# THE COST OF REGULATORY DELAY

Opponents of regulation claim that more needs to be done to check the ability of federal agencies to issue regulations. They claim that agencies are too quick to issue regulations and that they do so without regard to the impact of regulations on our economy. Unfortunately, in many cases our current system is characterized by exactly the opposite problem: long delays before needed regulations are issued—often at substantial cost in lives and monetary costs to industry and the public.

## YEARLY COSTS OF DELAY

- Worker Safety Protections, Cranes and Derricks: 22 preventable deaths
- Protecting Consumers from Contaminated Food, Salmonella in Eggs: 2,000 people sickened that could have been prevented
- Protecting Americans from Dangerous Air Pollution: 26,000 preventable deaths
- Protecting Consumers from Contaminated Food, Fresh Produce: 100 preventable deaths
- Workers Safety Protections, Safe Patient Handling: 19,000 preventable injuries
- Worker Safety Protections, Silica: 60 preventable deaths

## THE COST OF DELAY—OSHA'S CRANES AND DERRICKS STANDARD

The creation of the cranes and derricks standard began with a request from the industry for a new regulation. In 2003 representatives of labor, affected businesses (e.g. crane manufactures and construction companies) and government regulators began meeting to develop a regulation that met the needs of all parties. In 2004, after meeting 11 times the group produced a consensus proposal. Despite this consensus, it took six more years for the final rule to be issued.

Why did it take so long? According to an official with the Department of Labor's Occupational Safety and Health Administration (OSHA), bureaucratic requirements that have nothing to do with creating a good rule are to blame. They account for approximately 50 percent of the time the agency spends on developing new regulations.[1]

The final rule establishes standards for operator certification, crane inspection, set up and disassembly. It will address the major causes of worker injury and death from cranes and derricks, electrocution, collapse and overturning.

According to OSHA's regulatory analysis, the cranes and derricks standard will prevent 22 deaths and 175 injuries a year, as well as $7 million in annual property damage. If you convert the lives saved and injuries prevented into a monetary value and add in the cost of medical care and property damage avoided by implementing the rule, the total benefits of the rule would be $209.3 million per year. The annual cost for businesses to comply with the rule will be approximately $154.1 million. Therefore, the net benefit is $55.2 million per year.

All told, the six year delay in issuing the final rule resulted in 132 unnecessary deaths and 1,050 preventable injuries. The net cost of failing to implement the rule for those six years was $331.2 million. During the six years it took to finalize the rule, there were several high profile incidents where cranes on construction sites collapsed leading to worker deaths that could have been prevented.

## THE COST OF DELAY—*SALMONELLA* IN EGGS

In 1999, President Bill Clinton proposed that the Food and Drug Administration (FDA) issue regulations protecting the public against the danger of *Salmonella* in eggs. Progress on the rule slowed during the Bush administration.

William Hubbard, who was associate FDA commissioner from 1991 until 2005 told *The New Republic* that the delay was not accidental: "The FDA simply couldn't get through to the White House. They were very hostile to regulation. ... I was told that each 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.[2]

The FDA thought it had a compelling case. It would cost farmers $82 million a year to comply with the new rules, but the rule would prevent 79,000 illnesses and 30 deaths each year. If you convert the benefits of the regulation in terms of lives saved and injuries prevented into a monetary value, the regulation would save $1.5 billion a year. So the net benefit per year was $1.4 billion in 2005 dollars. Still, OMB "didn't think there were enough bodies in the street," Hubbard said.[3]

A proposed rule came out in 2004, but the comment period was extended and then no final rule ever came forward during the remainder of the Bush administration. Despite a well known hazard, it was not until 2009, under President Obama, that the FDA issued a final rule requiring egg producers to assure that eggs are produced under conditions that minimize chances of Salmonella contamination. The final regulation requires that laying hens be tested for *Salmonella* and that eggs are refrigerated promptly after they are laid. Farms were required to come into compliance with the regulation by July 2010. Unfortunately, that was too late to prevent an outbreak of *Salmonella* in eggs that began in May and eventually sickened 2,000 people and led to the recall of half a billion eggs. The recalled eggs were produced by two Iowa farms, Wright County Egg and Hillandale Farms.

