

# Avian Flu: The Consumer Costs of Preparing for Global Pandemic

By Joseph Nicosia III\*

## Introduction

The year 1918 is most commonly known for marking the end of World War I, a brutal four years in world history that accounted for the loss of over 10 million lives in combat.<sup>1</sup> While this number serves as a tragic reminder of the costs of human conflict, it is modest when compared to the estimated 20 to 40 million people that lost their lives as a direct result of the 1918 Spanish Influenza.<sup>2</sup> Today scientists find themselves fearful of another vicious strain of flu designated as H5N1, commonly known as the Avian Flu.<sup>3</sup>

According to the United States Government's official web site for information on pandemic flu and Avian Influenza, a pandemic is defined as a global disease outbreak.<sup>4</sup> A flu pandemic occurs when a new influenza virus surfaces for which people have little or no immunity and for which there is no known vaccine.<sup>5</sup> In the case of a pandemic, the disease usually spreads easily from person to person

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\* Joseph Nicosia III, J.D. candidate, May 2007, Loyola University Chicago School of Law; B.A. in Finance, summa cum laude, Boston College, 2004. The author would like to extend his gratitude to family and friends for their unyielding support and encouragement, as well as the faculty and students at Loyola University Chicago.

<sup>1</sup> Kristin Choo, *The Avian Flu Time Bomb*, A.B.A. J., Nov. 2005, at 36.

<sup>2</sup> PandemicFlu.gov, Pandemics & Pandemics Threats Since 1900, <http://www.pandemicflu.gov/general/historicaloverview.html> [hereinafter PandemicFlu.gov Historical Overview] (last visited Mar. 25, 2006). PandemicFlu.gov is an official U.S. government web site managed by the U.S. Department of Health & Human Services. *Id.*

<sup>3</sup> Choo, *supra* note 1, at 36.

<sup>4</sup> PandemicFlu.gov, General Information, <http://www.pandemicflu.gov/general/> (last visited Apr. 16, 2006).

<sup>5</sup> *Id.*

causing serious and often fatal illness.<sup>6</sup> Depending upon its ferocity, a pandemic can sweep across the globe with remarkable swiftness without regard to political, geographic, or cultural boundaries.<sup>7</sup>

While world governments may enact a variety of countermeasures to combat the threat of a flu pandemic in attempts to minimize its consequences, they cannot stop it from happening. Even if the current Avian Influenza strain does not materialize into a global pandemic, there is a strong likelihood that another deadly virus is likely to emerge in the next decade.<sup>8</sup> The threat of such a pandemic raises a laundry list of unanswered questions, including the management and enforcement of quarantine zones, forced medical treatment and vaccination, equal access to medicine, and the ability to pursue causes of action relating to injuries sustained from medical treatment and vaccination.<sup>9</sup> This article will not attempt to undertake the Herculean task of examining the legality of all current and proposed legislation on these issues. Instead, it will focus on the impact that such legislation will exact on health care consumers in the midst of a global pandemic and offer suggestions on how best to mitigate these effects.

## **I. Global Pandemics in the Modern Era**

Since 1900 three actual pandemics and numerous pandemic threats have occurred.<sup>10</sup> The first and most catastrophic of these pandemics was the 1918 Spanish Influenza, or “Spanish Flu”.<sup>11</sup> The Spanish Flu is the measuring stick against which all other modern pandemics are assessed.<sup>12</sup> It is estimated that the Spanish Flu infected between twenty and forty percent of the global population and claimed over 20 million lives, over 500,000 in the United States alone.<sup>13</sup> The dramatic loss of life is attributed to the virus’s high

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<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> Choo, *supra* note 1, at 41.

<sup>9</sup> *Id.* at 38.

<sup>10</sup> PandemicFlu.gov Historical Overview, *supra* note 2.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

mortality rate among young adults,<sup>14</sup> a trait that is shared with the modern strain of Avian Influenza.<sup>15</sup>

In February 1957, a second pandemic emerged after a strain of influenza known as the Asian Flu was identified in the Far East.<sup>16</sup> Sensing the possibility of a global outbreak similar to the one of 1918, the public health officials in the United States prepared by increasing surveillance and initiating vaccine development.<sup>17</sup> When the virus struck the United States in the summer of 1957, it first impacted school-aged children and pregnant women.<sup>18</sup> Although the spread of the flu tapered off in December, a “second wave” re-emerged in early 1958, infecting large populations of the elderly.<sup>19</sup> While advances in technology helped to alleviate the spread of the Asian Flu, nearly 70,000 people still died in the United States alone.<sup>20</sup>

A third and final flu pandemic surfaced in 1968.<sup>21</sup> The Hong Kong Flu claimed the lives of 33,800 Americans, making it the mildest of the three outbreaks.<sup>22</sup> Improved medical care and the peak occurrence during the school holidays in December are cited as the reasons for the lower number of fatalities.<sup>23</sup>

Since the Hong Kong Flu, three pandemic threats have emerged, including the recently discovered Avian Flu. In 1976, the Swine Flu was identified in Fort Dix, New Jersey, but it never moved beyond the immediate area of discovery.<sup>24</sup> In 1977, the Russian Flu spread throughout the world.<sup>25</sup> However, due to its concentration primarily in school-aged children it is not regarded as a true

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<sup>14</sup> *Id.*

<sup>15</sup> PandemicFlu.gov, Human Infection with Avian Influenza Viruses, <http://www.pandemicflu.gov/general/#human> (last visited Apr. 16, 2006).

