza pandemic occurs, we will be dealing with its impact on society for years thereafter. Planning during pandemic response efforts will be difficult if not impossible.

### **Private Sector Continuity of Operations Plans Lacking**

Pandemic preparedness activities have been undertaken by the private sector as well.<sup>123</sup> However, the need for continuity of operations planning for such a disease has met with mixed support.<sup>124</sup> Organizations that are able to translate the impact of an influenza pandemic into costs to business<sup>125</sup> are also better able to undertake planning efforts. Those that do not understand the inverse correlation between the severity of a pandemic and continuous profitable operations have not planned as they should.<sup>126</sup>

An influenza pandemic will so overwhelm the public sector that the private sector will not only be affected<sup>127</sup> but it may also have to provide



certain services that it would not ordinarily have to (such as providing shelter to their own employees),<sup>128</sup> not to mention dealing with lower or even negative profit margins<sup>129</sup> and the additional effects of much slower commerce.<sup>130</sup> Organizations such as the Chamber of Commerce<sup>131</sup> and Business Executives for National Security<sup>132</sup> have been addressing pandemic influenza and other infectious disease issues (such as bioterrorism) for a number of years, but now report declining interest and shifting away from this long-term preparedness priority, particularly during the current economic downturn.<sup>133</sup>

### **CHALLENGES POSED BY KEY MEDICAL RESPONSE REQUIREMENTS PARTIALLY ADDRESSED**

#### **Difficult Issues Left Unaddressed by the Bush Administration**

In getting the National Strategy for Pandemic Influenza<sup>134</sup> (including its Implementation Plan)<sup>135</sup> finalized and released, the Bush Administration shied away from grappling with complicated, sometimes controversial issues.<sup>136</sup> For example, the Bush Administration did not address the questions surrounding altered standards of care (although recognized by the HSC and the health care community<sup>137</sup> as important and relevant in the response to and recovery from pandemic influenza). In another example, when the HSC decided not to recommend border closures as a way of preventing the spread of influenza with demonstrated pandemic potential,<sup>138</sup> it did so without entering into significant discussion with Customs and Border Protection and the other organizations that address border issues that would be impacted. As a result of not addressing such issues, the National Strategy<sup>139</sup> and its Implementation Plan<sup>140</sup> contain weaknesses.

#### **Hospital Resource and Priority Management Problematic**

Hospital pandemic plans need to take into account current situations and characteristics in order to be realistic. For example, most hospitals<sup>141</sup> in the country do not have the capacity to surge their operations to any great extent,<sup>142</sup> so planners should not pretend that surge can occur easily. In another example,

pharmaceuticals – no matter how well targeted and able to treat a disease – are not the answer to what fundamentally remains a resource and priority management problem. Therefore, planning to distribute pharmaceuticals as the sole solution to an influenza pandemic is also unrealistic.

The profit-generating strategies utilized by hospitals today are rapidly losing their effectiveness<sup>143</sup> even when faced with only the usual cases and normal levels of disease and injury. During an influenza pandemic, these old strategies must be set aside and replaced with others that will utilize and allocate resources (including human) in ways that no health care professional has been trained.<sup>144</sup> Although training does occur with triage – particularly for those working to deliver emergency medicine or provide emergency management<sup>145</sup> – the situations for which this training is tailored do not resemble the incredibly daunting situation we would find ourselves in should an influenza pandemic sweep the Nation.<sup>146</sup>

Hospitals (whether private or public) find it difficult to prepare for the influenza pandemic of tomorrow when many are losing funds or are otherwise strapped for money today.<sup>147</sup> They are wondering how they will keep their doors open, let alone plan to accept hundreds and thousands of more patients.<sup>148</sup>

#### **Pharmaceutical Interventions Limited**

The term pharmaceutical intervention refers to the introduction and use of medicinal drugs during a disease outbreak to prevent the further spread of the disease. Members of the research establishment are developing pharmaceutical interventions, but struggle to address many possible characteristics and outcomes of an influenza pandemic without having the specific virus that will cause this disease.<sup>149</sup> Waiting for the advent of the specific virus that causes an influenza pandemic only then to be able to develop and produce the vaccine, antivirals, and/or other necessary medications carries a great deal of risk. Unfortunately, however, this is the state of science and technology today.<sup>150</sup>

Research is being carried out by the public and private sectors to develop vaccines and



treatments that do not need to be targeted so specifically (in other words, broad-spectrum).<sup>151</sup> However, too few organizations are involved in these efforts.

### **Recommendations for Non-Pharmaceutical Interventions Lacking**

The term non-pharmaceutical intervention refers to action taken during a disease outbreak to prevent further spread of the disease that does not involve or require medicinal drugs. Given the lack of pharmaceutical interventions currently available to us, some have called for planning and preparedness to be based upon the use of non-pharmaceutical interventions.<sup>152</sup> This is reasonable and logical.

While we do not want to take the pressure off of research and other establishments to develop effective pharmaceutical interventions, we must recognize that with current technology, vaccines and antivirals will not be available soon. However, many non-pharmaceutical interventions that can prevent the spread of disease also can be implemented at any time.

Even if cell-based vaccine production technology were available today, the time from virus isolation to vaccine production would be three months.<sup>153</sup> Using present (egg-based) technology, that period would be almost six months.<sup>154</sup> In that time, no targeted vaccine would be available. Antiviral medications present a slightly more optimistic story, because they can be produced now.<sup>155</sup> However, the production process is difficult and could take six to nine months,<sup>156</sup> and it is unclear as to whether antivirals will be effective against a pandemic strain of influenza.<sup>157</sup>

Many lives and dollars can be saved by a prepared public. Practicing effective hygiene and other non-pharmaceutical interventions can impede or prevent the spread of disease. Planners and those that allocate funds need to employ and support every tool available to them, including both pharmaceutical and non-pharmaceutical interventions.<sup>158</sup>

## **LEVEL OF PREPAREDNESS FOR PANDEMIC INFLUENZA UNCLEAR**

### **Measurement of and Reporting by Executive Branch Unsuitable**

As part of the multi-agency effort to create the Implementation Plan,<sup>159</sup> deadlines were identified for completion of activities contained therein. This should be considered a positive step for the Bush Administration, as it so often issued directives and undertook activities without clear deadlines. However, the HSC did not include requirements in the Implementation Plan<sup>160</sup> for the Federal Departments and Agencies to report back to the HSC Office of Health and Biodefense at certain times, nor did it state that it would regularly report status for the entire Executive Branch.<sup>161</sup> Unfortunately, things that do not get reported (and measured) do not get done.<sup>162</sup> Further, the HSC slid deadlines without alerting the public, causing further confusion and difficulty in measuring progress.<sup>163</sup>

The system for measurement of activities contained in the Plan<sup>164</sup> has not always been valid and related reporting requirements have not always made sense. For example, there are a number of activities that needed to be initiated and maintained on an ongoing basis.<sup>165</sup> However, members of the Executive Branch charged with conducting these activities had no choice but to report these activities as completed when in fact they were ongoing (as incomplete and partially incomplete were even less accurate descriptors). Reporting in this way did not allow for effective description of the actual status of activities.

Eventually, this was changed. Although the addition of ongoing as a choice was more valid, it introduced confusion regarding previously reported status (when ongoing was not a possible choice). Data cannot be compared now, unless old responses (that should have been described as ongoing but were listed as completed) are changed to allow for valid comparison. Unless and until this is done, efforts to prepare for pandemic influenza cannot be properly evaluated. Without proper evaluation, reports (such as the most recent report from the HSC suggesting that the vast majority of activities in the Implementation Plan have been completed)<sup>166</sup> are not believable.



## **Reporting Under the Bush Administration Inconsistent**

The HSC voluntarily and initially reported activity completion status<sup>167</sup> to the public at six<sup>168</sup> and twelve months<sup>169</sup> after the Implementation Plan<sup>170</sup> was released. However, the HSC did not continue reporting on a periodic basis thereafter. The two-year status report was released in October 2008, five months after the two-year anniversary of the Plan's initial release.<sup>171</sup> DHS and other Federal Departments and agencies were not reporting their status publicly and independently. Therefore, the HSC should have continued doing so itself, every six months or even more frequently.

## **Federal Priority on Pandemic Influenza Preparedness Lowered**

The HSC attempted to allow the Federal Departments and agencies to manage their own pandemic influenza preparedness efforts in 2007. This was done because new leadership within the HSC believed that the Bush Administration had done its part to get this preparedness enterprise off the ground. However, the rest of the Executive Branch did not take up the mantle as expected by the HSC. Instead, the Federal Departments and agencies, including DHS and HHS, seem to have taken the lack of near-daily inquiries on the part of the White House as a cue to prioritize pandemic preparedness efforts lower than other activities about which the White House does continue to inquire. The non-Federal public and private sectors now believe that the Federal Departments and agencies have broken their commitments to preparing for pandemic influenza and helping the rest of the public and private sectors to get ready as well.<sup>172</sup> They are wondering whether they can and should keep up their own efforts.<sup>173</sup>

## **Example Set by Executive Branch Departments and Agencies Working Together Poor**

States, Territories, Tribes, and localities have developed their plans by drawing upon the input of a variety of non-Federal governmental personnel.<sup>174</sup> Further, their plans have often been developed by a number of different entities (not just public health or health care delivery).<sup>175</sup> It is clear that an influenza pandemic will require

cross-jurisdictional efforts<sup>176</sup> to address the Homeland and National Security emergency while caring for the ill and disposing of the dead.<sup>177</sup> It would have been easier for these non-Federal governmental agencies to have incorporated different partners had the same effort been occurring at the Federal level.<sup>178</sup> Even when some of this has occurred, the feeling is that coordination and cooperation are lacking.<sup>179</sup> As a result, non-Federal entities do not have a consistent example of the Federal government to follow.



# WHAT SHOULD BE DONE

## **ESTABLISH EFFECTIVE LEADERSHIP AND COORDINATION**

### **Restore White House Leadership of National Efforts to Get Ready for Pandemic Influenza**

The nature of planning for an influenza pandemic requires White House leadership.<sup>180</sup> Departmental self-management and interagency coordination by the rest of the Executive Branch has met with limited success during the Bush Administration.<sup>181</sup> In addition, the HSC experienced changes in key leadership positions<sup>182</sup> and incoming leaders set different priorities.<sup>183</sup> For example, the HSC Office of Health and Biodefense decided that preparedness for antibiotic-resistant anthrax, improvement of delivery mechanisms for antibiotics and other treatments to the public, and several other issues should take priority over the management pandemic influenza preparedness efforts by the HSC. The result was that the Federal Departments and agencies shifted their priorities as well, leading to a lower priority being placed overall by the entire Executive Branch on pandemic influenza preparedness efforts.<sup>184</sup> Worse, without anyone from the HSC pressing for the status of their activity completion, the Departments and agencies neglected to take their own initiative to report frequently.

As manager of the Executive Branch,<sup>185</sup> the responsibility for ensuring that the Federal Departments and agencies continue to prepare for pandemic influenza falls on the President. It is important to hold the Departments and agencies accountable for completing the activities they have been assigned<sup>186</sup> in order for the Nation to achieve full readiness. Authority to conduct certain activities can be delegated, but responsibility cannot. The new Administration has an opportunity to lead and revitalize National pandemic influenza preparedness efforts<sup>187</sup> by the Federal Departments and agencies,<sup>188</sup> as well as by the non-Federal sectors.

### **Report on a Consistent Basis**

There has been inconsistent reporting regarding the execution of the activities within the Implementation Plan during the Bush

Administration.<sup>189</sup> This began when the Implementation Plan was released in May 2006.<sup>190</sup> At the time, the HSC established a passive reporting system to keep track of Federal activity status. Unfortunately, members of the Executive Branch who reported to the HSC did so occasionally and inconsistently.

Subsequently, still in 2006, the HSC actively contacted the Departments and agencies on a near-daily basis for over a year. This enabled the HSC to produce and publicly release two more comprehensive reports providing the status of Federal efforts at six<sup>191</sup> and twelve months after the Implementation Plan was originally released.<sup>192</sup> However, after the second status report was released (late by two months) in July 2007, many Federal Departments and agencies reported less and less frequently to the HSC. The Bush Administration finally released another report providing the status of Federal efforts two years after the release of the Implementation Plan (late by five months) in October 2008.<sup>193</sup>

The Federal Departments and agencies should not need daily phone calls to report on a consistent basis to the Executive Office of the President. With the change in Administrations, there is an opportunity to renew efforts to achieve National pandemic influenza readiness.<sup>194</sup> Technology can also help the White House keep up-to-date with the activities of the Federal Departments and agencies through web-based reporting. The rate of reporting to the Executive Office of the President should at least exceed the current rates at which avian and other strains of influenza are spreading across the world. A process in which the White House can track activity completion in real-time will allow for greater transparency and accountability.<sup>195</sup>

### **Set Better Example at the Federal Level for Public Health, Safety, and Security Coordination**

The Federal government has done an admirable job of requiring the States and Territories to have different organizations at their level plan and work together, but the Federal Departments and agencies have not been held sufficiently



accountable for doing so themselves by the Bush Administration. Even within the Federal Departments and agencies, this has not occurred well, but it must if we are to save lives during a pandemic.<sup>196</sup>

The incoming Administration has an opportunity to foster better coordination within, between, and among Federal Departments and agencies to address the threat of pandemic influenza. For example, the Federal Emergency Management Agency must be required to work extensively with the Office of Health Affairs and the law enforcement elements within DHS. Also, CDC must be required to work more efficiently with Customs and Border Protection in DHS. These and other intra- and inter-organizational activities must occur in order for the Nation to become ready for pandemic influenza, bioterrorist incidents that present similarly, and the threats they present to public health, safety, and security.<sup>197</sup>

Although some emphasis has been placed on exercising the Departments and agencies together<sup>198</sup> with support from the National Exercise Program,<sup>199</sup> there has not been enough to-date.<sup>200</sup> Congress should mandate and fund a National, comprehensive, and annual exercise regarding pandemic influenza. Exercising at least annually would ensure that awareness of the disease and the need to be ready for it. This exercise should include public and private sector participation, as well as all levels of government. If these disparate entities cannot work together in the artificial exercise environment, they will do no better in real-world situations. DHS should sponsor this National exercise (the way it does the TOPOFF exercises).<sup>201</sup>

## **ADDRESS AND MEET KEY MEDICAL REQUIREMENTS**

### **Discuss the Most Difficult Topics Regarding Life and Death Medical Decisions and Their Consequences**

Conversations must occur in which key members of the medical community are made to understand the full impact of a pandemic and realistically discuss the changes in health care delivery and management that will necessarily have to occur.<sup>202</sup> Although the social consequences of a

pandemic have been recognized,<sup>203</sup> few practitioners have had the time or inclination to delve significantly into the meaning of those consequences.<sup>204</sup> How a community manages the limited resources it has or can get will determine how many people live.<sup>205</sup> Liability and discrimination concerns must be addressed in order to ensure this dialogue occurs.<sup>206</sup>

Federal intentions to facilitate discussions have not been realized, and the Federal government is not positioned to help every community in the country deal with the significant bioethical decisions that must be made while a pandemic is occurring.<sup>207</sup> Grants may be provided for the purpose of having discussions and making these decisions in advance. However, the argument can also be made against Federal funding at all, so communities do not feel that have to make decisions of a certain type just to get the money.