## COST OF DELAY—MERCURY AND AIR TOXICS STANDARDS FOR BOILERS, CEMENT PLANTS, AND POWER PLANTS

Power plants, industrial boilers and process heaters, and cement plants are the largest emitters of mercury and other toxic air pollutants that still fail to comply with the Clean Air Act's requirements. The previous administration delayed issuing regulations addressing these dangers for over five years. According to the U.S. Environmental Protection Agency's (EPA) analysis, each year that the agency delays issuing regulations controlling these sources of pollution leads to **26,000 premature deaths, 18,000 hospital admissions and emergency room visits, 1,290,000 days when people must miss work or school due to respiratory illness. This translates into 500 premature deaths that could have been avoided for each week that these regulations are delayed.** The American people should not be forced to wait any longer for these life saving protections!

## COST OF DELAY—FOODBORNE DISEASE

Each year 128,000 Americans are hospitalized due to a foodborne illness, and 3,000 die.[4]
Congress passed and the president signed into law The FDA Food Safety Modernization Act in January 2011 in an effort to reduce the toll of foodborne illness on our nation. While some provisions of the law have taken effect without regulatory action, many require FDA to promulgate rules in order for the law to be in full effect.

Two of the provisions of the law that will not take effect until the FDA promulgates rules are one requiring safe production, harvesting, handling and packing of produce on farms and one creating a more effective system for monitoring the safety of imported produce. These provisions of the law were prompted by several highly publicized outbreaks of foodborne illness that were traced to produce.

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 s*almonella* 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 will die as a result of foodborne illnesses from produce, costing the public $1.4 billion.[5]

The FSMA calls for a regulation on how produce is handled by large farms and for a system of inspection of foreign farms to both be in place by 2013. We cannot assume that these regulations will eliminate all foodborne illnesses from produce, but if half of the illnesses due to contaminated produce can be eliminated, we would save 67 lives each year and prevent 3,562 hospitalizations.[6] During the time that it will take to write these regulations, over 100 people will die and over 7,000 will be hospitalized, deaths and illnesses that could have been prevented. **For each week that regulations are delayed beyond 2013, one person will die and 700 will be hospitalized due to illnesses that could have been prevented.** We cannot afford to push off these regulations by imposing additional requirements on the FDA rule-making process.

## THE COST OF DELAY—SAFE PATIENT HANDLING

Nurses' work-related musculoskeletal disorders (MSDs) are the leading and most costly occupational health problem in the United States: healthcare worker back injuries alone cost businesses an estimated $20 billion annually in direct and indirect costs. (In 2005, businesses spent $12.[7] billion in direct costs alone.)
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,7 and 12 percent who leave nursing each year attribute their departure from the bedside to a workplace injury caused by manual patient handling.

Of 487,900 cases of work-related musculoskeletal disorders involving days away from work, nursing aides, orderlies, attendants and registered nurses accounted for 55,200 of those cases.[8]

Unsafe patient handling can contribute to patient injury, such as falls during transfers and skin tears when moving or repositioning patients. Without safe patient handling, bedbound patients are at increased risk of developing pressure ulcers, pneumonia, blood clots (deep vein thrombosis), and muscle deconditioning, resulting in longer hospitalizations.

However, there is a proven solution to this problem. Leading hospitals from across the country have adopted Safe Patient Handling (SPH) programs that rely on modern lifting and transfer devices. Nine states have adopted SPH laws, including Hawaii, Illinois, Maryland, Minnesota, New Jersey, New York, Ohio, Rhode Island, Texas, and Washington.