<sup>16</sup> PandemicFlu.gov Historical Overview, *supra* note 2.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> PandemicFlu.gov Historical Overview, *supra* note 2.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

pandemic.<sup>26</sup>

In February 2003, another outbreak known as “Severe Acute Respiratory Syndrome,” or “SARS,” was identified in Asia.<sup>27</sup> SARS is a viral respiratory illness caused by a coronavirus, called SARS-associated coronavirus.<sup>28</sup> Over the first few months, the illness spread to more than two dozen countries in North America, South America, Europe, and Asia before it was finally contained.<sup>29</sup> Currently, there is no known SARS transmission anywhere in the world.<sup>30</sup> The most recent human cases of SARS infection were reported in China in April 2004 in an outbreak resulting from laboratory-acquired infections.<sup>31</sup>

## II. Avian Flu

Avian Flu, also called the H5N1 virus, is an influenza A virus subtype that occurs mainly in birds.<sup>32</sup> The virus is highly contagious and often fatal among birds but does not usually infect people.<sup>33</sup> Most human cases have resulted from direct or close contact with H5N1-infected poultry or contaminated surfaces.<sup>34</sup> The total number of human cases that have been reported globally since 2003 is 174,

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<sup>26</sup> PandemicFlu.gov Historical Overview, *supra* note 2.

<sup>27</sup> Ctr. for Disease Control (“CDC”), Fact Sheet: Basic Information About SARS, (May 3, 2005), <http://www.cdc.gov/ncidod/sars/factsheet.htm>.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> World Health Org. (“WHO”), China Confirms SARS Infection in Another Previously Reported Case; Summary of Cases to Date – Update 5, (Apr. 30, 2004), [http://www.who.int/csr/don/2004\\_04\\_30/en/index.html](http://www.who.int/csr/don/2004_04_30/en/index.html).

<sup>32</sup> Ctr. for Disease Control (“CDC”), Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus, (Feb. 7, 2006), <http://www.cdc.gov/flu/avian/gen-info/facts.htm>. “There are many different subtypes of type A influenza viruses. These subtypes differ because of changes in certain proteins on the surface of the influenza A virus. There are 16 known HA subtypes and 9 known NA subtypes of influenza A viruses. Many different combinations of HA and NA proteins are possible. Each combination represents a different subtype. All known subtypes of influenza A viruses can be found in birds.” *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

resulting in ninety-four confirmed deaths.<sup>35</sup> This startling fatality rate of over fifty percent, compared to only a two percent fatality rate for Spanish Flu, has been a major reason that medical experts and government legislators alike have expressed so much concern.<sup>36</sup>

Predicting the likelihood that the Avian Flu will develop the ability to easily travel from human to human is difficult.<sup>37</sup> However, one striking characteristic of the virus is its ability for rapid mutation in infected animals and humans.<sup>38</sup> While these mutations have affected patterns of virus transmission and spread among domestic and wild birds, they have not had any discernible impact on the modes of transmission among humans.<sup>39</sup>

Since the Avian Flu does not commonly infect humans, there is little or no immune protection against it in the human population.<sup>40</sup> Common symptoms of Avian Flu in humans have ranged from typical human influenza-like symptoms such as fever, cough, sore throat, and muscle aches to eye infections, pneumonia, severe respiratory diseases, and other severe complications.<sup>41</sup> No commercially available vaccine currently exists to protect humans against the Avian virus strain that was identified in Asia and Europe.<sup>42</sup> In 2005, research studies began testing a vaccine to combat the virus and a series of clinical trials are currently under way.<sup>43</sup> While some laboratory studies suggest that prescription medicines approved in the United States for human influenza viruses could be

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<sup>35</sup> World Health Org. (“WHO”), Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO, (Mar. 1, 2006), [http://www.who.int/csr/disease/avian\\_influenza/country/cases\\_table\\_2006\\_03\\_01/en/index.html](http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_03_01/en/index.html).

<sup>36</sup> Choo, *supra* note 1, at 38.

<sup>37</sup> WHO, Avian Influenza: Significance of Mutations in the H5N1 Virus, (Feb. 20, 2006), [http://www.who.int/csr/2006\\_02\\_20/en/index.html](http://www.who.int/csr/2006_02_20/en/index.html). Scientists do not presently know which specific mutations are needed to make the H5N1 virus easily transmissible among humans. *Id.* Influenza viruses are inherently unstable. *Id.* Specific mutations and evolution in influenza viruses cannot be predicted, making it difficult if not impossible to know if or when a virus such as H5N1 might acquire the properties needed to spread easily among humans. *Id.*

<sup>38</sup> Choo, *supra* note 1, at 38.

<sup>39</sup> WHO, *supra* note 37.

<sup>40</sup> CDC, Key Facts About Avian Influenza, *supra* note 32.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

effective in treating Avian Flu in humans, the viruses can become resistant to these drugs.<sup>44</sup>

Two antiviral medications commonly used for influenza, Amantadine and Rimantadine, have already proven to be ineffective in treating human cases of Avian Flu in Asia.<sup>45</sup> However, studies suggest that two other antiviral medicines, Oseltamavir and Zanamavir, would effectively treat influenza cases caused by the Avian.<sup>46</sup>

### **A. Meeting The Avian Threat**

The Department of Health and Human Services (“HHS”) has identified an influenza pandemic as the greatest potential cause of a rapid increase in death and illness of any natural health threat.<sup>47</sup> The Center for Disease Control and Prevention (“CDC”) has estimated conservatively that up to 207,000 Americans would die, and up to 734,000 would be hospitalized, during the next pandemic.<sup>48</sup> Estimates of the total direct costs pertaining to medical care and indirect costs of lost productivity and death associated with such a pandemic are estimated at between \$71 billion and \$166 billion.<sup>49</sup> These costs do not include the economic effects of pandemic on commerce and society.<sup>50</sup>

Amidst the backdrop of this potential viral onslaught, lawmakers have begun drafting new legislation to complement existing pandemic preparation measures. At the federal level, Congress is considering a bill known as Bioshield II, which is intended to encourage private development of medical solutions.<sup>51</sup> The goal of the bill is to entice pharmaceutical companies to invest in vaccinations through patent extensions, tax breaks, and protection from liability.<sup>52</sup> Additional notable federal proposals include the

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<sup>44</sup> CDC, Key Facts About Avian Influenza, *supra* note 32.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Pandemic Preparedness and Response Act, S. 1821, 109th Cong. § 2(1) (2005).