### **Reorient Approach to Health Care Delivery in the Case of Very Limited Resources**

If the potential numbers of ill are anywhere close to accurate, we can expect that our hospitals will not be able to hold them.<sup>208</sup> If the potential numbers are higher than have been predicted, we can expect that the entire health care system will be overwhelmed very quickly.<sup>209</sup> We must prepare the health care delivery community and those that will be pressed into delivering health care during an influenza pandemic now.

No one likes to contemplate decisions regarding the need to provide less than what is considered the best and most comprehensive level of care. However, situations arise during catastrophes, disasters, and some emergencies where such decisions must be made. Without a predetermined set of criteria for making these decisions, medical personnel will be forced to make on-the-spot decisions in stressful, chaotic, and disorienting circumstances. This can lead to extremely poor decisions, such as those which occurred at the New Orleans Medical Center in the aftermath of Hurricane Katrina by some hospital staff who decided to euthanize chronically ill patients who could not be transported.<sup>210</sup>

The approaches to health care delivery must be reoriented when overwhelming numbers are ill and resources are extremely limited.<sup>211</sup> The time



to learn how to make life-and-death decisions is not in the midst of such dire circumstances.<sup>212</sup> Nor is it a matter of adding a few more hours to standard medical and allied health curricula. Lastly, although some non-Federal entities have begun grappling with these issues, the establishment of a clearinghouse at/by HHS<sup>213</sup> is insufficient. The Federal government must undertake a comprehensive program for the facilitated discussion of the hard resource-constrained decisions that American health care deliverers rarely have to make.<sup>214</sup> Specifically, it must ensure that guidelines are developed regarding both altered standards of care and the level of crisis or emergency declaration that triggers the application of those standards. Lessons and approaches can be identified and learned from those health care delivery systems throughout the world that do not have enough resources.<sup>215</sup> Nations that have never had enough medical equipment, medications, and other resources may be better able to handle patients who fall prey to an influenza pandemic. The disease may just be another in a long line for which they do not have enough or any resources to address. The health care deliverers in these nations may well know better how to:

- Make tough decisions regarding resource allocation;
- Decide who lives and dies; and
- Deal with the guilt and grief that will ensue from those decisions.

Pandemic influenza has the potential to destroy the infrastructure throughout the world.<sup>216</sup> Now is the time to learn from other countries about delivering health care when resources are constrained or nonexistent, in advance of a disease that will serve as an unfortunate equalizer.

### **Identify and Activate Fast and Dependable Domestic Capacity to Produce Needed Pharmaceuticals**

The Federal government has at times recognized that there are some things that must be produced for security and defense purposes that do not ordinarily turn a profit. Pandemic influenza presents a situation in which the Federal government needs to address this market failure<sup>217</sup> and to foster the development of medical

treatments for the good of the country.<sup>218</sup> The Federal government has a number of choices, including but not limited to the following:

- Developing the necessary expertise within the Federal government that will allow it to create and produce what the Nation needs;
- Creating incentives and/or otherwise encouraging other organizations (such as pharmaceutical companies) to do so; and
- Creating a contractual enterprise that incorporates long-term commitments from the Federal government, some level of profit, and the ability to address numerous diseases for which pharmaceuticals are needed.

What the Federal government cannot continue to do is hope that the mechanisms it has employed thus far – Project BioShield<sup>219</sup> and the Biomedical Advanced Research and Development Authority (BARDA)<sup>220</sup> – will somehow increasingly entice the industry into entering this part of the security arena,<sup>221</sup> considering the uncertain profits and fear of liability.<sup>222</sup> Previous attempts via Project BioShield<sup>223</sup> and BARDA<sup>224</sup> to encourage the pharmaceutical industry must be assessed. If these attempts have not been successful and are not working, then the new Administration should – in consultation with the pharmaceutical industry, academia, and other potential producers – improve BARDA<sup>225</sup> and Project BioShield<sup>226</sup>

New approaches to vaccine research, development, production, and distribution must be developed and utilized to address the threat of pandemic influenza.<sup>227</sup> Such programs can be achieved through cooperative and coordinated efforts within DHS and HHS subordinate organizations from early research (at the National Institutes of Health),<sup>228</sup> development (via BARDA),<sup>229</sup> and procurement (via BioShield).<sup>230</sup>

## **EVALUATE AND UPDATE PLANS**

### **Update and Modify the National Strategy for Pandemic Influenza and its Implementation Plan**

No plan is perfect in its writing or execution. Further, the environment in which strategies and plans are created, as well as the circumstances they are designed to address vary over time.<sup>231</sup> With the change in Administrations, a review and



update of the National Strategy for Pandemic Influenza<sup>232</sup> and its Implementation Plan<sup>233</sup> is in order.<sup>234</sup> The review should include the following elements:

- Assessment of the current characterization of influenza variants, combination, and antigenic drift, as well as organizational affairs;
- Determination of how best to enhance and improve these and related documents quickly and efficiently; and
- Outreach to key stakeholders to ensure that trust and accuracy are maintained in the process.<sup>235</sup>

By doing so, the new Administration has the opportunity to build on previous efforts<sup>236</sup> and do some things better by:

- Including all relevant stakeholders;
- Setting more realistic deadlines;
- Estimating how much it will cost to carry out remaining, ongoing, and new action items,<sup>237</sup> and
- Working with Congress to hold the Departments and agencies accountable for fulfilling their responsibilities.<sup>238</sup>

### **Identify and Include Necessary Stakeholders in the Evaluation and Updating of the Implementation Plan**

All stakeholders necessary to the accomplishment of a particular goal or set of objectives must be identified and included in planning efforts.<sup>239</sup> Without the stakeholders responsible for carrying out critical activities or controlling mission-critical resources (necessary to the accomplishment of the goals or objectives),<sup>240</sup> the execution of these plans will be met with difficulty.<sup>241</sup> Therefore, it does not come as a surprise that there has been difficulty in fully executing the National Strategy for Pandemic Influenza<sup>242</sup> and its Implementation Plan.<sup>243</sup> The Bush Administration did not include a number of the stakeholders (including but not limited to those from the State, Territorial, Tribal, and local governments)<sup>244</sup> in its planning process.<sup>245</sup>

Given its preexisting ties to the community, and the emphasis it places on giving as many people as possible the opportunity to contribute to its endeavors,<sup>246</sup> the Obama Administration can

rectify this glaring weakness, gain the buy-in of key stakeholders, and support a more democratic and efficient preparedness process. The new Administration is ideally positioned – both organizationally and historically – to get the Nation ready for the next influenza pandemic.<sup>247</sup>

The activities described in the National Strategy for Pandemic Influenza<sup>248</sup> and its Implementation Plan<sup>249</sup> should be evaluated and revised with all key stakeholders included in this effort as well.<sup>250</sup> Additionally the Office of Management and Budget<sup>251</sup> should conduct evaluations that involve non-Federal public and private sectors participants.

### **Analyze and Comprehend How the National Strategies Interact**

It is necessary for National strategies, Presidential directives, and other policy and guidance documents to be analyzed in context with each other, identifying areas of overlap and synergy. It is not enough for the White House to review such documents for inconsistencies and contradictions. Our National leaders must recognize that:

- The execution of one strategy may affect the execution of another, at least in terms of resource allocation;
- Separate and disparate National strategies do not give any indication of which priorities found in one strategy take precedence over those found in others or when; and
- Efficiency and effectiveness in government begin with organized, well-aligned strategies that give birth to policies, missions, goals, objectives, and activities which work in concert when possible and do not work against each other.

In addition to analyzing the National strategies in this manner, there is a need to ensure that emergency management-, health-, and biodefense-related strategies (National, Federal, international, and transnational) interact efficiently. For example, the National Strategy for Pandemic Influenza<sup>252</sup> should not be out of sync with the National Response Framework,<sup>253</sup> National Health Security Strategy,<sup>254</sup> and the National Strategy for Public Health and Medical Readiness.<sup>255</sup> All members of the Executive Branch must realize that other subordinate and



peer entities are looking to these strategies for guidance in the absence of information specific to them. The White House should do everyone the favor of harmonizing – not just deconflicting – these strategies in advance of their release.

### **Understand How a Pandemic Could be Taken Advantage of by Terrorists and Plan Accordingly**

There has been a tendency by DHS as well as other members of the Intelligence Community to address different threats separately for a number of reasons, including that the requirements to do so can be very different and unique.<sup>256</sup> This separation may well prevent Homeland and National Security practitioners and operators from considering the use of avian and other influenza strains for terrorism, an event that could occur in a number of ways.

An enemy could take advantage of the next influenza pandemic to increase the force of an attack by combining the pandemic with intentionally-introduced diseases and epidemics.<sup>257</sup> An enemy could also take other actions to hasten the spread of strains of influenza that are thought to be harbingers of the pandemic. The intentional over-use of antivirals;<sup>258</sup> collocation of birds, pigs, and humans;<sup>259</sup> preventing the communication of health surveillance data;<sup>260</sup> and intentionally misrepresenting health surveillance data<sup>261</sup> are among the ways in which the spread of disease can be accelerated. It is also likely that terrorists would recognize that hospitals and other critical infrastructures would become even more appealing targets during a pandemic.

Instead of planning for pandemic influenza and terrorism (including but not limited to acts of biological terrorism) separately, DHS and other planners must at least consider the possibility of both occurring at the same time, and plan accordingly.<sup>262</sup> It is both insufficient and inefficient to plan for each as if they will always occur at different times.

### **Fill in the Federal Gap in Planning**

The biggest gap in planning for pandemic influenza has occurred at the Federal level. The HSC created a National Strategy<sup>263</sup> and

Implementation Plan for Pandemic Influenza.<sup>264</sup> HHS, DHS, and other Federal Departments and agencies required the States, Territories, Tribes, and localities applying for pandemic influenza grants to submit plans for review (the second iteration of that review having occurred in August 2008).<sup>265</sup> However, pandemic influenza planning seems not to have occurred significantly throughout the Federal government – or if it has, it is not apparent to the public.

If only those Federal Departments and agencies that have produced plans have posted them on Pandemicflu.gov,<sup>266</sup> then one must assume that the rest of the Federal government is not prepared for pandemic influenza, as preparedness must necessarily be the outcome of planning and their plans are missing. If this is not the case – if many Federal Departments and agencies have developed plans but not posted them publicly – then purposely withholding these plans prevents other agencies, the private sector, and the public from understanding what these Federal entities intend to do in advance of and during an influenza pandemic. This is particularly egregious for DHS in its role as coordinator for the Federal government.<sup>267</sup>

States, Territories, Tribes, localities, and private sector organizations often look to the Federal government for guidance. As it is now, these non-Federal entities can only look to the few Federal plans that have been posted,<sup>268</sup> grant guidance from those organizations that have put out grants,<sup>269</sup> and to the National Strategy<sup>270</sup> and its Implementation Plan<sup>271</sup> for clues as to what the Federal government should be doing and may be able to provide before, during, and after an influenza pandemic. This planning gap must be filled in order for Federal Departments and agencies to discharge the requirements of the National Strategy<sup>272</sup> and Plan,<sup>273</sup> and for non-Federal entities to better align their own efforts with those of the Federal government. Without filling this gap, the Nation cannot be prepared for an influenza pandemic.

### **Generate More than Grant Guidance for the Non-Federal Government**

The effective development of visions, mission statements, strategies, goals, objectives, and activities involves using a process that will allow



one to flow from the other. This ensures that completed activities roll up and accomplish goals, completed goals roll up and accomplish objectives, and accomplished objectives fulfill missions, visions, and overarching strategies.<sup>274</sup> Military planning and operations documents provide some of the best examples of how this can be done well.<sup>275</sup>

In the case of the National Strategy for Pandemic Influenza,<sup>276</sup> the White House did provide an overarching strategy, but neglected to fully articulate a vision<sup>277</sup> of what it wanted the end-state<sup>278</sup> to be. It generated an Implementation Plan<sup>279</sup> which used the three pillars within the Strategy<sup>280</sup> as goals, skipped objectives, and went directly to activities – activities to be undertaken almost entirely by the Federal government. Most of the Departments and agencies seem not to have picked up the ball and continued the planning process.<sup>281</sup>

A concerted thoughtful attempt must be made not only to include State, Territorial, Tribal, local, and private sector personnel in ongoing and future planning efforts – but also to better align Federal programs<sup>282</sup> and to translate the Strategy down to the tactical levels of all of our communities, considering public health, safety, and security personnel to be the troops on the ground. Those in the Executive Branch need to think beyond sharing strategy with each other and invite to the table those who will ultimately have to execute actions to save lives.<sup>283</sup>

Furthermore, before plans are issued and/or actions are assigned to State, Territorial, Tribal, local, and private sector organizations, the buy-in of these entities should be obtained.<sup>284</sup> It may be that these non-Federal entities initially reject such assignments due to lack of experience, data, or trust, but the dialogue must occur in which both sides are further educated.

### **Require Continuity of Operations Plans to Qualify for Federal Funds**

Information<sup>285</sup> and activities<sup>286</sup> regarding the need for continuity of operations planning for pandemic influenza have been provided by DHS, HHS, and others in the Federal government. However, many public and private sector organizations have

not created such plans, or exercised those that have been produced.<sup>287</sup>

The Federal government is capable of requiring businesses throughout the Nation to create, exercise, and eventually implement continuity of operations plans. It can require those organizations that receive any Federal funding (in the way of grants, contracts, or cooperative agreements) to already possess continuity of operations plans, with a passing review by the funding Federal organization of that plan within a specified timeframe after the award (if not before).

