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Pandemic Influenza: Is There a Corporate Duty to Prepare?

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PANDEMIC INFLUENZA: IS THERE A CORPORATE DUTY TO PREPARE?

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This article considers whether in the wake of an influenza pandemic companies may be exposed to claims of legal liability for failing to provide employees with access to antiviral medications, as the Department of Health and Human Services (HHS) now encourages businesses to do. It begins by describing influenza and influenza pandemics. It then discusses the benefits and limitations of antiviral therapies and the recent creation of antiviral option programs. It concludes by considering whether claims may be brought on the theory that corporate leadership is under a duty to prepare for a pandemic by considering whether to provide access to antiviral protection for employees.

I. CLINICAL PICTURE

Influenza (flu) is one of the most important and contagious infectious diseases. Flu is responsible for more morbidity and mortality each year in North America than all other respiratory diseases combined, and it results in tremendous economic costs from both hospital admissions and productivity losses.¹ In 1918, flu caused one of the greatest public health catastrophes in history. The disease is spread person-to-person by aerosol droplets that primarily infect the epithelial cells of the respiratory tract.² A patient may transmit disease before he becomes symptomatic himself. Flu typically causes fever abruptly, with temperatures reaching 38-41° C. (100.4° to 105.8° F.) during the first 24 hours. Local and systemic reactions to influenza may be prominent, and may include prostration, chills, headache, myalgias, dry cough and diarrhea. Upper respiratory tract infection may progress to primary pneumonitis, which is generally associated with high mortality rates. Injury to cells lining the respiratory tract may in turn pave the way to secondary bacterial pneumonias with organisms such as *Streptococci* (pneumococcus and beta hemolytic group A), *Staphylococci* and *Hemophilus influenzae*. These, in turn, can lead to acute respiratory distress syndrome (ARDS), septic shock, and less frequently, cardiac muscle (myositis), central nervous system (Reye syndrome, Guillain-Barré syndrome, encephalitis) and renal complications.³

A. Immunology

Influenza virus can live outside of cells for only short periods of time. It must attach to and invade a healthy cell, so it can replicate there. Its progeny must then

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¹ Stiver, Grant, *The Treatment of Influenza with Antiviral Drugs*, 168 (1) CAN. MED. ASSOC. J. 49-57, at 49 (2003).

² Hilleman, Maurice R., *Realities and Enigmas of Human Viral Influenza: Pathogenesis, Epidemiology and Control*, 20 VACCINE 3068-3087 (2002). In community outbreaks, secondary illness attack rates among family members depend on the circulating strains and range from 10 percent to nearly 40 percent. Hayden, Frederick G., Belshe, Robert, Villanueva, Catalina, et al., *Management of Influenza in Households: A Prospective, Randomized Comparison of Oseltamivir Treatment with or without Postexposure Prophylaxis*, 189 J. INFECT. DIS. 440-449, at 440 (2004).

³ Hilleman, *supra*, n. 2.

escape so they can attack other cells. But while the reproductive capacity of the flu virus is prodigious, its quality control is poor. Flu's high replication error rate results in a mixed viral population with many variants.⁴

There are three types of influenza virus, known as influenza A, B and C. Only influenza A and B cause the illness typically recognized as flu, and only influenza A viruses can produce pandemics.

To attack the virus, the human immune system recognizes proteins on the organism's surface, specifically hemagglutinin (H) and neuraminidase (N). Hemagglutinin binding to receptors on the surface of the target cell initiates viral infection. Neuraminidase acts later to promote "budding," the release of virus from infected cells.⁵ Among influenza A viruses, science has so far identified 16 different hemagglutinins and nine neuraminidases; hence, there are 144 known possible combinations of these antigens and thus 144 possible influenza A subtypes. Few of these subtypes are known to cause infection in man. An individual who has survived infection with any of the combinations will develop immunity against that subtype. If confronted a second time with the very same virus, the now-immune patient ordinarily destroys it readily. The organism depends for its survival, then, upon its ability to escape host immunity through antigenic alterations, minor changes within subtypes that the host has not seen before. This mechanism explains why humans can be repeatedly reinfected with the same subtype. In nature, escape occurs through one of two mechanisms: genetic drift by point mutation, principally in the hemagglutinin gene, resulting in year-to-year seasonal influenza; or genetic shift, where the virus changes from one subtype to another.⁶ Genetic shift causes flu pandemics.

The antigenic combination that is presently the source of greatest concern to public health authorities is influenza A H5N1 (hemagglutinin subtype 5 and neuraminidase subtype 1), which may or may not turn out to be the viral variant that causes a pandemic. H5N1 mainly affects poultry and wild birds, but can infect humans who have close contact with sick fowl.⁷ It can also spread from human to human, but so far it does so only infrequently, and apparently with considerable difficulty.⁸ Scientists' concern, however, is that, while retaining its ability to produce severe illness, H5N1 will mutate in a manner that permits efficient human-to-human transmission.⁹ If that were to happen, the last step necessary for a pandemic to arise will have been taken.

B. Epidemiology

Flu typically spreads easily among contacts of an infected person. Prevention of influenza among such contacts impedes spread of influenza in the community.¹⁰

⁴ Eigen, Manfred, *On the Nature of Virus Quasispecies*, 4 TRENDS MICROBIOL. 216-218 (1996).

⁵ Gubareva, Larisa V., Kaiser, Laurent, Matrosovich, Mikhail N., et al., *Selection of Influenza Virus Mutants in Experimentally Infected Volunteers Treated with Oseltamivir*, 183 J. INFECT. DIS. 523-31 (2001).

⁶ Hilleman, *supra*, n.2.

⁷ Hein, Tran Tinh, Liem, Nguyen Thanh, Dung, Nguyen Thi, et al., *Avian Influenza in 10 Patients in Vietnam*, 350 N. ENGL. J. MED. 1179-1188 (2004).

⁸ See, Wang, Hua, Feng, Sijian, Shu, Yuelong, et al., *Probable Limited Person-to-Person Transmission of Highly Pathogenic Avian Influenza A (H5N1) Virus in China*, 371 (9622) LANCET 1392-4 (2008); Writing Committee of the Second World Health Organization Consultation on Clinical Aspects of Human Infection with Avian Influenza A (H5N1) Virus, *Update on Avian Influenza A (H5N1) Virus Infection in Humans*, 358 N. ENGL. J. MED. 261-73 (2008) (Writing Committee).

⁹ *Pandemic Flu Threat Remains Substantial, Experts Say*, HEALTH EXPERIMENT (May 2008), available at <http://www.healthexperiment.com/2008/05/21/pandemic-flu-threat-remains-substantial-health-experts-say.html>, (last visited Jan. 19, 2009).

¹⁰ Welliver, Robert, Monto, Arnold S. & Carewicz, Otmar, et al., *Effectiveness of Oseltamivir in Preventing Influenza in Household Contacts: A Randomized Controlled Trial*, 285 (6) JAMA 748-754 (2001).

To date, H5N1 has been detected in at least 67 countries on three continents.¹¹ Of the top 10 countries that U.S. businesses use as outsourcing locations, 70 percent have had confirmed cases of avian influenza.¹² As of September 10, 2008, Indonesia had experienced 112 fatalities in three years, nearly half the world's avian flu mortality. According to the World Health Organization (WHO), which relies upon official pronouncements of national governments, H5N1 has infected 387 humans worldwide and killed at least 245 since it began ravaging Asian poultry stocks in late 2003.¹³ On one hand, the reported mortality rate is grim: greater than 60 percent worldwide; greater than 80 percent in Indonesia. On the other, while some confidence in the numerator may be justified, the denominators may well be doubtful. After all, most cases have so far arisen in parts of the world with resources sufficient to support only relatively limited public health services. Moreover, there may be reason to doubt the candor of certain governments in disclosing the prevalence of human infections and deaths. Nevertheless, the best information available suggests that although at present H5N1 has difficulty attacking human tissue, once it does it is often fatal.

Infectious diseases are particularly lethal among those at the extremes of age: babies and the elderly. During the 1918 pandemic, however, uniquely severe lethality occurred not only in the very young and the very old, but also among persons in the very prime of life: 20-40 years of age.¹⁴ There is no way to know whether, in the next pandemic, a similar age distribution will be observed, but that is certainly possible.

C. *Pandemics*

An epidemic is an outbreak of disease occurring suddenly in numbers clearly exceeding normal expectancy. A pandemic is an epidemic affecting a wide geographic area, perhaps the whole world. Pandemic influenza arises when a novel strain of the virus appears, to which the population has little or no immunity, and the virus is capable of causing both disease and sustained human-to-human transmission.

Epidemiological data demonstrate that the world has been struck by an influenza pandemic at least 10 times over the past 300 years.¹⁵ Given that the last influenza pandemic occurred during the 1968/1969 flu season, it is reasonable to ask whether the world may again be facing a flu pandemic in the near future. Many experts believe we will. Many also predict that, as in 1918, the next pandemic may occur in waves. That is, there will be a spike in incidence of influenza, and an accompanying spike in related mortality, followed by a respite of indeterminate length, followed by another spike, another respite, and, possibly, a third spike. It seems prudent to assume that this scenario could obtain, even though certainty is not possible. We do not know what the causative organism will be, so of course one cannot predict

¹¹ Levitt, Michael O., DHS, Pandemic Planning Update V, available at <http://www.pandemicflu.gov/plan/panflureport5.html>, (last visited Jan. 19, 2009).

¹² Dolan, Kerry A., *Top Ten Countries for Off-Shoring*, FORBES MAGAZINE (2004).

¹³ WHO, *Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO*, (September 10, 2008), available at http://www.who.int/csr/disease/avian_influenza/country/cases_table_2008_09_10/en/index.html, (last visited Jan.19, 2009).

¹⁴ Hilleman, *supra*, n. 2.

¹⁵ Hilleman, *supra*, n. 2. See also, PAHO Strategic and Operational Plan for Responding to Pandemic Influenza (2005) (stating that the "longest recorded inter-pandemic interval is 39 years"). <http://www.paho.org/English/AD/DPC/CD/vir-flu-PAHO-Plan-9-05.pdf> (last visited Jan. 19, 2009); and Nicholson, Karl G., Wood, John M. & Zambon, Maria, *Influenza*, 362 LANCET 1734-1745, at 1734 (2003).

its behavior in detail. The best evidence we have, however, suggests that we need to be prepared for a crisis that may persist over an extended period of time—probably in excess of 12 or possibly 18 months. In a single community, however, a wave may last only eight to 12 weeks before subsiding.

WHO has predicted that in the event the organism becomes capable of efficient human-to-human transmission, up to 25 percent of the population could be affected in any one wave, causing worker absenteeism rates to exceed 35 percent.¹⁶ Although no one knows for sure, experts have projected that in a comparatively mild pandemic 88,000 to 300,000 Americans will die. A severe pandemic could infect 30 percent of the U.S. population and cause 2.2 million deaths.¹⁷

II. ECONOMIC IMPACT

Economic projections are subject to considerable uncertainty.¹⁸ It seems clear, however, that the surge capacity of the world's healthcare system will be inadequate to cope with demand.¹⁹ Ventilators and oxygen, both very likely to be essential to supporting flu patients, will probably be particularly scarce.²⁰ Pandemic-generated panic could cause intense economic disruption.²¹ Supply chain disruption would be inevitable, and businesses relying upon just-in-time deliveries, including pharmacies and hospitals,²² could be placed in a precarious position. Schools, churches, theatres, sporting events and the like would be closed. Travel and trade are likely to be sharply curtailed. A severe pandemic will cause substantial business disruption and hence financial loss. Economists have projected, as part of a worldwide recession, an 80 percent decline in tourism, entertainment, and food services in the United States. Demand for transportation and warehousing is projected to drop 67 percent; for agricultural products, mining, construction, manufacturing, finance and education, 10 percent.²³ According to one estimate, the U.S. Gross Domestic Product (GDP) could drop over 5.5 percent, causing an estimated \$683 billion loss.²⁴ A so-called "ultra-pandemic," with mortality over two percent, is projected to lead to the loss of 140 million lives and an estimated \$4.4 trillion in worldwide GDP.²⁵

¹⁶ Marsh, Inc. and Albright Group, LLC, *Corporate Pandemic Preparedness: Current Challenges to and Best Practices for Building a More Resilient Enterprise*, (2007), Executive Summary at 1, available at http://global.marsh.com/risk/pandemic/pandemic2/Marsh-Albright_Corporate_Pandemic_Preparedness_Report_09-27-07.pdf, (last visited Jan. 19, 2009).

¹⁷ Trust for America's Health, *Pandemic Flu and Potential for U.S. Economic Recession*, (Mar. 2007), available at <http://healthyamericans.org/reports/flurecession/>, (last visited Jan. 19, 2009).

¹⁸ Avian Flu Working Group, International Monetary Fund, *The Global Economic and Financial Impact of an Avian Flu Pandemic and the Role of the IMF*, at 3 (Feb. 28, 2006), available at <http://www.imf.org/external/pubs/ft/afp/2006/eng/022806.htm>, (last visited Jan. 19, 2009) (Avian Flu Working Group).

¹⁹ WHO, *Ten Things You Need to Know About Pandemic Influenza*, Geneva, Switzerland (2005), available at <http://www.who.int/csr/disease/influenza/pandemic10things/en/>, (last visited Jan. 19, 2009). See also, Osterholm, Michael T., *Unprepared for a Pandemic*, 86 (6) FOR. AFF. 47 (2007).

²⁰ Christian, Michael A., Devereaux, Asha V., Richter, Jeffrey R., et al., *Definitive Care for the Critically Ill During a Disaster: Current Capabilities and Limitations*, 133 CHEST 8S-17S (2008).

²¹ Oxford, John, Balasingam, Shobana & Lambkin, Rob, *A New Millennium Conundrum: How To Use a Powerful Class of Influenza Anti-Neuraminidase Drugs (NAIs) in the Community*, 53 J. ANTIMICROB. CHEMOTHER. 133-136, abstract at 133 (2004).

²² See, Phillips, Sally, *Current Status of Surge Research*, 13 ACAD. EMERG. MED. 1103-1108 (2006).

²³ WHO, *supra*, n. 19.

²⁴ Trust for America's Health, *supra*, n. 17.