<sup>48</sup> *Id.* § 2(3).

<sup>49</sup> *Id.*

<sup>50</sup> *Id.*

<sup>51</sup> Project Bioshield II Act of 2005, S. 975, 109th Cong. (2005).

<sup>52</sup> Choo, *supra* note 1, at 39.

Pandemic Preparedness and Response Act, Pandemic and Seasonal Influenza Act of 2005, the Biodefense and Pandemic Vaccine and Drug Development Act of 2005, and the Influenza Preparedness and Prevention Act of 2005.<sup>53</sup> The President has also amended Executive Order 13295 to include reoccurring forms of influenza as a quarantinable communicable disease.<sup>54</sup>

At the state level, the Model State Emergency Health Powers Act (“MSEHPA”) and the Turning Point Model State Public Health Act (“Turning Point Act”) have served as a reference point for addressing a broad range of public health issues.<sup>55</sup> The Turning Point Act was drafted by the Center for Law & the Public’s Health at Georgetown and Johns Hopkins Universities (“Center for Law & Public’s Health”) under the direction of the Turning Point National Collaborative on Public Health Statute Modernization, a multi-disciplinary group comprised of representatives from five states, nine national organizations and government agencies, and experts in specialty areas of public health.<sup>56</sup> It was designed to serve as a tool for state, local, and tribal governments to use, revise, or update public health statutes and administrative regulations.<sup>57</sup> The MSEHPA was also created by the Center for Law & Public’s Health.<sup>58</sup> It grants public health powers to state and local public health authorities, “to ensure a strong, effective, and timely planning, prevention, and response mechanisms to public health emergencies while also

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<sup>53</sup> Pandemic Preparedness and Response Act, S. 1821 109th Cong. (2005); Pandemic and Seasonal Influenza Act of 2005, H.R. 4603, 109th Cong. (2005); Biodefense and Pandemic Vaccine and Drug Development Act of 2005, S. 1873, 109th Cong. (2005); Influenza Preparedness and Prevention Act of 2005, H.R. 4245, 109th Cong. (2005).

<sup>54</sup> Exec. Order No. 13,375, 70 Fed. Reg. 17,299 (Apr. 1, 2005) *See infra* Part II.C for a discussion of the Executive Order.

<sup>55</sup> MODEL STATE EMERGENCY HEALTH POWERS ACT (Ctr. for Law & the Public’s Health 2001), [hereinafter MSEHPA], *available at* <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>; TURNING POINT MODEL STATE PUB. HEALTH ACT (Pub. Health Statute Modernization Nat’l Excellence Collaborative 2003) [hereinafter TURNING POINT ACT], *available at* <http://www.hss.state.ak.us/dph/improving/turningpoint/PDFs/MSPHAweb.pdf>.

<sup>56</sup> Ctr. for Law & the Public’s Health, The Turning Point Model State Public Health Act, <http://www.publichealthlaw.net/Resources/Modellaws.htm#TP> (last visited Apr. 16, 2006).

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

respecting individual rights.”<sup>59</sup> While a number of states have incorporated all or part of these Acts into law, there is still little uniformity among the states.<sup>60</sup>

While each of these pieces of legislation offers a unique approach to preparing for a potential Avian Flu outbreak, each significantly affects the rights of health care consumers in the event of global pandemic. Four issues, in particular, are the subject of much debate and conjecture as lawmakers race to determine the best course for pandemic preparation: (1) the ability of government bodies to implement mandatory treatment, including forced vaccinations, (2) quarantine of individuals coming into contact with a contagious disease, (3) equal availability to drugs and vaccines for the lower socioeconomic classes, and (4) the legal remedies available for injuries sustained due to vaccination. The remainder of this paper will focus on how the aforementioned legislation pertains to each of these issues.

## **B. Mandatory Medical Treatment**

In 1905, the Supreme Court in *Jacobson v. Massachusetts* upheld a compulsory vaccination order in response to an outbreak of smallpox.<sup>61</sup> The case involved a well-known vaccine that had proven effective in treating a small pox threat.<sup>62</sup> In his opinion, Justice Harlan delivered a strong endorsement of the measure to promote public health.<sup>63</sup> Harlan noted that the only liberty an individual has is

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<sup>59</sup> *Id.*

<sup>60</sup> Ctr. for Law & the Public’s Health, Turning Point Act State Legislative Update Table, (Jan. 1, 2006), <http://www.publichealthlaw.net/Resources/ResourcesPDFs/MSPHA%20LegisTrack.pdf> (“From January 1, 2003—January 1, 2006, the subject matter or specific language from the Turning Point Act has been featured or introduced in whole or part through ninety (90) bills or resolutions in thirty-two (32) states. The extent to which the Act’s provisions are featured in these bills varies extensively.”) Since its completion on December 21, 2001, the *Center* has been tracking state legislative activity related to MSEHPA. Ctr. for Law & the Public’s Health, MSEHPA State Legislative Activity Table, (Feb. 1, 2006), <http://www.publichealthlaw.net/MSEHPA/MSEHPA%20Leg%20Activity.pdf>. As of February 1, 2006, the Act has been introduced in whole or part through bills or resolutions in forty-four states and the District of Columbia.” *Id.*

<sup>61</sup> *Jacobson v. Massachusetts*, 197 U.S. 11, 26-27 (1905).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 27.

that “regulated by law.”<sup>64</sup> He added that protection against an epidemic disease is part of the common good and it is “of paramount necessity.”<sup>65</sup> While the opinion did not address the legality of mandatory vaccinations using a relatively untested vaccine, it is precedent for the permissibility of government-enforced vaccinations.

