

OHIO LIVES AT RISK: THE LOCAL IMPACT OF FEDERAL “REGULATORY REFORM” PROPOSALS

KEY FINDINGS

The United States Congress is currently considering so-called “regulatory reform” legislation that would add new bureaucratic hurdles to stall and, in some cases, stop the creation of new safeguards and standards that hold corporations accountable and protect the public. According to our analysis, the result would be demonstrable harm for the people of Ohio.

In Ohio, allowing polluters to delay one year in meeting tougher standards limiting soot in our air will cause as many as:

- 76,314 asthma attacks among children—similar to one case for every student enrolled at Ohio State University
- 149,167 days of missed work or school due to air pollution-caused ailments—the equivalent of every police officer in the state of Ohio missing five days of work protecting the public each year
- 1,655 heart attacks
- 3,194 premature deaths

KEY “REGULATORY REFORM” PROPOSALS INCLUDE:

- Broad regulatory moratoria proposals such as the **Regulatory Time-Out Act of 2011** (S. 1538) and the **Regulatory Freeze for Jobs Act of 2012** (H.R. 4078)
- **The Regulations from the Executive in Need of Scrutiny** (REINS) Act (H.R. 10) (S. 299)
- **The Regulatory Accountability Act** (RAA) (H.R. 3010) (S. 1606)
- **The Regulatory Flexibility Improvement Act** (RFIA) (H.R. 527) (S. 1938)

In Ohio, allowing food processors to delay one year before using new standards from the U.S. Food and Drug Administration for safe handling of produce will cause approximately*:

- 380,000 local cases of foodborne illness—more than the entire city of Cincinnati

In Ohio, delaying the Affordable Care Act’s ban on health insurance companies discriminating against patients with pre-existing conditions for one year will put:

- 65,060 newly diagnosed cancer patients at risk of being denied health insurance

*based on latest-available state data

WHAT NO INDIVIDUAL CAN DO ALONE: PROTECTING AMERICA

At key points in our nation's history, citizens have successfully demanded that our government do what no individual can do alone: set standards and safeguards to hold large corporations accountable to the public interest. Americans are safer, healthier and more prosperous today because of the strong American system of safeguards designed to stop corporations from cutting corners at our expense. Our daily lives are filled with examples of the American regulatory system at work. For example, we no longer have to fear that the meat we buy is actually—as Upton Sinclair described in his 1906 book, *The Jungle*—just “guts and garbage” swept off the meatpacking plant floor and sold as “potted ham.” That is because citizens pressured Congress to pass laws that transformed the entire industry and are still protecting us today, the Meat Inspection and the Pure Food and Drug Acts of 1906.

For most of our history, the United States has been the world leader in setting a system of high and distinctly American standards for companies that want to do business here. Perhaps the most dramatic example of the U.S. leading the world in safeguarding our citizens came in 1960, when an FDA pharmacologist, Dr. Frances Kelsey, refused to let the U.S. follow 46 countries in allowing the sale of thalidomide, a drug for infants, children and pregnant women. Dr. Kelsey faced sustained opposition from the drug's maker, but in the end, America was vindicated: over 12,000 birth defects were linked to the drug worldwide—but because of U.S. safeguards, only 17 Americans were affected.¹

Unfortunately, today, America's proud tradition of setting innovative environmental and business standards is threatened by industry-supported legislation that could effectively end our government's ability to respond to new threats to the public or to correct unproductive imbalances in the marketplace. Instead of leading the world so that American products can claim the highest standards of quality, these bills would have us compete with developing nations for the most lax public health and safety standards.

American citizen activism helped pass the Clean Air Act of 1970, which still protects us today. In fact, in 2010 alone, the Clean Air Act prevented:

- 160,000 cases of premature death
- 130,000 heart attacks
- 1.7 million asthma attacks
- 13 million lost work days²

LEGISLATION ERECTING BARRIERS TO NEW STANDARDS & SAFEGUARDS: REINS, RAA, AND RFIA

The following section describes some of the key bills that, if passed, would erect bureaucratic impediments to the creation of new standards and safeguards: variations on a broad regulatory moratorium, the Regulations from the Executive in Need of Scrutiny (REINS) Act, the Regulatory Accountability Act (RAA), and the Regulatory Flexibility Improvement Act (RFIA). REINS, RAA, and RFIA have cleared the U.S. House and await action in the U.S. Senate. Broad regulatory moratoria proposals are under consideration in both houses.

