The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic

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Summary

The emergence and rapid spread of a new avian influenza virus (H5N1) and its potential for causing a human influenza pandemic have given rise to numerous issues. One of these is the general lack of surge capacity within the U.S. health-care system. Essentially, this means that a severe influenza pandemic could lead to much greater demand for vaccines, antiviral medications, and other medical technology, such as ventilators, than there are supplies. This potential imbalance has led to recommendations for priorities for medical resources for certain categories of individuals, including recommendations in the U.S. Department of Health and Human Services (HHS) Pandemic Influenza Plan and more recent guidance by a federal interagency working group. This report examines selected proposed priorities in light of the nondiscrimination provisions of the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act of 1973. It will be updated as appropriate.

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Introduction

The emergence and rapid spread of a new avian influenza virus (H5N1) and its potential for causing a human influenza pandemic have given rise to numerous issues. One of these is the general lack of surge capacity within our health-care system. Essentially, this means that a severe influenza pandemic could lead to much greater demand for vaccines, antiviral medications, and other medical technology, such as ventilators, than there are supplies. This potential imbalance has led to recommendations for priorities for medical resources for certain categories of individuals, including recommendations in the U.S. Department of Health and Human Services (HHS) Pandemic Influenza Plan and more recent guidance by a federal interagency working group. This report examines selected proposed priorities in light of the nondiscrimination provisions of the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act of 1973.

Background

The increased transmission of the H5NI virus among avian populations has raised concerns about a possible mutation of the virus that might cause a human influenza pandemic.[1] The possibility of a human influenza pandemic similar to the one in 1918, or even similar to the more moderate pandemics of 1957 and 1968, has raised questions about the ability of our health-care system to respond to such a crisis.[2] Julie Gerberding, the Director of the Centers for Disease Control and Prevention (CDC), stated in congressional testimony that "medical surge capacity is limited, and could be vastly outpaced by demand."[3]

In a House hearing, Dr. Tara O'Toole, the chief executive officer and director of the Center for Biosecurity at the University of Pittsburgh Medical Center, noted that CDC has created a computer model that allows each hospital to calculate how much surge capacity would be needed if a human influenza pandemic similar to that of 1918 were to occur. As an example, Dr. O'Toole calculated the data for the Atlanta area and provided the following description for those hospitals.

> For example, in a 1918 type pandemic, in the Atlanta metro area, that region would require *300%* of its current (pre-epidemic) hospital bed capacity to care for flu patients (and the necessary clinical staff to care for this increase in patients); *700%* of Atlanta's pre-epidemic

[1] For a detailed discussion of pandemic influenza, preparedness, and response, see CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by (name redacted).

[2] For a history of the 1918 pandemic, see John M. Barry, THE GREAT INFLUENZA (Penguin Books: New York, 2004). "In 1918 an influenza virus emerged—probably in the United States—that would spread around the world.... Before that world-wide pandemic faded away in 1920, it would kill more people than any other outbreak in human history.... The lowest estimate of the pandemic's worldwide death toll is twenty-one million, in a world with a population less than one-third today's.... Epidemiologists today estimate that influenza likely caused at least fifty million deaths worldwide, and possible as many as one hundred million.... And they died with extraordinary ferocity and speed. Although the influenza pandemic stretched over two years, perhaps two-thirds of the deaths occurred in a period of twenty-four weeks, and more than half of those deaths occurred in even less time, from mid-September to early December 1918." At 4-5.

[3] *Avian Influenza: Hearing Before the Subcommittee on Foreign Operations, Export Financing and Related Programs of the House Appropriations Committee*, 109th Cong., 2d Sess. (March 2, 2006), Testimony of Dr. Julie L. Gerberding, Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, reprinted at http://www.hhs.gov/asl/testify/t060302b.html.

> Intensive Care Unit capacity and nearly four times as many ventilators to care just for the flu patients. These demands do not take into account the resources that would be required to meet normal ongoing critical medical needs (care of heart attack victims, etc.).[4]

Similarly, although efforts are underway to develop vaccines and stockpile antiviral drugs, it is unlikely that there would be sufficient quantities of these medications for all who might seek them during a pandemic.[5] HHS has noted that it will be six months after the start of a pandemic before current technology will allow development of a well-matched vaccine.[6] In an effort to address this six-month period, the United States has, as of the end of 2007, stockpiled approximately 13 million doses of a pre-pandemic vaccine, with the expectation that this vaccine will provide at least partial protection against new virus strains.[7] To provide maximum protection, however, a vaccine must be developed from the virus that is causing a pandemic, and the specific virus would not be known until there is a pandemic. Matched vaccine supplies will be limited or nonexistent at the start of a pandemic.[8]

Antiviral drugs would also be in short supply during a pandemic. The United States is working toward a goal of stockpiling 81 million treatment doses, both federal and state.[9] Currently, approximately 50 million antiviral treatment courses have been stockpiled.[10] However, since viruses can develop resistance to current antiviral drugs, HHS has awarded $103 million to develop a new influenza antiviral drug.[11]

In situations such as bioterrorism or pandemic influenza, where resources are limited, issues concerning altered standards of care may arise. The allocation of scarce medical resources would be part of this broader issue.[12] One discussion of the overall issue of altered standards of care

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[4] *Pandemic Flu*: *Joint Hearing Before the Prevention of Nuclear and Biological Attack and Emergency Preparedness, Science and Technology Subcommittees of the House Homeland Security Committee,*109th Cong., 2d Sess. (February 8, 2006), Testimony of Dr. Tara O'Toole. Even with a moderate epidemic, the CDC has estimated an increase in hospitalization and intensive care unit demand of more than 25%. See HHS Pandemic Influenza Plan, Appendix D, http://www.hhs.gov/pandemicflu/plan/appendixd.html.