Although the inherent legality of imposing mandatory medical treatment has been established for nearly 100 years, little consistency exists in the law for implementing such measures. At the state level, the authorization of mandatory vaccination in times of health emergency varies. For example, in Hawaii and Arizona governors have the power to initiate mandatory vaccination programs during a public health emergency.<sup>66</sup> However, in Wisconsin an individual may refuse a vaccination for medical or religious reasons.<sup>67</sup> Under the MSEHPA, the powers a governor would wield in a public health emergency, such as an Avian Flu outbreak, would not include the ability to force an individual to be vaccinated.<sup>68</sup> In addition, while a Public Health Agency (“PHA”) would generally be empowered to use every available means for stopping the spread of the virus, patients could not be forced to receive medical treatment or undergo examination.<sup>69</sup> However, individuals refusing to accept such care could be subject to isolation or quarantine.<sup>70</sup>

In contrast, the Turning Point Act does allow the PHA to institute mandatory medical treatment and testing.<sup>71</sup> An individual that has been exposed to a contagious disease and poses a significant health risk to the public can be required to complete an appropriate

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> Angie A. Welborn, CRS Report for Congress: Mandatory Vaccinations: Precedent and Current Laws, (Jan. 18, 2005) 3, *available at* <http://www.fas.org/sgp/crs/RS21414.pdf>.

<sup>67</sup> *Id.* at 4.

<sup>68</sup> MSEHPA § 603 (Ctr. for Law & the Public’s Health 2001).

<sup>69</sup> *Id.* §§ 601-603.

<sup>70</sup> *Id.* §§ 602-603.

<sup>71</sup> TURNING POINT ACT §§ 5-106(c),107(b) (Pub. Health Statute Modernization Nat’l Excellence Collaborative 2003). The Center for Law & the Public’s Health at Georgetown and Johns Hopkins Universities has merged the MSEHPA into the Turning Point Act, which now addresses a broad range of emergency and non-emergency public health issues. Choo, *supra* note 1, at 39.

course of treatment.<sup>72</sup> However, any health care provider who examines or treats such individual is required to inform them about the reason for the treatment and measures to avoid reinfection.<sup>73</sup>

In addition, the Turning Point Act empowers the PHA to require the vaccination of any individual to prevent spread of an infectious disease.<sup>74</sup> In administering the vaccination, the PHA must comply with four requirements: informed consent must be obtained, the vaccine must be approved and federally licensed, the treatment must be justified, and pre-vaccination information must be provided.<sup>75</sup> Individuals who refuse to comply with vaccination are subject to court order and a criminal action.<sup>76</sup>

However, the Turning Point Act delineates four narrow exceptions under which an individual may refuse vaccination:<sup>77</sup> (1) if the individual has a prior existing medical condition that could lead to a detrimental reaction to the vaccine, (2) if the individual is already exhibiting symptoms of the disease, (3) if laboratory testing confirms an existing immunity to the disease, or (4) a signed objection based on sincere religious beliefs.<sup>78</sup>

In contrast, there are no federal regulations pertaining to mandatory vaccination programs during a public health emergency.<sup>79</sup> Under the Public Health Service Act, the Secretary of Health and Human Services has the authority to make and enforce regulations necessary to stopping the spread or transmission of communicable diseases from foreign countries and from one state to another.<sup>80</sup> While this would appear to grant broad authority to the federal government in preventing the spread of communicable disease, it only authorizes regulations related to the detention, apprehension, examination, and conditional release of individuals.<sup>81</sup> Any proposed federal regulation pertaining to mandatory vaccination would likely

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<sup>72</sup> TURNING POINT ACT § 5-107(b).

<sup>73</sup> *Id.* § 5-107(a).

<sup>74</sup> *Id.* § 5-109(a).

<sup>75</sup> *Id.* § 5-109(b).

<sup>76</sup> *Id.* § 5-101(c).

<sup>77</sup> TURNING POINT ACT § 5-109(h).

<sup>78</sup> *Id.*

<sup>79</sup> Welborn, *supra* note 66, at 5.

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

require jurisdictional limitations.<sup>82</sup> This reflects a generally accepted policy that protecting the public health is primarily the responsibility of the state and local governments.<sup>83</sup>

### C. Quarantines

Quarantines can be a powerful and essential tool in curbing the spread of virus or disease. While most agree that they are an essential aspect of a competent pandemic preparation procedure, quarantines also raise several concerns. Issues pertaining to personal liberty, due process, and privacy are chief among these.<sup>84</sup> However, like the other emergency health legislation, there is a lack of consistency throughout jurisdictions. In 2004, a University of Pittsburgh study identified nineteen “disconnects” among federal, state, and local public officials on the proper sequence of carrying out actions, such as declaring a state of emergency and imposing quarantine zones.<sup>85</sup> Recently, federal officials have taken steps to modernize existing quarantine laws to ensure readiness for a global pandemic or bio-terrorist attack.

In April of 2005, President Bush issued an amendment to Executive Order 13295 Relating to Certain Influenza Viruses and Quarantinable Communicable Diseases.<sup>86</sup> The amendment added, “reemergent influenza viruses that are causing, or have the potential to cause, a pandemic” to the list of emergencies for which the federal government is authorized to detain individuals under the Public Health Service Act.<sup>87</sup>

In addition, on November 30, 2005, the CDC issued a new proposed rule pertaining to federal quarantine regulations.<sup>88</sup> The proposal significantly expands the federal government’s quarantine power by vastly broadening the definition of “ill person” to include those experiencing symptoms commonly associated with a

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<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> Welborn, *supra* note 66, at 5.

<sup>85</sup> Choo, *supra* note 1 at 39.

<sup>86</sup> Exec. Order No. 13,375, 70 Fed. Reg. 17,299 (Apr. 1, 2005).