²⁵ Burns, Andrew, van der Mensbrugghe, Dominique & Timmer, Hans, *Evaluating the Economic Consequences of Avian Flu*, World Bank (June 2006) at 3; Lowy Institute for International Policy, *Global Macroeconomic Consequences of Pandemic Virus* (2006) at 26.

The likelihood that risk could be transferred through some insurance product, at least on a large scale, appears to be remote.²⁶

While much economic activity will likely resume after pandemic recedes, an estimated 73 percent of businesses that suffer prolonged (>10d) disruption close or suffer long-term impact.²⁷ Of businesses suffering a disaster, 43 percent never recover sufficiently to resume operations. Of those that do reopen, only 29 percent are still operating two years later.²⁸ Ineffective crisis response could decrease shareholder value by about 15 percent, whereas effective response could potentially enhance value by seven percent.²⁹ In a severe pandemic, profitability could drop twice as far without antivirals (see below) as it could with them (16.5 percent v. 8 percent).³⁰ Studies have concluded that, so long as the probability of pandemic is greater than once every 80 years, the economic benefit of antiviral stockpiling exceeds cost.³¹

III. COMBATING THE SPREAD OF FLU

Three main approaches exist to reduce viral transmission: 1) reducing contact rates through social distancing, 2) reducing the ease of transmission through good hygiene, personal protective equipment, treatment or isolation and 3) reducing the susceptibility of uninfected individuals by vaccination or antiviral medications or both.³² All of these are important; none should be neglected. Mathematical modeling suggests that combined interventions such as hospital and community control measures, antivirals and vaccines will be more effective than reliance upon any one modality alone.³³

A. Vaccines

Vaccination against the pandemic flu virus is likely to provide the best, most effective protection against illness.³⁴ Preseason influenza immunization of school-aged children, for example, reduces the risk of illness in adult and sibling contacts

²⁶ Marsh, Inc., *supra*, n. 16.

²⁷ DHS, Remarks of Cybersecurity and Communications Assistant Secretary Greg Garcia, Dartmouth CIO/CISO Executive Workshop on Cyber Security, (Oct. 11, 2007), available at http://www.dhs.gov/xnews/releases/pr_1192138142478.shtm, (last visited Jan. 19, 2009).

²⁸ National Archives and Records Administration, cited in *AcXess Signs Two Additional Business Continuity Customers*, BUSINESS WIRE, (Nov. 1, 2006), available at http://findarticles.com/p/articles/mi_m0EIN/is_2006_Nov_1/ai_n16852355, (last visited Jan. 19, 2009).

²⁹ Knight, Rory F. & Pretty, Deborah J., *The Impact of Catastrophes on Shareholder Value*, Oxford Executive Research Briefings, University of Oxford, available at <http://www.nrf.com/Attachments.asp?id=12546>, (last visited Jan. 19, 2009).

³⁰ Borba, Philip S., Fitch, Kathryn, Iwasaki, Kosuke & Pyenson, Bruce, *Pandemic Influenza Risk Management for Employers*, Milliman Consultants and Actuaries (May 2007), available at <http://www.milliman.com/expertise/healthcare/publications/tr/pandemic-influenza-risk-management-05-09-07.php>, (last visited Jan. 19, 2009).

³¹ Balicer, Ran D., Huerta, Michael, Davidovitch, Nadav & Grotto, Itamar, *Cost-Benefit of Stockpiling Drugs for Influenza Pandemic*, 11 (8) EMERG. INFECT. DIS. 1280-82 (2005).

³² Ferguson, Neil M., Cummings, Derek A. T., Cauchemez, Simon, et al., *Strategies for Containing an Emerging Influenza Pandemic in Southeast Asia*, 437 NATURE 209 (2005).

³³ Miriam, M., Chowell, Gerardo & Gunel, Abba B., *Assessing the Role of Basic Control Measures, Antivirals and Vaccine in Curtailing Pandemic Influenza: Scenarios for the U.S., U.K. and the Netherlands*, 4 J.R. SOC. INTERFACE 505-21 (2006), available at <http://math.lanl.gov/~gchowell/publications/pandemic-flu-scenarios.pdf>, (last visited Jan. 19, 2009). See also, Ira A., Azhar, Nizam, Xu, Shufu, et al., *Containing Pandemic Influenza at the Source*, 309 SCIENCE 1083 (2005).

³⁴ See, WHO, *Influenza Pandemic Preparedness and Response*, (2005), at 4, available at http://www.who.int/gb/ebwha/pdf_files/EB115/B115_44-en.pdf, (last visited Jan. 19, 2009).

and is associated with reduced morbidity and mortality in community-dwelling adults.³⁵ Vaccination can greatly reduce the impact of influenza and is particularly advisable for persons in high-risk groups, such as older persons or those with chronic illness.

Vaccination does not always prevent infection, however; outbreaks of influenza still occur annually despite increasing vaccine use.³⁶ A meta-analysis estimated vaccine efficacy at 68 percent in preventing mortality and 53 percent in preventing pneumonia in vulnerable older people.³⁷ According to another paper, influenza vaccine is only 40–60 percent effective in elderly patients, especially nursing home residents, and in patients with immunosuppression caused by underlying disease or by the drugs they are taking, because these individuals may not form sufficient antibodies.³⁸ Despite resident vaccination rates exceeding 85 percent, more than one-third of Canadian long-term care facilities for older people reported at least one influenza outbreak during the 1998/1999 season. Case fatality rates in vaccinated residents remain significant.³⁹ Based on the limited information available, conventional flu vaccines may not be sufficiently immunogenic in a pandemic, and two doses in conjunction with an adjuvant, rather than merely a single dose, may be needed.⁴⁰

Nevertheless, public health authorities everywhere are understandably eager to vaccinate as many potentially affected persons as possible. Vaccine efficacy depends on the closeness of the match of vaccine antigens with those of the relevant influenza strains and on the recipient's age and immunocompetence.⁴¹ Development of a vaccine against any organism requires, at minimum, identification of that organism,⁴² so that vaccine manufacturing is guided by its specific antigenic characteristics. The causative organism for the next influenza pandemic, of course, is not yet identifiable, so pandemic influenza vaccine cannot yet be developed. Pre-pandemic vaccines are available, and probably do offer some protection, because they may confer partial immunity to those vaccinated.⁴³

Effectiveness of vaccination and treatment also depends on how quickly cases are diagnosed and the speed with which treatment can be undertaken.⁴⁴ When the first U.S. pandemic wave starts, however, no vaccine or only limited quantities of stockpiled pre-pandemic vaccine may be available.⁴⁵ Only then can virus-specific vaccine manufacturing begin. Most experts predict that it will take six months

³⁵ Hayden, *supra*, n. 2.

³⁶ Peters, Patrick H., Gravenstein, Stefan, & Norwood, Paul, et al., *Long-Term Use of Oseltamivir for the Prophylaxis of Influenza in a Vaccinated Frail Older Population*, 49 J. AMER. GER. SOC. 1025-1031, at 1025 (2001).

³⁷ Bowles, Susan K., Lee, Wayne, Simor, Andrew E., et al., *Use of Oseltamivir During Influenza Outbreaks in Ontario Nursing Homes, 1999-2000*, 50 J. AMER. GER. SOC. 608-616, at 608 (2002).

³⁸ Stiver, *supra*, n. 1.

³⁹ Bowles, *supra*, n. 37.

⁴⁰ Nicholson, *supra*, n. 15.

⁴¹ Peters, *supra*, n. 36.

⁴² WHO, *Influenza Pandemic Preparedness*, *supra*, n. 34.

⁴³ Osterhaus, Albert D.M.E., *Pre- or Post-Pandemic Influenza Vaccine?* 25 VACCINE 4983-4984 (2007) (editorial); Gambotto, Andrea, Barratt-Boyes, Simon M., de Jong, Menno D., et al., *Human Infection with Highly Pathogenic H5N1 Influenza Virus*, 371 LANCET 1464-1475 (2008). See also, Advisory Committee on Immunization Practices (ACIP), *Prevention and Control of Influenza*, 57 (RR07) MMWR 1-60 (Aug. 8, 2008), available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5707a1.htm?s_cid=rr5707a1_e, (last visited Jan. 19, 2009).

⁴⁴ Nuno, *supra*, n. 33.

⁴⁵ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, 3 (June 6, 2008), available at <http://aspe.hhs.gov/panflu/antiviraluse.html>, (last visited Jan. 19, 2009).

or longer for large-scale pandemic-specific vaccine production to begin. Current vaccines are produced from virus grown in fertile hens' eggs.⁴⁶ The timeframe for large-scale production might grow shorter if we can replace traditional production methods with cell-based vaccines, and efforts are underway now to achieve that goal.⁴⁷ Nevertheless, between onset of pandemic and production of vaccine on an adequate scale, antivirals will be a mainstay.

B. Antivirals

As the name suggests, antivirals are medications designed to hamper the ability of a virus to replicate or to produce infection. In 1918, no such drugs existed. Since the 1960s, however, the first generation of influenza antivirals, known as the adamantanes, have been produced. Two are available in the United States: amantadine and rimantadine. In the right circumstances, such as in the management of Parkinson's disease, these agents still retain some value, but over the years since their introduction many strains of flu have developed resistance to them. They are not recommended against H5N1 because virtually all viruses of this subtype associated with human illness have become adamantane-resistant.

Neuraminidase inhibitors are a newer class of antivirals that work by preventing newly created virus particles from budding. A virus unable to bud is a virus unable to survive. Two neuraminidase inhibitors are available in the United States today: oral oseltamivir (Tamiflu, Roche) and inhaled zanamivir (Relenza, GlaxoSmith-Kline (GSK)). Others, such as peramivir, are in development, and may offer benefits eventually, but it is not possible to predict when that will occur, nor whether they will offer any advantages over the two agents presently available.

There are two ways that antivirals can be used: for treatment, or for prevention, also called prophylaxis. Prophylaxis, in turn, can be given either before or after exposure to influenza. There is evidence that treatment, pre-exposure prophylaxis, and post-exposure prophylaxis all have value. Therapeutic and prophylactic oseltamivir successfully interrupted an outbreak of influenza A in a long-term care facility, for example.⁴⁸ Each will be considered in turn.

C. Antiviral Therapy

In comparison with placebo during seasonal influenza, treatment with neuraminidase inhibitors within 48 hours of symptom onset has been efficacious in shortening the duration of illness by about 1-1.5 days.⁴⁹ An epidemiological study in Toronto, Canada, assessed the impacts of oseltamivir treatment at hospital admission for persons with confirmed influenza infection compared with an untreated control group. Most of the treated patients were elderly (mean age 79) and many had underlying health problems. Although this was not a randomized controlled trial, mortality in the treated and untreated groups was 3.9 percent and 10 percent, respectively. Treatment was associated with a significant reduction in mortality (odds

⁴⁶ Nicholson, *supra*, n. 15.

⁴⁷ Potentially, cell-culture vaccines may permit faster response to a pandemic and avoid the risks of contaminated eggs. Moreover, influenza viruses grown in mammalian cells more closely resemble those present in clinical samples than do viruses isolated and grown in eggs, hence offering the potential for more effective protection. *Id.*

⁴⁸ Chang, Yi-Mieng, Li, Wan-Cheung, Huang, Ching-Tai, et al. *Use of Oseltamivir During an Outbreak of Influenza A in a Long-Term Care Facility in Taiwan*, 68 J. HOSP. INFECTION. 83-87 (2008).

⁴⁹ Some have estimated 1.5-2.5 days. Stiver, *supra*, n. 1.

ratio 0.21, $p = 0.03$).⁵⁰ A Canadian observational study suggested that the shorter the interval between onset of symptoms and initiation of treatment, the greater the benefit: among persons presenting for treatment within the first 12 hours of illness, the duration of symptoms was shorter by three to four days.⁵¹ In both healthy and at-risk adults, treatment may reduce complications, hospitalizations (occurrence and length of stay), and mortality.⁵² Epidemiological studies comparing outcomes of patients who did or did not receive oseltamivir treatment also found significant reductions in pneumonia and hospital admissions.⁵³ In another study, bronchitis was reduced by 55 percent and pneumonia by 59 percent in patients with uncomplicated influenza treated with neuraminidase inhibitors.⁵⁴ Antiviral therapy reduces the need for antibiotics and hospitalization.⁵⁵ Under plausible assumptions, HHS projects that for the first wave of a 1918-like pandemic, antiviral treatment could prevent about 144,000 deaths and about 1.85 million hospitalizations.⁵⁶

From evidence such as this, experts tend to believe that, in addition to social distancing and scrupulous attention to hygiene, pandemic planning should focus on the ability to provide treatment as soon after onset of illness as possible⁵⁷ and at least within 48 hours. HHS recently stated that significant benefit has not been documented when treatment is begun more than 48 hours after symptom onset.⁵⁸ In the same draft Guidance, however, HHS acknowledged a recent study of persons treated at hospital admission suggesting that later treatment still may be effective in reducing mortality.⁵⁹

The conclusion that seems justified: if at all possible, treat early, preferably within 48 hours of the onset of symptoms or sooner. Should that prove impossible, however, later treatment may still be appropriate because it may reduce mortality, especially among those ill enough to require hospitalization.⁶⁰

IV. POST-EXPOSURE PROPHYLAXIS (PEP)

⁵⁰ McGreer, Allison, Green, Karen A., Plevneshi, Agron, et al., Toronto Invasive Bacterial Diseases Network, *Antiviral Therapy and Outcomes of Influenza Requiring Hospitalization in Ontario, Canada*, 45 CLIN. INFECT. DIS. 1568-75 (2007), cited in HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 17-18.

⁵¹ Aoki, Fred Y., Macleod, Malcolm D., Paggiaro, Pierluigi, et al., *Early Administration of Oral Oseltamivir Increases the Benefits of Influenza Treatment*, 51 J. ANTIMICROB. CHEMOTHER. 123-129 (2003).

⁵² *Id.*; Kaiser, Laurent, Wat, Cynthia, Mills, Tracy, et al., *Impact of Oseltamivir Treatment on Influenza-Related Lower Respiratory Tract Complications and Hospitalizations*, 163 ARCH. INT. MED. 1667-1672 (2003); Nordstrom, Beth L., Sung, Iyue, Suter, Pia, et al., *Risk of Pneumonia and other Complications of Influenza-Like Illness in Patients Treated with Oseltamivir*, 2 CURR. MED. RES. OP. 761-768 (2005); Bowles, *supra*, n. 37; McGeer, *supra*, n. 50; Lee, Nelson, Chan, Paul K.S., Choi, Kin Wing, et al., *Factors Associated With Early Hospital Discharge of Adult Influenza Patients*, 12 ANTIVIR. THER. 501-508 (2007), all cited in HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 4. See also package labels, oseltamivir: http://www.fda.gov/cder/foi/label/2002/21087S10lbl_update.pdf; zanamivir: <http://www.fda.gov/cder/foi/label/2001/21036s4lbl.pdf> (both last visited Jan. 19, 2009).

