

The Honorable Ron Johnson
Chairman
U.S. Senate
Homeland Security & Governmental Affairs Committee
Washington, DC 20510

The Honorable Thomas Carper
Ranking Member
U.S. Senate
Homeland Security & Governmental Affairs Committee
Washington, DC 20510

The Honorable James Lankford
Chairman
U.S. Senate
HSGAC Subcommittee
Regulatory Affairs & Federal Management
Washington, DC 20510

The Honorable Heidi Heitkamp
Ranking Member
U.S. Senate
HSGAC Subcommittee
Regulatory Affairs & Federal Management
Washington, DC 20510

Dear Senators:

At the Union of Concerned Scientists, our 450,000 members and supporters throughout the country are committed to science-informed regulation that makes a real difference in the lives of our families and the lives of future generations.

Our members are people who care about the environment, and environmental justice, public health and safety. They are parents and grandparents. They embrace a wide range of scientific professions; they are engineers, physicians, physicists, statisticians, oceanographers, economists, biologists, ecologists and chemists. Many of them work in federal agencies. On both a personal and professional level, they support science-informed common-sense regulations that protect public health and safety and the environment. They also want Congress to ensure that life-saving regulations are not delayed, weakened or blocked.

We appreciate this opportunity to illustrate with a few case studies why protective rules, implemented by federal agencies in a timely fashion, have real-world impacts both on our members and the larger American public.

Protecting small children and parents from the grief of avoidable backover crashes

In 2002, Long Island pediatrician Greg Gulbransen was backing out of the family SUV when he felt a bump. He stopped the car, wondering what he'd hit. What he discovered, he testified before Congress in 2007, "was my two-year old son Cameron in baby blue pajamas, holding his blanket, face up, dying of a massive head injury." Gulbransen had checked his rear-view and side-view mirrors, but larger models of cars often have blind zones where a driver can't see a small child. That's what happened in Gulbransen's accident. ⁱ

More than 200 persons are fatally struck each year from back-over accidents, and more than 40 percent of those accidents involve children aged five or younger. In more than two-thirds of these child-related accidents, the drivers are parents who run over their own children.ⁱⁱ An additional 15,000 people are injured each year.

Congress saw the need for action, and in 2008, approved bipartisan legislation to require the Department of Transportation to develop regulations to ensure better rear visibility to prevent these needless tragedies.

Congress required that a new rear visibility rule be implemented by 2011, but the Department of Transportation asked for four extensions between 2011 and 2013, and stated that it would not enforce the rule until 2015. Consumer advocates sued, and that pressure compelled DOT to announce in 2014 that it would require that “rear visibility technology” be standard equipment on all vehicles that weigh 10,000 pounds or more. The rule is based on the best available science, and the result of extensive NHTSA studies of the issue.ⁱⁱⁱ The automakers have until May 2018 to comply.^{iv}

Estimates vary about the additional per-vehicle cost of rear-view camera technology, but the highest estimate places the cost at \$142. Honda added the new technology along with other safety features to its 2015 Honda Fit at a cost of roughly \$100.^v

The cost of delay? Assuming that rear-view technology would eliminate just one-third the deaths and accidents caused because the driver did not see a pedestrian behind him, the statistics are dramatic: The seven-year delay of a regulation required by Congress to be implemented by 2011 means that up to 35,000 people were injured and an estimated 500 persons needlessly died in the intervening years. The cost to families in heartache and grief is incalculable.

Empowering consumers and reducing healthcare costs

Want to save taxpayers tens of billions of dollars each year? Treating obesity-related illnesses like diabetes, high blood pressure and heart disease annually costs this country \$190 billion.^{vi} Scientists increasingly are determining that consuming too much sugar is a major cause of our weight problem. Several scientific and health authorities—including the World Health Organization, the Department of Health and Human Services, the American Heart Association, and the U.S. Department of Agriculture—have studied and made recommendations for limiting our sugar consumption.

Many Americans would like to lose weight and want to serve healthy meals to their families. But even if they know that eating too much sugar causes weight gain, it is really difficult for them to monitor how much sugar they are consuming.

You don't have to believe in the “nanny state” to think that Americans ought to know about sugars that are added to foods, often in foods where we wouldn't suspect sugar – mayonnaise and ketchup, pasta, bread, and “healthy” foods like yogurt. For example, Yoplait Original yogurt contains 26 grams of sugar per serving—more than six teaspoons of sugar, more sugar than the American Heart Association recommends women consume during an entire day.

We know that food companies' multi-billion-dollar ad budgets have helped increase sugar consumption over time. In 1970, the average American consumed more than 18 teaspoons of sugar a day. By 2012, Americans were eating more than 20 teaspoons per day. This is almost double what the U.S. Department of Agriculture's recommended allowance of about 10 teaspoons per day. That total is more than double the American Heart Association's recommended daily allowance for men of 9 teaspoons, and more than triple the association's recommended allowance for women of six teaspoons. The quantity and availability today of foods and beverages with excessive added sugar leave all consumers, but especially children, vulnerable to the pressure from industry advertising and marketing to over-consume.^{vii}

The Food and Drug Administration is considering requiring food makers to report added sugars on the Nutrition Facts label, a move that would provide much needed information to consumers about the amount of sugar that has been added to their food.^{viii}

This rule would simply provide information. Consumers would be free to eat as they always do. But their choices would be based on the facts, not on food company ads.

If enacted, the rule could lead to better health outcomes because of both changes in consumer behavior and manufacturing practices. Such changes could mitigate Americans' sugar overconsumption and lower their risks for diabetes, cardiovascular disease and other adverse health effects. Our members believe that this regulation could make a difference.