Broad regulatory moratoria proposals. Moratoria proposals such as the Regulatory Time-Out Act of 2011 (S. 1538) and the Regulatory Freeze for Jobs Act of 2012 (H.R. 4078) would create broad prohibitions against agencies issuing or updating public safeguards for a set time period, ranging between 1 and 2 years or until the level of unemployment drops to a pre-specified level.

The REINS Act. The REINS Act would thwart implementation of new public safeguards and industry standards by requiring both the House and Senate to approve all major regulations in 70 days, an impossibly short timeframe. Rules that are not approved would become void automatically, despite the years of rigorous science and public comment that go into crafting them. Thus it would empower either chamber to unilaterally stop the implementation of important laws that Congress has already passed. This includes decades-old American laws that have overwhelming public support—such as the Clean Air Act and the Food, Drug, and Cosmetic Act.

The Regulatory Accountability Act. The RAA would delay the creation and weaken the substance of new rules by forcing agencies to prioritize the interests of industry over the public. It would require that government create rules that are “least costly” for the regulated businesses, even if an alternative rule would be less costly for the public, in the form of lives saved and harms prevented. This is a profound change that overrides 25 existing statutes, including the Clean Air Act, the Clean Water Act, and the Occupational Safety and Health Act, designed to prioritize public health and safety while still taking into account compliance costs for businesses.

In its letter to the House Judiciary Committee on the RAA, the American Bar Association (ABA) Section of Administrative Law and Regulatory Practice, the most authoritative body of experts in this area, wrote “[f]or some two decades, many administrative lawyers have voiced concerns about the increasing complexity of rulemaking and have been urging Congress not to add unnecessary analytical requirements to the...rulemaking process.” Rather than addressing these fundamental concerns, the RAA does exactly what the experts warned against, by adding more than 60 new analytical requirements to the law guiding the rulemaking process, including mandating agencies to make nearly impossible determinations such as the “indirect costs” or the “cumulative costs and benefits” of a proposed regulation. In addition, the bill greatly increases the power of the courts to second-guess the experts in the rulemaking process by expanding the issues on which courts could intervene. One expert estimates that enactment of the RAA would delay the creation of new rules by two to three years,³ meaning a loss of 71,400–107,100 American lives in the case of just one delayed rule: the particulate matter pollution limit.⁴

The Regulatory Flexibility Improvement Act. The RFIA would slow down the creation of new standards and safeguards by adding unnecessary, time-consuming steps to the review process. Like the RAA, it would require agencies to make nearly impossible determinations of “indirect costs” associated with regulations as well as a set of possible alternatives to any proposed regulation.

Lobbyists for Regulatory Reform. It is important to recognize the interests that have driven the “regulatory reform” agenda to date. In a detailed analysis of supporters of the REINS Act, the most extreme of the proposals, the non-partisan research group Public Citizen found that the energy industry was the single biggest force lobbying for the bill.⁵ This includes electric utilities, coal, oil and gas

companies. Many of these companies have expressed opposition to new pollution standards. However, REINS, RAA, and RFIA are not tailored to any specific area of regulation. Thus, they would delay standards indiscriminately across all industries and sectors of our economy, even reaching rules that are supported by the regulated entities—for example, the anti-food contamination standards that the farm lobby currently supports as a means to avoid costly recalls.⁶

THE IMPACT ON OHIO FAMILIES OF DELAYING NECESSARY SAFEGUARDS

Impact of Delaying Rule Making Our Food Safer: 380,000 Food-Poisoned Ohioans Per Year

Despite the creation of a more robust system of protections since Upton Sinclair's time, there continue to be gaps in the United States' food safety systems. Experts estimate that each year 128,000 Americans are hospitalized due to a foodborne illness, and 3,000 die.⁷ In Ohio, over three quarters of a million local residents fall ill from produce-related illnesses each year.⁸ Many of the recent outbreaks are, in part, the result of new developments in the farming industry that present new threats to the consumer and require an updating of existing safeguards. In 2006, more than 200 illnesses and three deaths were linked to bagged spinach contaminated with *E. coli*. Packaged greens represent an innovation by the food industry that meets a consumer need for convenience, but also carries with it new dangers. By cutting and mixing spinach into individual bags, a single contaminated plant now contaminates bags purchased by multiple consumers—whereas, before the contamination would have sickened a single consumer.