<sup>87</sup> *Id.*

<sup>88</sup> 70 Fed. Reg. 71,892-71, 948 (Nov. 30, 2005) (to be codified at 42 C.F.R. pt. 70 & 71). These proposed rules would update the Public Health Service Act §§ 361-368. *Id.*

quarantinable disease.<sup>89</sup> This change would greatly expand the discretion of federal quarantine station directors.<sup>90</sup> However, the new proposal has raised some concerns, as it fails to set forth specific criteria under which an individual may be detained.<sup>91</sup> Finally, the proposal does not set forth any requirements for maintaining safe living conditions or providing acceptable levels of medical care for those individuals under quarantine.<sup>92</sup> These ambiguities make assurances that detained individuals receive proper care and treatment much more difficult in times of medical crisis.

However, the proposed CDC rules are not the only federal legislation pertaining to quarantines. Although the Project Bioshield II's primary focus concerns encouraging production of vaccines, it would also increase the severity of penalties for violating federal quarantines.<sup>93</sup> Specifically, the Act would make the penalty for violating quarantine rules and regulations \$250,000 and up to ten years in prison.<sup>94</sup>

It should be noted that federal regulations authorizing the apprehension, detention, examination, or conditional release of individuals is generally limited to individuals entering into a state and does not extend to individuals residing in a state.<sup>95</sup> This is a jurisdictional limitation, and reinforces the primary role of the state and local governments in protecting the public health of its residents.<sup>96</sup>

At the state level both the MSEHPA and Turning Point Act provide for the quarantine of individuals that have come in contact with a contagious or possibly contagious disease.<sup>97</sup> However, the

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<sup>89</sup> Lawrence O. Gostin, Benjamin E. Berkman, David P. Fidler, *Comments on Department of Health & Human Services, Control of Communicable Diseases*, 2 (Nov. 30, 2005), available at <http://www.publichealthlaw.net/Resources/ResourcesPDFs/Center%20-%20CDC%20QRegs.pdf>.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.* at 2-3.

<sup>92</sup> *Id.* at 3.

<sup>93</sup> Project Bioshield II Act of 2005, S.975 §2503(a)(1)-(2).

<sup>94</sup> *Id.* This is considerably higher than the existing penalty of \$1,000 and up to one year in prison. *Id.*

<sup>95</sup> Welborn, *supra* note 66, at 5.

<sup>96</sup> *Id.*

<sup>97</sup> MSEHPA § 604(a) (Ctr. for Law & the Public's Health 2001); TURNING POINT ACT § 5-108(a) (Pub. Health Statute Modernization Nat'l Excellence

state acts provide for more civil liberty safeguards than the proposed federal legislation on quarantines.<sup>98</sup> Both Acts require compliance with eight conditions and principles to ensure that officials are held accountable for depriving individuals of their liberty and providing adequate standards of care.<sup>99</sup>

Specifically, the PHA must adhere to the following conditions: (1) Isolation and quarantine must be by the least restrictive means necessary. (2) Isolated individuals must be confined separately from quarantined individuals. (3) The health status of quarantined and isolated individuals must be monitored regularly to determine if further containment is necessary. (4) A quarantined individual who becomes infected must immediately be moved to isolation. (5) Containment must be terminated immediately when an individual no longer poses a health threat. (6) The needs of individuals must be addressed in a systematic and competent fashion, including providing adequate food, clothing, and shelter. (7) Outside premises shall be maintained in a safe and hygienic manner; and (8) to the extent possible cultural and religious beliefs shall be respected in addressing the needs of individuals.<sup>100</sup> These provisions offer individuals subject to quarantine and isolation a clearer set of rights and help to mitigate the possibility of abuse or neglect.

#### **D. Equal Availability for Medical Care**

Another critical area of crisis health care management pertains to the equal distribution of vaccines and medicine in times of shortage. Without question, an Avian pandemic will intensify the divisions between the world's wealthiest and poorest nations.<sup>101</sup> While wealthier nations would have access to limited supplies of vaccines and antiviral drugs, the poorer countries would endure much higher fatality rates, due to lack of medical treatments.<sup>102</sup> However, this division will likely be tangible domestically as well. An outbreak of

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Collaborative 2003).

<sup>98</sup> MSEHPA § 604(b); TURNING POINT ACT § 5-108(b).

<sup>99</sup> MSEHPA § 604(b); TURNING POINT ACT § 5-108(b).

<sup>100</sup> MSEHPA § 604(b); TURNING POINT ACT § 5-108(b).

<sup>101</sup> Thomas Abraham, *Preparing for a New Global Threat—Part II, When the Next Wave of Influenza Hits, the World's Poor will Stand to Lose the Most*, YALEGLOBAL, (Jan. 28, 2005), available at <http://yaleglobal.yale.edu/display.article?id=5191>.

<sup>102</sup> *Id.*

the Avian Flu would create an environment ripe for abuse, as more affluent individuals vie for precious medical care supplies.

Recognizing this threat, lawmakers have incorporated language that would require surveillance over medical care management to ensure that classes of underprivileged citizens are not deprived equal treatment.<sup>103</sup> The Pandemic Preparedness & Response Act proposed in both the House and Senate, directly addresses this issue. Under the bill, the National Director of Pandemic Preparedness and Response would be required to ensure that there is “a specific focus on traditionally underserved populations, including low-income, racial and ethnic minorities, immigrants, and uninsured populations.”<sup>104</sup> However, while the bill recognizes the potential for abuse, it does not list any specific remedies that must be implemented to ensure equal treatment.

In contrast, while the MSEHPA and the Turning Point Act provide for the control of health care supplies in times of shortage, neither makes any specific mention of overseeing delivery to traditionally underserved populations.<sup>105</sup> Instead, the Model Acts give the PHA the authority to regulate, control, and restrict the use, sale, dispensing, and transportation of any medical product relevant to protecting the public welfare.<sup>106</sup> This includes products not directly purchased by the PHA.<sup>107</sup>

The Model Acts also prevent one state government from hoarding drugs at the expense of another state where an outbreak has occurred.<sup>108</sup> In addition, preference may be given to health care providers, first responders, and mortuary staff.<sup>109</sup> While these rationing provisions address key problems of resource management, they do not address the possibility of poorer Americans having little or no access to medical supplies.