That's why 28,500 Union of Concerned Scientist members and supporters sent letters to General Mills and asked the company to change its position and support more consumer information on added sugar. UCS members also sent 23,000 comments to the Food and Drug Administration, asking the agency to require information about added sugars on nutrition labels.

If we believe that knowledge is power, American families need this knowledge to empower them to look out for their health.

Beneficial rule required by Congress will save lives

In 2005, Joshua Oukrop, a 21-year old college student from Grand Rapids, Minnesota, died suddenly when the defibrillator implanted by his doctors in 2002 shorted out. Oukrop had a genetic heart condition that can cause sudden heart failure, and the device was implanted to revive him. Oukrop was on a hike, felt faint and collapsed. His girlfriend saw him fall from his bike. CPR was attempted, but it was too late. He died of a heart attack. His physician did an autopsy and concluded that if the device had worked, Jacob would have lived. He also discovered that the company that made the device had known about its problems since 2002.^{ix}

Jacob's death was not a fluke. The FDA estimated that over the five-year period between 2007 and 2012 alone, more than 17,000 deaths were linked to faulty medical devices reported to the FDA.^x But during that same period, device makers have recalled more than 100,000 defective artificial hips, and tens of thousands of other types of implantable heart devices.^{xi}

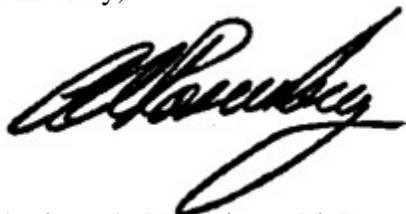
In 2012, we asked our UCs members to tell us their stories of the harmful and helpful impacts of drugs and devices on their lives. We received scores of responses. Some of our members permitted us to tell their stories. Sara, a registered nurse from DeKalb, Illinois, was one. Sara also needed a defibrillator because of a genetic heart defect like Joshua's. In 2001, she got the same type of defibrillator that Joshua received. It took three years for Sara's doctor to learn that her device was faulty and dangerous. Guidant, the company that made the device, would pay only for a replacement device, not the surgery or pre- or post-operative care. Sara was subjected to a second surgery when the replacement device's battery started to lose power. Her recovery was slower the second time, and she developed an infection. If a better tracking system had been in place before Sara received the first flawed Guidant device, it may have spared Sara trauma and expense, and at least one surgery. Her father, John, said it has been "heartbreaking to see her go through all this."^{xii}

Congress first required the FDA to develop a system to track implantable medical devices in 2007. When the regulation took years to develop, Congress in 2012 gave the FDA a second mandate with deadlines to achieve that goal.

Under this regulation, each implantable device will have a unique identifier. If the device proves to be faulty or dangerous, doctors will have the data about the device and be able to report the problem to the FDA. This early warning system will save countless lives. It will also prevent patients from undergoing costly and dangerous surgeries to remove flawed devices.^{xiii}

We appreciate your request for information about our members' concerns about regulation and its impacts. We look forward to working with the committee on this issue in the months ahead.

Sincerely,



Andrew A. Rosenberg, Ph.D.
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Union of Concerned Scientists

ⁱ Louise Radnofsky, "Mission: car safety," *Newsday*, Mar. 1, 2007, A8.

ⁱⁱ David Undercoffler, "U.S. orders rear cameras for new cars," *Los Angeles Times*, April 1, 2014, B1.
<http://articles.latimes.com/2014/mar/31/business/la-fi-back-up-cameras-20140401>

ⁱⁱⁱ "NHTSA announces final rule requiring rear visibility technology," March 31, 2014.
<http://www.nhtsa.gov/About+NHTSA/Press+Releases/2014/NHTSA+Announces+Final+Rule+Requiring+Rear+Visibility+Technology>

^{iv} David Undercoffler, op.cit.

^v David Undercoffler, op.cit.

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- ^{vi} “Sugary drinks and obesity fact sheet,” The Nutrition Source, T.H. Chan School of Public Health, Harvard University.
<http://www.hsph.harvard.edu/nutritionsource/sugary-drinks-fact-sheet/>
- ^{vii} Deborah Bailin, Gretchen Goldman, Pallavi Phartiyal, *Sugar-coating Science*, Center for Science and Democracy, Union of Concerned Scientists, May 2014. <http://www.ucsusa.org/sites/default/files/legacy/assets/documents/center-for-science-and-democracy/sugar-coating-science.pdf>
- ^{viii} “Proposed changes to nutrition facts label,” FDA, August 1, 2014.
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm#Summary>
- ^{ix} “When medical implants fail,” CBS News, April 4, 2012. <http://www.cbsnews.com/news/when-medical-implants-fail/>
- ^x Thomas M. Burton, “FDA Unveils Medical Device Tracking Plan,” *Wall Street Journal*, July 3, 2012.
<http://www.wsj.com/articles/SB10001424052702304211804577505094143301240>
- ^{xi} Matthew Perrone, “FDA requires tracking codes on medical implants,” *USA Today*, September 13, 2014.
<http://www.usatoday.com/story/news/nation/2013/09/20/fda-tracking-codes-medical-implants/2843835/>
- ^{xii} Michael Halpern, “For Sara, Faulty Medical Device Leads to Unnecessary, Invasive Surgery,” *The Equation Blog*, May 24, 2012.
<http://blog.ucsusa.org/for-sara-faulty-medical-device-leads-to-unnecessary-invasive-surgery>
- ^{xiii} Matthew Perrone, op. cit.