The security of our Nation depends on both the public and private sectors being ready for pandemic influenza.<sup>288</sup> Further, if the Nation's businesses and other organizations cannot continue to function during or after a pandemic, the Nation will cease to function.<sup>289</sup> The Federal government must add continuity of operations planning for pandemic influenza to the other requirements it puts in place for the receipt of Federal funds. Federal Departments and agencies also should set the example by developing their own continuity of operations plans if they have not done so already.

## **IMPROVE EARLY WARNING AND DETECTION**

### **Implement an Effective Public Awareness Campaign to Help Citizens**

Novel diseases (such as that which would cause pandemic influenza) will probably not be easily treatable with the pharmaceuticals currently available. Therefore, greater emphasis must be placed on non-pharmaceutical interventions. Much could be done to slow the spread of diseases of all kinds with improved and increased public education regarding personal health practices and the need for changes in social behaviors. Most everyone in the US knows to “stop, drop, and roll”<sup>290</sup> if they are on fire, and “click it or ticket” reminds them of the importance of using seat belts in vehicles.<sup>291</sup> This is due to effective public awareness campaigns.

Such campaigns should be employed to provide the public with information they can use to protect themselves, their families, and their communities against the spread of disease in general, and pandemic influenza in particular. Information on



the importance of having at least two weeks of food to allow for sheltering in place, simple personal health practices (such as proper hand washing and cough etiquette), the proper use of masks, effective social distancing (including decreased personal contact), the impact of lowering indoor air temperatures and humidity on the viability of organisms in the environment, the proper use of over-the-counter medications, and other useful practices must be provided to the public in advance of an influenza pandemic.

Preemptive public awareness campaigns should also inform the public as to how, where, and from whom they will receive information and instructions in the event of a biological crisis.<sup>292</sup> DHS and HHS should work together to communicate with the public in advance, during, and after an influenza pandemic.

### **Implement a Uniform Global Biological Surveillance Program to Provide Biological Warning of Incidents and Suspicious Events**

International biosurveillance that provides early detection and situational awareness is critical to controlling the spread of disease.<sup>293</sup> The US government should provide increased support to the World Health Organization in its efforts to establish effective biosurveillance activities worldwide. The US should also continue to engage in bilateral and multilateral agreements to share information that will allow for increased biosurveillance as well.

Our attempts at establishing biological surveillance systems have met with varying levels of success.<sup>294</sup> As a result, we do not have a functioning efficient global biological surveillance system. Instead of waiting for people to get very sick and/or die before we know an outbreak is occurring, we can identify and monitor certain groups of US personnel throughout the world on a continuing basis.

The US has governmental personnel (including but not limited to public health, foreign service, homeland security, intelligence, law enforcement, and military personnel) assigned to various locations, domestically and internationally. Our embassies, consulates, and diplomatic missions throughout the world have regular direct communications back to the Department of State

Operations Center<sup>295</sup> and the Diplomatic Security Command Center in the US.<sup>296</sup> Different types of data are already sent back to these Centers, monitored, and reported.<sup>297</sup>

The same types of information systems can be emplaced in our Federal buildings here in the US. Information from these systems can come to DHS via the Federal Protective Service (which is responsible for our Federal buildings). To be most effective, systems emplaced in Federal buildings throughout the Nation should be established and resourced similarly to the levels provided by the Diplomatic Security Service. Both should also be sufficiently similar as to allow for efficient data comparison, combination, and analysis.

Medical personnel (who are trained to recognize and diagnose diseases and other health conditions) are often assigned and present in these Federal buildings.<sup>298</sup> Additionally, public health personnel (who are trained to recognize when significant numbers of people are affected by disease and other health conditions) are sometimes assigned and present in Federal buildings.<sup>299</sup> Overseas, the State Department has Foreign Service regional medical officers and other health professionals positioned throughout the world to support diplomatic missions and activities<sup>300</sup> (but these seem to be disconnected from other overseas personnel, such as those from the CDC, which could result in the false assumption that the CDC and other organizations will be aware of what is happening in various international localities and alert the State Department). Chief Public Health Officers should be instituted throughout the Federal Departments and agencies, but particularly in any security or intelligence organization that is already conducting biosurveillance or would potentially gather or otherwise obtain information regarding diseases and other health conditions.

We can create a uniform global biosurveillance program to provide Biological Warning of Incidents and Suspicious Events (BioWISE) that will serve to provide a much more relevant, real-time, and global picture of disease and health conditions that could affect our security by:



- Mirroring the State Department's system here in the US;
- Adding needed resources to both systems (such as public health professionals who by profession analyze population health data via epidemiology and biostatistics, as opposed to medical personnel who do not have this training or education); and
- Combining these National and international systems.

Congress should mandate and support BioWISE, and require that information from it be provided to NBIC.

Other efforts to establish global biosurveillance must continue, of course. But we can no longer hope that these systems will be in place and able to pick up on the beginning of an influenza pandemic as it occurs. The specter of the disease is forcing us to think far differently than we have before. We must utilize old and new methods for biosurveillance until the comprehensive and linked biosurveillance systems we are building now can be made to function and provide truly advanced warning before large numbers of people become sick and die, affecting our Homeland and National Security.



# CONCLUSION

The Committee on Homeland Security continues to examine the issue of preparedness for pandemic influenza and bioterrorist events that present similarly because such events would affect all public and social infrastructures, directly impacting our Homeland<sup>301</sup> and National Security.<sup>302</sup> As the Committee exercises oversight<sup>303</sup> and jurisdiction over DHS<sup>304</sup> and the Federal Departments and agencies which interact with DHS<sup>305</sup> to address pandemic influenza, it is interested in:

- Preventing the spread of the disease as soon as possible after the new influenza variant causing it arises;
- Deterring its use for biological terrorism;
- Preparing for the pandemic;
- Detecting the pandemic quickly;
- Responding to the devastating impact of the pandemic;
- Recovering from the pandemic; and
- Mitigating the impact of such a disease the next time a pandemic occurs.

With the change in Administrations, there is an opportunity to renew Federal efforts to protect our country against all enemies, foreign and domestic. These enemies include infectious diseases such as pandemic influenza<sup>306</sup> – an enemy perhaps more fearsome than any human adversary.

This is a threat of which we are already aware. We know that a new strain of influenza will cause the pandemic. We know we are overdue for such a pandemic.<sup>307</sup> We are watching already virulent strains move across and around the world. No military force would rest knowing that it was not yet ready to fight the enemy that it knew was advancing to attack. Neither should we rest, having only become better prepared.

We can get beyond getting ready for pandemic influenza. We must get beyond getting ready and actually be ready.<sup>308</sup> This report identified weaknesses that can be strengthened, and activities that can be undertaken that will help achieve this goal. But as has been learned from executing the Implementation Plan for the National Strategy for Pandemic Influenza,<sup>309</sup>

it will take more than checking things off a list. Achieving National readiness for pandemic influenza will require:

- Strong leadership from the White House;
- Continued tough oversight from Congress;
- Courage to talk about horrifying circumstances and seemingly impossible decisions; and the
- Drive to make every effort to do what we can now to save as many lives as possible in the future.

We owe it to the citizens of our great Nation and of the world to stand ready to fight pandemic influenza when it occurs.



## ENDNOTES

- <sup>1</sup> “In the past 100 years, we have seen three pandemics – in 1918, 1957 and 1968.” American Public Health Association. Get the Facts: Pandemic Flu, p. 1. See: <http://www.apha.org/NR/rdonlyres/A12756DD-5FB1-4CDD-8746-C9F3B1099686/0/PandemicFlu.pdf>.
- <sup>2</sup> “We’re overdue for another pandemic. It’s not a question of if, but when.” American Public Health Association. Get the Facts: Pandemic Flu, p. 1. See: <http://www.apha.org/NR/rdonlyres/A12756DD-5FB1-4CDD-8746-C9F3B1099686/0/PandemicFlu.pdf>.
- <sup>3</sup> See global and country maps for avian influenza: <http://gamapserver.who.int/mapLibrary/app/searchResults.aspx>.
- <sup>4</sup> World Health Organization. (2008, September 10). Cumulative Number of Confirmed Human Cases of Avian Influenza A/H5N1 Report to WHO. See [http://www.who.int/csr/disease/avian\\_influenza/country/cases\\_table\\_2008\\_09\\_10/en/index.html](http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_09_10/en/index.html).
- <sup>5</sup> “An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous numbers of deaths and illness.” World Health Organization. Pandemic Preparedness: consequences of an influenza pandemic. See: <http://www.who.int/csr/disease/influenza/pandemic/en/>.
- <sup>6</sup> World Health Organization. (2008, September 10). Cumulative Number of Confirmed Human Cases of Avian Influenza A/H5N1 Report to WHO. See [http://www.who.int/csr/disease/avian\\_influenza/country/cases\\_table\\_2008\\_09\\_10/en/index.html](http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_09_10/en/index.html).
- <sup>7</sup> “Current epidemiological models project that a pandemic could result in 2 to 7.4 million deaths globally.” World Health Organization. Pandemic Preparedness: consequences of an influenza pandemic. See: <http://www.who.int/csr/disease/influenza/pandemic/en/>.
- <sup>8</sup> “With the increase in global transport, as well as urbanization and overcrowded conditions, epidemics due the new influenza virus are likely to quickly take hold around the world.” World Health Organization. Pandemic Preparedness: consequences of an influenza pandemic. See: <http://www.who.int/csr/disease/influenza/pandemic/en/>.
- <sup>9</sup> “An especially severe influenza pandemic could lead to high levels of illness, death, social disruption, and economic loss. Everyday life would be disrupted because so many people in so many places become seriously ill at the same time. Impacts can range from school and business closings to the interruption of basic services such as public transportation and food delivery.” What Would Be the Impact of a Pandemic? See: <http://www.pandemicflu.gov/general/#impact>.
- <sup>10</sup> See [www.PandemicFlu.gov](http://www.PandemicFlu.gov).
- <sup>11</sup> “We’re overdue for another pandemic. It’s not a question of if, but when.” American Public Health Association. Get the Facts: Pandemic Flu, p. 1. See: <http://www.apha.org/NR/rdonlyres/A12756DD-5FB1-4CDD-8746-C9F3B1099686/0/PandemicFlu.pdf>.
- <sup>12</sup> “After a closed-door briefing led by Michael Leavitt, the Secretary of Health and Human Services (HHS), and other senior government health officials in late September, fear of an outbreak swept Washington.” Cooper S. (2005, October 11). Don’t Fear Fear or Panic Panic: an economist’s view of pandemic influenza, p. 2. See: [http://www.bmonesbittburns.com/economics/reports/20051011/dont\\_fear\\_fear.pdf](http://www.bmonesbittburns.com/economics/reports/20051011/dont_fear_fear.pdf).
- <sup>13</sup> “No one in the world today is fully prepared for a pandemic -- but we are better prepared today than we were yesterday...” Leavitt M. (2005, November). HHS Pandemic Influenza Plan, p. 1. See: <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>.
- <sup>14</sup> “The Federal government has never before said – when speaking about a naturally-occurring disease threat – that we will devote all instruments of National power to an effort to address the threat.” Staley KW. (2007, August 1). Remarks made at the *HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop*. Fairmont Hotel, Washington, DC. See: <http://nmr.rampard.com/phemce/20070731/day2.html>.
- <sup>15</sup> Regarding efforts to prepare for pandemic influenza, Mr. Ginaitt stated that “we need to get beyond getting ready.” House Committee on Homeland Security Staff Interview with Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. (2008, June 30).
- <sup>16</sup> “...Clearly still more needs to be done and we have to also work to get beyond getting ready and we have to actually be ready.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- <sup>17</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).
- <sup>18</sup> “Where this becomes an incident that has National significance, there is no question, the leadership resides with the Secretary of Homeland Security.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.



“...Biothreats have a broader impact in our society, both from a public health perspective and from the wider intersectoral perspective in economics, in transportation and energy, etc.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>19</sup> “Even when we focus just on our own country, the projected numbers are still staggering – 200,000 dead, two million ill, all sectors and every aspect of the infrastructure negatively impacted.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“...These issues [are] of critical importance to our Nation’s security and well-being.” Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“...Emerging biological threats such as pandemic influenza or weaponized anthrax, among other things...could affect every sector of society and every person potentially on a global scale.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>20</sup> Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>21</sup> Field hearing on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>22</sup> Member briefing on *Pandemic Influenza Preparedness*. (2008, September 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC.

<sup>23</sup> Homeland Security Council. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>24</sup> Homeland Security Council. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>25</sup> For more information, see <http://www.pandemicflu.gov>.

<sup>26</sup> For more information, see <https://www.llis.dhs.gov/index.do>.

<sup>27</sup> For information regarding which activities in the Implementation Plan for the National Strategy for Pandemic Influenza, see: <http://www.pandemicflu.gov/plan/federal/index.html>.

<sup>28</sup> For more information, see [www.pandemicflu.gov](http://www.pandemicflu.gov).

<sup>29</sup> “Ongoing challenges include...inadequate funding and resources...” Testimony provided by L. Anthony Cirillo, MD, Chief, Center for Emergency Preparedness and Response, RI Department of Health. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>30</sup> “Now we’ve established and added to Federal and State stockpiles of drugs and equipment, but we’re not ready yet. We’ve engaged in planning efforts, but we’re not ready yet. We’ve done a great deal of research on developing methods to get us new drugs and better treatments faster, but we’re not ready yet. And we’ve increased communications between public and private sector, but we’re not ready yet.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>31</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>32</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.



<sup>33</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>34</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>35</sup> "Using...historical information and current models of disease transmission, it is projected that a modern pandemic could lead to the deaths of 200,000 to 2 million people in the United States alone." Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza, p. 1. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>36</sup> "These next steps...have to be built upon the concept of shared responsibility." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>37</sup> "Overall, our community and families depend on us for leadership. They depend on us for competency, for guidance, but most importantly, for action. We should not and we cannot let them down." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>38</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>39</sup> "Now we've established and added to Federal and State stockpiles of drugs and equipment, but we're not ready yet. We've engaged in planning efforts, but we're not ready yet. We've done a great deal of research on developing methods to get us new drugs and better treatments faster, but we're not ready yet. And we've increased communications between public and private sector, but we're not ready yet." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>40</sup> "...Our strategic goal here, our theory of victory, is a delay of this disease spread and a reduction in the absolute number of individuals who will be affected by the disease." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>41</sup> "We must not back down from the fight against biological threats of any types whether naturally-occurring or intentionally-produced by a terrorist." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>42</sup> Strikas R. (2006, July 25). Remarks made at *Pandemics: Are We Prepared?* US Chamber of Commerce, Washington, DC. See: [http://www.uschamber.com/webcasts/2006/060725\\_Pandemics.htm](http://www.uschamber.com/webcasts/2006/060725_Pandemics.htm).