⁵³ Nordstrom, *supra*, n. 52.

⁵⁴ Kaiser, *supra*, n. 52. See also, Nordstrom, *supra*, n. 52.

⁵⁵ Kaiser, *supra*, n. 52.

⁵⁶ HHS, *Proposed Guidance on Antiviral Drug Use During An Influenza Pandemic*, *supra*, n. 45.

⁵⁷ In the IMPACT study, initiation of therapy within the first 12 h after fever onset reduced the total median illness duration by 74.6 hours (3.1 days) more than did intervention at 48 hours. Earlier administration reduced the duration of fever, severity of symptoms, and times to return to baseline activity and health scores. Aoki, *supra*, n. 51.

⁵⁸ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 17.

⁵⁹ *Id.* at 11.

⁶⁰ Writing Committee, *supra*, n. 8.

Neuraminidase inhibitors appear to be efficacious in preventing influenza among contacts of infected persons.⁶¹ Unlike vaccination, antiviral chemoprophylaxis offers the possibility of immediate protection during household introductions of virus.⁶² For seasonal influenza, PEP among household contacts of persons with influenza infection has been shown to be very effective in preventing illness, especially when coupled with treatment of the index (ill source) case. PEP of household contacts of those with influenza reduced the likelihood of secondary cases in families when the initial household case is treated.⁶³ Prevention of influenza in family contacts is a means to control the spread of influenza within communities.⁶⁴ When started within 48 hours of the case's illness onset, PEP with a neuraminidase inhibitor is reportedly 70 percent to 90 percent effective in preventing seasonal flu in household settings.⁶⁵ Among contacts of an influenza-positive index case, the overall protective efficacy of oseltamivir against clinical influenza was 89 percent for individuals and 84 percent for households. Post-exposure prophylaxis with oseltamivir protected close contacts of influenza-infected persons against influenza illness, prevented outbreaks within households, and was reasonably well-tolerated. All virus isolates from oseltamivir recipients retained sensitivity to active metabolite.⁶⁶ In preventing influenza illness in household contacts, PEP with oral oseltamivir, combined with the treatment of index cases, was more effective than treating index cases alone.⁶⁷ Zanamivir has also been described as well-tolerated and effective in preventing influenza types A and B within households where the index patient was not treated.⁶⁸

Computer models have suggested that neuraminidase inhibitors may be able to contain a potential strain of influenza at its source.⁶⁹ Modeling has also suggested that early treatment may reduce transmission to close contacts and may improve the effectiveness of healthcare emergency services and other key community functions.⁷⁰

V. PRE-EXPOSURE PROPHYLAXIS

There have been comparatively few studies of pre-exposure prophylaxis. There is evidence, however, that just as antivirals can be given in treatment of the infected, or to prevent infection in the exposed, they can be used to prevent disease in those at risk of exposure. Doing so requires a more protracted course of treatment than either of the other two approaches. Oseltamivir taken orally daily for six weeks was 92 percent effective in preventing seasonal flu in a population of frail, older people living in housing for seniors. When influenza virus infection was either confirmed in a residential home or was reported to be spreading in the area, subjects were randomized to receive either 75 mg daily or placebo for six weeks. The majority of study subjects did receive that season's vaccination against influenza.

⁶¹ Hayden, *supra*, n. 2.

⁶² Hayden, *supra*, n. 2.

⁶³ PEP reduced the incidence of febrile influenza illness by 55 percent among pediatric contacts and by 80 percent among those who were not already infected with influenza. *Id.*

⁶⁴ Welliver, *supra*, n. 10; *see also*, Hayden, *supra*, n. 2.

⁶⁵ *Id.*; Monto, Arnold S., Pichichero, Michael E., Blanckenberg, Steve J., et al., *Zanamivir Prophylaxis: An Effective Strategy for the Prevention of Influenza Types A and B Within Households*, 186 J. INFECT. DIS. 1582-1588 (2002); Hayden, *supra*, n. 2, all cited in HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45.

⁶⁶ Welliver, *supra*, n. 10.

⁶⁷ Hayden, *supra*, n. 2.

⁶⁸ Monto, *supra*, n. 65.

⁶⁹ Longini, *supra*, n. 33; Ferguson, *supra*, n. 32.

⁷⁰ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45 at 18.

Vaccination cannot provide complete protection, however, and 12 of the 13 cases of laboratory-confirmed clinical influenza occurred in vaccinated subjects. These results suggest that the beneficial protection given by oseltamivir augments that provided by vaccination.⁷¹

In another study, long-term administration of oseltamivir either once or twice daily was safe and effective for preventing naturally-acquired influenza infection in healthy adults. It reduced the risk of influenza compared with placebo ($p < 0.001$). Tamiflu was 74 percent effective against influenza illness and 87 percent effective against culture-proven influenza.⁷²

A. *Countervailing Considerations*

Deciding whether to employ a pharmaceutical product, in a single patient or in an entire workforce, is a judgment call. The same is true of many other decisions in pandemic preparedness generally.⁷³ In evaluating options, companies may wish to confer with medical advisors and other trustworthy sources of information. WHO's Regional Office of Europe website, for example, provides information on prevention and treatment, including information on antiviral drugs.⁷⁴ Given the relentless regularity with which pandemics have afflicted mankind, however, and the foreseeable harms attendant to even relatively mild pandemics, it would appear to be prudent to err on the side of caution.

Of itself, though, such an admonition does not answer the question whether to make antivirals available to personnel. No drug is perfect, nor is any class of drugs. All drugs have side effects. Amantadine's side effects, for example, commonly include relatively minor problems such as nausea, vomiting and dizziness, but can sometimes include delirium, hallucinations, seizures and coma.⁷⁵ In evaluating antivirals, relevant risks, as well as potential benefits, should be considered. There are three classes of countervailing considerations: 1) scarce data; 2) the threat of resistance; and 3) side effects.

Data: The published data on antiviral efficacy report findings in those with seasonal, not pandemic flu. There have been few cases of H5N1 influenza so far, after all, and no controlled studies.⁷⁶ For obvious ethical reasons, there probably never will be. Similarly, once pandemic-specific vaccine becomes available, it will probably be used after only very limited testing also. The total number of persons studied so far has been relatively limited, and confidence limits around reported outcome estimates are often rather wide. In some research, relatively few persons at high risk of influenza complications were studied, and the analysis combined subjects

⁷¹ Peters, *supra*, n. 36.

⁷² Hayden, Frederick G., Atmar, Robert, Schilling, Margo, et al., *Use of the Selective Oral Neuraminidase Inhibitor Oseltamivir to Prevent Influenza*, 341 N. ENGL. J. MED. 1336-1343 (1999).

⁷³ Leavitt, Michael, Secretary of HHS, remarked ruefully "Anything you say before a pandemic just sounds alarmist, but anything you say after a pandemic is inadequate." See *Pandemic Planning*, GREENSBORO NEWS RECORD, Mar. 27, 2006, available at http://www.redorbit.com/news/health/445954/pandemic_planning/, (last visited Jan. 19, 2009).

⁷⁴ WHO Health Evidence Network, *Findings: Prevention and Treatment*, http://www.euro.who.int/HEN/Syntheses/pandemicflu_antivirals/20060106_10?language=German, (last visited Jan. 19, 2009).

⁷⁵ Hayden, Frederick and Aoki, Fred Y., *Amantadine, Rimantadine, and Related Agents*, in Yu, Victor L., Merigan, Thomas, & Barriere, Steven, eds., *ANTIMICROBIAL THERAPY AND VACCINES*, Williams & Wilkins, Baltimore (1999).

⁷⁶ Roehr, Bob, *Roche's tiered pricing enables poorer countries to stockpile drugs*, 333 BMJ 63 (2006), abstract available at <http://www.bmj.com/cgi/content/extract/333/7558/63>, (last visited Jan. 19, 2009).

from different trials studied under different protocols.⁷⁷ In other instances, clinical trials were not powered to assess the potential impact of treatment on influenza mortality because of their limited sample size. Based on the reduction in illness severity, defined by lower respiratory tract infection or a need for hospitalization, such an impact would be predicted.⁷⁸ Nevertheless, it must be acknowledged that there is much we do not know.

Resistance: In assessing the value of stockpiling, the development of resistance should also be considered.⁷⁹ As noted, first-generation adamantane antivirals appear to have lost much of their antimicrobial usefulness; we must ask whether a similar evolution could follow in the wake of widespread neuraminidase inhibitor therapy. So far, however, resistance appears to be an uncommon problem.⁸⁰ Oseltamivir treatment of the index case did not select for drug-resistant virus or reduce the protective efficacy of oseltamivir against influenza illness in close contacts.⁸¹ In the lab, in fact, it is difficult to deliberately select for influenza viruses with reduced susceptibility to oseltamivir.⁸² According to the latest CDC data available at the time of writing, 10.9 percent of influenza viruses A from the United States have been resistant to oseltamivir.⁸³ Significantly, all of the resistant viruses were H1N1. To date, there has been no H5N1 human disease in North America.⁸⁴ Moreover, when resistance does arise, it happens during treatment and often renders the virus less infectious.⁸⁵ The predominant mutation seen has been the substitution at a certain position of the viral neuraminidase of one amino acid for another. That mutation compromises the function of the organism's neuraminidase and decreases viral fitness so much that the virus carrying it is unlikely to be of clinical significance in man.⁸⁶ One cannot predict that this pattern will necessarily continue, and there are some examples of clinically significant neuraminidase-resistant influenza A virus,

⁷⁷ Kaiser, *supra*, n. 52.

⁷⁸ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 17.

⁷⁹ See, e.g., Lipsitch, Marc, Cohen, Ted, Murray, Megan, et al., *Antiviral Resistance and the Control of Pandemic Influenza*, PLoS MEDICINE, available at <http://www.medscape.com/viewarticle/556454>, (last visited Jan. 19, 2009) (The benefits of antivirals may be reduced, but not completely offset, by development of drug resistance).

⁸⁰ Gubareva, *supra*, n. 5.

⁸¹ Hayden, *supra*, n. 2.

⁸² Peters, *supra*, n. 36.

⁸³ CDC, *Influenza Activity—United States and Worldwide, May 18-Sept. 19, 2008*, 57 (38) MMWR 1046-1049 (June 27, 2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5725a5.htm>, (last visited Jan. 19, 2009). No resistance to oseltamivir was detected among influenza A (H3N2) or influenza B viruses. *Id.*

⁸⁴ CDC, *Avian Influenza: Current H5N1 Situation*, (2008), available at <http://www.cdc.gov/flu/avian/outbreaks/current.htm>, (last visited Jan. 19, 2009). See also, CDC FLUVIEW, *2008-2009 Influenza Season Week 1 ending January 10, 2009*, available at <http://www.cdc.gov/flu/weekly/index.htm>, (last visited Jan. 19, 2009).

⁸⁵ Lipsitch, Marc, *supra*, citing, e.g., Yen, Hui-Ling, Herlocher, Louise M., Hoffmann, Erich, et al., *Neuraminidase Inhibitor-Resistant Influenza Viruses May Differ Substantially in Fitness and Transmissibility*, 49 (10) ANTIMICROB. AGENTS CHEMOTHER. 4075-4084 (2005), and Herlocher, Louise M., Truscon, Rachel, Elias, Stephanie, et al., *Influenza Viruses Resistant to the Antiviral Drug Oseltamivir: Transmission Studies in Ferrets*, 190 J. INFECT. DIS. 1627-1630 (2004). See also, Carr, Jackie, Ives, J., Kelly, L., et al., *Influenza Virus Carrying Neuraminidase with Reduced Sensitivity to Oseltamivir Carboxylate has Altered Properties in vitro and is Compromised for Infectivity and Replicative Ability in vivo*, 54 ANTI-VIRAL RES. 79-88 (2002). The incidence of emergence of virus resistance to neuraminidase inhibitors is low and, in contrast to rimantadine-resistant viruses that retain full infectivity, resultant viral mutants are 100- to 1000-fold less infectious than wild-type virus in animal studies. Welliver, *supra*, n. 10, citing Covington, E., Mendel, D.R., Escarpe, P., et al., *Phenotypic and Genotypic Assay of Influenza Virus Neuraminidase Indicates a Low Incidence of Viral Drug Resistance During Treatment with Oseltamivir*, 18 J. CLIN. VIROL. 253 (2000).

⁸⁶ Carr, *supra*, n. 85.

including H5N1.⁸⁷ Nevertheless, based on what has been seen so far, neuraminidase inhibitor-resistant influenza virus variants may be substantially inferior in fitness and transmissibility to those strains that remain susceptible to drug.⁸⁸

Resistance to one adamantane typically means resistance to the other. Significantly, that is not true of the neuraminidase inhibitors. Resistance to oseltamivir does not mean resistance to zanamavir, nor vice-versa.⁸⁹ The mechanisms of resistance to these two agents are different, and so cross-resistance has not been observed. That is one of the reasons why most experts who advocate drug stockpiling also recommend that a supply of both be maintained.

Side effects: Across all subjects (children, adolescents and adults), oseltamivir is generally well tolerated when administered for both treatment and prophylaxis, but gastrointestinal, respiratory, and general disorders are the most frequently reported adverse events. Most have been of mild or moderate intensity, and few are considered to be drug-related.⁹⁰ Oseltamivir causes mild nausea and vomiting (in about seven percent of cases) that is relatively short-lived (first day or two of therapy), and in the published trials this did not affect compliance.⁹¹ Nevertheless, the package inserts for both available neuraminidase inhibitors state:

There have been postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who were receiving neuraminidase inhibitors ... Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon based on usage data ... These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of [neuraminidase inhibitors] to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.⁹²

The incremental risk of such harms may be modest, or even illusory. A review of abnormal behavior in 50 children hospitalized with flu reported such conduct in six children before antiviral therapy and in eight after. Thirteen were treated with oseltamivir, one with zanamavir, and one with both.⁹³ Concern about these threats nevertheless prompted Japan to limit use of oseltamivir in children. Experience with neuraminidase inhibitors in the United States does not seem to have been accompanied by problems such as these, but these agents have been used less often here than in Japan.