As in previous eras, the steady drumbeat of high profile incidents involving food contamination due to a lack of industry standards led to action. Congress passed and the President signed into law the FDA Food Safety Modernization Act (FSMA) in January 2011. While some provisions of the law have taken effect, the provisions of the law requiring farmers to create checklists to assure that safety procedures are followed in the production, harvesting, handling and packing of produce will not take effect until the FDA issues a rule detailing the new requirements for the industry.⁹

Each year that we delay the creation of this standard means additional suffering. While better rules will not eliminate all foodborne illnesses from produce, if half of the illnesses due to contaminated produce can be eliminated—as the FDA has estimated is possible for a comparable rule for fish¹⁰—then **each year of delay would result in approximately 380,000 Ohio residents falling ill¹¹—comparable to the entire city of Cincinnati being poisoned by bad produce every year.**¹²

Impact of Delaying Clean Air Rules: 3,194 Deaths Per Year

Despite our nation's success to date in cleaning up the air we breathe, there are still many preventable deaths and sicknesses due to air pollution. The Clean Air Act requires the EPA to periodically review the standards for pollution it has set in order to assure that they are protecting the public with an adequate margin of safety. The Act directs the agency to review its standards for fine particulate matter, commonly known as soot, every five years in order to consider the latest scientific evidence

and ensure that the public health is being adequately protected.¹³ The last review ended in October 2006. The results of that review were contested by a group of environmental organizations, and the courts rejected the 2006 standards as inadequately protective of the public's health. Even if those standards had been adequate, based on the five year time frame specified by the Clean Air Act, they should have been reviewed last year. The agency now says it will issue a draft rule in June of this year.¹⁴

Sadly, the failure by the EPA to update its standards for soot is not just a harmless bureaucratic hold-up; it is costing lives. Diesel vehicles and coal-fired power plants are among the biggest sources of soot. Soot particles' microscopic size— $1/30^{\text{th}}$ the width of a human hair—allows them to bypass the body's natural ability to expel larger particles with a cough or a sneeze. This means that soot can lodge deep within the lungs, aggravating asthma and increasing the risk of heart attack. Those with pre-existing lung or heart disease, diabetics, the elderly and children are most at risk. Children are easily sickened by soot because of their developing lungs, smaller size, high levels of physical activity and time spent outdoors, which increases their exposure to air pollution.¹⁵

All of the proposed "regulatory reform" bills could add years of delay to the already overdue lifesaving soot rule.

In their report, "Sick of Soot," Earthjustice, the American Lung Association, and the Clean Air Task Force quantify the annual cost of delaying the soot pollution rule.

For each year that we delay bringing down soot pollution to a safer level (an annual limit of $11\mu\text{g}/\text{m}^3$ and a daily limit of $25\mu\text{g}/\text{m}^3$) there are up to:

- **1.4 million** asthma attacks among children nationally
- **2.7 million** days of missed work or school due to air pollution-caused ailments
- **23,290** visits to the hospital and emergency room
- **2,350** heart attacks
- **35,700** premature deaths¹⁶

In Ohio, each year we fail to reduce soot pollution causes as many as:

- **76,314** asthma attacks among children—**similar to one case for every student enrolled at Ohio State University¹⁷**
- **149,167** days of missed work or school due to air pollution-caused ailments—**the equivalent of every police officer in the state of Ohio missing five days of work protecting the public each year¹⁸**
- **1,655** visits to the hospital and emergency room
- **162** heart attacks
- **3,194** premature deaths¹⁹

Impact of Delaying Pre-Existing Condition Rule: 65,060 Ohio Cancer Patients' Health Coverage At Risk Per Year

Today in Ohio, for those who do not have health insurance coverage through their employer and have a pre-existing health condition, it can be challenging to get coverage. That is because health insurance companies concerned about their bottom line often charge more or refuse to cover people who have a pre-existing condition and are therefore likely to use more health care services, making them more expensive to cover.

Congress recognized this problem when it drafted and passed the Patient Protection and Affordable Care Act. Under the law, by 2014 the federal government must issue rules requiring insurers to offer coverage without regard to patients' health history. This rule will be particularly important for people with serious medical conditions.

In Ohio, there are 65,060²⁰ new cases of cancer each year. For each year that the rule protecting patients' right to purchase health insurance is delayed due to new red tape, **these 65,060 Ohioans are at risk of being denied health insurance coverage because they have cancer.**

CONCLUSION

Ohio citizens have much to lose from the passage of legislation that would delay the creation of protections for their food, air and health care. For each year that new safeguards are delayed, they will suffer as many as 380,000 preventable cases of foodborne illness, as many as 3,194 preventable deaths due to air pollution-caused ailments, and they will see 65,060 newly diagnosed cancer patients at risk of being denied health insurance coverage.

Demos and U.S. PIRG wish to thank Earthjustice, the American Lung Association, the Clean Air Task Force and the Energy Foundation for the previously unpublished state level data on the health impacts of stricter controls on particulate matter included in this report.