<sup>43</sup> The Department of Health, Education, and Welfare officially became the Department of Health and Human Services on May 4, 1980. Department of Health and Human Services. (2008, April 4). What is the History of HHS? See: <http://www.hhs.gov/faq/about/department/1894.html>.

<sup>44</sup> Remarks made by Ray Strikas, MD at *Pandemics: Are We Prepared?* (2006, July 25). U.S. Chamber of Commerce. See: [http://www.uschamber.com/webcasts/2006/060725\\_Pandemics.htm](http://www.uschamber.com/webcasts/2006/060725_Pandemics.htm).

<sup>45</sup> "An especially severe influenza pandemic could lead to high levels of illness, death, social disruption, and economic loss. Everyday life would be disrupted because so many people in so many places become seriously ill at the same time. Impacts can range from school and business closings to the interruption of basic services such as public transportation and food delivery." What Would Be the Impact of a Pandemic? See: <http://www.pandemicflu.gov/general/#impact>.

<sup>46</sup> "The Federal government has never before said – when speaking about a naturally-occurring disease threat – that we will devote all instruments of National power to an effort to address the threat." Staley KW. (2007, August 1). Remarks made at the *HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop*. Fairmont Hotel, Washington, DC. See: <http://nmr.rampard.com/phemce/20070731/day2.html>.

"...Public policies of this magnitude, duration and complexity require nothing less than central management and direction – by the White House staff." Patterson BH. (2000). *The White House Staff: Inside the West Wing and Beyond*. Washington, DC: Brookings Institution Press. p.273.

<sup>47</sup> The National Strategy for Pandemic Influenza is a very brief document, all of 12 pages in length. Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.



- <sup>48</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>49</sup> The Implementation Plan is composed of 324 action items. Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.
- <sup>50</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>51</sup> "Troubled by what he perceives as the din of advocacy in the bureaucracy, and not finding...enough sensitivity to his own personal goals and priorities, a president tends to rely for policy development less and less on his cabinet Departments and more and more on his White House staff." Patterson BH. (2000). *The White House Staff: Inside the West Wing and Beyond*. Washington, DC: Brookings Institution Press. p. 35.
- <sup>52</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>53</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.
- <sup>54</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.
- <sup>55</sup> Homeland Security Council, the White House. (2008, October). Implementation Plan Two Year Summary. See: <http://www.pandemicflu.gov/plan/federal/summaryprogress2008.html>.
- <sup>56</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).
- <sup>57</sup> House Committee on Homeland Security Staff Interview with Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. (2008, June 30).
- <sup>58</sup> House Committee on Homeland Security Staff Interview with Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. (2008, June 30).
- <sup>59</sup> Regarding efforts to prepare for pandemic influenza, Mr. Ginaitt stated that "we need to get beyond getting ready." House Committee on Homeland Security Staff Interview with Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. (2008, June 30).
- <sup>60</sup> "...Clearly still more needs to be done and we have to also work to get beyond getting ready and we have to actually be ready." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- <sup>61</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).
- <sup>62</sup> "...It's striking that...all hazard, all jurisdiction capability for biosurveillance falls in the context of our clinical public health relationship." Testimony provided by Daniel M. Sosin, MD, Associate Director for Science, Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, Atlanta, GA. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.
- <sup>63</sup> For example, even here in the U.S., more than 20% of the States do not possess adequate disease surveillance systems. Hayes H. (2008, January 2). Twelve States Lack CDC-compatible Disease Surveillance System. Government Health IT. See: <http://www.govhealthit.com/online/news/350157-1.html>.
- <sup>64</sup> For more information on SARS, see: <http://www.cdc.gov/ncidod/sars/>.
- <sup>65</sup> "China's measures to control the outbreak were 'by far not adequate' and...'certain departments have not done enough.' [Wen] conceded that China has not gathered accurate data, and that has hindered its effort to fight the disease." Nakashima E and Pomfret J. (2003, April 29). China's Leader Vows Truthful SARS Reporting. The Washington Post. See: <http://cmbi.bjmu.edu.cn/news/0304/210.htm>.
- <sup>66</sup> For more information on how different countries handled SARS in 2002 and later, see: <http://www.who.int/csr/sars/en/>.
- <sup>67</sup> World Health Organization. (2008, September 10). Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO. 245 deaths out of 387 cases = 63.3% mortality rate. See: [http://www.who.int/csr/disease/avian\\_influenza/country/cases\\_table\\_2008\\_09\\_10/en/index.html](http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_09_10/en/index.html).



<sup>68</sup> World Health Organization. (2008, September 23). H5N1 Avian Influenza: timeline of major events. See: [http://www.who.int/csr/disease/avian\\_influenza/Timeline\\_08%2009%2023.pdf](http://www.who.int/csr/disease/avian_influenza/Timeline_08%2009%2023.pdf).

<sup>69</sup> "Influenza viruses can change through antigenic drift, which is a process in which mutations to the virus genome produce changes in the viral H or N. Drift is a continuous ongoing process that results in the emergence of new strain variants. The amount of change can be subtle or dramatic, but eventually one of the new variant strains becomes dominant, usually for a few years, until a new variant emerges and replaces it. In essence, drift affects the influenza viruses that are already in worldwide circulation." Department of Health and Human Services. (2005, November 2). [HHS Pandemic Influenza Plan](#), p. B-4.

<sup>70</sup> "...The World Health Organization (WHO) supports an international laboratory-based surveillance network for influenza to detect the emergence and spread of new antigenic variants of influenza." Department of Health and Human Services. (2005, November 2). [HHS Pandemic Influenza Plan](#), p. G-51.

<sup>71</sup> For more information on BioSense, see: <http://www.cdc.gov/BioSense/>.

<sup>72</sup> For more information on BioPHusion, and how it relates to BioSense, see: [www.cdc.gov/biosense/files/BioSense\\_talk\\_3.19.ppt](http://www.cdc.gov/biosense/files/BioSense_talk_3.19.ppt).

<sup>73</sup> Office of the Inspector General, Department of Homeland Security. (2007, July). Better Management Needed for the National Bio-Surveillance Integration System Program, OIG-07-61. See: [http://www.dhs.gov/xoig/assets/mgmt/rpts/OIG\\_07-61\\_Jul07.pdf](http://www.dhs.gov/xoig/assets/mgmt/rpts/OIG_07-61_Jul07.pdf).

<sup>74</sup> Office of the Inspector General, Department of Homeland Security. (2007, July). Better Management Needed for the National Bio-Surveillance Integration System Program, OIG-07-61. See: [http://www.dhs.gov/xoig/assets/mgmt/rpts/OIG\\_07-61\\_Jul07.pdf](http://www.dhs.gov/xoig/assets/mgmt/rpts/OIG_07-61_Jul07.pdf).

<sup>75</sup> These 12 agencies are the: Department of Agriculture, Department of Commerce, Department of Defense, Department of Health and Human Services, Department of Homeland Security, Department of Interior, Department of Justice, Department of State, Department of Transportation, Department of Veterans Affairs, Environmental Protection Agency, and the US Postal Service.

"Currently, twelve Federal Member Agencies comprise the NBIS community...The NBIS community provides situational awareness through the acquisition, integration, analysis and dissemination of information from existing human disease, food, agriculture, water, meteorological, and environmental surveillance systems and relevant threat and intelligence information." Joint Statement of Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, Eric Myers, NBIC Director, and Jeffrey Stiefel, BioWatch Director, DHS Office of Health Affairs. Hearing on *One Year Later-Implementing the Biosurveillance Requirements of the 9/11 Act*. (2008, July 16). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. See: <http://homeland.house.gov/SiteDocuments/20080716143618-13187.pdf>.

<sup>76</sup> As of July 2008, the Departments of Agriculture, Defense, Health and Human Services, Interior, State, and Transportation have all executed MOUs with DHS, agreeing to participate in NBIC. The Departments of Commerce, Justice, and Veterans Affairs, as well as the Environmental Protection Agency and the US Postal Service, have not executed MOUs. (2008, July 16). Joint Statement of Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, Eric Myers, NBIC Director, and Jeffrey Stiefel, BioWatch Director, DHS Office of Health Affairs. Hearing on *One Year Later-Implementing the Biosurveillance Requirements of the 9/11 Act*. (2008, July 16). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. See: <http://homeland.house.gov/SiteDocuments/20080716143618-13187.pdf>.

Letters have been sent inquiring as to the status of outstanding MOUs and the reason for delay. Thompson, BG and Langevin JR. (2008, October 7). Letter to Alexander Lazaroff, Chief Postal Inspector, US Postal Service; letter to Carlos M. Gutierrez, Secretary, Department of Commerce; letter to James B. Peake, Secretary, Department of Veterans Affairs; letter to Michael B. Mukasey, Attorney General, Department of Justice; and letter to Stephen L. Johnson, Administrator, Environmental Protection Agency.

As of December 2008, the Department of Commerce and Department of Veterans Affairs have also executed its MOU. Electronic communication from Eric Myers, Director, National Biosurveillance Integration Center, Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, and Julie Schmidt, Program Analyst, Office of Health Affairs, Department of Homeland Security with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on 17 December, 2008. Electronic communication from Stephen Trynosky, Assistant Director, Office of Legislative and Intergovernmental Affairs, Department of Homeland Security with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on 22 December, 2008. Email messages on file with the Committee.

<sup>77</sup> As of December 2008, HHS has executed an ISA with NBIC regarding HHS/FDA ELEXNET. Electronic communication from Eric Myers, Director, National Biosurveillance Integration Center, Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, and Julie Schmidt, Program Analyst, Office of Health Affairs, Department of Homeland Security with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on 17 December, 2008. Email on file with the Committee.

<sup>78</sup> As of July 2008, "...NBIC and potential member agencies have finalized 6 of 11 MOUs; however, they have not finalized any ISAs or IAAs." Written testimony provided by William O. Jenkins, Director, Homeland Security and Justice Issues, Government Accountability Office. Hearing on *One Year Later-Implementing the Biosurveillance Requirements of the 9/11 Act*. (2008, July 16). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. See: <http://homeland.house.gov/SiteDocuments/20080716143642-97818.pdf>.

As of December 2008, HHS has completed an IAA. Electronic communication from Eric Myers, Director, National Biosurveillance Integration Center, Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, and Julie Schmidt, Program Analyst, Office of Health Affairs, Department of Homeland Security with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on 17 December, 2008. Email on file with the Committee.



<sup>79</sup> “As of July 2008, NBIC has been able to secure one detailee from a member agency.” Written testimony provided by William O. Jenkins, Director, Homeland Security and Justice Issues, Government Accountability Office. Hearing on *One Year Later-Implementing the Biosurveillance Requirements of the 9/11 Act*. (2008, July 16). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. See: <http://homeland.house.gov/SiteDocuments/20080716143642-97818.pdf>.

That detailee is from HHS. Electronic communication from Eric Myers, Director, National Biosurveillance Integration Center, Robert Hooks, Deputy Assistant Secretary for WMD and Biodefense, and Julie Schmidt, Program Analyst, Office of Health Affairs, Department of Homeland Security with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on 17 December, 2008. Email on file with the Committee.

<sup>80</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>81</sup> GAO is “...concerned that despite the fact that States, local, and Tribal entities will be on the front lines of the pandemic, these stakeholders were not directly involved in developing the [National] Strategy and the [Implementation] Plan.” Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“It makes no sense to develop a plan among Federal officials and then just tell the local officials how it is going to work without integrating them and involving them in the first place, and also including with the development those plans the understanding of how it is going to be implemented and carried out.” Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>82</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>83</sup> Briefings made to the association community and others by Rajeev Venkayya, MD, Special Assistant to the President, Homeland Security Council, in May 2006.

<sup>84</sup> “The Implementation Plan represents a comprehensive effort by the Federal Government to identify the critical steps that must be taken immediately and over the coming months and years to address the threat of an influenza pandemic. Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza, p. viii. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>85</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>86</sup> “Research designed to develop a vaccine against a pandemic strain could require the generation of a more virulent strain that could itself be used as a weapon of mass effect.” George AM. (2007, Winter). The Public Health Tesseract: Managing the Multiplicative Threat. *Minnesota Journal of Law, Science and Technology*, 8(1): p.240. See: [http://milst.umn.edu/pdfs/81\\_george.pdf](http://milst.umn.edu/pdfs/81_george.pdf)

<sup>87</sup> A particularly clear definition of bioterrorism is provided by the Arizona Department of Health Services, Division of Public Health Services, Bureau of Emergency Preparedness and Response. (2005, July 15). “Definition of bioterrorism: bioterrorism can be described as the use, or threatened use, of biological agents to promote or spread fear or intimidation upon an individual, a specific group, or the population as a whole for religious, political, ideological, financial, or personal purposes.” See: <http://www.azdhs.gov/phs/edc/edrp/es/bthistor1.htm>.

<sup>88</sup> National Security Council, the White House. (2006, September). National Strategy for Combating Terrorism. See: <http://www.whitehouse.gov/nsc/nsct/2006/nsct2006.pdf>.

<sup>89</sup> Homeland Security Council, the White House. (2007, October 5). National Strategy for Homeland Security. See: <http://www.whitehouse.gov/infocus/homeland/nshs/NSHS.pdf>

<sup>90</sup> The White House. (2003, February). National Strategy for the Physical Protection of Critical Infrastructure and Key Assets. See: [http://www.whitehouse.gov/pcipb/physical\\_strategy.pdf](http://www.whitehouse.gov/pcipb/physical_strategy.pdf).

<sup>91</sup> National Security Council, the White House. (2007, October). National Strategy for Information Sharing. See: [http://www.whitehouse.gov/nsc/infosharing/NSIS\\_book.pdf](http://www.whitehouse.gov/nsc/infosharing/NSIS_book.pdf).

<sup>92</sup> Conway M. (2004). Scenario Planning: an innovative approach to strategy development. Australian Association for Institutional Research. See: <http://www.aair.org.au/jir/2004Papers/CONWAY.pdf>.

<sup>93</sup> “I will tell you, it is very hard for this government to have a vision on anything. We are totally stove-piped, and we live within these compartments. This is not by way of a complaint. This is not by way of an excuse. It is by way of a fact,” Bodman SW as referenced in Weisman J. (2003, December 13). Bush Economic Aid Says Government Lacks Vision. *The Washington Post*, p. A-01. See: <http://www.ncpa.org/abo/quarterly/20034th/clips/dc200312113.htm>.

<sup>94</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.