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<sup>103</sup> See Pandemic Preparedness & Response Act, S. 1821, 109th Cong. § 2142(b)(15) (2005).

<sup>104</sup> *Id.* The Pandemic Influenza Preparedness Plan shall include a specific focus on surveillance, prevention, and medical care for traditionally underserved populations, including low-income, racial and ethnic minority, immigrant, and uninsured populations. *Id.* § 2144(b)(2)(B).

<sup>105</sup> MSEHPA § 505(b); TURNING POINT ACT § 6-103(e)(2).

<sup>106</sup> MSEHPA § 505(b); TURNING POINT ACT § 6-103(e)(2).

<sup>107</sup> MSEHPA § 505(b); TURNING POINT ACT § 6-103(e)(2).

<sup>108</sup> MSEHPA § 505(d); TURNING POINT ACT § 6-103(e)(3).

<sup>109</sup> MSEHPA § 505(c); TURNING POINT ACT § 6-103(e)(2).

One difficulty in ensuring that all classes will receive equal access to care is the differences at the state and local levels of the public and private sector capacity to administer care in a state of emergency.<sup>110</sup> It is generally assumed, that at a minimum, the state or local government will take responsibility for immunizing not only first responders and health workers, but the poor and uninsured as well.<sup>111</sup> This means that state and local governments must customize their resource allocations in each jurisdiction based on the mix of public and private sector capabilities that currently exist, as well as the anticipated demand of the poor and uninsured during a pandemic.<sup>112</sup>

Since the demand for public resources will be specific to individual localities, it will be nearly impossible for a national agency to oversee the adequate distribution of healthcare to traditionally neglected groups. This puts the efforts of the states at the forefront of ensuring that plans and procedures are in place to adequately address the demand on public resources in the event of a pandemic.

An additional aspect of availability addressed by lawmakers is the prospect of consumers getting charged exorbitantly high prices in the midst of a pandemic. Under the Pandemic Preparedness and Response Act, it would be unlawful for any person to sell a drug for the prevention or treatment of influenza at a price that is unconscionably excessive or indicates the seller is taking unfair advantage of the circumstances to increase prices unreasonably.<sup>113</sup> However, the Act does not specify any sanctions that may be imposed for such violations.

The MSEHPA also addresses this concern by granting public health officials property control measures over certain commercial

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<sup>110</sup> Ill. Dept. of Pub. Health, *Pandemic Influenza Preparedness and Response Plan*, 74 (Oct. 2005), available at <http://www.idph.state.il.us/flu/Pandemic%20Main%20Planfinal0302revised0105.pdf>.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> Pandemic Preparedness and Response Act, S. 1821, 109th Cong. § 4(i)(1)(A) (2005). In making this determination a court shall take into account whether the amount charged represents a gross disparity between the price of the drug for the prevention or treatment of influenza and the price at which the drug was offered for sale in the usual course of the seller's business immediately prior to the public health emergency; or whether the amount charged grossly exceeds the price at which the same or similar drug, was readily obtainable by other purchasers in the area in which the declaration applies. *Id.* § 4 (i)(1)(B).

transactions and practices such as price gouging.<sup>114</sup> Under the MSEHPA, officials are allowed to regulate the distribution of scarce health care supplies and control the price of critical items during an emergency.<sup>115</sup>

### **E. Legal Remedies for Injury**

A key aspect of nearly all pandemic legislation is providing incentives to drug manufacturers and healthcare administrators to ensure that the proper resources and infrastructure are available when necessary. A central component of this effort is providing protection from liability for injuries sustained during the administration of vaccines or other medical care.<sup>116</sup> While this protection is often a necessary condition of spurring innovation, it must be accompanied by a fair and equitable compensation regime for potential injured parties. Since the primary goal of liability protections is to spur drug manufacturers all over the world to provide vaccines and medical treatments on a national scale, this aspect of pandemic preparedness is restricted to federal initiatives.

Concerns over vaccine manufacturer liability first surfaced when insurers would no longer cover vaccine manufacturers.<sup>117</sup> Their refusal can be attributed in large part from the case of *Reyes v. Wyeth Laboratories*, in which polio vaccine manufacturers were held strictly liable for failing to provide product warnings to individuals that had been vaccinated.<sup>118</sup> The prospect of a large number of strict liability suits led insurers to stop offering that kind of insurance to vaccine manufacturers.<sup>119</sup>

The federal government's vaccine liability and compensation program began with the National Swine Flu Immunization Program

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<sup>114</sup> James G. Hodge, Jr. & Lawrence O. Gostin, *The Model State Emergency Health Powers Act - A Brief Commentary* (Jan. 2002), 19, *available at* <http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf>

<sup>115</sup> *Id.*

<sup>116</sup> Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context Pre-Event Vaccine Immunization Programs*, 8 J. HEALTH CARE L. & POL'Y 7, 36 (2005).

<sup>117</sup> *Id.* at 11.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

of 1976.<sup>120</sup> The Act authorized the establishment and implementation of an emergency Swine Flu immunization program and provided an exclusive remedy for personal injury or death arising out of the manufacture, distribution, or administration of the Swine Flu vaccine.<sup>121</sup> Under the Act, injured plaintiffs asserted claims directly against the United States through the Federal Tort Claims Act, instead of against the party that committed the actual wrong.<sup>122</sup> The United States thereby assumed the liability of manufacturers, distributors, and vaccinators under a system that made the government liable to all plaintiffs that could demonstrate an injury caused by the swine flu vaccine.<sup>123</sup> Although claimants first had to file an administrative claim with the agency before proceeding to federal district court, there were no limits on the amount of award that could be obtained.<sup>124</sup>

In 2004, Congress passed the Project Bioshield Act, immunizing manufacturers from liability for harm caused by certain vaccines and other agents by designating them as federal employees under the Federal Tort Claims Act.<sup>125</sup> Project Bioshield applies to research and development of qualified countermeasures pertaining to chemical, radiological, or nuclear agents that may be used in a terrorist attack.<sup>126</sup> Like the Swine Flu Act, the Project Bioshield Act did not establish a no-fault compensation system but allows personal injury claims to be brought directly against the federal government.<sup>127</sup>

Under the proposed Bioshield II Act, additional measures would be implemented to spur new drug innovation further. Bioshield II would specifically cover countermeasures “designed, developed, modified, used, or procured for the purpose of preventing, detecting, identifying, or treating pandemic influenza or limiting the harm such

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<sup>120</sup> *Id.*

<sup>121</sup> Nat’l Swine Flu Immunization Program of 1976, 42 U.S.C. § 247(b) (2004).