ENDNOTES

- ¹ Ballard Campbell, *Disasters, Accidents and Crisis in American History* (New York: Facts on File, Inc, 2008).
- ² U.S. Environmental Protection Agency, “The Benefits and Costs of the Clean Air Act from 1990 to 2020,” March 2011, <http://www.epa.gov/cleanairactbenefits>.
- ³ Sidney Shapiro, Testimony on H.R. 3010, the Regulatory Accountability Act of 2011 before the House Committee on the Judiciary, October 25, 2011, <http://judiciary.house.gov/hearings/pdf/Shapiro%2010252011.pdf>.
- ⁴ There are 35,700 premature deaths per year, due to failure to meet tougher standards. American Lung Association, Clean Air Task Force, and Earth Justice, “Sick of Soot: How the EPA Can Save Lives By Cleaning Up Fine Particle Air Pollution,” <http://www.catf.us/resources/publications/view/159>.
- ⁵ Amit Narang and Taylor Lincoln, “Decoding the Bill,” Public Citizen, August 2011, <http://citizen.org/documents/decoding-the-bill.pdf>.
- ⁶ The organizations representing fresh produce growers opposed the Food Safety Modernization Act, because it did not create standards that were strict enough. See United Fresh, Letter to the Senate, November 18, 2010, <http://www.unitedfresh.org>. The grocery industry also supports stricter standards, see Food Marketing Institute Press Release, “Food Safety Modernization Act Passes For the Third Time in U.S. House of Representatives,” December 2010, http://www.fmi.org/news_releases/index.cfm?fuseaction=mediatext&id=1191.
- ⁷ Elaine Scallan, et al, “Foodborne Illness Acquired in the United States—Unspecified Agents,” *Emerging Infectious Diseases*, 17(1) (January 2011): 16-22.
- ⁸ In Ohio, approximately 828,000 people a year will be sickened by foodborne illness from produce. See Robert Scharff, “Health Related Costs from Foodborne Illness in the United States,” Produce Safety Project at Georgetown University, March 2010, <http://www.producesafetyproject.org/admin/assets/files/Health-Related-Foodborne-Illness-Costs-Report.pdf-1.pdf>. In 2011, the Centers for Disease Control updated their methodology for calculating national incidents of foodborne illness. However, state-by-state data based on the 2011 figure is not yet available. Because the change in methodology resulted in a lower figure for 2011, forthcoming state-level estimates are expected to be lower.
- ⁹ The FDA Food Safety Modernization Act (Pub. Law 111-353) requires the FDA to create a rule to “establish science-based minimum standards for safe production and harvesting of...fruits and vegetables.” The Act required that a draft of the rule be available for public comment in January of this year and that the agency begin enforcing the final rule one year after the period for public comment has closed, approximately March of 2013.
- ¹⁰ For FDA’s estimate of the number of illnesses that would be prevented by the application of a similar rule, the Hazard Analysis and Critical Control Points (HACCP) Standard for seafood processors, see Federal Register, December 18, 1995, pp. 65185-7.
- ¹¹ Robert Scharff, p. 15. Of the 828,000 cases of foodborne illness from produce each year in Pennsylvania, the produce rule would prevent approximately half, over 414,000, of these cases. Figures based on latest available state data. Forthcoming state-level figures for total number of illnesses are expected to be lower based on methodological change described in endnote 8, above.
- ¹² The population of Cincinnati is 296,943, <http://quickfacts.census.gov/qfd/states/39/3915000.html>.
- ¹³ (42 U.S.C. 7409).
- ¹⁴ Mireya Navarro, “States Sue E.P.A. Over Delayed Soot Rules,” *New York Time Blog*, February 10, 2012, <http://green.blogs.nytimes.com/tag/soot>.
- ¹⁵ American Lung Association.
- ¹⁶ Ibid.
- ¹⁷ There are a total 64,429 students, graduate and undergraduate, enrolled at Ohio State University, <http://www.osu.edu/osutoday/stuinfo.php#enroll>.
- ¹⁸ There are 25,992 sworn police officers in Ohio, <http://bjs.ojp.usdoj.gov/content/pub/pdf/cs1lea08.pdf>.
- ¹⁹ State level data is from unpublished results of a study commissioned by Earthjustice, the American Lung Association, and the Clean Air Task Force with support from the Energy Foundation. National level data is included in “Sick of Soot,” see above
- ²⁰ American Cancer Society, “Cancer Facts and Figures 2011,” <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-029771.pdf>.

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