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<sup>95</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>96</sup> For more information on HSPD 10, see: <http://www.whitehouse.gov/news/releases/2004/04/20040428-6.html>.

<sup>97</sup> For more information on HSPD 21, see: <http://www.whitehouse.gov/news/releases/2007/10/20071018-10.html>.

<sup>98</sup> U.S. Government. (2008, March 11). Federal Guidance to Assist States in Improving State-level Pandemic Influenza Operating Plans, p. 22. See: <http://www.pandemicflu.gov/news/guidance031108.pdf>.

<sup>99</sup> “The Federal government has issued some guidance in these and other areas, but we have not made enough headway.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>100</sup> An example of such guidance can be found in the program guidance for the FY 2006 Homeland Security Grant Program. Department of Homeland Security. (2005, December). See: <http://www.ojp.usdoj.gov/odp/docs/fy2006hsgp.pdf>.

<sup>101</sup> An example of such guidance can be found in Program Announcement AA154-FY2008 (Budget Period 9). Centers for Disease Control and Prevention. (2008, May 29). See: <http://emergency.cdc.gov/cotper/coopagreement/08/pdf/fy08announcement.pdf>.

<sup>102</sup> “...Shifting and evolving Federal grant priorities related to pandemic flu and overall public health preparedness...create inefficiencies in program management.” Testimony provided by L. Anthony Cirillo, MD, Chief, Center for Emergency Preparedness and Response, RI Department of Health. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>103</sup> “The Federal government has issued some guidance in these and other areas, but we have not made enough headway.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>104</sup> State Pandemic Plans. See: <http://www.pandemicflu.gov/plan/states/stateplans.html>.

<sup>105</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>106</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>107</sup> Federal Agency Pandemic Planning Implementation Plans. See: <http://www.pandemicflu.gov/plan/federal/index.html>.

<sup>108</sup> State Pandemic Plans. See: <http://www.pandemicflu.gov/plan/states/stateplans.html>.

<sup>109</sup> Department of Health and Human Services and the Centers for Disease Control and Prevention. (2005, December). State and local Pandemic Influenza Planning Checklist. See: <http://www.pandemicflu.gov/plan/pdf/checklist.pdf>.

<sup>110</sup> Department of Health and Human Services and the Centers for Disease Control and Prevention. (2005, December). State and local Pandemic Influenza Planning Checklist. See: <http://www.pandemicflu.gov/plan/pdf/checklist.pdf>.

<sup>111</sup> U.S. Government. (2008, March 11). Federal Guidance to Assist States in Improving State-level Pandemic Influenza Operating Plans, p. 22. See: <http://www.pandemicflu.gov/news/guidance031108.pdf>.

<sup>112</sup> Submissions were due on June 16, 2008. U.S. Government. (2008, March 11). Federal Guidance to Assist States in Improving State-level Pandemic Influenza Operating Plans, p. 22. See: <http://www.pandemicflu.gov/news/guidance031108.pdf>.

<sup>113</sup> Submissions were due on June 16, 2008. U.S. Government. (2008, March 11). Federal Guidance to Assist States in Improving State-level Pandemic Influenza Operating Plans, p. 22. See: <http://www.pandemicflu.gov/news/guidance031108.pdf>.

<sup>114</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>115</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>116</sup> “State, Territorial, Tribal and local entities have found themselves preparing for a pandemic without adequate funding, necessary resources, strategy-driven guidance or strong leadership.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on



Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>117</sup> An example of such guidance can be found in the program guidance for the FY 2006 Homeland Security Grant Program. Department of Homeland Security. (2005, December). See: <http://www.ojp.usdoj.gov/odp/docs/fy2006hsgp.pdf>.

<sup>118</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>119</sup> For example, "...We have been working for several years now on how do we respond as a State to this threat. We have also developed a more comprehensive 122-page guideline for pandemic influenza that outlines what we specifically need to do in each stage of the pandemic." Testimony provided by David L. Lakey, MD, Commissioner, TX Department of Health State Services, Austin, TX. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

State Pandemic Plans. See: <http://www.pandemicflu.gov/plan/states/stateplans.html>.

<sup>120</sup> GAO "...found that much more needs to be done to make sure that Federal leadership roles are clear..." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

Federal Agency Pandemic Planning Implementation Plans. See: <http://www.pandemicflu.gov/plan/federal/index.html>.

<sup>121</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>122</sup> For example, "The Federal Emergency Management Agency, in its biggest test since the bungled Hurricane Katrina relief effort in 2005, is getting better reviews for its response to Hurricane Ike in Texas. Despite some glitches, the agency received praise for more efficient coordination with state and local officials as well as a show of moxie after the storm." Bliss J. (2008, September 18). FEMA Gets Better Marks for Response to Ike After Katrina Fiasco. See: <http://www.bloomberg.com/apps/news?pid=20601087&sid=awOukwNJ2X80&refer=home>.

<sup>123</sup> U.S. Chamber of Commerce. Pandemic Planning. See: [http://www.uschamber.com/issues/index/defense/pandemic\\_influenza.htm](http://www.uschamber.com/issues/index/defense/pandemic_influenza.htm).

U.S. Chamber of Commerce. Pandemic Roundtables. See: [http://www.uschamber.com/issues/pandemic\\_roundtables.htm](http://www.uschamber.com/issues/pandemic_roundtables.htm).

<sup>124</sup> "We also are struggling with how do we continue our operations to make sure we have continuity of operation plans. In a situation where you have 30% or 40% of workers absent, how do we continue to keep government functional, businesses functional, utilities...provided?" Testimony provided by David L. Lakey, MD, Commissioner, TX Department of Health State Services, Austin, TX. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>125</sup> "The costs associated with influenza include direct healthcare costs, indirect costs such as lost productivity, and intangible cost of pain, grief and social disruption. In general, 'cost of illness' refers to all costs that are borne by society. This includes factors such as loss of productivity in the work force and loss of income by the patient, which results in a loss of tax revenues and an inability to purchase the goods and services that drive the economy. The important point is that everyone in society bears the cost - healthcare providers, patients, third-party payers, and business and industry." Solvay Pharmaceuticals. (2008, September 12). See: <http://www.solvay-influenza.com/aboutinfluenza/costofinfluenza/0,,2655-2-0,00.htm>.

<sup>126</sup> Brown D. (2006, May 2). Business Plan for Pandemic? Most Firms Haven't Prepared for Possibility of a Global Outbreak. *The Washington Post*, p.D-01. See: <http://www.washingtonpost.com/wp-dyn/content/article/2006/05/01/AR2006050101608.html>.

<sup>127</sup> "Few industries will be insulated from the economic effects resulting from absenteeism in the workplace or from the downstream effects stemming from supply-chain and travel disruption." U.S. Chamber of Commerce. See: [http://www.uschamber.com/issues/index/defense/pandemic\\_influenza.htm?n=tb](http://www.uschamber.com/issues/index/defense/pandemic_influenza.htm?n=tb).

<sup>128</sup> American Red Cross. (2003, February). Fact Sheet on Shelter-in-Place. See: <http://www.redcross.org/services/disaster/beprepared/shelterinplace.pdf>.

<sup>129</sup> Occupational Safety and Health Administration. (2007). Guidance on Preparing Workplaces for an Influenza Pandemic, 3327-02N, p.7. See: <http://www.osha.gov/Publications/OSHA3327pandemic.pdf>.

<sup>130</sup> "Few industries will be insulated from the economic effects resulting from absenteeism in the workplace or from the downstream effects stemming from supply-chain and travel disruption." U.S. Chamber of Commerce. See: [http://www.uschamber.com/issues/index/defense/pandemic\\_influenza.htm?n=tb](http://www.uschamber.com/issues/index/defense/pandemic_influenza.htm?n=tb).



<sup>131</sup> U.S. Chamber of Commerce. Pandemic Planning. See: [http://www.uschamber.com/issues/index/defense/pandemic\\_influenza.htm?n=tb](http://www.uschamber.com/issues/index/defense/pandemic_influenza.htm?n=tb).

<sup>132</sup> Business Executives for National Security. (2007, January). Getting Ready: company primer on preparedness and response planning for terrorist and bioterrorist attacks, p. 44-50. See: [http://www.bens.org/mis\\_support/Getting-Ready.pdf](http://www.bens.org/mis_support/Getting-Ready.pdf).

<sup>133</sup> Electronic communication from Ann M. Beauchesne, Vice President, National Security and Emergency Preparedness Department, U.S. Chamber of Commerce with Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security, on October 27, 2008. Email on file with the Committee.

<sup>134</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>135</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>136</sup> "Decision-making when lives are at stake is difficult at best especially when large numbers of people could be affected. I realize that there are certain decisions that no leader wants to make. But emergencies, disasters and catastrophes demand this of us." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>137</sup> "Altered standards of care need to also take into consideration and recognition that a reduction in the workforce will further complicate and compound the stresses in healthcare during major events. While identifying the needs of hospitals and the expected volumes of patients in both the clinical settings within the hospital, as well as the activation of an alternate care site, personnel will play a major role in the operational successes and/or failures of these types of events. It is estimated that staff reductions could reach upwards of 50 plus percent in the case of pandemic influenza." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>138</sup> Homeland Security Council, the White House. (2006, May). Chapter Five – Transportation and Borders, Implementation Plan for the National Strategy for Pandemic Influenza. See: [http://www.whitehouse.gov/homeland/nsipi\\_implementation\\_chap05.pdf](http://www.whitehouse.gov/homeland/nsipi_implementation_chap05.pdf).

<sup>139</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>140</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>141</sup> "Hospitals are our lifeline within this country and there are many concerns out there, especially when we deal with major events such as pandemic influenza." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>142</sup> "We also have to look at hospital surge capacity...This will be a major stress on the hospital system and the medical system during a pandemic." Testimony provided by David L. Lakey, MD, Commissioner, TX Department of Health State Services, Austin, TX. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

For example, "...in RI, the Station Night Club Fire served as an important event highlighting the need for improved coordination and management of surge capacity. In February 2003, the Station Night Club in West Warwick, RI caught fire with an estimated 400 persons attending a rock concert. Hundreds were sent or self-transported to area hospitals. The fast moving fire caused 100 fatalities, making it the fourth deadliest fire in United States history at the time. This tragic event provided RI with a real world mass casualty fatality response experience." Testimony provided by Thomas J. Kilday, Homeland Security Program Manager, RI Emergency Management Agency, Cranston, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"Hospitals around the State [of RI] have individually addressed their surge capacity plans and have acknowledged that they needed to build out additional resources." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>143</sup> "Hospitals are closing and if we're planning for huge service necessities, it would seem that that's not a very good idea. But they close not because they want to. They close because they don't – they can't pay their bills." Remarks made by Representative William J. Pascrell (D-NJ 8<sup>th</sup> District). Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*.



(2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"Trying to operate a major initiative and controlling and being ready for emergency preparedness while you're trying to pay for the very people that keep the doors open in that hospital, again is a daunting task." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>144</sup> "In a planning phase for any hazard where a mass casualty situation could exist it is imperative that the healthcare system remain functional and that the ability to deliver acceptable quality of care to preserve the greatest number of lives to be preserved. This philosophy is made more challenging with the need to allocate scarce resources in a manner that will optimize the saving of lives. The challenge, however, is the allocation of these resources in a fair, open, and transparent way while maintaining a safe, infection-free environment for the delivery of care." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>145</sup> Burkle FM. (2002). Mass Casualty Management of a Large-scale Bioterrorist Event: an epidemiological approach that shapes triage decisions. *Emergency Medicine Clinics of North America*, 20: 411. See: <http://www.dshs.state.tx.us/comp/epid/cdc05/burkle.pdf>.

<sup>146</sup> "Health care providers are not accustomed to having to allocate inadequate personnel, equipment and supplies on the scale they will confront in a pandemic." *Development of a Process to Address Ethical Issues and Altered Standards of Care in a Pandemic: Model for the Commonwealth of Virginia*, p. 4. See: <http://www.ama-assn.org/ama1/pub/upload/mm/415/virginia.pdf>.

<sup>147</sup> For example, "The hospital is the latest medical facility to close in Southern California. The closure of many community clinics and hospitals in recent years has left the region's health care system overburdened." Associated Press. (2008, August 23). "Troubled Century City Doctors Hospital Closing." *San Francisco Chronicle*, p. B-2.

<sup>148</sup> "I cringe a little bit about the word thousands, but it is something we're working towards." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>149</sup> "The challenge here is...we have an H5N1 vaccine that we know is safe and effective, but we don't know that that's the bug that we could be hit with..." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>150</sup> "...Pandemic influenza vaccine only can be developed once the pandemic virus is identified." Department of Health and Human Services. Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic. See: <http://aspe.hhs.gov/panflu/antiviraluse.html>.

"In the event of an influenza pandemic, it is currently highly unlikely that a well-matched vaccine, the best countermeasure, will be available when a pandemic begins." Testimony provided by Peter A Shult, PhD, Director, Communicable Diseases Division, WI State Laboratory of Hygiene, Madison, WI. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>151</sup> "...The next horizon we're looking for is can we develop a carrier that would allow you to vaccinate with a single vaccine for a wide variety of diseases, as opposed to have to give unique vaccines for each and every disease." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"In terms of universal vaccines, such as, for example, flu, we are still back at the conceptual stage, but that is a direction we are moving to...We think it will come down the way, but we are still some years away from even having something that we can move into development at this point in time, but it is a strategy and a concept that we are pushing on and moving forward on. And I think we will get there." Testimony provided by Michael G. Kurilla, MD, PhD, Director of the Office of Biodefense Research Affairs and Associate Director for Biodefense Product Development, National Institute of Allergy and Infectious Diseases, Bethesda, MD. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>152</sup> For example, "...Current National plans call for the initiation of drastic community mitigation measures augmented with distribution of limited antiviral supplies to impede the pandemic's progress." Testimony provided by Peter A Shult, PhD, Director, Communicable Diseases Division, WI State Laboratory of Hygiene, Madison, WI. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.



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For example, “one of the strategies in public health to respond – one of the cornerstones – is called social distancing, basically keeping individuals apart so they do not spread the disease one to another.” Testimony provided by David L. Lakey, MD, Commissioner, TX Department of Health State Services, Austin, TX. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>153</sup> Cell-culture technology could produce a vaccine in 12 weeks. Write PF. (2008, June 12). Vaccine Preparedness – Are We Ready for the Next Influenza Pandemic? *New England Journal of Medicine*, 358(24): 2541. See: <http://content.nejm.org/cgi/reprint/358/24/2540.pdf>.