⁸⁷ See, de Jong, Menno D., Than, Tran Tan, Khahn, Truong Huu, et al., *Oseltamivir Resistance During Treatment of Influenza A (H5N1) Infection*, 353 N. ENGL. J. MED. 2667-2672 (2005); see also, Le, Q. Mai, Someya, Kazuhiko, Sakai, Yuko T., et al., *Isolation of Drug-Resistant H5N1 Virus*, 437 NATURE 1108 (2005).

⁸⁸ Yen, *supra*, n. 85.

⁸⁹ CDC, *Influenza Activity—United States and Worldwide, May 18-Sept. 19, 2008*, *supra*, n. 83. Of 187 isolates studied at the WHO Collaborating Center for Surveillance, Epidemiology, and Control of Influenza at CDC, 185 were sensitive to zanamavir, and two required additional testing. *Id.*

⁹⁰ Hayden, *supra*, n. 2; Aoki, *supra*, n. 51.

⁹¹ Stiver, *supra*, n. 1.

⁹² See, Tamiflu package insert, available at <http://www.rocheusa.com/products/tamiflu/pi.pdf>, and Relenza package insert, available at http://us.gsk.com/products/assets/us_relenza.pdf, (both last visited Jan. 19, 2009).

⁹³ Goshima, Noriko, Nakano, Takashi, Nagao, Mizuho, et al. *A Clinical Study of Abnormal Behaviors in Patients with Influenza*, 18 INFECTION & IMMUNITY IN CHILDHOOD 376 (2006).

In considering side effects, however, one must recognize that influenza itself poses risks of serious neurological problems. Febrile seizures are the most frequently encountered influenza-associated CNS complication, with one in five children hospitalized with flu experiencing one or more events. Usually, symptoms resolve without neurological sequelae, but the risk for subsequent afebrile convulsions may be increased.⁹⁴ Influenza-associated encephalitis/encephalopathy is a less common but potentially more serious complication, most widely reported in Japan but also observed in other East Asian nations, North America and Europe. Symptoms and signs include febrile seizures and abnormal behavior in mild cases, with rapid evolution through decreased consciousness to coma in severe forms. Death or grave neurological sequelae occur in the most serious cases.⁹⁵ Influenza may also trigger Reye's syndrome, Guillain-Barré syndrome, post-encephalitic Parkinson's disease, and the rare Kleine-Levin syndrome.⁹⁶ In weighing the possibility of side effects of antivirals, then, one should consider not only the mortality of the disease under treatment, but also its neurologic morbidity.

VI. OFFICIAL CONCLUSIONS

A. Japan

On July 11, 2008, the Japanese government asked the country's Drug Safety Committee to consider lifting the ban on oseltamivir prescriptions for children between ages 10 and 19 after a study revealed that psychotic behavior was not increased in these patients. The study, funded by Japan's Ministry of Health, Labor and Welfare, collected data from 10,000 flu patients up to age 18, and found that 12 percent of 7,487 patients less than 18 years old taking oseltamivir behaved abnormally, compared with 13 percent of 2,728 not taking the drug. The study seems to suggest that abnormal behaviors may actually be related not to the drug but to the influenza it is prescribed to treat.⁹⁷

B. The WHO Position

Despite limited data, the possibility of resistance, and the risk of side effects, an expert panel convened by WHO strongly recommended oseltamivir for persons with avian H5N1 influenza infection.⁹⁸

⁹⁴ Toovey, Stephen, *Influenza also Created Central Nervous System Dysfunction: A Literature Review*, 6 TRAVEL MED. INFECT. DIS. 114-124 (2008).

⁹⁵ *Id.*

⁹⁶ *Id.* Kleine-Levin syndrome is a rare form of periodic hypersomnia seen predominately in males and associated with excessive appetite for food and sometimes for sex, accompanied by behavioral abnormalities, impaired thought processes, and hallucinations. National Institute of Neurological Disorders and Stroke, Kleine-Levin Syndrome Information Page, available at http://www.ninds.nih.gov/disorders/kleine_levin/kleine_levin.htm, (last visited 9 October 2009).

⁹⁷ Matsuyama, Kanoko, *Roche May Boost Tamiflu Sales After Tests Deny Tamiflu Link*, BLOOMBERG, (July 11, 2008), available at <http://www.bloomberg.com/apps/news?pid=20601202&sid=a0R4y8jTnk.E&refer=healthcare>, (last visited Jan. 19, 2009). *But see*, Ministry to Review Links Between Tamiflu, Behavior, THE YOMIURI SHIMBUN, (Aug. 7, 2008), available at <http://www.yomiuri.co.jp/dy/national/20080807TDY03302.htm>, (last visited Aug. 8, 2008) (Japan's Health, Labor and Welfare Ministry to review findings on the issue after a private company reported discovering errors in the processing of data in the original study).

⁹⁸ Schunemann, Holger J., Hill, Suzanne R., Kadad, Meetal, et al., *WHO Rapid Advice Guidelines for Pharmacological Management of Sporadic Human Infection with Avian Influenza A (H5N1) Virus*, 7 LANCET 21-31 (2007) cited in, HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 18.

C. *The U.S. Government Position*

The Federal government appears to have reached the same conclusion. In fact, the government strongly encourages private sector antiviral stockpiling as a part of a comprehensive pandemic plan.⁹⁹ HHS wrote: "Implementing prophylactic antiviral drug strategies ... will require the establishment of stockpiles in the private sector. This approach is consistent with the role employers play in protecting their workers and operations against other types of risk."¹⁰⁰ The federal government takes the position that the private sector ought to stockpile because the government will not do so, at least not to the extent necessary:

Implementation of recommendations for prophylaxis of healthcare and emergency services workers who have high-risk exposures and for PEP in recommended settings will depend largely on private sector organizations and businesses purchasing and stockpiling antiviral drugs for their employees. The [government's] working group encourages governments, healthcare organizations and other employers, and families and individuals as appropriate, to purchase and stockpile sufficient antiviral drug supply to support recommended antiviral drug use strategies and to plan for effective implementation at the time of a pandemic as part of comprehensive pandemic planning and preparedness.¹⁰¹

Nor is the passage quoted above the agency's only articulation of this view:

Expanded [production] capacity now allows expanded recommendations. However, these recommendations do not obligate the Federal Government or public sector to purchase or stockpile antiviral drugs for all recommended uses and implementation will depend on the actions of other sectors of society. Pandemic preparedness is a shared responsibility of all levels of government, businesses, families, and individuals. Responsibility for purchasing and stockpiling antiviral drugs for prophylaxis of occupationally defined groups will largely be in the private sector.¹⁰²

HHS has specifically called upon critical infrastructure companies to stockpile: businesses that provide goods or services essential to community health, safety or well-being. In addition to healthcare and emergency services, critical infrastructure sectors, as defined by the Department of Homeland Security, include utilities (electricity, natural gas, water), communications and information technology, transportation, food and agriculture, banking and finance, pharmaceuticals, chemicals, oil and postal and shipping.¹⁰³ Especially important to provide for are those workers who are individually critical and whose absence would jeopardize provision of essential services.¹⁰⁴ On repeated occasions, various branches of the federal government have asserted that companies making up the critical infrastructure are under

⁹⁹ CDC, *Proposed Considerations For Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*, (Oct., 2007), available at <http://aspe.hhs.gov/panflu/stockpiling.html>, (last visited Jan. 19, 2009).

¹⁰⁰ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45.

¹⁰¹ *Id.*, at 1-2.

¹⁰² *Id.*, at 7.

¹⁰³ *Id.* at 23.

¹⁰⁴ *Id.* 45, at 2.

a “special responsibility” to plan to maintain their services in a pandemic.¹⁰⁵ The government has declared that antiviral prophylaxis is one intervention that can protect the health of workers, decrease absenteeism, and help preserve the ability to deliver essential goods and services.¹⁰⁶

This emphasis does not mean that companies outside critical infrastructure industries can ignore the issue; according to HHS, these companies also “should strongly consider antiviral prophylaxis.”¹⁰⁷ Using prescription antiviral drugs to treat and prevent infection will be an important component of a pandemic influenza response.¹⁰⁸

VII. ANTIVIRAL STOCKPILING OPTIONS PROGRAMS

In event of a pandemic, the availability of antivirals is apt to become problematic. Demand will outstrip supply.¹⁰⁹ The SARS outbreak demonstrated that when the next influenza global or pandemic virus arises there will be virtually unlimited demand for antiviral drugs and vaccines.¹¹⁰ Even in a nation as prosperous as the United States, rationing will probably be necessary; medical ethicists have explicitly called for restriction of medications, including oseltamivir in pandemic.¹¹¹ An approach that may solve this problem is to stockpile antivirals in advance. Obviously, this entails costs: the purchase price, plus the cost of storage; and the risk of expiration of products with limited (five-year) shelf lives.¹¹²

¹⁰⁵ See, e.g., Pandemic Flu Business Letter, 12/6/05, from Michael O. Leavitt, Secretary, HHS, Carlos M. Gutierrez, Secretary, Department of Commerce, and Michael Chertoff, Secretary, Department of Homeland Security, <http://www.pandemicflu.gov/plan/workplaceplanning/panbusletter.html>, (last visited Jan. 19, 2009). See also, Implementation Plan for the National Strategy for Pandemic Influenza, Ch. 2, *U.S. Government Planning for a Pandemic*, available at http://www.whitehouse.gov/homeland/nspi_implementation_chap02.pdf, (last visited Jan. 19, 2009) (“Because the impact of a pandemic will be felt across society, it is essential that all institutions prepare for what would normally be left to the purview of the health and medical communities. This requires a shift in thinking for most governmental and non-governmental entities, particularly businesses, which may not be accustomed to planning around health considerations. While these organizations have a responsibility to plan on behalf of their employees, customers, students, and other stakeholders, it is incumbent upon the health and medical communities to provide guidance on how to accomplish this planning. This can only be accomplished through the establishment of relationships between the health community and agencies across the government and entities across the community.”). See also, DHS, *Pandemic Influenza: Preparedness, Response, and Recovery, Guide for critical infrastructure and key resources*, Section 1: Introduction, 1.3, Situation, at 2, available at <http://www.pandemicflu.gov/plan/pdf/cikrpanemicinfluenzaguide.pdf>, (last visited Jan. 19, 2009) (“Preparedness for and response to a pandemic outbreak is a shared responsibility of all levels of government and the private sector.”); Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan: One Year Summary* (July 2007), Executive Summary, at 1; Introduction at 6 available at <http://www.whitehouse.gov/homeland/pandemic-influenza-oneyear.html>, (last visited Jan. 19, 2009) (“It is everyone’s responsibility to remain vigilant.”); GAO, “Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy,” GAO-07-781 (Aug. 2007), at 25, available at <http://www.gao.gov/new.items/d07781.pdf>, (last visited Jan. 19, 2009) (“The [Homeland Security Council’s 2005 *National Strategy for Pandemic Influenza*] recognizes that preparing for a pandemic is more than a purely federal responsibility, and that the nation must have a system of plans at all levels of government and in all sectors outside of government that can be integrated to address the pandemic threat.”).

¹⁰⁶ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45, at 12.

¹⁰⁷ *Id.* at 2.

¹⁰⁸ *Id.* at 1.

¹⁰⁹ Marsh, Inc., *supra*, n. 16.

¹¹⁰ Oxford, *supra*, n. 21.

¹¹¹ Deveraux, Asha, et al., *Summary of Suggestions from the Task Force for Mass Critical Care Summit, January 26-27, 2007*, 133 CHEST 1S-7 (2008).

¹¹² For a microeconomic analysis of the costs and benefits of preparing for pandemic, see, Mawani, Amin, *Making a Case for Investing in Pandemic Preparedness*, Paper presented at the World Conference on Disaster Management, (June 15-18, 2008), Toronto, Canada, available at <http://www.schulich.yorku.ca/pandemic>, (last visited Jan. 19, 2009).

Both Roche and GSK have recently developed low-cost means to secure supplies of their antiviral products. Under the Roche Antiviral Protection Program (RAPP), Roche will charge corporate customers a yearly fee of \$6.00 per covered employee. In exchange, Roche will dedicate a supply of drug for that purchaser and store it properly. Under RAPP, Roche anticipates that within 48 hours of learning of the customer's request, it will deliver a course of treatment of Tamiflu, at its Wholesale Acquisition Cost (WAC), to the location the customer chooses. This provision directly addresses the supply/demand imbalance inevitable in a pandemic. RAPP is offered as a means to permit securing a yearly stockpile of the drug, with its five-year shelf life, without actually requiring the customer to store the capsules itself. The stock is rotated as product nears expiry. The customer has the right to terminate the agreement at any time.

GSK, manufacturer of Relenza (zanamavir), announced a similar program on September 3, 2008.¹¹³ The GSK program, like Roche's, will provide to participating companies the right to purchase a designated supply of its product, which GSK will store in an appropriate environment until needed. The GSK decision means that now companies may utilize an options program for either or both of the two available neuraminidase inhibitors. "Both [medications] are in the U.S. Government's Strategic National Stockpile, which contains 80 percent oseltamivir and 20 percent zanamavir. Relenza is in a powder form that is inhaled from a breath-activated plastic device and is intended to be taken twice a day."¹¹⁴

The new programs raise a number of potential legal issues. Both antivirals are prescription medications, for example, and so can be made available to patients only after evaluation by an authorized prescriber.¹¹⁵ Should anyone using either drug claim to have been injured as a result, liability issues could arise.¹¹⁶ An antiviral option program will have to be integrated into whatever other benefits the company provides to employees.¹¹⁷ The tax consequences of creating one may need to be considered as well.¹¹⁸ These and other issues are beyond the scope of this paper. We turn, instead, to the question whether a company may be under a duty to consider programs such as those now available from manufacturers of antivirals.

VIII. ARE COMPANIES UNDER A DUTY TO CONSIDER ANTIVIRAL STOCKPILING OPTIONS PROGRAMS?

When a corporation itself fails to take action against a director or officer whose actions or inactions cause a corporate loss, shareholders may be able to sue "derivatively," that is, in the name of the company.¹¹⁹ Could failure to take cost-effective

¹¹³ See, Center for infectious Disease Research and Policy (CIDRAP), *Glaxo Offers Programs to Boost Employer Antiviral Stockpiling*, available at <http://www.cidrap.umn.edu/cidrap/content/influenza/biz-plan/news/sep0308relenza.html>, (last visited Jan. 19, 2009).