[5] See Department of Health and Human Services (HHS), *Pandemic Planning Update* (March 13, 2006); Lawrence O. Gostin, "Medical Countermeasures for Pandemic Influenza: Ethics and the Law," 295 JAMA 554 (February 1, 2006). Information from WHO has projected that the potential supply of pandemic influenza vaccine has sharply increased due to recent scientific advances and increased vaccine manufacturing capacity. "Last spring, the World Health Organization (WHO) and vaccine manufacturers said that about 100 million courses of pandemic influenza vaccine based on the H5N1 avian influenza strain could be produced immediately with standard technology. Experts now anticipate that global production capacity will rise to 4.5 billion pandemic immunization courses per year in 2010." "Projected Supply of Pandemic Influenza Vaccine Sharply Increases," http://www.who.int/mediacentre/news/releases/2007/pr60/en/index.html.

[6] Department of Health and Human Services (HHS), *Pandemic Planning Update IV* at 7 (July 18, 2007) http://www.pandemicflu.gov/plan/panflureport4.html.

[7] Department of Health and Human Services (HHS), *Pandemic Planning Update V* (March 17, 2008) http://www.pandemicflu.gov/plan/panflureport5.html.

[8] World Health Organization, "WHO Guidelines on the Use of Vaccines and Antiviral During Influenza Pandemics," (2004) http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2004_8/en/index.html.

[9] Department of Health and Human Services (HHS), *Pandemic Planning Update IV* at 9 (July 18, 2007) http://www.pandemicflu.gov/plan/panflureport4.html.

[10] Department of Health and Human Services (HHS), *Pandemic Planning Update V* (March 17, 2008) http://www.pandemicflu.gov/plan/panflureport5.html.

[11] Department of Health and Human Services (HHS), *Pandemic Planning Update IV* at 9 (July 18, 2007) http://www.pandemicflu.gov/plan/panflureport4.html.

[12] In addition to short supplies of vaccines and antivirals, many hospitals and emergency rooms are currently operating either at or over capacity with little surge capacity for a large influx of additional patients. A report by the Institute of (continued...)

noted that "under normal conditions, current standards of care might be interpreted as calling for the allocation of all appropriate health and medical resources to improve the health status and/or save the life of each individual patient. However, should a mass casualty event occur, the demand for care provided in accordance with current standards would exceed system resources."[13] This report also notes that "altered standards" is not defined but "generally is assumed to mean a shift to providing care and allocating scarce equipment, supplies, and personnel in a way that saves the largest number of lives in contrast to the traditional focus on saving individuals."[14] This could mean applying principles of triage, the process of sorting victims according to their need for treatment and the resources available.

Federal Pandemic Influenza Plan and Selected Allocation Proposals

National Strategy and Implementation Plan for Pandemic Influenza

National Strategy for Pandemic Influenza

On November 1, 2005, President Bush issued the National Strategy for Pandemic Influenza. The national strategy is a guide to preparedness and response to an influenza pandemic and provides a framework for federal government planning for an influenza pandemic.[15] The goals of the national strategy are "(1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society." The National Strategy also emphasizes the need to establish priorities for the allocation of vaccines and antivirals prior to the outbreak of a pandemic. These priorities would be updated immediately after the outbreak begins, based on the at-risk populations, available supplies, and the characteristics of the virus.[16]

(...continued)

Medicine noted that in many cities hospitals and trauma centers have problems dealing with multiple car highway crashes and concluded that "the lack of adequate hospital surge capacity is a serious and neglected element of current disaster preparedness efforts." See Institute of Medicine, *Hospital-Based Emergency Care: At the Breaking Point* 206-207 (June 14, 2006).

[13] Health Systems Resources, "Altered Standards of Care in Mass Casualty Events," 8 (April 8, 2005), prepared for the Department of Health and Human Services, printed at http://www.ahrq.gov/research/altstand/altstand.pdf.

[14] *Id.*

[15] It should be noted that states and localities are generally responsible for public health emergency response. For a discussion of state pandemic plans that are required as a condition of federal funding for pandemic preparedness, see CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by (name redacted) and (name redacted).

[16] *National Strategy for Pandemic Influenza*, November 1, 2005, at http://www.whitehouse.gov/homeland/pandemic-influenza.html. The National Strategy is to be consistent with The National Security Strategy and the National Strategy for Homeland Security.

National Strategy for Pandemic Influenza Implementation Plan

In May 2006, the Homeland Security Council issued the implementation plan for the National Strategy. This plan is described as "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."[17]

In its chapter on protecting human health, the implementation plan discusses priorities for scarce resources and notes that federal guidelines are being developed. These guidelines are to reflect the goals of the national strategy, as noted above. The implementation plan noted that priorities for vaccines and antiviral drugs will vary depending on the severity of the pandemic and the supply of vaccines and antiviral medications. For example, if supplies of vaccine and antiviral drugs are limited, vaccine may be reserved for personnel who maintain critical infrastructure and health care providers. The implementation plan further notes that the recommendations that are included in the HHS Pandemic Influenza Plan, discussed *infra*, provide initial guidance regarding the potential target groups being considered.

The implementation plan discusses medical standards of care and observes that "[i]f a pandemic overwhelms the health and medical capacity of a community, it will be impossible to provide the level of medical care that would be expected under pre-pandemic circumstances."[18] The plan also notes that approaches to medical care would change.

> In a pandemic, hospital and ICU beds, ventilators, and other medical services may be rationed. As in other situations of scarce medical resources, preference will be given to those whose medical condition suggests that they will obtain the greatest benefit from them. Such rationing differs from approaches to care in which resources are provided on a first-come, first-served bases or to patients with the most severe illnesses or injuries.[19]

HHS 2005 Recommendations Regarding Prioritization

The Department of Health and Human Services (HHS) issued a pandemic influenza plan in November 2005 that provides initial guidance for HHS pandemic influenza preparedness planning and response and offers detailed guidance to states and localities for their planning and response.[20] The executive summary of the plan notes that "an influenza pandemic has the potential to cause more death and illness than any other public health threat" and that "it is unlikely that there will be sufficient personnel, equipment, and supplies."[21] The plan also

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[17] Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan*, viii (May 2006). See also *National Strategy for Pandemic Influenza Implementation Plan One Year Summary* (July 17, 2007) http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html.

[18] *Id.* at 110.

