

## The Cost of Regulatory Delay

The inordinate amount of time it takes to develop effective public health and safety standards and to get them enacted illustrates a significant flaw in our regulatory system. While American families are waiting for new safety standards to be established, children are getting sick from tainted food, workers' lungs are filling with dust, and cranes are falling on innocent people who happen to be on the wrong sidewalk on the wrong day.

The failure to establish and publish health and safety rules creates individual and family tragedies across the country, and it costs businesses money. Increased health costs from sick workers cost money. When tainted food and toxic products appear, whole industries lose billions of dollars as consumer anxieties rise. The following examples – two regulations which have finally been put in place and five which are still pending – demonstrate how much it costs when regulations are delayed.

### ***Food Safety: Salmonella in Eggs***

In 1999, President Clinton asked the Food and Drug Administration (FDA) to issue new rules on the handling of eggs to reduce the danger of *Salmonella* contamination. The final rule was not implemented until 2010. In the 11 years between the request for a new rule and its completion, an estimated 330 people in the United States died from *salmonella* poisoning from tainted eggs, and almost 800,000 were sickened from the disease.<sup>1</sup> One outbreak alone, from May through November 2010, caused 1,939 people to become sick and led to the recall of half a billion eggs<sup>2</sup>, at an estimated industry cost of hundreds of millions of dollars.<sup>3</sup> William Hubbard, associate FDA commissioner from 1991 until 2005, told *The New Republic*, “[E]ach time FDA tried to get the rule cleared through OMB, the response was that there were ‘not enough bodies in the street,’ – that the number of cases, hospitalizations and deaths did not rise to the level to justify greater regulation of egg producers.”<sup>4</sup>

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<sup>1</sup> “New Public Health Regulation to Improve Egg Safety and Reduce Salmonella Illnesses,” U.S. Food and Drug Administration, Press Release, 7 July 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170788.htm> (accessed 18 July 2011).

<sup>2</sup> Centers for Disease Control and Prevention, *Multistate Outbreak of Human “Salmonella” Enteritidis Infections Associated with Shell Eggs*, 2 Dec. 2010, <http://www.cdc.gov/salmonella/enteritidis/> (accessed 18 July 2011).

<sup>3</sup> Jeff Casale, “Safety, over in focus after huge egg recall”, *Business Insurance*, 30 Aug. 2010, <http://www.businessinsurance.com> (accessed 18 July 2011).

<sup>4</sup> Jonathan Cohn, “Reagan, Bush, and Rotten Eggs,” *The New Republic*, 25 Aug. 25 2010, <http://www.tnr.com> (accessed 18 July 2011).

Yet cost-benefit estimates produced at the time showed better sanitation and handling of eggs would cost farmers \$82 million a year, while the monetary benefit attached to lives lost and injuries prevented was \$1.4 billion a year.<sup>5</sup>

### ***Worker Safety: OSHA's Cranes and Derricks Standard***

In 2004, a consortium of stakeholders within the construction industry (labor, affected businesses and government regulators) agreed on a new safety standard that would have improved workplace safety and prevented avoidable costs to businesses. It took six years for the final rule to be issued. The six-year delay resulted in 132 unnecessary deaths and 1,050 preventable injuries.<sup>6</sup> The net cost of failing to implement the rule for those six years was \$331.2 million.

According to OSHA's analysis, the new cranes and derricks standard will prevent 22 deaths and 175 injuries a year, as well as \$7 million in annual property damage. Converting the lives saved and injuries prevented into a monetary value and adding in the cost of medical care and property damage avoided by implementing the rule, the total benefits of the rule will be \$209.3 million per year. The annual cost for businesses to comply with the rule will be approximately \$154.1 million.

### Currently Pending Regulations

#### ***Public Health and Clean Air: Mercury and Air Toxics Standards***

Power plants, industrial boilers and process heaters, and cement plants are the largest emitters of mercury and other toxic air pollutants, but the standards defining their compliance with the Clean Air Act have been delayed for more than five years. According to EPA analyses, the pollutants produced by these plants and products every year result in 26,000 premature deaths, 18,000 hospital admissions and emergency room visits, and 1,290,000 days of missed work or school due to respiratory illness.<sup>7</sup>

#### ***Drug Safety: Protecting Pregnant Women***

Delays in finalizing drug labeling rules have left pregnant women and their health care providers without information they desperately need about the safety and effectiveness of drugs commonly used during pregnancy. Despite the unique risks some drugs pose for pregnant women, the plethora of new drugs on the market and new drug advertising practices, current rules have not been updated since 1979.

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<sup>5</sup> Lyndsey Layton, "Unsafe Eggs Linked to U.S. Failure to Act," *The Washington Post*, 11 Dec. 2010.

<sup>6</sup> Data used throughout this section comes from: Occupational Safety and Health Administration, "Cranes and Derricks in Construction: Final Rule," *Federal Register* 75, no. 152 (9 Aug. 2010): 47906, 47913-14. When referring to the six year period, the annual data used in the *Federal Register* is multiplied by six.

<sup>7</sup> House Committee on Energy and Commerce, Subcommittee on Energy and Power, "Testimony of John D. Walke," *Hearing on "Recent EPA Rulemaking Relating to Boilers, Cement Manufacturing Plants, and Utilities,"* 112th Cong., 15 Apr. 2011.

In 2008, the FDA proposed a rule that would include on all drug labels information detailing the established risks of drugs for pregnant women and their fetuses. Three years later, the rule still has not been finalized. However, in the meantime, the FDA has issued numerous safety warnings about birth defects or harm to newborns and pregnant women caused by specific medications used during pregnancy. For example, the FDA has made statements warning about the serious health risks of a drug used to prevent preterm labor, two drugs used to treat epilepsy, and entire classes of opioid painkillers and anti-psychotics.<sup>8</sup> But, because the labeling rule has still not been finalized, these warnings still do not appear on the drugs themselves.