¹¹⁴ *Id.*

¹¹⁵ See, e.g., § 503(b)(4) of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. 353(b)(4) and state statutes governing prescribing.

¹¹⁶ Companies may need to analyze the effect of workers' compensation laws, for example, and of enactments such as the Public Readiness and Emergency Preparedness (PREP) Act, Pub. L. 109-148, 119 Stat. 2680 (2005).

¹¹⁷ The company may have to factor in provisions of the Employee Retirement Income Security Act of 1974, as amended, Pub. L. 93-406, 88 Stat. 829 (1974), the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99-272, 100 Stat. 82 (1985), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, 110 Stat. 1936 (1996).

¹¹⁸ See, e.g., Internal Revenue Code, §§ 105 and 106 (Thomson-West Suppl. 2008).

¹¹⁹ See *BLACK'S LAW DICTIONARY*, 475 (8th ed. 2004).

precautions against a reasonably foreseeable future influenza pandemic provide the basis of a shareholder derivative suit?

Owing to recent weakening of the traditional defense provided by the business judgment rule, discussed below, the ability of a plaintiff's derivative suit to survive a motion to strike, and hence the cost of litigating the claim, has been rising. Courts seem to see themselves as playing a more supervisory role than they have historically. Some courts considering derivative suits appear to be prepared in some instances to hold corporate directors to a simple negligence standard, which may expose directors to liability for failure to take reasonable, cost-effective steps to protect the company's interests. Evolution in judicial thinking, then, seems to justify asking whether failure to take precautions against pandemic-related harms could expose corporate directors not only to costly future shareholder derivative litigation but even, possibly, to adverse verdicts.

A. *Fiduciary Duty*

Members of a corporation's board of directors owe a fiduciary duty to the corporation's shareholders.¹²⁰ That duty, a common law concept developed on the equity side of state courts, requires that directors "act for the benefit of [shareholders] on all matters within the scope of their relationship."¹²¹ A board's fiduciary duty has two parts: the duty of due care and the duty of loyalty.¹²² Directors breaching either leg of the duty may face personal liability for resulting damages.¹²³

1. *Care*

The duty of due care requires that when making corporate decisions directors exercise reasonable prudence. Directors must make a good faith effort to investigate issues and deliberate sufficiently to make an informed business judgment.¹²⁴ Although variously defined, good faith generally means "an honest exercise of business judgment."¹²⁵ Traditionally, analysis of a director's duty has focused mainly on the process of decision-making rather than on the decision's substance.¹²⁶ This emphasis upon process rather than substance means that, when making a business

¹²⁰ See, e.g., *Smith v. Van Gorkom*, 488 A.2d 858, 872 (Del. (1985)) (holding that directors were liable to shareholders for a failure to make an informed decision regarding the stock price offered during a cash-out merger, constituting gross negligence sufficient to overcome business judgment rule).

¹²¹ BLACK'S LAW DICTIONARY, 658 (8th ed. 2004).

¹²² *In re Walt Disney*, 907 A.2d 693, 745 (Del. Ch. (2005)) (plaintiffs claimed that corporate directors breached their fiduciary duty by approving an excessively generous severance package for an outgoing president). See also, *Mills Acquisition Co. v. Macmillan, Inc.*, 559 A.2d 1261, 1280 (Del. (1989)); ALI, *Principles of Corporate Governance: Analysis and Recommendations* pt. IV (duty of care), pt. V (duty of loyalty) (1994); Model Bus. Corp. Act § 8(C), (F) (2005). Delaware allows directors making decisions to rely on corporate officers, committees of other directors, and professional advisors, but only so long as they act in good faith, Del. Code Ann. tit. 8, § 141(e) (2003); *Brehm v. Eisner*, 746 A.2d 244, 261-2 (Del. (2000)), and only so long as such advisors have been selected "with reasonable care." Del. Code Ann. tit. 8, § 141(e) (2003).

¹²³ See *Emerald Partners v. Berlin*, 787 A.2d 85, 90 (Del. (2001)); see also, *ATR – Kim Eng. Fin. Corp. v. Araneta*, No. CIV.A. 489-N, 2006 WL 378350, at * 23 (Del. Ch. (2006)).

¹²⁴ See *Smith v. Van Gorkom*, *supra*, n. 120, 488 A.2d at 873; *In re Caremark Int'l. Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. (1996)) (holding that a corporate director's unconsidered inaction does not constitute an exercise of business judgment).

¹²⁵ *Smith v. Van Gorkom*, *supra*, n. 120, 488 A.2d at 889.

¹²⁶ See *Caremark*, *supra*, n. 124, 698 A.2d at 698.

decision, a director has met his duty of care to the company only when that director has made a good faith effort to acquire information adequate to do so.¹²⁷

Because directors and officers have a duty to “keep their eyes open,”¹²⁸ a court analyzing a due care claim must ask “whether there was a good faith effort to be informed and exercise judgment.”¹²⁹ In *Aronson v. Lewis*,¹³⁰ a shareholder sued the directors of Meyers Parking System, Inc. for waste of corporate assets in connection with an employment contract. In discussing the availability of the business judgment rule to defendant directors, the Delaware Supreme Court held that “directors have a duty to inform themselves, prior to making a business decision, of all material information reasonably available to them. Having become so informed, they must then act with requisite care in the discharge of their duties.”¹³¹ Thus, the duty of care entails “the need to pay attention, to ask questions and to act diligently and reasonably to become and remain generally informed.”¹³²

2. Loyalty

Classically, the duty of loyalty demands that directors place the interests of the company ahead of personal goals.¹³³ Loyalty prevents directors from self-dealing, such as enriching themselves at the expense of shareholders by means of misleading statements.¹³⁴ The original concept of loyalty has been broadened, however.¹³⁵ It now includes cases alleging bad faith—“any action that demonstrates a faithlessness or a lack of true devotion to the interests of the corporation and its shareholders,”¹³⁶ not just those asserting self-dealing.¹³⁷

B. The Business Judgment Rule

In shareholder derivative litigation, corporate directors often invoke the business judgment rule as a defense to claims alleging a breach of their fiduciary duty to the corporation.¹³⁸ The business judgment rule is a presumption that directors who make informed business decisions act in the best interests of the company.¹³⁹ Such a presumption protects corporate directors and reflects a policy judgment: it

¹²⁷ See *Caremark*, *supra*, n. 124, 698 A.2d at 698.

¹²⁸ *Gaillard v. Natomas Co.*, 256 Cal. Rptr. 702 (Ct. App. (1989))

¹²⁹ *Caremark*, *supra*, n. 124, 237 A.2d at 698.

¹³⁰ 473 A.2d 805 (Del. 1984), *overruled in part on other grounds*, *Brehm v. Eisner*, 746 A.2d 244, 253-54 (Del. (2000)). *Aronson* has been criticized, as in Johnson, Lyman, *The Modest Business Judgment Rule*, 55 BUS. LAW 625 (2000).

¹³¹ *Id.* at 812, *see also* *Paramount Communications, Inc. v. QVC Network, Inc.*, 637 A.2d 34, 48 (Del. (1994)); *Hanson Trust PLC v. ML SCM Acquisition, Inc.*, 781 F.2d 264, 274 (2d Cir. (1986)).

¹³² Am. Bar Ass’n. *Corporate Director’s Guidebook: Third Ed.*, 56 BUS. LAW 1571, 1582 (2001).

¹³³ *See, e.g.*, *Grove v. Bedard*, 2004 WL 2677216 (D. Me. (2004)).

¹³⁴ *See, e.g.*, *Sample v. Morgan*, 914 A.2d 647, 668 (Del. Ch. (2007)) (holding that director dishonesty towards shareholders constituted a breach of the duty of loyalty).

¹³⁵ *Stone ex rel. AmSouth Bancorporation v. Ritter* (*Stone v. Ritter*), 911 A.2d 362, 370 (Del. (2006)) (en banc) (holding that the duty of loyalty extends beyond cases involving self-dealing and other directorial conflicts of interest. The court wrote: “*Caremark* articulates the necessary conditions for assessing director oversight liability.” *Id.* at 365.

¹³⁶ *In re Bridgeport Holdings, Inc.*, 388 BR 548 (Bkrcty. Del. (2008)) quoting *Ryan v. Gifford*, 918 A.2d 341, 357 (Del. Ch. (2007)).

¹³⁷ *See, Stone*, *supra*, n. 135, 911 A.2d at 370. *See generally*, Bordonaro, Peter D., *Good Faith: Set in Stone?* 82 TUL. L. REV. 1119, 1133 (2008).

¹³⁸ *See, e.g.*, *Disney*, *supra*, n. 121, 907 A.2d at 746.

¹³⁹ *See, e.g.*, *Disney*, *supra*, n. 121, 907 A.2d at 747. *Aronson*, *supra* n. 130, 473 A.2d 805, is probably the most frequently cited judicial formulation of the business judgment rule.

is meant to “preclude a court from imposing itself unreasonably on the business and affairs of a corporation.”¹⁴⁰ To succeed in its claim against a corporate director, the plaintiff in a derivative suit must rebut the business judgment rule’s presumption that the director’s business decisions were informed and thus not reviewable by a court.¹⁴¹ Directors facing shareholder suits are often able to use the business judgment rule to persuade courts to dismiss cases against them before the costly process of discovery and trial.¹⁴²

A few examples may serve to illustrate how courts have utilized the business judgment rule.

In *Tomczak v. Thiokol*,¹⁴³ plaintiffs alleged that when approving the sale of a part of the corporation to another company the defendant directors breached their duty of care to stockholders. The court found that even though the decision to sell had been made hastily, the fact that the defendant directors had consulted outside experts (Goldman Sachs) demonstrated a good faith effort to be informed about the decision. Given the consultation and good faith effort, the court found that the defendant directors were not grossly negligent and the business judgment rule protected them.

In *Guttman v. Huang*,¹⁴⁴ plaintiff shareholders sued defendant directors alleging insider trading. Relying on *Caremark*,¹⁴⁵ the court ruled that to make a successful claim against a director, the plaintiffs had to show that “the directors were conscious of the fact that they were not doing their jobs.” Plaintiff also had to show that the defendants engaged in a systemic and sustained failure of oversight.

In *Mitchell v. Highland-Western Glass*,¹⁴⁶ plaintiff shareholders sued defendant directors for breach of fiduciary duty in the purchase of another corporation and for losses resulting from that purchase. Specifically, plaintiffs alleged that defendant directors failed to satisfy their duty of care by failing to obtain enough information about the company to be acquired. The defendant directors relied entirely on the target company’s account records and did not seek out information independently. The court found that relying on such information did not represent an “unintelligent and unadvised judgment.” Defendant directors were protected by the business judgment rule.

The business judgment rule, then, remains alive and well. The rule does not guarantee a corporate director’s success in shareholder derivative litigation, however.¹⁴⁷ Nor is the rule a complete bar to director liability: under certain circumstances a court will not apply the rule’s presumption.¹⁴⁸ Specifically, a director who makes an “unintelligent or unadvised judgment” may not be able to convince the court that he has exercised business judgment, and if not he will not be presumed to

¹⁴⁰ See, e.g., *Disney*, *supra*, n. 121, 907 A.2d at 746 (quoting *Cede v. Technicolor, Inc.*, 634 A.2d 345, 360 (Del. (1993))).

¹⁴¹ See, e.g., *Disney*, *supra*, n. 121, 907 A.2d at 748.

¹⁴² *In re PSE&G Shareholder Litig.*, 173 N.J. 258, 276-77 (2002) (citations omitted) (Plaintiff must show the decisionmaker’s “self-dealing or other disabling factor.” If he succeeds, “the presumption of the rule is rebutted, and the burden of proof shifts to the defendant . . . to show that the transaction was, in fact, fair to the corporation.”) See generally, Scarlett, Ann M., *Confusion and Unpredictability in Shareholder Derivative Litigation*, 60 FLA. L. REV. 589 (2008) (describing the changing and confusing application of corporate law in the Delaware courts).

¹⁴³ *Tomczak v. Morton Thiokol, Inc.*, (iv. A. No. 796), 1990 WL 42607 (Del. Ch. (1990)).

¹⁴⁴ 823 A.2d 492 (Del. Ch. (2003)).

¹⁴⁵ *Caremark*, *supra*, n. 124, 698 A.2d 959.

¹⁴⁶ 177 A. 831 (Del. Ch. (1933)).

¹⁴⁷ See, e.g., *Sample*, *supra*, n. 134, 914 A.2d 247.

¹⁴⁸ See *Disney*, *supra*, n. 121, 907 A.2d at 748.

have fulfilled his duty of care.¹⁴⁹ On the other hand, directors who are “reasonably informed”¹⁵⁰ and who “exercise reasonable oversight” may be able to invoke the rule successfully.

1. *The Good Faith Requirement*

As noted, good faith informs the care analysis. To establish lack of good faith, plaintiff must show a “sustained or systematic failure of the board to exercise oversight.”¹⁵¹ On its face, this seems a heavy burden to carry. Good faith is nevertheless “the Achilles heel of both the business judgment rule and statutory exculpation [from liability].”¹⁵²

Application of the good faith requirement in asserting the business judgment rule is illustrated in *In re Walt Disney*.¹⁵³ The Walt Disney Company’s shareholders initiated a derivative suit against its corporate directors alleging that the severance package for outgoing president Michael Ovitz was too generous.¹⁵⁴ Specifically, the shareholders alleged that the incumbent CEO breached his fiduciary duty to the company by failing to negotiate a more advantageous agreement with Mr. Ovitz, and that the directors had shirked their duty to confer respecting the deal or to question the terms of decision to terminate.¹⁵⁵ The agreement cost the corporation tens of millions of dollars when Mr. Ovitz left after little more than a year of service.¹⁵⁶ While the defendant corporate directors eventually prevailed in the suit against them, the litigation lasted 10 years and required a four-month trial.¹⁵⁷

In *Disney*, the court defined good faith as encompassing “all actions required by a true faithfulness and devotion to the interests of the corporation and its shareholders.”¹⁵⁸ A failure to act in good faith may be shown, said the court, where the fiduciary “intentionally acts with a purpose other than that of advancing the best interests of the corporation, where the fiduciary acts with the intent to violate applicable positive law, or where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties.”¹⁵⁹ The *Disney* court held that a plaintiff could rebut the business judgment rule by showing that the board of directors acted in bad faith.¹⁶⁰ “Where a director consciously

¹⁴⁹ *Id.* There are other limits on the power of the business judgment rule. “Whatever its merit ... the business judgment rule extends only as far as the reasons which justify its existence. Thus, it does not apply in cases, e.g., in which the corporate decision lacks a business purpose, is tainted by a conflict of interest, is so egregious as to amount to a no-win decision, or results from an obvious and prolonged failure to exercise oversight or supervision.” *Resolution Trust Corp. v. Dean*, 854 F.Supp. 626, 637 (D.Ariz.(1994)), quoting *Joy v. North*, 692 F.2d 880, 886 (2d Cir.(1982)), *cert. denied*, 460 U.S 1051, 103 S. Ct. 1498, 75 L.Ed.2d 930 (1983) (judgment for plaintiff for an irrational decision, not mere procedural flaws) (Conn. law, not Delaware) (superseded by statute. *See*, *Hill v. State Farm Mut. Auto. Ins. Co.*, 2008 WL 4277389, *37 (Cal. App. (2008))).