[19] *Id.*

[20] HHS Pandemic Flu Plan http://www.hhs.gov/pandemicflu/plan/overview.html. The ethical issues regarding allocation of medical resources are beyond the scope of this report. For a discussion of these issues, see CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by (name redacted) and (name redacted). Similarly, quarantine and isolation issues are also beyond the scope of this report. See CRS Report RL33201, *Federal and State Quarantine and Isolation Authority*, by (name redacted) and (name redacted), and CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by (name redacted) and (name r edacted).

[21] *Id.*

emphasizes that influenza preparedness is a "shared responsibility" between the federal, state, and local governments.[22]

Appendix D of the HHS pandemic influenza plan contains recommendations regarding prioritization of pandemic influenza vaccine and antiviral drugs and includes the rationale for the prioritization. The first priority individuals for vaccines would be those involved in vaccine and antiviral manufacturing and medical workers, because they would be needed to assure maximum production of vaccine and antiviral drugs and to provide medical care. The second group would be individuals at high risk of hospitalization and death, excluding the elderly in nursing homes and those who are immunocompromised, because they would not be expected to respond well to vaccination. The recommendations also rank various other groups. Healthy children do not receive priority under these recommendations.

The recommendations for priority treatment differ for antiviral drug use. The first priority group to receive antiviral drugs would be patients admitted to the hospital due to severe influenza illness; the second priority group would be health-care workers. The next tier would include influenza patients at greatest risk of hospitalization and death, including immunocompromised persons and pregnant women. After this group would be pandemic health responders, including vaccine and antiviral manufacturers, police, fire fighters, corrections officials, and government decision makers. The recommendations also rank various other groups.[23] The individuals in these groups may receive antiviral drugs for treatment or, in some cases, as a preventative measure.

Interagency Working Group Guidance on Allocating and Targeting Pandemic Influenza Vaccine

On July 23, 2008, HHS and the Department of Homeland Security (DHS) issued a report entitled "Guidance on Allocating and Targeting Pandemic Influenza Vaccine."[24] On December 14, 2006, HHS had issued a request for information (RFI) in the *Federal Register* asking for "input on pandemic influenza vaccine prioritization considerations from all interested and affected parties...."[25] In addition, the request for information indicated that limiting transmission may be an objective. The Homeland Security Council Implementation Plan requires HHS with the Department of Homeland Security (DHS) to make priority recommendations for access to pre-pandemic and pandemic influenza vaccines. The recommendations are to reflect the pandemic response goals that were described in the Implementation Plan,[26] as well as maintaining national security.

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[22] *Id.* For a discussion of how this shared responsibility might work, see "Enhancing Public Health and Medical Preparedness: Reauthorization of Public Health Security and Bioterrorism Preparedness and Response Act," Hearing before the Senate Committee on Health, Education, Labor and Pensions, 109th Congress, 2d Sess. (March 16, 2006), Testimony of Richard A. Falkenrath.

[23] See HHS Pandemic Influenza Plan, Appendix D http://www.hhs.gov/pandemicflu/plan/appendixd.html.

[24] U.S. Department of Health and Human Services, U.S. Department of Homeland Security, "Guidance on Allocating and Targeting Pandemic Influenza Vaccine," (July 23, 2008) http://www.hhs.gov/news/press/2008pres/07/20080723a.html.

[25] 71 Fed.Reg. 75252 (December 14, 2006).

[26] These goals are "(1) stopping, slowing or otherwise limiting the spread of a pandemic to the United States; (2) limiting the domestic spread of a pandemic, and mitigating disease, suffering and death; and (3) sustaining infrastructure and mitigating impact to the economy and the functioning of society." *National Strategy for Pandemic Influenza*, November 1, 2005, at http://www.whitehouse.gov/homeland/pandemic-influenza.html.

The federal interagency working group used the input gained from this RFI and issued draft guidance on October 17, 2007.[27] After consideration of comments, final guidance was issued on July 23, 2008.[28] The guidance for pandemic vaccine differs markedly from the HHS 2005 recommendations. Although both schemes would give priority to health care workers and vaccine manufacturers, the 2005 recommendations largely emphasize treatment for the most vulnerable populations, the sick and elderly, while the guidance would give lower priority to these groups. The guidance creates tiers for coverage, and varies the vaccination priority depending on the severity of the pandemic. Since pandemics that have higher case fatality rates are more likely to disrupt essential services, threaten public order and homeland security, and disrupt supply chains, individuals who are necessary for these functions would receive a higher priority in a severe pandemic. Conversely, individuals with high risk conditions making them more vulnerable to serious illness would receive greater priority in a less severe pandemic.[29]

The guidance gives its highest rank to deployed forces, critical health-care workers, fire and police, and pregnant women, infants, and toddlers. The importance of maintaining homeland and national security is highlighted and the guidance recognizes the following objectives as the most important:

- protecting those who are essential to the pandemic response and providing care for persons who are ill,
- protecting those who maintain essential community services,
- protecting children, and
- protecting workers who are at greater risk of infection due to their job.[30]