### **Food Safety: Foodborne bacteria**

In 2006, more than 200 illnesses and three deaths were linked to bagged spinach contaminated with *E. coli*. In 2008, 1,400 people were infected with *Salmonella* from serrano peppers from a contaminated farm in Mexico. The Emerging Pathogens Institute at the University of Florida estimates that each year, 1.2 million people get sick, 7,125 are hospitalized, and 134 die as a result of foodborne illnesses from produce, costing the public \$1.4 billion.<sup>9</sup>

To reduce the toll of foodborne illness, Congress passed a law that calls for a regulation directing how produce is to be handled by large farms and for a system of inspection of foreign farms. Both are to be in place by 2013. During the two years that it will take to write these regulations, more than 200 people will die and more than 14,000 will be hospitalized. If these rules are delayed beyond 2013, one person will die and 68 will be hospitalized each week due to illnesses that could have been prevented.<sup>10</sup>

### **Worker Safety: Safe Patient Handling**

The work-related musculoskeletal disorders (MSDs) that nurses incur in the course of their work are the leading and most costly occupational health problem in the United States. Health care worker back injuries cost businesses an estimated \$20 billion annually in direct and indirect costs.<sup>11</sup> In 2005, businesses spent \$12.7 billion in direct costs alone.<sup>12</sup>

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<sup>8</sup> U.S. Food and Drug Administration, "FDA Drug Safety Communication: Antipsychotic drug labels updated on use during pregnancy and risk of abnormal muscle movements and withdrawal symptoms in newborns," 22 Feb. 2011, <http://www.fda.gov/Drugs/DrugSafety/ucm243903.htm> (accessed 18 July 2011).

<sup>9</sup> Michael B. Batz, et al., "Ranking the Risks: The 10 Pathogen-Food Combinations with the Greatest Burden on Public Health," *Emerging Pathogen Institute*, University of Florida, 28 Apr. 2011.

<sup>10</sup> Internal calculations: half of weekly deaths and hospitalizations due to foodborne illness as determined by the Emerging Pathogens Institute. The estimate of being able to prevent half of all illnesses is based on FDA's estimates for the number of cases of salmonellosis that would be prevented by the application of HACCP to seafood processors. See Department of Health and Human Services: Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," *Federal Register* 60, no. 242 (18 Dec. 1995): 65096, 65185-87.

<sup>11</sup> James W. Collins, et al, "Safe Lifting and Movement of Nursing Home Residents," National Institute for Occupational Safety and Health, Publication No. 2006-117, Feb 2006.

Every year, 40 to 50 percent of nurses experience back injuries, and the leading cause of these injuries is repeated manual lifting, transferring, and repositioning of patients and residents;<sup>13</sup> 12 percent of those who leave nursing each year attribute their departure to a workplace injury caused by manual patient handling.

At least half of the workplace injuries requiring days away from work could be prevented by safe patient handling (SPH) requirements.<sup>14</sup> Yet the states that have not adopted SPH account for 71 percent of the nation's population. Each year that OSHA fails to develop regulations addressing this issue results in more than 19,000 injuries. Each week, there are 750 preventable injuries. This not only costs nurses their livelihoods, it costs society skilled health care workers.

### ***Worker Safety: Silica Dust in the Workplace***

Fifteen years ago, crystalline silica dust was classified as a human carcinogen; breathing in the dust can cause the respiratory disease silicosis, which in severe cases can be disabling or fatal. There is no cure for silicosis. Nearly 2 million American workers are exposed to silica dust in the workplace each day, and more than 100,000 are in high-risk jobs such as abrasive blasting, foundry work, stonecutting, rock drilling, quarry work and tunneling.<sup>15</sup>

The OSHA silica rule has been under development since 2001. After peer review requirements and political inaction delayed the proposed rule for years, it was sent to OMB for review in February 2011, but OMB has extended its review, causing further delays.

Lowering silica exposure by the level recommended in the proposed rule would prevent 60 worker deaths a year – 41 from silicosis and 19 from lung cancer. Hundreds of cases of non-fatal silicosis would also be prevented annually. In the 10 years OSHA has been working on the silica rule, 600 workers have died because of the failure to act<sup>16</sup>.

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<sup>12</sup> "From Research to Reality: 2007 Annual Report of Scientific Activities," Liberty Mutual Research Institute for Safety, <http://www.libertymutualgroup.com> (accessed 18 July 2011).

<sup>13</sup> Harwood Nelson, et al, "Myths and Facts about Safe Patient Handling in Rehabilitation," *Rehabilitation Nursing*, 33(1), 10-17.

<sup>14</sup> Herman E. Carlson and P. Brown, "Effectiveness of a ceiling mounted lift system," *Journal of the Association of Occupational Health Professionals in Healthcare*, 25(3), 24-26.

<sup>15</sup> Occupational Safety and Health Administration, *Crystalline Silica Exposure - Health Hazard Information for Construction Employees*, (OSHA 3177 - 2002), <http://www.osha.gov/pls/publications/publication.searchResults?pSearch=3177> (accessed 18 July 2011).

<sup>16</sup> "Report of the Small Business Advocacy Review Panel on the Draft OSHA Standards for Silica," 19 Dec. 2003, [http://archive.sba.gov/advo/laws/is\\_silicarpt.pdf](http://archive.sba.gov/advo/laws/is_silicarpt.pdf) (accessed 18 July 2011).