¹⁵⁰ Caremark, *supra*, n. 124, 145, 698 A.2d at 970

¹⁵¹ *Id.* at 971.

¹⁵² Bishop, Carter G., *Directorial Abdication and the Taxonomic Role of Good Faith in Delaware Corporate Law*, 2007 MICH. ST. L. REV. 905, 928 (2007).

¹⁵³ *Disney*, *supra*, n. 121, 907 A.2d 693 (Del. (2005)).

¹⁵⁴ *See, id.*, at 697.

¹⁵⁵ *Id.*, at 737.

¹⁵⁶ *Id.*

¹⁵⁷ *See* Scarlett, Confusion, *supra*, n. 142, at 604-606.

¹⁵⁸ *Disney*, *supra*, n. 121, 907 A.2d at 755.

¹⁵⁹ *In re Walt Disney Co. Derivative Litig.*, 906 A.2d 27 (Del. (2006)), *aff'd*, 906 A.2d at 67.

¹⁶⁰ *Id.* at 152. *See generally*, Bainbridge, Stephen M., Lopez, Star, & Oklan, Benjamin, *The Convergence of Good Faith and Oversight*, 55 UCLA L. REV. 559, 583 (2008).

ignores his or her duties to the corporation, thereby causing economic injury to its stockholders, the directors' actions are either 'not in good faith' or 'involve intentional misconduct.'"¹⁶¹

In *McCall v. Scott*,¹⁶² shareholders sought to hold corporate officers and directors liable for healthcare fraud allegedly perpetrated by the company. The court held that, where the duty of care claims arose from the board's unconscious failure to act, "a conscious disregard of known risks, ... if proven, cannot have been undertaken in good faith[; thus,] ... plaintiffs' claims are not precluded by [the company's charter provision designed to take advantage of Delaware's exculpatory statute]."¹⁶³

An earlier derivative suit against Caremark International asked whether directors' "unconsidered inaction" gave rise to liability.¹⁶⁴ In *Caremark*, the Delaware Chancery Court considered directors' duties to exercise care in assessing the company's compliance with legal requirements. It held that "a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists—will establish the lack of good faith that is a necessary condition to liability."¹⁶⁵ Chancellor Allen concluded that "liability to the corporation for a loss" could indeed "arise from an unconsidered failure of the board to act in circumstances in which due attention would, arguably, have prevented the loss."¹⁶⁶

These cases indicate that a director defending on the basis of the business judgment rule may face allegations of bad faith offered as a means to overcome the defense. The importance of good faith to the efficacy of the business judgment rule defense becomes clear when one considers the defendants' liability exposure without it. Professors Hill and McDonald have argued that if plaintiffs can successfully plead that a board did not act in good faith, two consequences follow. First, the defendants lose the business judgment rule's protective power. Second, the defendants become unable to invoke otherwise available state law exculpatory provisions to avoid personal liability.¹⁶⁷ If plaintiffs can succeed in adequately pleading either a loyalty violation (discussed below) or bad faith, then the case cannot, merely on the basis of an exculpatory statute, be dismissed on the pleadings. If the case survives the pleading stage, then defendants attempting to invoke an exculpa-

¹⁶¹ Walt Disney Co. Derivative Litig., 825 A.2d 275, 290 (citing Del. Code Ann. tit. 8, § 102(b)(7)(ii) (2001)).

¹⁶² 250 F.3d 997, 999-1001 (6th Cir. (2001))(McCall II), amending on denial of rehearing *McCall v. Scott*, 239 F.3d 808, 2001 Fed.App. 0040P (6th Cir. (2001)) (McCall I).

¹⁶³ *Id.* See also, *In re Abbot Labs. Derivative Shareholders Litig.*, 325 F.3d 795, 809-811 (7th Cir. (2003)). ("By 1986 [one year after *Van Gorkom*, *supra*, n. 120, was handed down], Delaware had already enacted a statute enabling a corporation to limit or eliminate the personal liability of directors for breaches of their duty of care. Some version of this approach has now been implemented in all fifty states, and virtually all of the nation's largest corporations include these exculpatory provisions in their charters." Lloyd L. Drury III, "What's the Cost of a Free Pass? A Call for the Re-Assessment of Statutes that Allow for the Elimination of Personal Liability for Directors," Social Science Research Network (2007), abstract, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=996423&rec=1&srcabs=960315, (last visited Jan. 19, 2009)).

¹⁶⁴ *Caremark*, *supra*, n. 124, 698 A.2d at 968.

¹⁶⁵ See *Id.*, at 971. See also, Williams, Cynthia A. & Conley, John M., *Is There an Emerging Fiduciary Duty to Consider Human Rights?* 74 U. CIN. L. REV. 75, 91 (2005).

¹⁶⁶ *Id.* at 967. See, Bainbridge, et al., *supra*, n. 160, 55 UCLA L. REV. at 599.

¹⁶⁷ Hill, Claire A. & McDonnell, Brett H., *Stone v. Ritter and the Expanding Duty of Loyalty*, 76 FORDHAM L. REV. 1769, 1773, 1774 (2007), citing Delaware General Corporation Law (DGCL), Del. Code Ann. tit. 8, § 102(b)(7)(ii) (2004) (statutory power to exculpate directors not available "for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law"); DGCL § 145(b) (power to indemnify directors, officers, employees and agents if "the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation").

tory statute must prove good faith. Thus, since most Delaware corporations have exculpation clauses in their certificates of incorporation, whether a pleading can survive a motion to dismiss may frequently depend on whether the plaintiffs have adequately pled a lack of good faith.¹⁶⁸

2. *Business Judgment Rule Applies to Actual Judgments Only*

The business judgment rule provides no protection to idle directors.¹⁶⁹ “Application of the [business judgment] rule of necessity depends upon a showing that informed directors did, in fact, make a business judgment authorizing the transaction under review.”¹⁷⁰ “[W]here directors have either abdicated their functions, or absent a conscious decision, failed to act,” the rule does not apply.¹⁷¹ Nor is it applicable to claims that directors failed to monitor management adequately, because in such cases the directors fail to exercise business judgment.¹⁷² Hence, to invoke the rule successfully, the director must show that he was a player on the field, not a spectator in the stands.

3. *Business Judgment Rule Requires Action on an Informed Basis*

The presumption of the business judgment rule applies only where “the directors ... acted on an informed basis, in good faith, and in the honest belief that the action taken was in the best interests of the company.”¹⁷³ “[T]o invoke the rule’s protection, directors have a duty to inform themselves, prior to making a business decision, of all material information reasonably available to them.”¹⁷⁴ So, a director wishing to invoke the rule must show not only that he acted, but that his actions were reasonably well-informed.

4. *Limitations on Application of the Business Judgment Rule in Bankruptcy*

Finally, the business judgment rule may offer little or no protection against claims asserted by creditors in bankruptcy, as opposed to shareholders. In *Auerbach v. Bennett*,¹⁷⁵ the New York Court of Appeals suggested that a director’s fiduciary duty may run to creditors.¹⁷⁶ Where a statute permits them to, shareholders have the right to limit the personal exposure of their directors, but have no right to do so on behalf of company creditors.¹⁷⁷ An insolvent corporation’s creditors may be entitled to assert derivative claims against directors on behalf of the corporation

¹⁶⁸ *Id.*

¹⁶⁹ Branson, Douglas M., *No Seat at the Table* 56 (2007).

¹⁷⁰ Kaplan v. Centex Corp., 284 A.2d 119, 124 (Del. Ch. (1971)).

¹⁷¹ Aronson, *supra* n. 130, 473 A.2d at 812, 813.

¹⁷² *In re Walt Disney Co. Derivative Litig.*, 907 A.2d 693, 748 (Del. Ch. (2005)), *aff’d*, 906 A.2d 27 (Del. (2006)).

¹⁷³ Aronson, *supra* n. 130, 473 A.2d at 812.

¹⁷⁴ *Id.* at 812. A director can be held accountable for “general inattention” to his duties. *Barnes v. Andrews*, 298 F. 614 (S.D.N.Y. (1924)). Because no harm to the corporation was shown, judgment was entered for the defense, but dereliction of duty is not protected by the business judgment rule. *Id.* At 617.

¹⁷⁵ 393 N.E.2d 994 (N.Y. (1979)).

¹⁷⁶ Lyda, Brian S., *The Y2K Problem and Director Liability: Does the Business Judgment Rule Apply?* 10 ALB. L.J. SCI. & TECH. 167, 198 (1999).

¹⁷⁷ Black, Bert & Whitener, Robert L., *Director Liability for Bad Judgment and Bad Faith*, 43 TRIAL 26, 28 (2007).

for breach of directors' duties if the corporation's assets have not been properly applied for the benefit of creditors in preference to the claims of shareholders.¹⁷⁸ After all, the directors "may be the last resource from which an injured party can seek retribution for damages sustained as a result of a corporate wrongdoing."¹⁷⁹

In *Francis v. United Jersey Bank*,¹⁸⁰ a widow, Mrs. Pritchard, and her two sons served as directors of the board of a closely-held family corporation. Unfortunately, Mrs. Pritchard's alcoholism prevented her from riding herd on her sons, who misappropriated corporate funds. Since she neglected her duties as a director, the bankruptcy trustee could recover from her and from her sons.¹⁸¹ Hence, in bankruptcy, the business judgment rule may offer less protection than it does for directors of a going concern.

For all its power, then, the business judgment rule can be overcome for actions taken in bad faith, for failures to act, and for actions insufficiently well-informed.

C. *The Changing Application of the Business Judgment Rule*

Delaware state courts are often seen as leading authorities on matters of corporate law.¹⁸²

In the wake of Enron and other public corporate scandals, Delaware courts appear to have been attempting to use their power in shareholder derivative lawsuits to exercise greater oversight over corporations.¹⁸³ In fact, Delaware courts have been allowing more shareholder derivative suits to proceed beyond the stage at which defendants move to dismiss for failure to state a claim.¹⁸⁴ This heightened receptivity to shareholder claims extends specifically to care in which directors invoke the business judgment rule.¹⁸⁵ Given the leadership of Delaware courts in corporate law, that trend could signal greater exposure for director defendants across the country.¹⁸⁶

¹⁷⁸ See *Schnelling v. Crawford* (In re James River Coal Co.), 360 B.R. 139, 170 (Bankr. E.D. Va. (2007)) (finding that post-confirmation trustee had standing to bring claims against directors for breach of fiduciary duty on behalf of creditors as a whole). In Delaware, creditors may not sue directly. See *N. Am. Catholic Educ. Programming Found., Inc. v. Gheewalla*, 930 A.2d 92, 102 (Del. (2007)) (holding that creditors have no direct cause of action against directors, even where corporation is insolvent).

¹⁷⁹ See *Technic Eng'g, Ltd. v. Basic Envirotech, Inc.*, 53 F.Supp.2d 1007, 1011 (N.D. Ill. 1999) (stating that "this Court predicts that the Illinois Supreme Court would find that both corporate officers and directors have a fiduciary duty to the corporation's creditors when the corporation becomes insolvent") cited in *Lyda*, *supra*, n. 176, at 199.

¹⁸⁰ 432 A.2d 814 (N.J. 1981).

¹⁸¹ *Francis v. United Jersey Bank*, 432 A.2d 814, 818-19 (1981).

¹⁸² Over half of U.S. public companies are incorporated in Delaware, and almost 60 percent of the FORTUNE 500. See, e.g., *Datko, Karen, The election is over—now what?* MONEYBLOG SMART SPENDING (2008), available at <http://blogs.moneycentral.msn.com/smartspending/archive/2008/11/05/the-election-is-over-now-what.aspx>, (last visited Jan. 19, 2009).

¹⁸³ See *Scarlett, Confusion*, *supra*, n. 142. See also, *Kerr, Janet E., Developments in Corporate Governance: The Duty of Good Faith and Its Impact on Director Conduct* 13 GEO. MASON L. REV. 1037, 1038-1039 (2006).

¹⁸⁴ See *Scarlett, Confusion*, *supra*, n. 142, at 608. See also, *Pereira v. Cogan*, 294 B.R. 449, 528 (S.D.N.Y. (2003)), *rev'd sub nom. Pereira v. Farace*, 413 F.3d 330 (2d Cir. (2005)); *In re Tyson Foods, Inc. Consol. Shareholder Litig.*, 919 A.2d 563 (Del. Ch. (2007)), *Joy*, *supra*, n. 149.

¹⁸⁵ See *Scarlett*, *supra*, n. 142.

¹⁸⁶ *Id.* at 591. See also, *Strine, Jr., Leo E., Derivative Impact? Some Early Reflections on the Corporation Law Implications of the Enron Debacle*, 57 BUS. LAW 1371 (2002) ("Enron might exert pressure on courts to look more carefully at whether directors have made a good faith effort to accomplish their duties." *Id.* at 1373, especially where directors "knew that their inadequate knowledge disabled them from discharging their duties with fidelity." *Id.* at 1393 (emphasis in original).