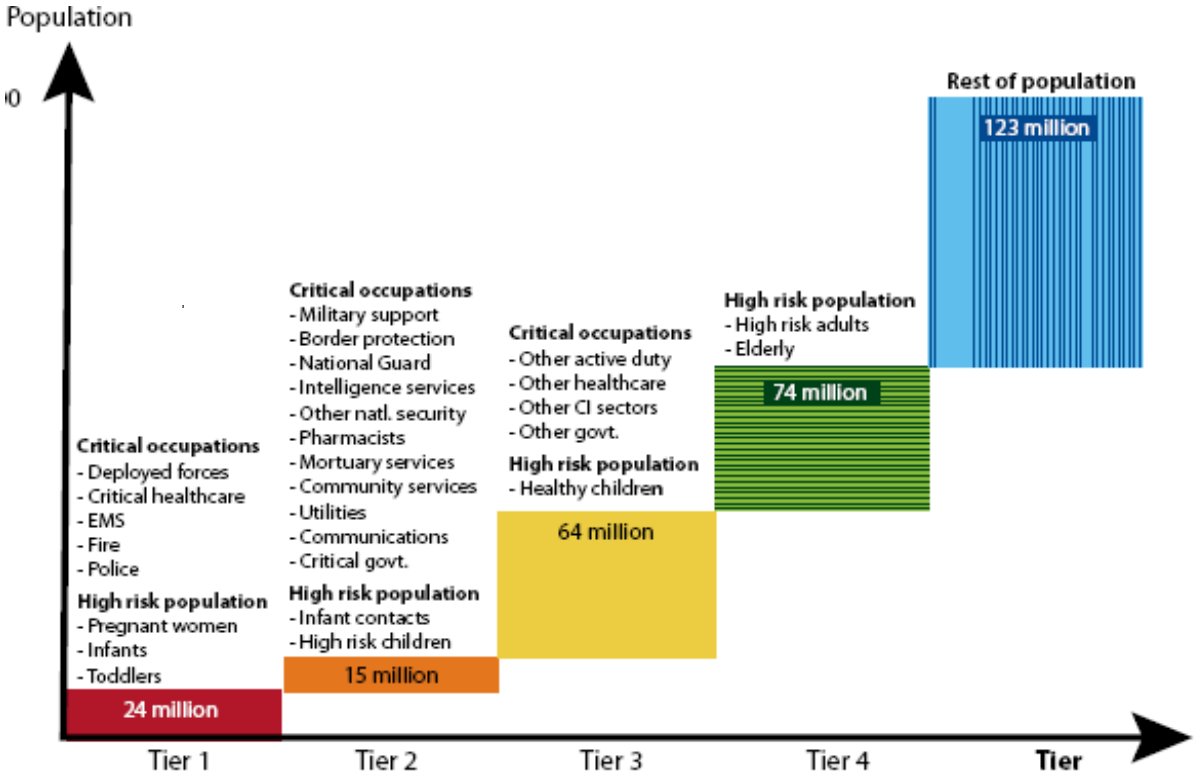
[27] "Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine," http://www.pandemicflu.gov/vaccine/prioritization.html.

[28] U.S. Department of Health and Human Services, U.S. Department of Homeland Security, "Guidance on Allocating and Targeting Pandemic Influenza Vaccine," (July 23, 2008) http://www.hhs.gov/news/press/2008pres/07/20080723a.html.

[29] *Id.* at 10-11.

[30] *Id.* at 3.

Figure 1. Vaccination Tiers and Target Groups for a Severe Pandemic



Source: U.S. Department of Health and Human Services, U.S. Department of Homeland Security, "Guidance on Allocating and Targeting Pandemic Influenza Vaccine," (July 23, 2008) http://www.hhs.gov/news/press/2008pres/07/20080723a.html.

Other Allocation Proposals

Other proposals also have been made for the allocation of scarce medical resources.[31] The World Health Organization (WHO) has suggested, as planning guidance, providing vaccines to "essential service providers, including health care workers" and groups at high risk of death and severe complications.[32]

In addition, other individuals have advanced allocation proposals in journal articles. For example, two emergency medicine physicians have proposed criteria for ventilatory support administration and for withdrawal of ventilatory support. The first tier for not offering and withdrawing ventilatory support under this proposal would include individuals with persistent hypotension unresponsive to adequate fluid resuscitation and signs of additional end-organ dysfunction. This proposal has as its second tier for receiving no services patients with various preexisting

[31] For a more detailed discussion of various proposals, see CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by (name redacted) and (name redacted). It should be noted that other countries use other ranking systems. For example, the Canadian plan would rank healthy children below healthy adults, whereas the 2005 HHS plan would group healthy adults and children together. The Canadian plan may be found at http://www.phac-aspc.gc.ca/cpip-pclcpi/index.html.

[32] World Health Organization, "WHO Guidelines on the Use of Vaccines and Antiviral during Influenza Pandemics," http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_RMD_2004_8/en/index.html.

conditions, such as acute renal failure requiring hemodialysis and AIDS.[33] Another group of commentators has explored the issues relating to "reverse triage," that is, discharging certain patients from hospitals to create room for other patients.[34]

Other commentators have argued for a "life-cycle allocation principle," rejecting other commonly used ethical principles for allocation such as "save the most lives," and "first come, first served."[35] Their theory would give priority to individuals from early adolescence to middle age "on the basis of the amount the person (has) invested in his or her life balanced by the amount left to live."[36]

A September 2008 article took a slightly different approach and argued for priorities to be based on essential functions for society.[37] The commentators argued that the secondary consequences of a severe pandemic, such as threats to infrastructure including water and food supplies, necessitate priority access to vaccinations and other treatment for a diverse group of individuals and businesses. Some, but not all, health care workers would continue to receive priority treatment. The need for households and businesses to prepare for self-sufficiency was emphasized and the commentators concluded that "[m]ultiple measures to keep key functions, agencies, and households ever skeletally functional during a pandemic allow us to be less susceptible to the secondary consequences of pandemic influenza, allow us to better attend to those most vulnerable, and allow us to increase the chance that, when pandemic waves pass, there will be a society to which we can all return."[38]

The Infectious Diseases Society of America (IDSA) issued a report in January 2007 containing principles for action during an influenza pandemic and specific recommendations.[39] IDSA emphasized the need for guidance concerning priorities for vaccines and observed that "[t]he U.S. must preserve medical readiness by ensuring that health care workers, including physicians, nurses, pharmacist, allied health personnel, first responders, and others are able to perform their

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[33] John L. Hick, MD and Daniel T. O'Laughlin, MD, "Concept of Operations for Triage of Mechanical Ventilation in an Epidemic," 13 ACADEMIC EMERGENCY MEDICINE 223 (February 2006). For an analysis and criticism of this article and a discussion of an "evidence-based standard of care," see Kriti L. Koenig, David C. Cone, Jonathan L. Burstein, and Carlos A. Camego, Jr., "Surging to the Right Standard of Care," 13 ACADEMIC EMERGENCY MEDICINE 195 (February 2006). See also Lawrence O. Gostin, "Medical Countermeasures for the Pandemic Influenza: Ethics and the Law," 295 JAMA 554 (February 1, 2006).

[34] Chadd K. Kraus, Frederick Levy, and Gabor Kelen, "Lifeboat Ethics: Considerations in the Discharge of Inpatients for the Creation of Hospital Surge Capacity," 1 DISASTER MEDICINE AND PUBLIC HEALTH PREPAREDNESS 51 (July 2007).