Research indicates that at least half of the workplace injuries requiring days away from work could be prevented by safe patient handling requirements.[9] The states that have not yet adopted SPH account for 71 percent of the nation's population. So, if we assume that the new federal regulation would only have an impact in those states that do not have SPH on the books, then the total number of cases that could be impacted each year would be 39,192 (71 percent of the 55,200 total)  This means that each year that OSHA fails to develop regulations addressing this issue results in over 19,000 injuries that could have been prevented. For each week, there are 750 workers whose injuries could have been prevented. We cannot afford to push off protecting workers by imposing additional requirements on the OSHA rule-making process.

## THE COST OF DELAY—SILICA DUST IN THE WORKPLACE

Crystalline silica is a basic component of soil, sand, granite, and many other minerals. Silica exposure remains a serious threat to nearly 2 million U.S. workers, including more than 100,000 workers in high-risk jobs such as abrasive blasting, foundry work, stonecutting, rock drilling, quarry work and tunneling. Some 15 years ago, the International Agency for Research on Cancer (IARC) classified crystalline silica dust as a human carcinogen. Ad-

ditionally, breathing crystalline silica dust can cause silicosis, which in severe cases can be disabling, or even fatal. There is no cure for silicosis.

The OSHA silica rule has been under development since 2001. The Small Business Regulatory Enforcement Fairness Act (SBREFA) panel was completed in 2003, but peer review requirements and political inaction delayed the proposed rule for years. The draft proposed rule was sent to OMB for review in February 2011, but OMB has extended its review, causing further delays.

According to the SBREFA report on the draft OSHA silica rule, reducing silica exposure to the National Institute for Occupational Safety and Health (NIOSH) recommended level of 50 ug/$m^3$ 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 agency's failure to act. **Every week that passes, another worker becomes so sick from exposure to silica that they will eventually die.** We cannot afford to further delay regulating silica exposure by imposing additional requirements on the OSHA rule making process.

## THE COST OF DELAY—REGULATIONS TO PROTECT PREGNANT WOMEN

Delays in finalizing a vitally important drug labeling rule have left pregnant women and their healthcare providers without the information they desperately need about the safety and effectiveness of drugs commonly used during pregnancy. According to a recently published study in the American Journal of Obstetrics & Gynecology, 70% of women take at least 1 prescription medication during pregnancy and more than 15% of pregnant women take 4 or more prescription medications.[10]

Despite the millions of women using prescription drugs during pregnancy and the unique risks some drugs pose for pregnant women, current rules, in place since 1979, fail to communicate the full range of information about known and possible risks. Under these rules, drug labels only convey information about risks for which a causal relationship has been established, omitting information about suspected risks even where some evidence of harm exists, thereby depriving women and their health care providers of the opportunity to weigh the potential for harm that unnecessary drug exposure might cause to the fetus against the benefit of the drug for the woman.

In 2008, the FDA released a proposed rule that would replace the current, overly simplistic system with a requirement that drug labels include safety information detailing the established risks of drugs for pregnant women and their fetuses, as well as any available data on suspected risks. Three years later, this rule still has not been finalized. In the meantime, the FDA has issued numerous safety warnings about birth defects or harm to newborns and pregnant women caused by many medications frequently used during pregnancy, both drugs for pregnant women specifically and those used for chronic conditions requiring treatment during pregnancy. For example, the FDA has warned about the health risks of a drug used to prevent preterm labor,[11] two drugs used to treat epilepsy,[12] [13] and entire classes of opioid painkillers[14] and anti-psychotics.[15]

Women and their healthcare providers deserve a better system. Women need updated information so that they can safely use medications during pregnancy. The regulatory system already moves too slowly, additional delays would further endanger the health of women and their children.