<sup>154</sup> Egg-based technology could produce a vaccine in 22 weeks. Write PF. (2008, June 12). Vaccine Preparedness – Are We Ready for the Next Influenza Pandemic? *New England Journal of Medicine*, 358(24): 2541. See: <http://content.nejm.org/cgi/reprint/358/24/2540.pdf>.

<sup>155</sup> For more information on antivirals, see: <http://www.cdc.gov/flu/professionals/antivirals/>.

<sup>156</sup> “...since the lead time for new production is around 6 to 9 months, it will not be possible for Roche to respond immediately to a surge in demand by governments or corporations looking to purchase Tamiflu.” Roche. (2008, May). Preparing for the Next Influenza Pandemic: roles and responsibilities of Roche and other stakeholders, p. 3. See: [http://www.roche.com/sus\\_csoc-acc\\_influenza.pdf](http://www.roche.com/sus_csoc-acc_influenza.pdf).

<sup>157</sup> “The effectiveness of antivirals against a new pandemic influenza virus cannot be predicted..” Department of Health and Human Services. HHS Pandemic Influenza Plan, Supplement 7: Antiviral Drug Distribution and Use. See: <http://www.hhs.gov/pandemicflu/plan/sup7.html>.

<sup>158</sup> For example, “...The other point I would make is that antivirals are not the entire answer. We really want to be careful to make everyone understand that having an antiviral isn’t necessarily 100% curative or preventative. But in fact, it is incorporated into a wide range of strategies that don’t include pharmaceuticals...” Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>159</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>160</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>161</sup> GAO “...noted that there is no provision in the [Implementation] Plan for monitoring and reporting on progress and for updating the plan to reflect lessons learned from exercises or changes in leadership responsibilities or other policy decisions.” Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>162</sup> “The things that get measured are the things that get done.” LeBoeuf M. (1986). The Greatest Management Principle in the World for Anyone That Needs to Get Things Done.

<sup>163</sup> “One thing your Administration must do is start holding Federal agencies accountable for meeting their deadlines, rather than accommodating lackluster performance.” Thompson BG. (2007, December 12). Letter to the President of the United States from Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District), Chairman, Committee on Homeland Security, House of Representatives, U.S. Congress. See: <http://homeland.house.gov/SiteDocuments/20071212170121-76256.pdf>.

<sup>164</sup> “...It is appropriate to recognize that for the major challenges like a pandemic influenza that face the Nation that it does take the efforts of multiple departments and competencies. But how exactly that works still has to be figured out. That is why we argued so strongly for having tests and exercises. Only when you go through a simulation of an actual situation can those kinds of details be worked out. We understand it conceptually, but how it would work in practice we need to see.” Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>165</sup> An example of such an ongoing activity is 5.2.1, “Advance mechanisms for “real-time” clinical surveillance in domestic acute care settings such as emergency departments, intensive care units, and laboratories to provide local, State, and Federal public health officials with continuous awareness of the profile of illness in communities, and leverage all Federal medical capabilities, both domestic and international, in support of this objective.” Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza, p.89. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>166</sup> Homeland Security Council, the White House. (2008, October). Implementation Plan Two Year Summary. See: <http://www.pandemicflu.gov/plan/federal/summaryprogress2008.html>.

<sup>167</sup> “I think for some of the pain that’s been involved, [reporting has] been very helpful actually, for holding ourselves accountable for what we promised and also for helping the public at large understand what we’re doing...” Staley KW. (2007, August 1). Remarks made at the *HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop*. Fairmont Hotel, Washington, DC. See: <http://nrm.rampard.com/phemce/20070731/day2.html>.



<sup>168</sup> Homeland Security Council, the White House. (2006, December). National Strategy for Pandemic Influenza Implementation Plan: summary of progress. See: <http://www.pandemicflu.gov/plan/federal/strateryimplementationplan.html>.

<sup>169</sup> Homeland Security Council, the White House. (2007, July). National Strategy for Pandemic Influenza Implementation Plan One Year Summary. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html> and <http://www.pandemicflu.gov/plan/federal/summaryprogress2007.html>.

<sup>170</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>171</sup> Homeland Security Council, the White House. (2008, October). Implementation Plan Two Year Summary. See: <http://www.pandemicflu.gov/plan/federal/summaryprogress2008.html>.

<sup>172</sup> "This needs to be sustained. There has to be sustained commitment and consistent direction from the Federal level in order to ensure that these programs that have been developed continue." Testimony provided by David L. Lakey, MD, Commissioner, TX Department of Health State Services, Austin, TX. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>173</sup> For example, maintaining the capability for "...documentation of the emergence of a novel influenza virus and confirmation of sustained community transmission of the virus using highly specialized laboratory testing performed solely by a public health laboratory...and response readiness will be a challenge for the public health laboratory, given limited and now declining Federal support and a greatly expanded role, well beyond diagnostic testing, in emergency preparedness and response." Testimony provided by Peter A Shult, PhD, Director, Communicable Diseases Division, WI State Laboratory of Hygiene, Madison, WI. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"...Not only in my jurisdiction, but across the country, people are wondering, 'Well, should we go make the extra effort, or are we going to be stuck?'" Testimony provided by Michael C. Caldwell, MD, Commissioner, Duches County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"Funding cycles must be beyond a single year and progressive buildout of a system of resources and staff support must be clearly delineated. While grant funding is essential, working under unrealistic time parameters with the hope of an extension or face loss of grant funding is all too often counterproductive and often results in quick fixes. Multi-year funding, while federally problematic to manage is the only real answer to build the structural framework for system saving response." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"We've seen in the organization of DHS, it's shifted, clearly...over the years, and we've seen from the top down and now we are working with the regional focus where the regional planners are out in the community working with us out of FEMA Region 1 specifically, although we are concerned that the system will flex and change again and it takes a great deal of staff time to flex and change again and it takes away from program activities." Testimony provided by Thomas J. Kilday, Homeland Security Program Manager, RI Emergency Management Agency, Cranston, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>174</sup> For example, "health departments are planning, but the success of those plans relies on the crucial linkages that have been built between our local public health departments and a range of governmental and community partners at the local level, including also the State and the Federal level." Testimony provided by Michael C. Caldwell, MD, Commissioner, Duches County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>175</sup> For example, see the Pandemic Influenza Planning Membership list for RI. RI Department of Health. (2006, January 25). Pandemic Influenza Plan, p. 188-9. See: <http://www.health.ri.gov/pandemicflu/pandemicfluplan.pdf>.

<sup>176</sup> For example, local health departments are "...completing the ICS-300 training with colleagues from emergency response – police, fire, EMS, water plant operators, State emergency management officials, State troopers, public health nurses. We really have made progress in that arena." Testimony provided by Michael C. Caldwell, MD, Commissioner, Duches County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>177</sup> "...The opportunities in pandemic preparedness based on grant funding for pandemic really play out in overall all-hazards preparedness, giving public health, emergency management, security, law enforcement – all the elements that come to play in complex crises – an opportunity to sit down together and go through the scenarios, while mostly focused on pandemic in this case, allow them to get to know each other, get to know their various needs and the unique aspects of their roles, and help to coordinate those, and can only have benefits for other crises." Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats,



Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"Now when it comes to large-scale issues like diseases for which we have few or no treatments and which could sweep across the country and the world, it's clear that no one sector or entity is solely responsible for prevention, deterrence, preparedness, detection, response, recovery or mitigation. Different sectors must partners with each other and the kids of partnerships that we need to see between the Department of Homeland Security and the Department of Health and Human Services or the State Emergency Management Agency and the State Department of Health are critical." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>178</sup> "...We look to the Federal government to be able to serve as an example to us at the local level. If we see that there is miscommunication and mis-coordination at the Federal level, that impacts us at the local level and makes our jobs more difficult." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>179</sup> "Unfortunately, we have seen mixed messages from our Federal leadership. There does not appear to be adequate coordination or cooperation between the planners of [the Department of] Health and Human Services and the Department of Homeland Security." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"...We are much better prepared, however, we are not fully ready and part of that is because we still exist in our operational silos more than we reasonably should." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>180</sup> "...Public policies of this magnitude, duration and complexity require nothing less than central management and direction – by the White House staff." Patterson BH. (2000). *The White House Staff: Inside the West Wing and Beyond*. Washington, DC: Brookings Institution Press. p.273.

<sup>181</sup> The Bush Administration has "...set clear priorities, but no one in the White House has spent much time monitoring or coordinating their implementation." Adams G. (2008, June 30). Establishing the Next President's National Security Agenda: the role of the White House. *Bulletin of the Atomic Scientists*. See: <http://www.thebulletin.org/web-edition/columnists/gordon-adams/establishing-the-next-presidents-national-security-agenda-the-ro>.

<sup>182</sup> For example, the Homeland Security Advisor, the Deputy Homeland Security Advisor, and the Special Assistant to the President for Health and Biodefense (also part of the HSC) all experienced changeover within the last year.

<sup>183</sup> This is not unlike the National Security Council, where, "...the short-term takes precedent; tactics overwhelm strategy; and planning capabilities are thin." Adams G. (2008, June 30). Establishing the Next President's National Security Agenda: the role of the White House. *Bulletin of the Atomic Scientists*. See: <http://www.thebulletin.org/web-edition/columnists/gordon-adams/establishing-the-next-presidents-national-security-agenda-the-ro>.

<sup>184</sup> As indicated in testimony, Dr. Jeffrey W. Runge said that although preparing for pandemic influenza was necessary, the need to address the threat of bioterrorism using agents such as anthrax is a higher priority. "...It's the intentional use of biological agents by a terrorist or terrorist group that keeps me up at night." Testimony provided by Jeffrey W. Runge, MD, Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>185</sup> "Within the executive branch itself, the president has broad powers to manage national affairs and the workings of the federal government." U.S. Department of State. Outline of U.S. Government, Chapter 3 – The Executive Branch: Powers of the Presidency. See: <http://usinfo.state.gov/products/pubs/outusgov/ch3.htm>.

<sup>186</sup> "Within the executive branch itself, the president has broad powers to manage national affairs and the workings of the federal government." U.S. Department of State. Outline of U.S. Government, Chapter 3 – The Executive Branch: Powers of the Presidency. See: <http://usinfo.state.gov/products/pubs/outusgov/ch3.htm>.

<sup>187</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>188</sup> "Within the executive branch itself, the president has broad powers to manage national affairs and the workings of the federal government." U.S. Department of State. Outline of U.S. Government, Chapter 3 – The Executive Branch: Powers of the Presidency. See: <http://usinfo.state.gov/products/pubs/outusgov/ch3.htm>.



<sup>189</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>190</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>191</sup> Homeland Security Council, the White House. (2006, December). National Strategy for Pandemic Influenza Implementation Plan: summary of progress. See: <http://www.pandemicflu.gov/plan/federal/strateryimplementationplan.html>.

<sup>192</sup> Homeland Security Council, the White House. (2007, July). National Strategy for Pandemic Influenza Implementation Plan One Year Summary. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html> and <http://www.pandemicflu.gov/plan/federal/summaryprogress2007.html>.

<sup>193</sup> Homeland Security Council, the White House. (2008, October). Implementation Plan Two Year Summary. See: <http://www.pandemicflu.gov/plan/federal/summaryprogress2008.html>.

<sup>194</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>195</sup> "...Within the [Implementation] Plan there is no institutional process for updating it as new events unfold, as we learn from exercises and so on. There is no process to update the Plan or to monitor progress on a regular basis." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>196</sup> "Now when it comes to large-scale issues like diseases for which we have few or no treatments and which could sweep across the country and the world, it's clear that no one sector or entity is solely responsible for prevention, deterrence, preparedness, detection, response, recovery or mitigation. Different sectors must partners with each other and the kids of partnerships that we need to see between the Department of Homeland Security and the Department of Health and Human Services or the State Emergency Management Agency and the State Department of Health are critical." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>197</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>198</sup> "...On some of the larger exercise issues, we have plans within our Principal Federal Official group to exercise within that group and then lead that into a series of leadership level interagency exercises and to culminate in another cabinet-level exercise over a period of time as the schedule develops." Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>199</sup> "The purpose of the NEP is to test and evaluate the readiness of the national preparedness system to prevent, respond to, recover from, and mitigate against terrorist attacks, major disasters and other man-made emergencies. The scope of the NEP spans Federal, State, local, tribal, non-governmental and private sector efforts to design, implement, and evaluate exercises. The NEP does not supplant individual department and agency exercise programs; rather it is an overarching exercise program that unifies and links individual programs into a single, comprehensive effort. An effective NEP, coupled with a system for analysis of lessons learned and tracking of corrective actions, will improve the readiness and capabilities of all partners in the national preparedness system." Written statement submitted by John Bridges, Assistant Administrator of the National Integration Center, National Preparedness Directorate, Federal Emergency Management Agency. Member briefing held in Washington, DC on pandemic influenza. (2008, September 23). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC.

<sup>200</sup> Only four noteworthy pandemic influenza exercise initiatives that have occurred to-date: National Governors Association Pandemic Influenza Series (March – August 2007), FEMA Region I Pan-Ex (December 2007), Principal Level Exercise (February 20, 2008), and a DHS internal table-top exercise (October 28, 2008). Written statement submitted by John Bridges, Assistant Administrator of the National Integration Center, National Preparedness Directorate, Federal Emergency Management Agency. Member briefing held in Washington, DC on pandemic influenza. (2008, September 23). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC.

<sup>201</sup> For more information on DHS exercise activities, including the TOPOFF series, see: <http://www.ojp.usdoj.gov/odp/exercises.htm>.

<sup>202</sup> For example, "...this is now the opportunity to think about if we do have limited supplies, whether of antivirals or vaccines, if we were to have pandemic influenza in the nearer term, what sort of priorities are we going to set for distributing those supplies. That is, I think, a key question for us." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.



<sup>203</sup> "...Governments, international and regional organizations, and others have focused international attention on this global threat, which spans issues related to animal health, human health, and the broad range of economic and social consequences that would occur during a severe pandemic." Remarks made by U.S. Ambassador John E. Lange, Special Representative on Avian and Pandemic Influenza at Chatham House, London, United Kingdom. (2007, October 17). See: <http://www.state.gov/g/avianflu/93627.htm>.

<sup>204</sup> "...Although we recognize that difficult decisions will need to be made regarding the delivery of medical care, when resources are short, and patients number in the millions, we're not ready yet to make those decisions." Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>205</sup> "Although the challenge is formidable, our best chances of protecting health and maintaining functioning communities during a pandemic rely on optimal adherence to public health measures and a coordinated response within and between communities." Blendon RJ, Koonin LM, Benson JM, Cetron MS, Pollard WE, Mitchell EW, Weldon KJ and Herrmann MJ. (2008, May). Policy Review: Public Response to Community Mitigation Measures for Pandemic Influenza. *Emerging Infectious Diseases*,14(5): 785. See: <http://www.cdc.gov/eid/content/14/5/778.htm>.