[35] Ezekiel J. Emanuel and Alan Wertheimer, "Who Should Get Influenza Vaccine When Not All Can?" 312 SCIENCE 854 (May 12, 2006).

[36] *Id.* at 855. Several organizations, including the Institute of Medicine and the National Vaccine Program Office in the Department of Health and Human Services, sponsored a public engagement pilot project on pandemic influenza (PEPPPI) to discuss and rank goals for a pandemic influenza vaccination program and to test a model for engaging citizens on vaccine related policy decisions. The report of these groups concluded that assuring the functioning of society should be the first immunization goal followed by reducing individual deaths and hospitalizations. There was little support among this group for vaccinating younger people first. See "Citizens Voices on Pandemic Flu Choices: A Report of the Public Engagement Pilot Project on Pandemic Influenza" (December 2005).

[37] Nancy E. Kass, Jean Otto, Daniel O'Brien and Matthew Minson, "Ethics and Severe Pandemic Influenza: Maintaining Essential Functions Through a Fair and Considered Response," 6.3 BIOSECURITY AND BIOTERRORISM: BIODEFENSE STRATEGY, PRACTICE, AND SCIENCE 227 (Sept. 2008).

[38] *Id.*

[39] http://www.idsociety.org/WorkArea/showcontent.aspx?id=5728.

duties during an influenza pandemic."[40] In its response to the HHS request for information on vaccine prioritization, IDSA noted that the principle served by the priorities should be "mitigation of suffering and death while sustaining the functioning of society."[41] The exact implementation of this principle would depend upon the particular epidemiological characteristics of a pandemic. For example, a pandemic that caused high death rates among children but not adults would necessitate different priorities. Generally, IDSA noted the importance of critical infrastructure personnel and key health care providers. However, the comments also noted that "a scheme that incorporates consideration of years of life lost, or years of quality life lost should be considered" and that the life-cycle proposal of Ezekiel Emanuel and Alan Wertheimer, which was discussed previously, was a "good starting point."

The New York State Department of Health issued a draft plan on March 15, 2007, for determining who would receive ventilator treatment during a pandemic where there is a shortage of ventilators.[42] The draft plan would apply to all patients in acute care hospitals in the state without regard for age, occupation, or role in the community, and would be applicable only as a last resort after hospitals had canceled elective medical procedures. The plan did not list specific diseases or age as exclusion criteria but focused on functionality, using a sequential organ failure assessment score. There would be no priority for health care workers or first responders. The proposal also addresses legal issues, noting that the document, when finalized, would provide strong evidence regarding an acceptable standard of care. The New York State Department of Health is seeking comments on the draft plan.

Although a detailed analysis of the plans of various countries is beyond the scope of this report, it should be noted that different countries approach priorities for vaccines and other medical supplies in various ways. A 2006 analysis of pandemic plans from forty-five countries found marked variability in proposed vaccine priority schemes, in particular with respect to the priority ranking assigned to children.[43]

The Americans with Disabilities Act and Section 504 of the Rehabilitation Act

Overview

The Americans with Disabilities Act (ADA)[44] has often been described as the most sweeping nondiscrimination legislation since the Civil Rights Act of 1964. It provides broad nondiscrimination protection in employment, public services, public accommodation and services operated by private entities, transportation, and telecommunications for individuals with disabilities. Congress found that individuals with disabilities continually encounter various forms

[40] *Id.* at 15.

[41] http://www.idsociety.org/WorkArea/showcontent.aspx?id=5728.

[42] http://www.health.state.ny.us/press/releases/2007/2007-08-23_vent_comments.htm.

[43] L. Uscher-Pines et al., "Priority Setting for Pandemic Influenza: An Analysis of National Preparedness Plans," PLoS Medicine, vol. 3, no. 10, October 17, 2006.

[44] 42 U.S.C. §§12101 *et seq.* For a more detailed discussion of the ADA, see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by (name redacted).

of discrimination, often resulting from "stereotypic assumptions not truly indicative of the individual ability of such individuals to participate in, and contribute to, society."[45] As stated in the act, the ADA's purpose is "to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities."[46]

Title II of the ADA prohibits discrimination by state and local governments, whereas Title III of the ADA prohibits discrimination by places of public accommodation, which are defined to include hospitals or offices of a health-care provider.[47] Many of the concepts used in the ADA originated in Section 504 of the Rehabilitation Act of 1973[48] and its interpretations, and the two statutes are generally interpreted in the same manner, although their areas of coverage differ somewhat. Section 504 prohibits discrimination against individuals with disabilities in any program or activity receiving federal financial assistance, in the executive branch, or the U.S. Postal Service; the ADA covers the private sector and state and local governments.

Although the ADA does not specifically mention coverage of disasters, its provisions are broad and would provide nondiscrimination protection for emergency situations. The Department of Justice has observed that "one of the most important roles of local government is to protect their citizenry from harm, including helping people prepare for and respond to emergencies. Making local government emergency preparedness and response programs accessible to people with disabilities is a critical part of this responsibility. Making these programs accessible is also required by the ADA."[49]

The Department of Justice has issued an ADA guide for local governments regarding making community emergency preparedness and response programs accessible to people with disabilities.[50] This guide includes planning for individuals who use oxygen or respirators or who have need for medications; however, the guide is focused on disasters that occur during a short period of time and in a specific location, such as a terrorist attack or hurricane, rather than on an influenza pandemic, which could last more than a year and span the world. Despite this focus, the ADA would appear to require planning undertaken regarding a potential influenza pandemic to including planning for individuals with disabilities.

Definition of Disability

The starting point for an analysis of rights provided by the ADA or Section 504 is whether an individual is an individual with a disability. The ADA and Section 504 definitions of disability were amended by the ADA Amendments Act, P.L. 110-325 to broaden the definition of disability from that provided by Supreme Court interpretations.[51] The ADA Amendments Act defines the term disability with respect to an individual as "(A) a physical or mental impairment that

[45] 42 U.S.C. §12101(7).

[46] 42 U.S.C. §12101(b)(1).