*THIS BRIEF WAS COMPILED BY DĒMOS WITH MAJOR CONTRIBUTIONS FROM THE FOLLOWING ORGANIZATIONS, WHICH ARE MEMBERS OF THE COALITION FOR SENSIBLE SAFEGUARDS: AMERICAN FEDERATION OF LABOR-CONGRESS OF INDUSTRIAL ORGANIZATIONS, THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST, THE INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA, THE NATIONAL WOMEN'S HEALTH NETWORK, NATURAL RESOURCES DEFENSE COUNCIL, OMB WATCH, PUBLIC CITIZEN, AND THE SERVICE EMPLOYEES INTERNATIONAL UNION. FOR ADDITIONAL INFORMATION, PLEASE CONTACT BEN PECK AT BPECK@DEMOS.ORG.

## ENDNOTES


1. Public Citizen, "Cranes and Derricks: The Prolonged Creation of a Key Public Safety Rule," April 2011.
2. Jonathan Cohn, Reagan, Bush, and Rotten Eggs The New Republic, August 25, 2010.
3. Lindsey Layton, "Salmonella-tainted eggs linked to US failure to act" The Washington Post, Dec. 11, 2010.
4. Elaine Scallan, et al., Foodborne Illness Acquired in the United States—Unspecified Agents, 17 Emerging Infectious Diseases, 16, 20, (Jan. 2011).
5. 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, 11, (2011).
6. The estimate of being able to prevent half of all illnesses is based on FDA's estimates for the number of cases of Salmonella that would be prevented by the application of HACCP to seafood processors. See Federal Register December 18, 1995, pp. 65185-7.
7. Nelson, A, Harwood, K.J., Tracley, C., Dunn, K.L. (2008). Myths and Facts about Safe PatientHandling in Rehabilitation. Rehabilitation Nursing, 33(1), 10-17
8. U.S. Department of Labor, Bureau of Labor Statistics. (2002). Retrieved 6/9/04 fromhttp://stats.bls.gov/oshhome.htm?H6
9. Carlson, E., Herman, B., and Brown, P. (2005). Effectiveness of a ceiling mounted lift system.Journal of the Association of Occupational Health Professionals in Healthcare, 25(3), 24-26.
10. Mitchell, AA, Gilboa SM, Werler MM, et al. "Medication use during pregnancy, with particular focus on prescription drugs 1976-2008." American Journal of Obstetrics & Gynecology. 2011; 204
11. "FDA Drug Safety Communication: New warnings against use of terbutaline to treat preterm labor." http://www.fda.gov/Drugs/DrugSafety/ucm243539.htm
12. "Information for Healthcare Professionals: Risk of Neural Tube Birth Defects following prenatal exposure to Valproate."http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm192649.htm
13. "FDA Drug Safety Communication: Risk of oral clefts in children born to mothers taking Topamax (topiramate)." http://www.fda.gov/Drugs/DrugSafety/ucm245085.htm
14. "Opioid Pain Killers Linked to Increased Risk of Some Birth Defects." http://www.cdc.gov/media/releases/2011/p0302_opioidbirthdefects.html
15. "FDA Drug Safety Communication: Antipsychotic drug labels updated on use during pregnancy and risk of abnormal muscle movements and withdrawal symptoms in newborns." http://www.fda.gov/Drugs/DrugSafety/ucm243903.htm


COALITION FOR SENSIBLE SAFEGUARDS


**CONTACT**
1742 Connecticut Ave., N.W.
Washington, DC 20009
Phone: (202) 234-8494
info@sensiblesafeguards.org
www.sensiblesafeguards.org


Dēmos.org


220 Fifth Avenue, 2nd Floor
New York, New York 10001
Phone: (212) 633-1405
Fax: (212) 633-2015
info@dēmos.org

**MEDIA INQUIRIES**
Tim Rusch,
Communications Director
trusch@dēmos.org
(212) 389-1407


**CONNECT WITH US**
**WWW.DEMOS.ORG**

@DEMOS_ORG
FACEBOOK.COM/DEMOSIDEASACTION