

Key Recommendations for The Next Regulatory Czar’s Critical Mission: Will He Rebuild a Regulatory System that Works for the Public Interest?

Introduction

When President Obama’s second term comes to an end, will Americans find that they are better protected against threats to public health, consumer and worker safety, and the environment? The answer to that question depends on how Dr. Howard Shelanski – the president’s nominee to serve as the next administrator of the Office of Information and Regulatory Affairs (OIRA) – approaches the job if he is confirmed.

Background

For over 30 years, OIRA administrators have taken full advantage of this power to block, weaken, rewrite, or simply delay key safeguards opposed by special interests, transforming the office into a critical chokepoint in the rulemaking process. In a present example, the Occupational Safety and Health Administration’s (OSHA) rule to protect workers against excessive exposure to silica dust has been stuck at OIRA for more than two years. OSHA estimates that this rule will save at least 60 lives per year, but until the OIRA administrator gives it his okay, it will never see the light of day.

Presently, the office has more than 150 rules bottled up – one of the largest backlogs in its history. Nearly 80 of those rules have been stuck there for longer than the 120-day period allowed for rule reviews at the same time that the nation faces a lengthy to-do list of public health, safety, and environmental challenges. From the network of decaying natural gas pipelines that crisscross beneath our homes to the threat of imported food tainted with *Salmonella*, botulism, or other contaminants showing up on grocery store shelves; from the myriad risks of hydraulic fracturing to the continuing perils of the unregulated compounding pharmacy industry – these problems are severe and urgent and demand effective and timely solutions.

The United States needs public protections that work for all of us. If we are to meet these challenges, the next OIRA administrator must help lead the charge by affirmatively supporting federal agencies in their work to protect people and the environment.

What the Senate Should Address During the Confirmation Process

The members of the Senate Committee on Homeland Security and Governmental Affairs can seize this opportunity to ensure that Shelanski is the agent of change that OIRA so desperately needs. As they review and contemplate his nomination, senators should seek his views regarding the following crucial matters. As next OIRA Administrator will he pledge to:

- **Quickly complete safeguards that are stuck in the regulatory pipeline?**
 - Crucial standards to address food safety, pedestrian safety, and worker safety remain held up at OIRA. These delays create real harm to real people and their environment – harm that is preventable.

- One EPA rule on toxic chemicals has been stuck at OIRA for almost three years.
- A Food and Drug Administration (FDA) rule to improve the safety of imported foods has been delayed for nearly a year and a half.

Recommendation: OIRA should meet its required 120-day deadline for the completion of rules and commit to completing reviews as quickly as possible to ensure that critical safeguards are not unreasonably delayed. OIRA should not be allowed to exceed this deadline without issuing a public justification regarding why they cannot meet the deadline and when the public can expect the proposed or final rule to be published.

- **Embrace a proactive agenda for confronting threats to public health, safety and the environment?**
 - The recent industrial catastrophe in West, Texas, is a reminder that when risky practices slip through the regulatory cracks, there are tragic consequences. News reports in the wake of the tragedy tell a damning story of several agencies not taking responsibility for addressing the threat posed by the storage of highly explosive fertilizers.
 - OIRA has become so fixated on rooting out the imaginary problem of “regulatory overreach” that it ignores the very real problem of inadequate public safeguards.
 - As the overseer of the entire regulatory system, OIRA is well positioned to identify the gaps in standards and protections that allow industrial catastrophes – such as, the West, Texas, explosion or the fungal meningitis outbreak linked to the inadequately supervised compounding pharmacy industry – to occur.

Recommendation: OIRA should seek to identify these gaps and then work with relevant agencies – including identifying needed legal authority and resources – to properly address them.

- **Support federal regulatory agencies as they work to fulfill the purposes for which they were created?**
 - For too many agencies, outdated legal authority and inadequate resources are hampering efforts to protect people and the environment.
 - The statute under which EPA operates to protect people against toxic chemicals is nearly 40 years old. In that time, the agency has only been able to implement safeguards for a handful of the 80,000 unique chemicals that currently are sold and used.
 - Meanwhile, agency budgets have remained unchanged – or in most cases have actually shrunk – even as their missions have grown larger and more complicated. As agencies become hollowed out, they are less able to put needed safeguards in place.

Recommendation: OIRA can reverse these trends by working with agencies to identify the resources and legal authority they need to fulfill their statutory missions in a timely and effective manner, and it must advocate on behalf of these agencies to the president and Congress.

- **Ensure public health and safety concerns have primacy over strict cost-benefit estimates in rule reviews?**
 - In most major health, safety and environmental laws, Congress instructed agencies to base their regulatory decisions using evaluation systems other than attempting strict calculations of regulatory benefits and costs.
 - Provisions in the Clean Water Act direct the EPA to base its decisions on what kinds of technology are available.
 - Provisions in the Clean Air Act direct the EPA to set standards based on what is needed to protect public health.
 - Throughout its history, OIRA has required agencies to discount the law and science and instead base their decision-making heavily on cost-benefit analysis, even when it conflicts with the law.
 - Cost-benefit analysis has inherent limitations for evaluating regulations, and it relies on techniques that consistently understate regulatory benefits (including some that defy monetization) while overstating regulatory costs.

Recommendation: OIRA should recognize the limitations of cost-benefit analysis. When cost-benefit estimates are considered, they should not be used as the only analytical method, or used to force agencies to take actions that conflict with statutes.

- **Respect the expertise of federal agency scientists and scientific methods when reviewing health and environmental risks?**
 - Agencies such as OSHA, the EPA, and the U.S. Fish and Wildlife Service employ experts in the fields of science, engineering, and medicine. They are best-positioned to understand the complex scientific issues that underlie much agency decision-making.
 - Though staffed almost entirely by economists, OIRA routinely substitutes its non-expert judgment on scientific matters, often resulting in weakened standards and safeguards.
 - In 2009, for example, OIRA attempted to meddle with EPA’s Endocrine Disruptor Screening Program, a scientific area; it backed down when the episode came to public attention

Recommendation: During rule reviews, OIRA should limit its input to questions of economics – and only where relevant.

- **Proactively disclose the materials, studies, and conversations that OIRA staff uses in decision-making. Annotate the changes OIRA demands of the rules submitted by agencies with an explanation for why these changes were made?**
 - OIRA has long operated as a “black box” in the rulemaking process: Rules emerge from its review process drastically changed, but the reasons for these changes are seldom revealed. Indeed, the exact nature of these changes can only be ascertained through careful scrutiny; almost invariably, however, this scrutiny reveals that the protections offered by the rule have been significantly weakened.

- The office lacks openness despite the fact that OIRA operates under several transparency requirements.
 - OIRA is supposed to reveal all the communications between its staff and outside groups during rule reviews. It seldom does.
 - OIRA is supposed to encourage agencies to publicly disclose how and why rules were changed during review. But it has, at least in some cases, OIRA has *discouraged* agencies from doing so.
- Without information on rule reviews and outside meetings, it is impossible for the public to independently verify that rule changes made at OIRA are intended to advance the public interest. It also makes it impossible for the public to hold decision makers accountable for the rules that affect the American people.

Recommendation: At a minimum, OIRA should commit to obeying all applicable transparency requirements.

The [Coalition for Sensible Safeguards](http://www.SensibleSafeguards.org) is an alliance of consumer, labor, scientific, research, good government, faith, community, health, environmental, and public interest groups, as well as concerned individuals, joined in the belief that our country's system of regulatory safeguards provides a stable framework that secures our quality of life and paves the way for a sound economy that benefits us all.