[47] 42 U.S.C. §12181(7).

[48] 29 U.S.C. §794.

[49] http://www.usdoj.gov/crt/ada/emergencyprep.htm. This requirement would be under Title II of the ADA, which covers state and local governments. For a discussion of emergency preparedness under the ADA, see CRS Report RS22254, *The Americans with Disabilities Act and Emergency Preparedness and Response*, by (name redacted).

[50] *Id.*

[51] For a detailed discussion of the amendments see CRS Report RL34691, *The ADA Amendments Act: P.L. 110-325*, by (name redacted).

substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment (as described in paragraph (3)).”[52] Although this is essentially the same statutory language as was in the original ADA, P.L. 110-325 contains new rules of construction regarding the definition of disability which provide that

- the definition of disability shall be construed in favor of broad coverage to the maximum extent permitted by the terms of the act;
- the term “substantially limits” shall be interpreted consistently with the findings and purposes of the ADA Amendments Act;
- an impairment that substantially limits one major life activity need not limit other major life activities to be considered a disability;
- an impairment that is episodic or in remission is a disability if it would have substantially limited a major life activity when active;
- the determination of whether an impairment substantially limits a major life activity shall be made without regard to the ameliorative effects of mitigating measures, except that the ameliorative effects of ordinary eyeglasses or contact lenses shall be considered.[53]

The most likely discrimination issue that would arise under the ADA or Section 504 during an influenza pandemic would be whether an existing disability, such as visual impairment, affects the provision of medical services to an individual. However, there could also be situations where infection with the pandemic influenza virus could raise issues under these statutes. Individuals with serious contagious diseases, such as pandemic influenza, would most likely be considered individuals with disabilities,[54] although the nondiscrimination mandates are not applicable if an individual is a direct threat to the health or safety of others.[55] Thus, even if an individual infected with a pandemic influenza virus was determined to be an individual with a disability, a physician or other health-care provider may not be required to treat that individual if doing so would create a direct threat to the health of the provider.[56]

[52] P.L. 110-325, §4(a), amending 42 U.S.C. §12102(3).

[53] Low vision devices are not included in the ordinary eyeglasses and contact lens exception.

[54] See *Bragdon v. Abbott*, 524 U.S. 624 (1998), where the Supreme Court found that an HIV-infected individual was covered by the ADA, and *School Board of Nassau County v. Arline*, 480 U.S. 273 (1987), where the Supreme Court found that an individual with tuberculosis was covered under Section 504.

[55] For a more detailed discussion of this issue, see CRS Report RS22219, *The Americans with Disabilities Act (ADA) Coverage of Contagious Diseases*, by (name redacted).

[56] *Bragdon v. Abbott*, 524 U.S. 624 (1998). In *Bragdon*, although the HIV-infected individual was found to be an individual with a disability, and thus covered under the ADA, the direct threat exemption was discussed and the case was remanded for consideration of whether filling the cavity of an HIV-infected individual would create a direct threat of transmission.

Application of the ADA and Section 504 to the Allocation of Scarce Medical Resources

Introduction

Title II of the ADA prohibits discrimination by state and local governments, whereas Title III of the ADA prohibits discrimination by places of public accommodation, including hospitals or offices of a health-care provider.[57] Section 504 prohibits discrimination against individuals with disabilities in any program or activity receiving federal financial assistance, in the executive branch, or in the U.S. Postal Service.[58] If a state or locality provides a service, a "qualified individual with a disability" may not be denied the benefits of the service or be subject to discrimination.[59] "Qualified individual with a disability" is defined for the purposes of Title II of the ADA as "an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity."[60] The Section 504 regulations define the term "qualified handicapped person" as meaning in relevant part "a handicapped person who meets the essential eligibility requirements for the receipt of such services."[61]

There has been no situation directly analogous to one that might be posed by allocation issues regarding medical resources during an influenza pandemic, but some situations have arisen that may be instructive. These include situations involving individual medical treatment decisions, the reduction of the number of inpatient hospital days paid for by Medicaid, allocating health-care services under Medicaid in a proposed Oregon Medicaid waiver, and organ transplant allocation policies.

Individual Medical Treatment Decisions

The ADA and Section 504 of the Rehabilitation Act of 1973 have been found not to apply to individual medical treatment decisions.[62] In other words, a physician's medical judgment concerning treatment will be given deference and generally will not trigger discrimination issues. The requirement that an individual with a disability be qualified has been seen by at least one court to be "geared toward relatively static programs or activities such as education" and thus is unable to be applied in "the comparatively fluid context of medical treatment."[63] When the

[57] 42 U.S.C. §12181(7).

[58] 29 U.S.C. §794.

[59] 28 C.F.R. §35.130 (ADA regulations); 45 C.F.R. 84.4 (Section 504 regulations).

[60] 42 U.S.C. §12131(2).

[61] 45 C.F.R. §84.3(l)(4).

[62] *Burger v. Bloomberg*, 418 F.3d 882 (8th Cir. 2005)("... a lawsuit under the Rehab Act or the Americans with Disabilities Act (ADA) cannot be based on medical treatment decisions."); *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1289, 1294 (11th Cir. 2005); *Fitzgerald v. Corr. Corp. of America*, 403 F.3d 1134, 1144 (10th Cir. 2005); *Wilson v. Woodford*, 2006 U.S. Dist. LEXIS 12330 (E.D. Calif. March 23, 2006)("The treatment, or lack of treatment, concerning Plaintiff's medical condition does not provide a basis upon which to impose liability under the RA or ADA.")