<sup>122</sup> Greenberger, *supra* note 116, at 12.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at 13. Compare this to the approach taken under the National Childhood Vaccine Injury Act of 1986 where the government established a two-staged, no fault compensation system for specific childhood vaccines. Public Health Service Act, 42 U.S.C. § 300aa-25 (1987).

<sup>125</sup> Project Bioshield Act of 2004, 42 U.S.C. §§ 247d-6a (2004).

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

influenza might otherwise cause.”<sup>128</sup> Under the proposed bill, an individual’s right to pursue a civil action for injuries sustained would still exist. However, this right would be limited by a number of liability restrictions.

Specifically, in claims involving healthcare volunteers and hospitals there would be an exclusive Federal cause of action if the governor of that State declared a state of emergency, or the Secretary of Health and Human Services declared that a public health emergency was in effect in that State, or the President signed a disaster declaration for that State.<sup>129</sup> This action could only be brought in the United States district court for the District of Columbia and recovery would only be allowed for injuries that were caused by willful or wanton misconduct.<sup>130</sup> In addition, injured consumers are not able to recover for punitive damages or non-economic damages under the Act.<sup>131</sup>

The Bioshield II Act would also place limits on the amount of recovery that an injured consumer would be able to receive under such circumstances. In instances in which a hospital is providing care under emergency conditions and such care is not administered for or in expectation of compensation, then the maximum liability to the Federal Government on behalf of the hospital, or its employees, volunteers, officers, and directors, is \$250,000 for each claimant.<sup>132</sup>

The Biodefense Act has proposed even more extreme limitations on consumer recovery. Under the Act, a consumer must petition the Secretary to investigate any allegations relating to injuries prior to filing suit against a “manufacturer, distributor or administrator of a security countermeasure or a qualified pandemic and epidemic product . . . or a health care provider.”<sup>133</sup> The decision to commence an investigation “shall be within the Secretary’s discretion and shall not be subject to judicial review.”<sup>134</sup> In making this determination, the Secretary must find clear and convincing

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<sup>128</sup> Project Bioshield II Act, S. 975, 109th Cong. § 341(a)(6)(A)(ii)(II)(bb) (2005).

<sup>129</sup> *Id.* § 319F-10(a)(1).

<sup>130</sup> *Id.*

<sup>131</sup> *Id.* § 319F-10(b)(2)-(3).

<sup>132</sup> *Id.* § 319F-10(b)(1).

<sup>133</sup> Biodefense and Pandemic Vaccine and Drug Development Act of 2005, S. 1873, 109th Cong. § 319F-3(a) & (b)(1)(C)(ii) (2005).

<sup>134</sup> *Id.* § 319F-(b)(1)(C)(ii).

evidence that the manufacturer, distributor, administrator, or health care provider (1) “violated a provision of the Federal Food, Drug, and Cosmetic Act” or the Biodefense Act, (2) that they acted with willful misconduct,<sup>135</sup> (3) that such misconduct “caused the product to present a significant or unreasonable risk to human health”, and (4) “that it proximately caused the injury alleged by the party.”<sup>136</sup>

The framework for recovery under the Biodefense Act places far too high a burden on injured consumers. While manufacturers, distributors, administrators, and health care providers have the ability to seek judicial review of the Secretary’s determination, consumers do not.<sup>137</sup> This disparity in rights is unwarranted and fails to consider the harsh impact on health care consumers.

### III. Recommendations

As lawmakers continue updating existing medical emergency legislation in light of the recent Avian Flu threat, it is imperative that they coordinate their efforts at the state and federal levels to minimize the impacts on consumers. While it is the primary responsibility of state and local governments to manage the public health of its citizens, the support of a cooperative federal government is indispensable. Therefore, it is essential that lawmakers examine the strengths and weaknesses of legislation at both levels to ensure an effective and synchronized pandemic response.

One major obstacle to ensuring an organized and effective response to an Avian pandemic is the lack of uniformity in existing legislation among jurisdictions. This lack of uniformity has a detrimental effect on the ability to implement a coordinated effort, as well as maintaining the trust and understanding of citizens. Without knowledge about emergency procedures, government reliance on the voluntary cooperation of potential patients will be futile.

A major component of building an informed population of health care consumers needs to be directed at ensuring that individuals are aware of the consequences of the decisions that they make.<sup>138</sup> This includes not only an understanding of the personal

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<sup>135</sup> *Id.* § 319F-(b)(1)(D)(i)(I)-(II).

<sup>136</sup> *Id.* § 319F-(b)(1)(D)(ii)(I)-(II).

<sup>137</sup> *Id.* § 319F-(b)(1)(D)(v).

<sup>138</sup> Wendy E. Parmet, *Informed Consent and Public Health: Are They Compatible When it Comes to Vaccines?*, J. HEALTH CARE L. & POL’Y, 70, 110 (2005).

risks associated with medical decisions, but the repercussions that these decisions have on the public welfare as well.<sup>139</sup> Decisions such as whether or not to be vaccinated or follow recommended preventive measures such as wearing a facemask, are all crucial to this process.<sup>140</sup> Each of these personal decisions affects the community at large, especially the sick and vulnerable, by altering the number of potential carriers of disease.<sup>141</sup> If properly informed, individuals will be better equipped to comprehend the public costs of their actions and develop the habit of taking the health of others into account when an emergency arises.<sup>142</sup>

Moreover, if the government wants individuals to comply with directives pertaining to vaccinations and quarantines, it would be wise to provide them with the reasons to do so before an emergency occurs.<sup>143</sup> Informed consent about routine vaccinations, including flu vaccines, may provide a unique opportunity for this assignment.<sup>144</sup> Information provided about vaccines can begin the process of reminding people of the public impact of their health care decisions and the public benefits of vaccines.<sup>145</sup> The state government is uniquely situated to handle this task, as it is the body that oversees these routine health care procedures.