<sup>206</sup> "NMAs should anticipate the different practice environments that may evolve during pandemic conditions and be prepared to discuss liability and related issues with health authorities and advise members on such issues." World Medical Association. (2006, October). The World Medical Association Statement on Avian and Pandemic Influenza, adopted by the WMA General Assembly, Pilanesberg, South Africa, October 2006. See: <http://www.wma.net/e/policy/a28.htm>.

"The prospects of allocation on this scale, understandably, cause profound concern within the health care community because such decisions are inextricably tied to liability. These providers understand that they have a duty to render care in accordance with the applicable standard of care or face liability for malpractice. "Altered" standards of care, which by definition do not meet the traditional standard of care, implicate and exacerbate these concerns. Providers in Virginia, both hospitals and physicians, expressed concerns about this very issue to VHHA. These concerns were so strong that, at the extreme, some providers were contemplating closing their doors during a pandemic instead of providing care under "altered" standards unless they had some degree of liability protection." Development of a Process to Address Ethical Issues and Altered Standards of Care in a Pandemic: Model for the Commonwealth of Virginia, p. 4. See: <http://www.ama-assn.org/ama1/pub/upload/mm/415/virginia.pdf>.

<sup>207</sup> "It will require community, State, regional and national activity and the GAO report I think was on target that now is the time people are ready and while we will not dictate from a Federal perspective, we can facilitate and provide guidelines for dealing with these issues." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>208</sup> "This degree of clinical care reduction will further stress the actual healthcare delivery system and will require that we operate under different ratios to care for people. The expectations for current standards of care, while we strive to achieve these expected levels, will most likely be stretched during these labor- and care-intensive periods while experiencing large staff reductions and increased patient numbers." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>209</sup> "...As I travel around the country and I hear from other hospitals that have surge capacity plans, they're very proud of the fact that they can take an additional 25 people in. I sit there and I look at the grand scene of what a major event could do to this picture, and I break out into a cold sweat as far as where our pandemic plans are going." Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>210</sup> Whorisky P and Skipp C. (2006, July 19). Three Arrested in New Orleans Hospital Deaths: Doctor, Two Nurses Charged with Second-Degree Murder. *The Washington Post*, p. A03. See: <http://www.washingtonpost.com/wp-dyn/content/article/2006/07/18/AR2006071800448.html>.

<sup>211</sup> "I understand when you're overwhelmed and the resources aren't there, the staff isn't there, it's not going to be tip-top medicine and the best of facilities..." Remarks made by Delegate Donna M. Christensen (D-VI At Large). Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"What we're talking about...is where you have too few assets, how will you reasonably and equitably consider your triage decisions in that reality? No physician wants to be in that position, but in fact, and indeed, this is a reality that will occur." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>212</sup> "What we're talking about...is where you have too few assets, how will you reasonably and equitably consider your triage decisions in that reality? No physician wants to be in that position, but in fact, and indeed, this is a reality that will occur....It's our view that communities really need to think that through ahead of time about how they will deal with those kinds of challenges. The answer of what constitutes equitability is an ethical



challenge that people at the community level really need to work though and answer.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>213</sup> The establishment of such a clearinghouse was recommended by GAO. Government Accountability Office. (2008, June). *Emergency Preparedness: States are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources*, p. 29. See: <http://www.gao.gov/new.items/d08668.pdf>.

<sup>214</sup> “It will require community, State, regional and national activity and the GAO report I think was on target that now is the time people are ready and while we will not dictate from a Federal perspective, we can facilitate and provide guidelines for dealing with these issues.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>215</sup> “Although many consider the public health infrastructures of third world countries to be inadequate, such countries may very well find themselves in better stead when it comes to dealing with pandemic influenza because they focus many of their public health efforts on combating epidemics from other diseases on an ongoing basis.” George AM. (2007, Winter). *The Public Health Tesseract: Managing the Multiplicative Threat*. *Minnesota Journal of Law, Science and Technology*, 8(1): p.243. See: [http://mjlst.umn.edu/pdfs/81\\_george.pdf](http://mjlst.umn.edu/pdfs/81_george.pdf).

<sup>216</sup> “...Localized disease outbreaks could overwhelm any country’s public health infrastructure, and pandemic influenza could overwhelm the public health infrastructure in every country around the world.” George AM. (2007, Winter). *The Public Health Tesseract: Managing the Multiplicative Threat*. *Minnesota Journal of Law, Science and Technology*, 8(1): p.243. See: [http://mjlst.umn.edu/pdfs/81\\_george.pdf](http://mjlst.umn.edu/pdfs/81_george.pdf).

<sup>217</sup> Market failure “...refers to a situation when a market left to itself does not allocate resources efficiently. Where market failures exist, there is a potential role for government to improve outcomes for the community, the environment, businesses and the economy.” New South Wales Government Department of Premier and Cabinet Better Regulation Office. (2008, April). *Guide to Better Regulation*, p.39. See: [http://www.betterregulation.nsw.gov.au/\\_data/assets/pdf\\_file/0009/16848/01\\_Better\\_Regulation\\_eGuide\\_April\\_2008.pdf](http://www.betterregulation.nsw.gov.au/_data/assets/pdf_file/0009/16848/01_Better_Regulation_eGuide_April_2008.pdf).

<sup>218</sup> For example, “...There’s a limited amount of advanced development NIH can do. They’re in the research business. They can take the development to a certain point...[then they]...have to...give it up at that point. Either the industry and venture capital pick it up or not.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

For example, “...At NIH we are not, and do not intend to be, a commercial manufacturer, distributor of products. And so the products that we develop to a certain point in the pathway towards licensure I have to hand off to a customer.” Testimony provided by Michael G. Kurilla, MD, PhD, Director of the Office of Biodefense Research Affairs and Associate Director for Biodefense Product Development, National Institute of Allergy and Infectious Diseases, Bethesda, MD. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>219</sup> For more information on Project BioShield, see: <http://www.whitehouse.gov/infocus/bioshield/>.

Government Accountability Office. (2007, October). *Project BioShield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine*. See: <http://www.gao.gov/new.items/d0888.pdf>.

<sup>220</sup> For more information on BARDA, see: <http://www.hhs.gov/aspr/barda/index.html>.

<sup>221</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>222</sup> “...The lure of billions did little to attract private investment by pharmaceutical firms. The prospect of liability suits and uncertain profits were two main factors in the lack of interest.” Henry L. Stimson Center. (2007, May 30). *Project BioShield*. See: <http://www.stimson.org/cnp/?SN=CT200705111255#text2>.

<sup>223</sup> For more information on Project BioShield, see: <http://www.whitehouse.gov/infocus/bioshield/>.

<sup>224</sup> For more information on BARDA, see: <http://www.hhs.gov/aspr/barda/index.html>.

<sup>225</sup> For more information on BARDA, see: <http://www.hhs.gov/aspr/barda/index.html>.

<sup>226</sup> For more information on Project BioShield, see: <http://www.whitehouse.gov/infocus/bioshield/>.

<sup>227</sup> For example, it has been recommended that, “The US develop a Pandemic Vaccine Research and Development Master Plan to systemize and greatly enhance the current US and international vaccine research and development strategies, bringing together the knowledge of government and private industry scientists. The program would provide a comprehensive approach to vaccine development, production, and delivery.” Trust for



America's Health and the Infectious Disease Society of America. (2006, October 4). Experts Warn Nation's Pandemic Flu Preparedness Not Keeping Pace with Advancements in Science and Technology. See <http://healthyamericans.org/newsroom/releases/release100406.pdf>.

<sup>228</sup> For more information on pandemic influenza research at the National Institutes of Health, see: <http://www3.niaid.nih.gov/topics/Flu/Research/Pandemic/>.

<sup>229</sup> For more information on BARDA, see: <http://www.hhs.gov/aspr/barda/index.html>.

<sup>230</sup> For more information on Project BioShield, see: <http://www.whitehouse.gov/infocus/bioshield/>.

<sup>231</sup> "...Planning, preparation, resourcing and responding to a biological threat or other domestic incident is a continual process that must adapt to a complex and changing security environment." Testimony provided by Major General Robert T. Bray, RI Adjutant General and Commanding General RI National Guard, Cranston, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>232</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>233</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>234</sup> "Although the [Implementation] Plan did a good job in defining the problem and discussing constraints and challenges, it is missing some significant elements." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"...It is also now time for us to review and update what are the gaps that still persist and what are the challenges that are ahead." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>235</sup> "Trust in a policy process is as fragile as in a personal relationship; it doesn't take much to break it, and it takes a vigilant commitment to fair process to keep it strong." Patterson BH. (2000). *The White House Staff: Inside the West Wing and Beyond*. Washington, DC: Brookings Institution Press. p.273.

<sup>236</sup> "...It is also now time for us to review and update what are the gaps that still persist and what are the challenges that are ahead. Our belief is it should be built upon some of the success that has occurred." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>237</sup> "...In the National Strategy and [Implementation] Plan, there is no mention of the resources that are going to be required to carry out the plan. There are well over 300 action items in the Plan. Dr. Vanderwagen and Dr. Jolly mentioned earlier the vaccine program and supplemental appropriations. But there are many others that are called for in the Plan beyond those that are covered in the supplemental appropriations, and there is not even an estimate of what would be entailed. So that is one important gap. And certainly, from an oversight perspective, it is really critical." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"We did calculations in RI for a year-long pandemic in order to try and have enough medical equipment, supplies and to be able to provide some reimbursement to health care providers who would come and assist the State, and the price tag for that, for one year, was \$550 million...those were rough calculations, but that gives you some sense of the amount of money that it would take to really continue to deliver health care to...an increasingly sick and large number of patients." Testimony provided by L. Anthony Cirillo, MD, Chief, Center for Emergency Preparedness and Response, RI Department of Health. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>238</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>239</sup> "Experience has shown that inclusion of the full range of stakeholders is not only an essential pre-condition for successful participatory decision-making but also vital for promoting equity and social justice in urban governance. For example, when decisions are made, priorities set, and actions taken without involving those relevant stakeholders, the result is usually misguided strategies and inappropriate action plans which are badly (if at all) implemented and which have negative effects on the beneficiaries. and on the city at large. These approaches, which fail to properly involve stakeholders, have been widely proven to be unsustainable." United Nations Centre for Human Settlements (Habitat). (2001). Tools to Support Participatory Urban Decision Making. See: <http://www.serid.ait.ac.th/ump/html/st.htm>.



<sup>240</sup> "Ultimately, the local public health departments are the boots on the ground element of our Nation's disease system." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

It is "...imperative that every State and every local jurisdiction be adequately prepared to handle catastrophic events across the threat spectrum." Testimony provided by Jeffrey W. Runge, MD, Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>241</sup> "It makes no sense to develop a plan among Federal officials and then just tell the local officials how it is going to work without integrating them and involving them in the first place, and also including with the development those plans the understanding of how it is going to be implemented and carried out." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>242</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>243</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>244</sup> "...State and local and Tribal entities weren't involved in actually producing the [Implementation] Plan and preparing the Plan. They are responsible for close to 100 of the action items, either as the lead or in some sort of support capacity and yet they weren't consulted when the Plan was being developed." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>245</sup> "The Implementation Plan represents a comprehensive effort by the Federal Government to identify the critical steps that must be taken immediately and over the coming months and years to address the threat of an influenza pandemic. Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza, p. viii. See: <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>246</sup> "We want to ensure that we give the American people a "seat at the table" and that we receive the benefit of their feedback. Accordingly, any documents from official meetings with outside organizations will be posted on our website for people to review and comment on. In addition to presenting ideas as individuals at [www.change.gov](http://www.change.gov), the American people deserve a "seat at the table" as we receive input from organizations and make decisions." Podesta JD. Memorandum re: "Seat at the Table" Transparency Policy. (2008, December 4). For more information, see: [http://change.gov/open\\_government/yourseatatthetable](http://change.gov/open_government/yourseatatthetable).

<sup>247</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>248</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.

<sup>249</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

<sup>250</sup> GAO "...recommended that the Homeland Security Council establish a specific process and timeframe for updating the [Implementation] Plan, one that involves key non-Federal stakeholders and fills in other gaps that we identified." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

"...Resiliency...is built when you provide people with the opportunity to build tools and activities that will lead to control in the face of chaos in these kinds of events." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

"...Our shared responsibility demands that we reach out to our stakeholders at the State, local, family and individual level if we are going to move ahead with the new steps that remain to be addressed." Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>251</sup> For information on OMB and its responsibility for evaluation, see: <http://www.whitehouse.gov/omb/organization/role.html>.