[63] *United States v. University Hospital*, 729 F.2d. 144, 156 (2d Cir. 1984).

disability is related to the condition to be treated, courts have found that "it will rarely, if ever, be possible to say ... that a particular decision was 'discriminatory.'"[64] However, in one district court case, Section 504 was found to require the provision of medical treatment to an anencephalic infant, despite the advice of physicians and the hospital's ethics committee recommending that the child not be resuscitated.[65]

Alexander v. Choate

Questions have also been raised regarding the application of Section 504 and the ADA to the application of policies regarding medical resources. In *Alexander v. Choate*,[66] the Supreme Court grappled with the issue of whether a reduction of the number of inpatient hospital days paid for by Medicaid would violate Section 504. This reduction would have a disparate impact on individuals with disabilities, but this alone was not seen as sufficient to violate the nondiscrimination requirements. Upholding Tennessee's 14-day limitation, the Supreme Court stated:

> Section 504 does not require the State to alter this definition of the benefit being offered simply to meet the reality that the handicapped have greater medical needs.... Section 504 seeks to assure even-handed treatment and the opportunity for handicapped individuals who participate in and benefit from programs receiving federal assistance... The Act does not, however, guarantee the handicapped equal results from the provision of state Medicaid, even assuming some measure of equality of health could be constructed.[67]

Oregon Medicaid Waiver Proposals

Similar issues were raised in the early 1990s by the state of Oregon Medicaid waiver proposal, which attempted to set priorities for allocating health-care services.[68] The methodology used to set the priorities for the ranking in the Oregon plan involved data supplied by health-care providers (e.g., the likelihood of recovery from certain diseases or conditions) and "values" contributed by the general public through public hearings and community meetings, in a telephone survey, and by the Oregon commissioners. The values were given weight based on three attributes: value to society, value to an individual needing the services, and whether it was essential to a basic health-care package. The value to an individual included an element described as "quality of life," which was quantified largely through a telephone survey in which the respondents scored the severity of certain symptoms or functional impairments on a scale of 1 to 100, with 0 representing death and 100 representing perfect health. The survey did not reach 53.4% of the randomly dialed numbers, and the Commission's report indicated that this was due to various factors, including "deaf/language barrier."[69] The U.S. Department of Health and

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[64] *United States v. University Hospital*, 729 F.2d. 144, 157 (2d Cir. 1984), discussing the application of Section 504 to the treatment of a newborn with multiple physical and mental disabilities. Several cases alleging violations of Section 504 were brought on behalf of infants with disabilities in the 1980s. For a detailed discussion of this issue, see Bonnie P. Tucker and Bruce A. Goldstein, Legal Rights of Persons with Disabilities: An Analysis of Federal Law §20 (1992).

[65] *In the Matter of Baby K*, 832 F.Supp. 1022 (E.D. Va. 1993), *aff'd on other grounds*, 16 F.3d 590 (4th Cir. 1994).

[66] 469 U.S. 287 (1985).

[67] *Id.* at 303-304.

[68] For a detailed discussion of this proposal, see Office of Technology Assessment, "Evaluation of the Oregon Medicaid Proposal," OTA-H-531 (May 1992).

[69] Oregon Health Services Commission, PRIORITIZATION OF HEALTH SERVICES C-2 (1991).

Human Services (HHS) denied the waiver application based on conflicts with the ADA, especially the "quality of life" components.[70] One commentator noted that this decision made "a legitimate point of fundamental difficulty in any rationing scheme that gives quality of life measurement a significant role."[71]

Organ Transplant Policies

The intersection of the ADA and organ allocation policies is another similar issue. The Public Health Service Act provisions relating to organ procurement and transplantation[72] require the Secretary of HHS to contract with a private, nonprofit corporation to establish and operate the Organ Procurement and Transplantation Network (OPTN). In 1986, the United Network for Organ Sharing (UNOS) was awarded a federal contract to administer the OPTN, whose primary function is to maintain a national computerized list of potential recipients and a system that matches donors and recipients.[73]

In *McElroy v. Patient Selection Committee*,[74] the plaintiff alleged a violation of Title III of the ADA when the hospital refused to provide kidney transplant services due to the plaintiff's mental illness. The district court found no ADA violation and granted summary judgment for the hospital since the evidence showed that the rejection of the plaintiff's application for a kidney transplant was for medical reasons. The doctor who evaluated the plaintiff on behalf of the hospital's patient selection committee had testified that the transplant procedure "is complex and intrusive and requires long-standing adherence to immuno-suppressive agents and cooperation with the various different people who treat a patient.... Adherence to immuno-suppressive agents and cooperation with his medical team is highly doubtful in light of his history and his chronic psychotic illness for which he has yet to establish complete and autonomous control."

Another transplant situation raised potential ADA issues, but did not give rise to litigation. Sandra Jensen was an individual with Down Syndrome who needed a heart-lung transplant. Surgeons at two hospitals initially rejected her for the procedure claiming that she lacked the mental capacity to participate in her care. However, pressure from community members and advocacy groups led the hospitals to reconsider and, after further examination, Stanford University surgeons determined that they had misjudged Ms. Jensen's ability to comprehend her condition and handle her care, and performed the surgery.[75]

[70] See Paul T. Menzel, "Oregon's Denial: Disabilities and Quality of Life," 22 THE HASTINGS CENTER REPORT 21 (November/December 1992).

[71] *Id.* See also David Orentlicher, "Rationing and the Americans With Disabilities Act," 271 JAMA 308 (January 26, 1994).

[72] 42 U.S.C. §§273 *et seq.*

[73] For a more detailed discussion of this system, see CRS Report RL30109, *Medicare and Medicaid Organ Transplants*, by (name redacted), available upon request.

[74] 2007 U.S.Dist.LEXIS 86321 (D. Neb. Nov. 21, 2007).

[75] For a more detailed discussion of this situation and an argument for the application of the ADA, see Angela T. Whitehead, "Rejecting Organs: The Organ Allocation Process and the Americans with Disabilities," 24 AMERICAN J. OF LAW AND MEDICINE 481 (1998).

Application

How, then, could these ADA and Section 504 precedents be applied to proposed priorities for the allocation of scarce medical resources when the scenarios that arise from a possible influenza pandemic are imposed on modern society? First, it should be noted that there are numerous ways in which allocation priorities could be made and that these priorities vary depending on, for example, whether the situation involves the distribution of vaccine or the provision of antiviral medications or the use of ventilators. In addition, the HHS pandemic influenza plan recommendations for priorities emphasize that the recommendations were based on certain critical assumptions that might change.[76] Similarly, the guidance issued by HHS and DHA on allocating and targeting pandemic influenza vaccine contains a number of variables depending on the severity of a pandemic and the vulnerability of various groups. This analysis, therefore, will be general in nature.