Disney provides a particularly current and enlightening warning to corporate directors. During its long and costly course, the case spanned both the pre- and post-Enron treatment of shareholder derivative suits.¹⁸⁷ In a motion to dismiss for failure to state a claim decided before the Enron scandal broke, the director defendants succeeded on the basis of the business judgment rule in terminating the suit before the onset of discovery.¹⁸⁸ The Delaware Supreme Court permitted the shareholder plaintiffs to amend their complaint, however.¹⁸⁹ After the second filing of the case, which occurred post-Enron, the trial court refused to dismiss the case on the basis of the business judgment rule.¹⁹⁰ In fact, in a 46-page section of the opinion, the court extensively reviewed the defendant directors' decision-making process and the substance of the decision itself.¹⁹¹ Such drawn-out litigation and extensive factual analysis of corporate directors' business decisions suggest that courts may be growing increasingly willing to review in detail the substance, rather than merely the procedure, of business decisions.¹⁹² This change in application of the business judgment rule means that the overall defense may be weaker and more unpredictable than in the past.¹⁹³

D. *Shareholder Derivative Suits Based on the Corporate Director Duty of Care*

1. *Erosion of the Gross Negligence Standard?*

Under Delaware law, directors must exercise "that amount of care which ordinarily careful and prudent men would use in similar circumstances."¹⁹⁴ This is classic negligence language; in negligence theory, liability attaches for harms caused by conduct falling below that which a reasonable person would engage in. The standard for a breach of care is nevertheless not simple negligence, as the quoted language suggests, but rather gross negligence,¹⁹⁵ demonstrated by actions taken "without the bounds of reason and recklessly"¹⁹⁶ or "so far without information that they can be said to have passed an unintelligent and unadvised judgment."¹⁹⁷ Although it is difficult to draw a bright line between simple and gross negligence, it is obviously more difficult to prove the latter than the former. According to one formulation, gross negligence is "reckless indifference to or a deliberate disregard of the whole body of stockholders' or actions which are 'without the bounds of reason.'"¹⁹⁸

¹⁸⁷ See Scarlett, *Confusion*, *supra*, n. 142, at 605.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Disney*, *supra*, n. 121, 907 A.2d 699-645.

¹⁹² See Scarlett, *supra*, n. 142.

¹⁹³ *Id.*

¹⁹⁴ *Rabkin v. Philip A. Hunt Chem. Co.*, 1997 WL 28436, at *2 (Del. Ch. (Dec. 17, 1987)) (the court considered and denied a motion for reargument of the court's decision that plaintiffs stated a claim against the Hunt directors based upon their alleged failure to learn of a one-year price commitment made by defendant Olin Corporation at the time it purchased a majority of the stock of Hunt.).

¹⁹⁵ *Smith v. Van Gorkom*, *supra*, n. 120, 488 A.2d at 873 (citing *Aronson v. Lewis*, *supra* n. 130, 473 A.2d at 812).

¹⁹⁶ *Gimbel v. Signal Companies, Inc.*, 316 A.2d 599, *aff'd per curiam*, 316 A.2d 619 (Del. Supr. (1974)), cited in *Van Gorkom*, *supra*, n. 120, 488 A.2d at 873, n. 13.

¹⁹⁷ *Van Gorkom*, *supra*, n. 120 at 873 n. 13.

¹⁹⁸ *Tomczak*, *supra*, n. 143 (quoting *Allaun v. Consol. Oil Co.*, 147 A. 257, 261 (Del. Ch. (1929)).

Although the gross negligence standard remains good law, ordinary negligence has been applied as a standard when, because the Board fails to act, the business judgment rule is inapplicable.¹⁹⁹ Courts typically apply a negligence standard in tort cases in which one party's failure to exercise due care has allegedly harmed another.²⁰⁰ To prove that a defendant is negligent, a plaintiff must show that the defendant acted unreasonably in failing to prevent some alleged harm.²⁰¹ Under this standard, a defendant's actions will be judged based on whether the substance of the defendant's decisions was reasonable.²⁰² In this way, the negligence standard may impose obligations different from, and potentially broader than, those arising under a more forgiving gross negligence standard.²⁰³

The significance of the simple negligence standard may be illustrated by a couple of examples. Where plaintiff alleged that directors failed to learn of a one-year price commitment made by a defendant purchaser corporation, and also failed to take action respecting that commitment before it expired, the court applied an ordinary negligence standard:

Consistent with the wide latitude granted to them under the business judgment rule, directors who undertake their decision making responsibility will not be held liable either for a fault in the decision making process or the decision itself unless they were grossly negligent. It does not seem logical to accord the same deference to directors who abdicate their managerial responsibilities. There would be little meaning to the business judgment rule if, in cases not implicating the duty of loyalty, directors were given the same protection from liability whether it applies or not. Accordingly, I conclude that ordinary negligence is the appropriate standard of liability in director neglect claims. I am satisfied that the decisions in *Aronson* and *Allis-Chalmers*²⁰⁴ support this result and that *Van Gorkom* did not adopt the gross negligence standard in claims such as this one.²⁰⁵

A plaintiff who can convince the court to apply a simple negligence standard has a better chance of surviving a motion to strike than one laboring under a duty to show gross negligence.

A New York court ruled recently that even though its state courts recognize the presumption afforded corporate directors under the business judgment rule, a director's decisions can still be evaluated under a negligence standard if challenged in a shareholder derivative suit.²⁰⁶ This ruling means that if a plaintiff can overcome the presumption of the business judgment rule, a New York court may

¹⁹⁹ *In re Walt Disney Co. Derivative Litig.*, 907 A.2d 693, 760 (Del. Ch. (2005)), citing *Rabkin v. Philip A. Hunt Chem. Corp.*, *supra*, n. 194. *See also*, *Cinerama, Inc. v. Technicolor, Inc.*, 663 A.2d 1134 (Del. Ch. (1994)) (establishes a simple negligence standard for directors acting as trustees, while discussing the similarities and differences of trust law and corporate law.)

²⁰⁰ *See, e.g.*, *Resag v. Washington Nat. Ins. Co.*, 414 N.E.2d 107 (Ill. App. Ct. (1980)) (holding that a defendant was not negligent for owning a building whose design was such that high wind velocities in its plaza caused a plaintiff harm).

²⁰¹ *See, e.g.*, 57A AM. JUR. 2d *Negligence* § 132 (2008).

²⁰² *See, e.g.*, 57A AM. JUR. 2d *Negligence* § 132 (2008).

²⁰³ *See, e.g., supra*, n. 145, 698 A.2d 959.

²⁰⁴ *Graham v. Allis-Chalmers Mfg. Co.*, 188 A.2d 125 (Del. Supr. (1963)).

²⁰⁵ *Rabkin v. Philip A. Hunt Chem. Co.*, *supra*, n. 194.

²⁰⁶ *Hellman v. Helman*, 860 N.Y.S.2d 817, 2008 WL 659801, 14 (N.Y. Sup. Ct. (2008)) (holding that a negligence standard would apply to a director's decision to sign a disadvantageous lease if the plaintiff could overcome the business judgment rule presumption).

evaluate the substance of the directors' decision for its reasonableness.²⁰⁷ Decisions such as these suggest that, in certain circumstances, a director may face personal liability if he is unable to show to a judge looking retrospectively at his decision that it was reasonable.

2. *Substance, Not Just Procedure*

Historically, derivative suits alleging a breach of the duty of care based on the substance of the director's decisions, as distinct from the process by which that director made them, have generally failed.²⁰⁸ More recently, however, courts have become more willing to consider the substance of directors' decisions. Once again, *Disney* is a good example: The court explicitly evaluated each director's judgment respecting the provisions of the contract offered the outgoing officer. "With regard to [directors] [Sidney] Poitier and [Ignacio] Lozano, ... [Chancellor] Chandler ... reached his decision [that defendants acted in the best interest of Disney] by judging the substantive wisdom of their actions. This is precisely what a strict interpretation of the business judgment rule is supposed to prohibit."²⁰⁹

3. *Lack of Knowledge*

According to the proverb, "ignorance of the law is no excuse." In the context of corporate board decisionmaking, a lack of knowledge resulting from abdication of directorial responsibility affords no defense to care claims. "Directors who knowingly allow others to make major decisions affecting the future of the corporation wholly without supervision or oversight may not defend on their lack of knowledge, for that ignorance itself is a breach of duty."²¹⁰

4. *Officers Not Protected*

Although case law on the question is limited,²¹¹ some scholarly commentary has suggested that decisions of officers may be vulnerable to more searching judicial scrutiny than that trained upon directors. The argument is that the business judgment rule need not apply to officers, because the policy reasons justifying its application to directors do not obtain.²¹² The argument, then, becomes: Officers owe a duty of ordinary care;²¹³ hence officers may be held to a standard of ordinary, not gross, negligence.²¹⁴ Moreover, officers, unlike directors, may not be statutorily exculpated from personal liability.²¹⁵ If a plaintiff can convince a court to embrace this approach, officers may be more vulnerable to liability than directors.

²⁰⁷ *Id.*

²⁰⁸ See Caremark, *supra*, n. 124, 698 A.2d at 698.

²⁰⁹ Rosenberg, David, *Galactic Stupidity and the Business Judgment Rule*, 32 J. CORP. L. 301, 318 (2007).

²¹⁰ Joy, *supra*, n. 149, 692 F.2d at 896.

²¹¹ Platt v. Richardson, Fed. Sec. L. Rep. (CCH) ¶94,786 (M.D. Pa. (1989)); Gaillard v. Natomas Co., *supra* n.128, 208 Cal.App. 1250, 256 Cal. Rptr. 702 (1989).

²¹² Johnson, Lyman, *Corporate Officers and the Business Judgment Rule*, 60 BUS. LAW 439 (2005); Johnson, Lyman & Ricca, Robert V., *(Not) Advising Corporate Officers About Fiduciary Duties*, 42 WAKE FOREST L. REV. 663, 665 (2007).

²¹³ Restatement (Second) of Agency § 379 (1958).

²¹⁴ Johnson, Lyman & Millon, David, *Recalling Why Corporate Officers are Fiduciaries*, 46 WM. & MARY L. REV. 1597, 1600 (2005).

²¹⁵ Del. Code Ann. tit. 8, § 102(b)(7) (2001).

E. *Shareholder Derivative Suits Based on the Duty of Loyalty*

As noted above, loyalty claims are no longer limited to “financial or other cognizable fiduciary conflicts of interest.”²¹⁶ Loyalty now also includes good faith. In *Stone v. Ritter*,²¹⁷ shareholders sued directors after the company paid \$50 million in fines and civil monetary penalties for violating the Bank Secrecy Act.²¹⁸ Plaintiffs alleged that although the company did have a program to monitor compliance with the law, the program was inadequate. The Delaware Supreme Court clarified that breach of good faith is a “necessary condition to liability” for a violation of the duty of loyalty.²¹⁹ Acts done in bad faith breach the duty of loyalty.²²⁰ As a result, instead of being recognized as a separate fiduciary duty, good faith has been subsumed by loyalty. “A director cannot act loyally towards the corporation unless she acts in the good faith belief that her actions are in the corporation’s best interest.”²²¹

When discussing the merits of the defendants’ business judgment rule argument, the *Ryan v. Gifford*²²² court cited *Stone*. In *Ryan*, plaintiffs sued John Gifford, the founder of the business, its CEO and board chairman, for backdating stock options. Chancellor Chandler rearticulated the *Stone* holding by stating that “acts taken in bad faith breach the duty of loyalty.”²²³ The court then recited the examples of bad faith noted first in *Disney* and cited in *Stone*.²²⁴ Referring to the three examples in *Disney* of conduct breaching the duty of good faith as “bad faith” conduct, the *Ryan* court acknowledged that more examples might exist.²²⁵ “These examples include any action that demonstrates a faithlessness or lack of true devotion to the interests of the corporation and its shareholders.”²²⁶

1. *Failure to Act in the Face of Duty Breaches the Duty of Loyalty*

Abdication of director duty is evidence of disloyalty.²²⁷ As the *Disney* court observed, “Deliberate indifference and inaction in the face of a duty to act is ... conduct that is clearly disloyal to the corporation. It is the epitome of faithless conduct.”²²⁸

2. *Liability for Ignorance*

Caremark involved directors who allegedly failed to monitor adequately the corporation’s compliance with the law.²²⁹ In *Caremark*, the company settled the

²¹⁶ *Stone*, *supra*, n. 135, 911 A.2d at 370.

²¹⁷ *Id.* at 362.

²¹⁸ 31 U.S.C. § 5318, *et seq.* (2006).

²¹⁹ 911 A.2d 369 (citing *In re Caremark*, *supra*, n. 124, at 971. *See*, Bordonaro, *supra*, n. 137, 82 TUL. L. REV. 1119.

²²⁰ *Stone*, *supra*, n. 135, 911 A.2d 362.

²²¹ *Id.* at 369 (quoting Guttman *supra*, n. 144).

²²² 918 A.2d 341, 357 (Del. Ch. (2007)).

²²³ *Id.*

²²⁴ *Id.*, *see* *Stone v. Ritter*, *supra*, n. 135, 911 A.2d at 369; *In re Walt Disney Co. Derivative Litig.*, 906 A.2d 27, 67 (Del. (2006)).

²²⁵ *Ryan*, *supra*, n. 222, 918 A.2d at 357.

²²⁶ *See, id.* *See also*, Bordonaro, *supra*, n. 137, 82 TUL. L. REV. at 1138-1139.

²²⁷ *Cede & Co. v. Technicolor, Inc.*, *supra*, n. 140, 634 A.2d at 363.

²²⁸ *In re The Walt Disney Co. Derivative Litig.*, No. CIV. A 15452, 2005 WL 2056651, at *36 (Del. Ch. (2005)).