- <sup>252</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>253</sup> Department of Homeland Security. (2008, January). National Response Framework. See: <http://www.fema.gov/pdf/emergency/nrf/nrf-core.pdf>.
- <sup>254</sup> PL 109-417: The Pandemic and All-Hazards Preparedness Act, 109<sup>th</sup> Congress. Section 103 National Health Security Strategy. See: <http://healthyamericans.org/reports/bioterror07/PAHPAPublicLaw.pdf>.
- <sup>255</sup> The White House. (2007, October 18). Homeland Security Presidential Directive/HSPD-21: National Strategy for Public Health and Medical Preparedness. See: <http://www.whitehouse.gov/news/releases/2007/10/print/20071018-10.html>.
- <sup>256</sup> "The public health community tends to manage population issues separately. For example, we separate bioterrorism from antibiotic-resistant tuberculosis from obesity from influenza, and so on. Understandably, this has occurred because the requirements for dealing with each of the many different public health issues can be complex and unique." George AM. (2007, Winter). The Public Health Tesseract: Managing the Multiplicative Threat. *Minnesota Journal of Law, Science and Technology*, 8(1): p.237. See: [http://mjlst.umn.edu/pdfs/81\\_george.pdf](http://mjlst.umn.edu/pdfs/81_george.pdf).
- <sup>257</sup> "...Naturally-occurring or human-generated biological or non-biological agents could be released while a pandemic is already underway." George AM. (2007, Winter). The Public Health Tesseract: Managing the Multiplicative Threat. *Minnesota Journal of Law, Science and Technology*, 8(1): p.239-41. See: [http://mjlst.umn.edu/pdfs/81\\_george.pdf](http://mjlst.umn.edu/pdfs/81_george.pdf).
- "The Homeland Security Council has created a chilling scenario of how terrorists could launch an anthrax attack in the United States—and the horrific chain of events that would follow... This scenario describes a single aerosol [anthrax] attack in one city delivered by a truck using a concealed improvised spraying device in a densely populated urban city with a significant commuter workforce... The situation in the hospitals will be complicated by the following facts: The release has occurred at the beginning of an unusually early influenza season and the prodromal [early] symptoms of inhalation anthrax are relatively non-specific." Graham B, Talent J, Allison G, Cleveland R, Rademaker S, Roemer T, Sherman W, Sokolski H, and Verma R. (2008, December). *World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*. New York: Vintage Books, p.5-6. See: [http://documents.scribd.com/docs/2ivtt0cj8sc0dz60yiu6.pdf?utm\\_source=PreventWMD&utm\\_medium=Nuclear\\_Risks&utm\\_campaign=pdf%2Bdownloads](http://documents.scribd.com/docs/2ivtt0cj8sc0dz60yiu6.pdf?utm_source=PreventWMD&utm_medium=Nuclear_Risks&utm_campaign=pdf%2Bdownloads).
- <sup>258</sup> Cyranoski D. (2005, June 22). China's Chicken Farmers Under Fire for Antiviral Abuse. *Nature* 435: 1009. See: <http://www.nature.com/drugdisc/news/articles/4351009a.html>.
- <sup>259</sup> Osterholm MT. (2005). Preparing for the Next Pandemic. *New England Journal of Medicine*, 352(1839): 1841-2. See: <http://content.nejm.org/cgi/content/full/352/18/1839>.
- <sup>260</sup> Ferguson NM, Fraser C, Donnelly CA, Ghani AC and Anderson RM. (2004). Public Health Risk from the Avian H5N1 Influenza Epidemic. *Science*, 304(5673): 968-9.
- <sup>261</sup> Sautédé E. (2003, May-June). The Snares of Modernity. *China Perspectives*, 47, see: <http://chinaperspectives.revues.org/document273.html.#ftn1>.
- <sup>262</sup> For example, the DHS has recognized that this may not always be the case, pre-identifying both National and regional Principle Federal Officials for Pandemic Influenza and Bioterrorism Events that Present Similarly. "Consistent with his role under Homeland Security Presidential Directive Five, Secretary Chertoff pre-designated Vice Admiral Vivien Crea, the vice commandant of the United States Coast Guard as the National Principal Federal Official, or PFO, for pandemic influenza, and has pre-designated five regional PFOs and 10 deputy PFOs." Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- <sup>263</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>264</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.
- <sup>265</sup> Submissions were due on June 16, 2008. U.S. Government. (2008, March 11). Federal Guidance to Assist States in Improving State-level Pandemic Influenza Operating Plans, p. 22. See: <http://www.pandemicflu.gov/news/guidance031108.pdf>.
- <sup>266</sup> Federal Agency Pandemic Planning Implementation Plans. See: <http://www.pandemicflu.gov/plan/federal/index.html>.
- <sup>267</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).
- <sup>268</sup> Federal Agency Pandemic Planning Implementation Plans. See: <http://www.pandemicflu.gov/plan/federal/index.html>.
- <sup>269</sup> An example of such guidance can be found in Program Announcement AA154-FY2008 (Budget Period 9). Centers for Disease Control and Prevention. (2008, May 29). See: <http://emergency.cdc.gov/cotper/coopagreement/08/pdf/fy08announcement.pdf>.



- <sup>270</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>271</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>
- <sup>272</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>273</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>
- <sup>274</sup> "At the core of capability is the need for clearly defined roles, missions and responsibilities." Testimony provided by Major General Robert T. Bray, RI Adjutant General and Commanding General RI National Guard, Cranston, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.
- <sup>275</sup> A good example is the Joint Operation Planning and Execution System. Joint Chiefs of Staff. (1995, May 1). Users Guide for JOPES. See: [http://www.dtic.mil/doctrine/jel/other\\_pubs/jopes.pdf](http://www.dtic.mil/doctrine/jel/other_pubs/jopes.pdf).
- <sup>276</sup> Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>277</sup> "...A National strategy should provide a clear statement about what the nation hopes to achieve." Decker RJ. (2003, March 3). Combating Terrorism: observations on National strategies related to terrorism, GAO-03-519T. Government Accountability Office, p. 2. See: <http://www.iwar.org.uk/cyberterror/resources/gao/d03519t.pdf>.
- <sup>278</sup> "We must move towards a clear and understandable goal within the Federal government and support that goal with a plan of funding and implementation." Testimony provided by Peter T. Ginait, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.
- <sup>279</sup> Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.
- <sup>280</sup> The three pillars are: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment. Note that in the Strategy, these are not identified as goals. Instead, they are described as "strategic principles." Homeland Security Council, the White House. (2005, November). National Strategy for Pandemic Influenza, p. 3. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza.html>.
- <sup>281</sup> For the few Federal strategic plans for pandemic influenza that have been produced and posted publicly, see: <http://www.pandemicflu.gov/plan/federal/index.html#implementation>.
- <sup>282</sup> "...It is critical that all Federal preparedness programs related to a pandemic or other public health emergencies be more closely aligned and coordinated so that we at the State level can more effectively7 develop an appropriate response to all public health emergencies." Testimony provided by L. Anthony Cirillo, MD, Chief, Center for Emergency Preparedness and Response, RI Department of Health. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- <sup>283</sup> GAO is "...concerned that despite the fact that States, local, and Tribal entities will be on the front lines of the pandemic, these stakeholders were not directly involved in developing the [National] Strategy and the [Implementation] Plan." Testimony provided by Bernice Steinhardt, Director, Strategic Issues, Government Accountability Office. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- "It makes no sense to develop a plan among Federal officials and then just tell the local officials how it is going to work without integrating them and involving them in the first place, and also including with the development those plans the understanding of how it is going to be implemented and carried out." Testimony provided by Michael C. Caldwell, MD, Commissioner, Dutchess County Health Department, Poughkeepsie, NY. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.
- <sup>284</sup> "Experience has shown that inclusion of the full range of stakeholders is not only an essential pre-condition for successful participatory decision-making but also vital for promoting equity and social justice in urban governance. For example, when decisions are made, priorities set, and actions taken without involving those relevant stakeholders, the result is usually misguided strategies and inappropriate action plans which are badly (if at all) implemented and which have negative effects on the beneficiaries and on the city at large. These approaches, which fail to properly involve stakeholders, have been widely proven to be unsustainable." United Nations Centre for Human Settlements (Habitat). (2001). Tools to Support Participatory Urban Decision Making. See: <http://www.ser.d.ait.ac.th/ump/html/st.htm>.



<sup>285</sup> “Develop a plan to continue operations that anticipates, responds to, and supports voluntary or mandatory travel restrictions or cancellations, border restrictions, event restrictions, and quarantines.” Department of Health and Human Services and the Centers for Disease Control and Prevention. Travel Industry Pandemic Influenza Planning Checklist. See: <http://www.pandemicflu.gov/plan/workplaceplanning/travelchecklist.html#1>.

<sup>286</sup> For example, the Federal Emergency Management Agency has conducted exercises regarding continuity of operations planning. Federal Emergency Management Agency. (2006, September 22). *Determined Accord* Increases Pandemic Influenza Preparedness. See: <http://www.fema.gov/government/coop/pandemic.shtm>.

<sup>287</sup> “Most agencies have continuity-of-operations plans that explain how to carry on after a disaster. But few if any have such a plan tailored to the unique challenges posed by a pandemic.” Doolittle A. (2007, October 15). Ill Prepared. See: <http://www.federaltimes.com/index.php?S=3109974>.

<sup>288</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>289</sup> “Economic disruptions on the supply side would come directly from high absenteeism, as people may be asked to stay at home, or may choose to do so to care for sick relatives or because of fear of being exposed themselves. There may also be disruptions to transportation, trade, payment systems, and major utilities, exposing some financially vulnerable enterprises to the risk of bankruptcy. Moreover, demand could contract sharply, with consumer spending falling and investment being put on hold. Financial repercussions could further exacerbate the economic impact.” International Monetary Fund. (2006, February 28). *The Global Economic and Financial Impact of an Avian Flu Pandemic and the Role of the IMF*, p. 3. See: <http://www.imf.org/external/pubs/ft/a/p/2006/eng/022806.pdf>.

<sup>290</sup> The advice to stop, drop, and roll if on fire has become so pervasive that even children’s books are being written about it. For example, see: Cuyler M. (2001) *Stop, Drop, and Roll*. New York: Simon and Schuster.

<sup>291</sup> For more information on the “Click It or Ticket” campaign, see: <http://www.nhtsa.gov/portal/site/nhtsa/menuitem.ce4a601cdf97c239d17110cba046a0>.

<sup>292</sup> University of Pittsburg Medical Center. (2004). *Leading During Bioattacks and Epidemics with the Public’s Trust and Help: A Manual for Mayors, Governors, and Top Health Officials*. See: [http://www.upmc-biosecurity.org/website/resources/leadership/curriculum/leadership\\_manual.pdf](http://www.upmc-biosecurity.org/website/resources/leadership/curriculum/leadership_manual.pdf).

<sup>293</sup> Ostfield M. (2007, March 9). *Global Progress on Biosecurity: US Vision and International Efforts*. See: <http://www.state.gov/g/oes/rls/rm/2007/81611.htm>.

<sup>294</sup> “...With the advent of technology and health information exchanges, we should be able to have a much better surveillance process than is out there...We need a better system for symptoms early on.” Testimony provided by Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>295</sup> “The Operations Center (S/S-O) is the Secretary’s and the Department’s communications and crisis management center. Working 24 hours a day, the Operations Center monitors world events, prepares briefings for the Secretary and other Department principals, and facilitates communication between the Department and the rest of the world. The Operations Center also coordinates the Department’s response to crises and supports task forces, monitoring groups, and other crisis-related activities.” Department of State. Department Organization. See: <http://www.state.gov/r/pa/ei/rls/dos/436.htm>.

<sup>296</sup> “The Diplomatic Security Command Center operates 24-hours daily to monitor and report information regarding threats against U.S. diplomatic missions, the Secretary of State, and American citizens abroad. The Command Center’s staff coordinates information with the more than 265 U.S. diplomatic facilities Diplomatic Security protects worldwide.” Department of State. (2005, August 1). Diplomatic Security Command Center. See: <http://www.state.gov/m/ds/rls/50458.htm>.

<sup>297</sup> “The Diplomatic Security Command Center operates 24-hours daily to monitor and report information regarding threats against U.S. diplomatic missions, the Secretary of State, and American citizens abroad. The Command Center’s staff coordinates information with the more than 265 U.S. diplomatic facilities Diplomatic Security protects worldwide.” Department of State. (2005, August 1). Diplomatic Security Command Center. See: <http://www.state.gov/m/ds/rls/50458.htm>.

<sup>298</sup> For example, there are medical personnel located throughout the buildings utilized by Congress in the offices of the Capitol Physician. Other personnel may be in Federal offices dedicated to occupational health and safety, medical control, health policy, etc.

<sup>299</sup> For example, public health personnel are detailed to the DHS National Operations Center.

<sup>300</sup> For more information on Foreign Service Regional Medical Officers, see: <http://careers.state.gov/specialist/opportunities/medoff.html>.

<sup>301</sup> “Where this becomes an incident that has National significance, there is no question, the leadership resides with the Secretary of Homeland Security.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“...Biothreats have a broader impact in our society, both from a public health perspective and from the wider intersectoral perspective in economics, in transportation and energy, etc.” Testimony provided by W. Craig Vanderwagen, MD, Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness*:



*Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>302</sup> Even when we focus just on our own country, the projected numbers are still staggering – 200,000 dead, two million ill, all sectors and every aspect of the infrastructure negatively impacted.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“...These issues [are] of critical importance to our Nation’s security and well-being.” Testimony provided by B. Tilman Jolly, MD, Associate Chief Medical Officer, Department of Homeland Security. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

“...Emerging biological threats such as pandemic influenza or weaponized anthrax, among other things...could affect every sector of society and every person potentially on a global scale.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>303</sup> “Oversight sometimes is obviously...difficult, painful sometimes for those on the other side of the table to go through, but it’s an important part of being able to evaluate where we are and where we want to get to.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Field hearing held in Providence, RI on *Emerging Biological Threats and Public Health Preparedness: Getting Beyond Getting Ready*. (2008, July 22). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=159>.

<sup>304</sup> House of Representatives. (2008, March 11). Rules of the House of Representatives 110<sup>th</sup> Congress, p. 7. See: <http://www.rules.house.gov/ruleprec/110th.pdf>.

<sup>305</sup> “The Committee on Homeland Security shall review and study on a continuing basis all Government activities relating to homeland security, including the interaction of all departments and agencies with the Department of Homeland Security. (2008, March 11). Rules of the House of Representatives 110<sup>th</sup> Congress, p. 9. See: <http://www.rules.house.gov/ruleprec/110th.pdf>.

<sup>306</sup> Interview with Representative Bennie G. Thompson (D-MS 2<sup>nd</sup> District) by Asha M. George, DrPH, Senior Professional Staff (Democratic Majority), House Committee on Homeland Security at the Rayburn House Office Building, Washington, DC. (2008, December 10).

<sup>307</sup> “We’re overdue for another pandemic. It’s not a question of if, but when.” American Public Health Association. Get the Facts: Pandemic Flu, p. 1. See: <http://www.apha.org/NR/rdonlyres/A12756DD-5FB1-4CDD-8746-C9F3B1099686/0/PandemicFlu.pdf>.

<sup>308</sup> Regarding efforts to prepare for pandemic influenza, Mr. Ginaitt stated that “we need to get beyond getting ready.” House Committee on Homeland Security Staff Interview with Peter T. Ginaitt, Director, Emergency Preparedness, Lifespan Hospital Network, Providence, RI. (2008, June 30).

“...Clearly still more needs to be done and we have to also work to get beyond getting ready and we have to actually be ready.” Remarks made by Representative James Langevin (D-RI 2<sup>nd</sup> District), Chairman, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, House of Representatives, U.S. Congress. Hearing on *Beyond the Checklist: Addressing Shortfalls in National Pandemic Influenza Preparedness*. (2007, September 27). House of Representatives, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, Committee on Homeland Security, Washington, DC. For more information, see: <http://homeland.house.gov/Hearings/index.asp?ID=89>.

<sup>309</sup> The Implementation Plan is composed of 324 action items. Homeland Security Council, the White House. (2006, May). Implementation Plan for the National Strategy for Pandemic Influenza. Available at <http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html>.