Exactly how the ADA or Section 504 will affect priorities for the allocation of scarce medical resources is uncertain. No event comparable to the scenarios projected by a pandemic influenza, such as the one of 1918, has occurred since the enactment of the ADA or Section 504, although other national disasters have happened, such as the terrorist attacks on 9/11 and the devastation of hurricanes Katrina, Rita, and Wilma.[77] These disasters have highlighted the difficulty of providing medical equipment and supplies to individuals with disabilities, including homebound individuals, and the importance of planning.[78] However, they do not provide much guidance on how scarce medical resources are to be allocated.

It should be reiterated that Title II of the ADA would apply to policies implemented by states and localities and that ADA Title III would apply to private entities, such as hospitals, whereas Section 504 would cover recipients of federal financial assistance, federal executive agencies, and the U.S. Postal Service. After finding coverage, the next step is to determine whether the individual is an individual with a disability and whether discrimination has occurred.

[76] The assumptions for the vaccine prioritization recommendation were (1) that the greatest risk of hospitalization and death would be infants, the elderly, and those with underlying health conditions; (2) that the health-care system would be "severely taxed if not overwhelmed due to the large number of illnesses and complications"; (3) that during a pandemic wave between 25% and 30% of persons will become ill during a six-to eight-week outbreak; (4) that there is limited information available to assess potential impacts on critical infrastructure sectors, such as transportation and utility services; and (5) that the U.S.-based vaccine production capacity would be 3 to 5 million doses per week, with three to six months needed before the first doses were produced. These assumptions, however, could change. For example, individuals who are at greatest risk of hospitalization and death may not be infants, the elderly, and those with underlying health conditions. In the 1918 pandemic, most deaths occurred in young adults. See HHS Pandemic Influenza Plan, Appendix D, http://www.hhs.gov/pandemicflu/plan/appendixd.html.

[77] An influenza pandemic differs from these other disasters in that it would be global in nature; span a year or more, with waves of peak activity in various areas; and have significantly greater potential mortality. One commentator found that "If 1918-19 mortality data are extrapolated to the current U.S. population, 1.7 million people could die, half of them between the ages of 18 and 40. Globally, those same estimates yield 180-360 million deaths...." Michael T. Osterholm, "Preparing for the Next Pandemic," 84 FOREIGN AFFAIRS 24 (July/August 2005).

[78] See e.g., National Council on Disability, SAVING LIVES: INCLUDING PEOPLE WITH DISABILITIES IN EMERGENCY PLANNING (April 15, 2005), reprinted at http://www.ncd.gov/newsroom/publications/2005/saving_lives.htm; Congressional briefing, *Emergency Management and People with Disabilities: Before, During and After* (November 10, 2005), reprinted at http://www.ncd.gov/newsroom/publications/2005/transcript_emergencymgt.htm; *Emergency Preparedness for the Elderly and Disabled: Field Hearing Before the Senate Special Committee on Aging*, 107th Cong., 2d Sess. (February 11, 2002).

Certainly some situations (e.g., denial of a vaccine to an individual solely because of a visual or mobility impairment unrelated to how that individual would respond to the vaccine) would most likely run afoul of the ADA's goal of eliminating actions resulting from stereotypic assumptions and of its nondiscrimination requirements.[79] A determination of who is to receive vaccines or other medical treatments that are in limited supply should involve careful consideration and safeguards to avoid the reliance on stereotypical assumptions that might trigger a violation of the ADA or Section 504. However, a determination that an individual not receive a vaccine because the vaccine would not be effective given his or her health situation would be unlikely to raise ADA concerns, because it would be based on a medical determination of treatment. The mere fact that a decision would have a disparate impact on individuals with disabilities would not necessarily be sufficient to violate the nondiscrimination mandates.[80]

Many of the situations that might occur are likely to be much more difficult to analyze, especially if physicians and hospital staff are faced with the kind of extreme situations described in congressional hearings.[81] For example, decisions regarding who should be admitted to a hospital when there is a shortage of beds, as well as who should receive scarce medications, could be difficult to make. To the extent that these decisions are based on an individual medical treatment decision (e.g., where the individual is allergic to the scarce medication or would not mount an immune response to the vaccine), case law under the ADA and Section 504 would indicate that a violation of these statutes would be unlikely. However, to the extent that the decision is based on stereotypical assumptions, there may be a violation of the ADA or Section 504.

An influenza pandemic with shortages of medical supplies, such as ventilators, could raise issues concerning whether treatment that has begun should be stopped. For example, if an individual with a severe underlying medical condition such as heart failure were infected with the influenza virus and, as a result of the virus, was on a ventilator with unlikely prospects for survival, would the removal of such an individual from the ventilator so it could be used for an individual with a stronger likelihood of survival violate the nondiscrimination mandates of the ADA or Section 504?[82] This situation would raise novel legal issues.[83] These issues may be presented in extreme situations, such as where hospitals are grossly overcrowded and understaffed and where the hospitals may be operating in a triage situation. Finally, these types of issues involve not only the application of law, but also an application of the underlying ethical considerations.

[79] 42 U.S.C. §12101.

[80] *Alexander v. Choate*, 469 U.S. 287 (1985).

[81] See e.g., *Pandemic Flu*: *Joint Hearing Before the Prevention of Nuclear and Biological Attack and Emergency Preparedness, Science and Technology Subcommittees of the House Homeland Security Committee,*109th Cong., 2d Sess. (February 8, 2006), Testimony of Dr. Tara O'Toole.

[82] This is one of scenarios examined, although not in the context of the ADA or Section 504, in John L. Hick, MD and Daniel T. O'Laughlin, MD, "Concept of Operations for Triage of Mechanical Ventilation in an Epidemic," 13 ACADEMIC EMERGENCY MEDICINE 223 (February 2006).

[83] The closest analogy would be to the situations raised by assisted suicide or "right to die" cases; however, these cases do not directly concern an immediate shortage of medical equipment. For a discussion of these issues, see CRS Report 97-244, *The "Right to Die": Constitutional and Statutory Analysis*, by (name redacted).

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