A second issue that legislators must address is setting adequate standards for implementing and enforcing quarantines and isolations.<sup>146</sup> As noted, these tools are an integral component of ensuring that the spread of the Avian Flu is contained in the midst of a pandemic. However, these countermeasures also create an immense opportunity for abuse. Any deprivation of liberty on the part of government must be accompanied by rigorous standards for evaluating the circumstances under which an individual may be held, as well as the environment in which they may be kept.

In this regard, the MSEHPA and the Turning Point Act more astutely balance the necessities and dangers of quarantines and

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<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> Parmet, *supra* note 138, at 110.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

isolations than the proposed federal legislation.<sup>147</sup> Under the federal approach, the CDC's proposed rules significantly expand the scope of federal power pertaining to quarantines.<sup>148</sup> Specifically, the federal rules encompass a wide array of symptoms for which an individual may be quarantined.<sup>149</sup> This affords directors of federal quarantine stations unfettered discretion.<sup>150</sup> In addition, the CDC's rules do not provide for specific standards of shelter or medical care during detention.<sup>151</sup>

In contrast, under the MSEHPA and Turning Point Act quarantine and isolation powers are more restrained. Such powers are only exercised so long as is reasonably necessary, and only among people who pose a risk to others.<sup>152</sup> Also, individuals retain the right to contest a quarantine order within 48 hours unless there are extraordinary circumstances, giving due regard to the public's health and the rights of the affected individuals.<sup>153</sup> Finally, both Acts spell out specific procedures that must be followed during quarantine and isolation to preserve an adequate level of medical care.<sup>154</sup> This greater specificity will provide more guidance to consumers as to their rights in a medical emergency, as well as a higher level of government restraint.

While federal and state quarantine efforts will operate independently of one another due to jurisdictional limitations, the importance of cooperation and uniformity cannot be overstated. In this regard, federal lawmakers should consider implementing quarantine regulations that resemble the Model Acts in specifying the rights and care afforded to detainees in times of medical emergency.

Although lawmakers have proposed legislation protecting consumers against price gouging for medicines and vaccines during an influenza pandemic, there has been little concern given to ensuring

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<sup>147</sup> MSEHPA § 604(b) (Ctr. for Law & the Public's Health 2001); TURNING POINT ACT § 5-108(b) (Pub. Health Statute Modernization Nat'l Excellence Collaborative 2003). See *supra* Part II.C.

<sup>148</sup> Gostin, *supra* note 89, at 2.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.* at 3.

<sup>152</sup> MSEHPA § 604(b); TURNING POINT ACT § 5-108(b); see also Hodge & Gostin, *supra* note 114, at 9-10.

<sup>153</sup> MSEHPA, § 604(b); TURNING POINT ACT § 5-108(f).

<sup>154</sup> MSEHPA, § 604(b); TURNING POINT ACT § 5-108(b)(6)-(7).

that there are adequate resources available to treat the poor and uninsured. At the federal level, the Pandemic Preparedness & Response Act proposed by Congress does acknowledge the existence of this problem, however; it does not give any specificity as to the efforts to avoid inequitable treatment.<sup>155</sup>

At the state and local level more needs to be done to ensure that large and concentrated densities of underprivileged groups are not left with inadequate resources for medical treatment. State and local governments must develop forecasts regarding the type of demand that they would have to satisfy given their specific socioeconomic attributes. This will aid efforts to distribute medical care according to need and not politics.

Finally, Congress must continue to be generous with its vaccine liability and compensation structure. Pharmaceutical companies will undoubtedly be hesitant to engage in research and development of vaccines unless they are afforded stringent liability protections. This will support other government efforts to stimulate development of crucial countermeasures against fatal viruses such as Avian Flu.

However, these measures should be balanced with a fair and adequate compensation structure for potentially harmed consumers of these medicines and vaccines. This should include a quick and well-defined compensation regime that will allow injured victims a determinable amount of compensation in the event that unknown complications materialize. Consumers must also be afforded a cause of action against the federal government if they find this compensation regime to be inadequate. An effective compensation and liability program will drastically increase the participation of both drug manufacturers and consumers in preparing for an influenza pandemic.

While these recommendations do not nearly encompass all the potential impacts on consumers, they serve as a starting point for legislators in drafting and ratifying pandemic legislation. They account for a large portion of the reservations that health care consumers have about the government response to an influenza outbreak. As such, the government can go a long way in bolstering the trust and cooperation of its citizens by ensuring that they are protected against and aware of the risks and responses during a global pandemic.

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<sup>155</sup> Pandemic Preparedness and Response Act, S. 1821, 109th Cong. § 4(i)(1)(A) (2005).

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**IV. Conclusion**

In order to ensure a high level of readiness, state and federal lawmakers must work together to guarantee that pandemic preparedness regulations and procedures complement each other. Although the approaches currently taken by each level of government differ, they are not entirely incompatible. As noted, it is primarily the role of the state and local authorities to ensure the public health. This means the role of the federal government should be mainly directed toward facilitating the states' efforts, as well as bolstering national production and supply of vaccines and crucial medical supplies. While both levels of government need to continue to improve their coordination efforts, the national recognition of an Avian Flu threat has forced lawmakers at all levels into action and resulted in a great deal of legislative progress. However, these initiatives must be accompanied by a corresponding effort to increase the awareness of health care consumers as to their rights and obligations in times of medical emergency.