²²⁹ *Caremark*, *supra*, n. 124, 698 A.2d at 960-962.

government's fraud charges by pleading guilty to one count and paying criminal fines and civil claims in the amount of approximately \$165 million.²³⁰ The directors had been ignorant of the wrongdoing.²³¹ Chancellor Allen distinguished liability arising from 1) an unwise or negligent board decision or from 2) a board's unconsidered failure to act where action would have prevented the loss.²³² Here, under 2), the Board's duty was to determine whether "the corporation's information and reporting system [was] in concept and design adequate to assure the board that appropriate information [would] come to its attention in a timely manner as a matter of ordinary operation, so that it [could] satisfy its responsibility."²³³ The court found Caremark's information system to represent "a good faith attempt to be informed of the relevant facts,"²³⁴ but opined in *dicta* that a failure in good faith to assure that such a system was in place "under some circumstances [could] ... render a director liable for losses."²³⁵ In *In re Caremark International, Inc. Derivative Litigation*,²³⁶ the Delaware chancery court noted that directors' sustained or systematic failure to oversee the corporate decisionmaking process is sufficient to prove bad faith even without proof of a bad faith motive.²³⁷ The *Caremark* chancellor stated that, to prevail, the plaintiffs must prove that the directors knew or should have known that illegal activities were occurring, that the directors made no good faith effort to prevent or address the situation, and that their failure to act proximately caused the damages.²³⁸ The chancellor did not require the plaintiff to prove that the directors had a bad faith motive or intent, however.²³⁹

3. Liability for Recklessness

"Recklessness" is the "knowing disregard of a substantial and unjustifiable risk."²⁴⁰ A reckless actor intends no harm.²⁴¹ Instead, he has an "I don't care" attitude.²⁴²

Consistent with *Caremark*, the Delaware chancery court recently concluded that directors' conscious and sustained failure to fulfill their oversight duties was sufficient to establish bad faith in *In re Walt Disney Co. Derivative Litigation*²⁴³ even though there was no proof of a bad faith motive. The chancellor found that the plaintiffs had sufficiently pleaded that the directors "consciously and intentionally disregarded their responsibilities,"²⁴⁴ acted with "deliberate indifference,"²⁴⁵ and

²³⁰ *Id.*, at 965 n.10.

²³¹ *Id.* at 971-2.

²³² *Id.* at 967.

²³³ *Id.* at 970.

²³⁴ *Id.* at 971.

²³⁵ *Id.* at 971.

²³⁶ 698 A.2d 959 (Del. Ch. (1996)).

²³⁷ *See, id.* at 971.

²³⁸ *Id.* at 971.

²³⁹ *See id.* *See also*, Berry, Matthew R., *Does Delaware's Section 102(B)(7) Protect Reckless Directors From Personal Liability? Only if Delaware Courts Act in Good Faith*, 79 WASH. L. REV. 1125, 1130-1132 (2004).

²⁴⁰ *Cont'l Ins. Co. v. Dooley*, No. CIV.A.02C-07-065JOH, 2003 WL 1903771, at 6 (Del. Super. Ct. (Feb. 4, 2003)) (applying the definition of recklessness at Del. P.J.I. Civ. 5.9).

²⁴¹ *Id.*, at 6 (quoting Del. P.J.I. Civ. 5.9)

²⁴² *See* Del. P.J.I. Civ. 5.9; *see also*, Dooley, *supra*, n. 240, at 6 (applying the definition of recklessness from Del. P.J.I. Civ. 5.9). *See generally*, Berry, *supra*, n. 239, 79 WASH. L. REV. at 1135.

²⁴³ 825 A.2d 275, *supra*, n. 161, at 278 (Del. Ch. (2003)).

²⁴⁴ *Id.* at 289 (emphasis omitted)

²⁴⁵ *Id.*

“adopted a “we don’t care about the risks’ attitude”²⁴⁶ The chancellor stated that when directors abdicate all responsibility in making a material corporate decision, it raises the question whether the board’s decisionmaking process was conducted in good faith.²⁴⁷ The chancellor concluded that if directors caused harm to shareholders by consciously ignoring their corporate duties, then the directors acted in bad faith or committed intentional misconduct.²⁴⁸ *Disney* does not discuss “recklessness” per se, but one could interpret the court’s discussion of directors’ conduct in terms consistent with and reminiscent of recklessness.²⁴⁹ For example, the chancellor stated that the directors “consciously and intentionally disregarded their responsibilities” and “adopted a “we don’t care about the risks attitude.”²⁵⁰ This description does not seem to be very different from a “knowing disregard” of risk, and the court allowed the case to proceed.

In *McCall I*,²⁵¹ plaintiffs alleged that in failing to take steps to prevent healthcare fraud, the directors may have acted recklessly, but not intentionally. The court agreed that “[t]o the extent that recklessness involves a conscious disregard of a known risk,” these allegations brought the case within the exculpatory statute’s good faith exception.²⁵² The directors allegedly knew that the senior managers’ policies encouraged employees to engage in unlawful activities, but the directors recklessly failed to address these policies.²⁵³ The court found that the directors’ “sustained inattention to their management obligations” and “intentional ignorance of” and “willful blindness” to “red flags” surpassed mere breaches of the duty of due care.²⁵⁴ “[W]hile it is true that duty of care claims alleging only grossly negligent conduct are precluded by a [statutory] waiver provision, it appears that duty of care claims based on reckless or intentional misconduct are not.”²⁵⁵ “[W]e find that [plaintiffs] have alleged a conscious disregard of known risks, which conduct, if proven, cannot have been undertaken in good faith.”²⁵⁶

Two years later, *In re Abbott Laboratories*²⁵⁷ followed *McCall* by concluding that evidence of directors’ reckless conduct is sufficient to prove bad faith.²⁵⁸ The *Abbott* plaintiffs accused the directors of acting grossly negligent, recklessly, and intentionally when the directors failed to address employee misconduct that led to repeated violations of FDA regulations.²⁵⁹ In discussing Delaware’s recklessness standard, the Seventh Circuit quoted the *McCall* decision extensively and concluded that an Illinois statute modeled after Delaware’s exculpatory statute²⁶⁰ did not protect the directors from liability arising from their recklessness.²⁶¹

²⁴⁶ *Id.*

²⁴⁷ *See id.* at 289-290.

²⁴⁸ *Id.* at 290. (“Where a director consciously ignores his or her duties to the corporation, thereby causing economic injury to its stockholders, the director’s actions are either ‘not in good faith’ or ‘involve intentional misconduct.’” (quoting Del. Ann. tit. 8, § 102(b)(7)(ii) (2003))). Berry, *supra*, n. 239, 79 WASH. L. REV. at 1130-1132.

²⁴⁹ *See In re Walt Disney Co. Derivative Litig.*, 825 A.2d 275, *supra*, n. 161, at 278, 290 (Del. Ch. (2003)).

²⁵⁰ *See id.* at 289. *See also*, Berry, *supra*, n. 239, 79 WASH. L. REV. at 1140.

²⁵¹ 239 F.3d 808, *supra*, n.162.

²⁵² *Id.* at 818 (Delaware law).

²⁵³ *Id.* at 808.

²⁵⁴ *Id.* at 1001 (internal quotations omitted).

²⁵⁵ *Id.* at 1000.

²⁵⁶ *Id.* at 1001.

²⁵⁷ 325 F.3d 795 (7th Cir. (2003)).

²⁵⁸ *See id.* at 811.

²⁵⁹ *Id.*

²⁶⁰ *Id.* at 810.

²⁶¹ *Id.* at 811. *See*, Berry, *supra*, n. 239, 79 WASH. L. REV. at 1142.

4. *The Business Judgment Rule Does Not Protect Against Caremark Claims*

Since *Stone* moved oversight liability cases from care to loyalty,²⁶² this effectively removed *Caremark* failure-to-monitor claims from the protection of Delaware's exculpatory statute, which provides that directors may be exculpated from personal liability except, as clarified in *Stone*, in the case of loyalty violations.²⁶³ Whatever weaknesses might tend to diminish the ability of the business judgment rule to defeat care claims, it is clear that the rule remains good law there. It offers no solace for directors accused of breach of loyalty.

IX. APPLICATION TO PANDEMIC PREPAREDNESS

No case holds that directors are liable for losses occasioned by a failure to take steps to minimize the impact of a pandemic on their company. Such losses are certainly foreseeable, however, and there is evidence that precautions could decrease the company's losses. While any plaintiff bringing a claim against the directors for pandemic-related losses would be sledding uphill, evolution in applicable law suggests that the plaintiff might prevail on a motion to strike, and hence that the company could be forced to bear the expense of defense.

Corporate boards often concern themselves with such major issues as a change of control, or selection and where necessary discharge of a CEO. Rarely do they attend to the terms and conditions of employment for any employees outside the C-suite. One approach to defending a claim arising from arguably avoidable pandemic-related harms might be to assert that business continuity is not a board-level issue. But pandemics cannot be properly filed under sick leave. As discussed above, a severe pandemic poses an existential threat to the corporation, because its ubiquitous impact will be felt not only at all levels within the ranks of the company's own personnel, but at all suppliers and customers as well, probably for a protracted period and possibly in waves. Substantially all companies will lose money, and some will fail entirely. The impact upon the life of the company may be every bit as substantial as replacement of company leadership, for example. Indeed, since the executives are at neither higher nor lower risk of illness than their subordinates, one question each company should ask itself is how it will function if key personnel become unavailable. Board-level attention to such questions does not seem misplaced.

The probability that claims asserting breach of fiduciary duty for failure to prepare against pandemic will arise may be enhanced by governmental documents that repeatedly assert that businesses, especially those in the critical infrastructure, are under a "special duty" to prepare or are "responsible" for protecting their employees.²⁶⁴ But potentially troublesome language does not originate solely with the government. The U.S. Chamber's Institute for Legal Reform, for example, hardly an ally of the plaintiffs' bar, has said: "An organization's board of directors and senior management are collectively responsible for the organization's business

²⁶² Chiappinelli, Eric A., *Delaware Court on Good Faith (Again) and the Duties of Care on Loyalty*, (Nov. 8, 2006), available at http://businessentitiesonline.typepad.com/new_developments/2006/11/delaware_suprem.html.

²⁶³ Del. Code Ann. tit. 8, §102(b)(7) (2006). See generally Bordonaro, *supra*, n. 137, 82 TUL. L. REV. at 1136 (2008).

²⁶⁴ See, n. 105, *supra*.

continuity.”²⁶⁵ Plaintiffs could argue that corporate directors failing to carefully consider potentially effective measures to mitigate a pandemic’s effect, such as antiviral stockpiling options programs, have violated their duty of care to the corporation’s shareholders.²⁶⁶

Consider a Board that ignores the pandemic threat, which materializes, causing losses. The plaintiffs’ theory might be: “Had you prepared better against the consequences of pandemic, as by taking advantage of an antiviral option program, among other steps, you could have protected our workers better. We would have experienced less disruption and smaller losses.” Such a claim might be particularly plausible if a competing company, having adopted measures to ameliorate the harm, fared better and lost less money. Even though the company’s directors may eventually win a derivative suit based on such a theory, as happened in *Disney*, the costs in time, money, and emotional capital attendant to defending the suit could be substantial.

Claims proceeding on a care theory would stress directors’ duty to base actual decisions on informed judgment. Plaintiffs will suggest that, because action was not taken, or at least not taken in good faith, the business judgment rule does not apply, and ordinary negligence, not gross negligence, is the proper standard. This would invite or perhaps even require the court to engage in a reasonableness inquiry, possibly in the form of a cost-benefit analysis. Because the burden of proof could be less onerous, there may be some heightened exposure for officers as distinct from directors.

In discussing private antiviral stockpiling before options programs became available, HHS identified several business concerns that might deter a decision to stockpile antiviral drugs: cost, shelf-life, regulatory and logistical issues, potential liability, and the possibility that private stockpiles could be appropriated by the government.²⁶⁷ The first two of these appear to be directly ameliorated under the antiviral stockpiling options programs. The cost of such programs would be the \$6/person annual option price plus the additional cost of antiviral purchase at exercise. The expiration problem is eliminated under an arrangement that assures rotation of stock by the vendor. While the other factors have not disappeared, official governmental support for private stockpiling should go far towards addressing all of them.

Of course, even if there is a duty to consider taking precautions against pandemic, such a duty falls well short of an explicit duty to take a specific step, such as subscribing to an antiviral options program. It does suggest, though, that the risks and benefits of such a course will have to be considered.

Claims based on loyalty obligations would stress conscious disregard of a foreseeable risk. On a loyalty theory, plaintiffs will allege a duty to be aware of the threat posed by pandemic, and to act on that knowledge, and assert that in failing to act directors were disloyal. This theory may be attractive to plaintiffs because the business judgment rule provides no defense against loyalty claims. Plaintiffs might well also posit that a failure to consider risks and options is actionable recklessness, which does not require a showing of intent.

²⁶⁵ U.S. Chamber Institute for Legal Reform, *Securities Class Action Litigation: The Problem, Its Impact, and the Path to Reform*, (July 2008), available at <http://www.instituteforlegalreform.com/issues/docload.cfm?docId=1213> (last visited Jan. 19, 2009).

²⁶⁶ See Caremark, *supra*, n. 124, 698 A.2d 959.

²⁶⁷ HHS, *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*, *supra*, n. 45.

By no means is it clear that a plaintiff proceeding in this fashion would win on the merits. There certainly is no articulated legal principle that companies must stockpile drugs or take any other specific anti-pandemic precaution. But in the post-Enron era, there appears to be a better chance that a plaintiff could survive a motion to strike if he sued a Board that had substantially ignored the threat and could make a *prima facie* showing that avoidable loss ensued.

X. CONCLUSION

Because some courts appear now to be more willing to engage in detailed factual analysis of a corporate director's decision, corporate directors may be faced with a retrospective judicial evaluation of the costs and benefits of a corporate director's choices respecting disaster preparedness. After a pandemic, this could include, among other determinations, a decision to participate in or forgo antiviral stockpiling options programs. If relatively good results are obtained among individuals treated with antivirals, particularly among individuals employed by competitors providing access to antivirals, a court might be prepared to see such benefits as adequate to outweigh a relatively low cost. While the business judgment rule remains an important bulwark, it may not be entirely bullet-proof, and even if in the end it affords protection, it may not be adequate to prevent a filing and the ensuing costs of defense.

The solution to the problem seems straightforward: The Board, by committee or otherwise, should evaluate the available preventive and ameliorative measures, including antiviral option programs. If after due consideration a judgment is made to decline the option, the board can demonstrate its good faith by having engaged in the exercise. It will be able to demonstrate that it did indeed "keep its eyes open." This approach would serve both to discourage claims and to improve the chances of successful defense. And, should the Board decide to stockpile, it just might save some lives and avoid some losses.

Although there are other compelling reasons for any company to consider the impact of pandemic upon their organizations, then, one such may be the potential for shareholder derivative litigation alleging avoidable losses. While any such derivative suit would likely face an uphill battle, the cost in defending against such an action and even the possibility of its success suggest that reasonable consideration ought to be given to antiviral stockpiling options programs.