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Time for Radiation Regulation to Evolve

BY BRANT A. ULSH and EDWARD J. CALABRESE

We use radiation for everything from generating electricity, to gaining a look at the inside of our bodies without resorting to a scalpel, to rescuing patients from the ravages of cancer, to sterilizing medical equipment and food, to numerous industrial applications. Modern society benefits greatly from technologies that harness the beneficial uses of radiation. Nuclear power alone has saved 1.8 million lives worldwide by avoiding air pollution, and medical imaging has been recognized as one of the top 15 medical advances of the past 170 years.

The use of radiation is regulated by a legal framework that establishes radiation dose limits for workers and the public. The framework calls for ever-lower exposures that are “as low as reasonably achievable” (ALARA), taking social and economic factors into account.

Over the decades since the discovery of radiation, this legal framework has unquestionably protected workers and others who once received radiation doses that today we recognize as alarmingly high. However, today further reductions that are compelled by ALARA often provide only trivial benefits or simply demonstrate novel technologies. There is no serious debate that enormous radiation exposures—for example, what a person might receive within several hundred meters of ground zero of a nuclear detonation—measurably increase the risk of cancer. But with very rare exceptions, people today are not receiving doses anywhere near that high. Adverse health effects from the extremely low radiation doses typical of modern occupational and environmental exposure scenarios are so rare that they cannot be directly observed, if they exist at all.

Ultra-low exposure limits do not just

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impose a cost in the form of more and more radiation-reduction measures, but also in the suppression of beneficial uses of radiation. Another cost comes from the promotion of unjustified levels of fear of radiation among the public. Moreover, in practice, the “reasonability” of dose-reduction efforts explicitly embedded in the very definition of ALARA is frequently overlooked, and doses are instead driven as low as technologically possible, ignoring the costs and consequences of doing so. In the United States, this has led to excessive regulatory burden, which is a major driver of the premature closing of an increasing number of nuclear power plants that provide more than half of the country’s emission-free energy.

Linear dose / Underlying ALARA is the assumption that increases in cancer risk observed after enormous radiation doses can be extrapolated down to doses that are less than a hundredth or a thousandth of the size—like those typical of modern occupational and environmental doses. This idea, known as the linear no-threshold (LNT) model, predicts that any radiation dose, no matter how small, increases cancer risk in linear proportion to the reference dose all the way down to zero exposure. It discounts the possibility of there being a safe exposure level. The LNT assumption provides the justification for driving already trivial doses even lower.

How did this assumption arise? A seminal event was the National Academy of Sciences’ formal recommendation in 1956 that the threshold model of radiation effects be rejected in favor of the LNT model.

Careful examination of historical records has revealed that the studies upon which the 1956 adoption of the LNT model was based—the work of Nobel-winning geneticist Hermann Muller—did not in fact support the LNT model. Muller examined gene mutations in fruit flies exposed to radiation doses so high (that is, about 100 million times greater than background) that they would be lethal to humans, and concluded that mutations increased linearly with radiation dose, even at doses close to zero. But later research by his team showed that there was a dose-rate threshold. Modern fruit fly experiments show that not only do low radiation doses fail to increase the number of mutations, they actually *reduce* mutations below the normal background level of mutations in nonexposed flies. (See “The Troubled History of Cancer Risk Assessment,” Spring 2019.)

This phenomenon is known as “hormesis”: low radiation doses stimulate natural biological defense mechanisms to provide a mild protective effect, while high radiation doses overwhelm these defenses and cause negative effects. Thousands of experiments in cells and whole organisms ranging from bacteria to humans, using diverse measures of biological effects, confirm that hormesis is a general phenomenon that has been conserved over the course of the evolution of life on Earth.

Rather than systematically evaluating and employing this vast body of scientific literature, regulatory agencies and advisory groups steadfastly ignore it even as the evidence continues to accumulate. Biological studies using modern techniques to determine the effects of radiation in genes and chromosomes provide compelling evidence consistent with hormesis, not the LNT model. Yet, modern radiation regulations are based almost exclusively on epidemiological studies that have limited statistical power and significant uncertainty at low doses that prevent them from illuminating the effects of those doses.

Using circular logic, in the decades since the adoption of the LNT model in 1956, reviews conducted by advisory groups and regulators start with the assumption that



the LNT model is accurate. They do this for no other reason than that is what they have assumed in the past. They will only abandon this assumption if there is incontrovertible epidemiological proof that the LNT is incorrect—a practically impossible threshold. The uncertainty in epidemiological data, combined with the exclusion of biological data supporting thresholds and hormesis, and most importantly the a priori assumption that the LNT is true, combine to provide the perfect environment for the continued survival of this discredited theory. This subtle and improper shift in the burden of proof has consequences in the form of irrational public fear of radiation and the public health consequences born of that fear.

Nuclear power / Major nuclear accidents are exceedingly rare but they do happen, as evidenced by Three Mile Island, Chernobyl, and Fukushima. The harm from those incidents was made far worse by *bad decisions*. That makes it imperative that we learn the lessons those tragic events have to offer.

One mistake made at both Chernobyl and Fukushima was based on the LNT model and offers a cautionary tale of the consequences of irrational fear. In both incidents, the public health responses caused more harm than good, and indeed more harm than the accidents themselves. In the aftermath of Chernobyl, tens of thousands of terrified expectant mothers across Europe succumbed to the fear of

having babies deformed by radiation and chose to have elective abortions. This was in spite of the lack of evidence that radiation causes heritable genetic mutations in humans. Likewise, the highest plausible doses received by these women were less than a thousandth of the level observed to cause birth defects. As at Chernobyl, LNT-induced fear of radiation caused the mass evacuation of Fukushima's residents and their multi-year exile from their homes. This caused over 2,000 avoidable deaths during the evacuation and widespread mental health effects among displaced Fukushima residents. Arguments have been raised that these effects were caused by misunderstanding and misapplication of the LNT model rather than the LNT model itself, but honest policy analysis has to account for the real-world consequences of regulations, whether intended or not.

Need for reform / Resistance to reforming radiation regulations away from reliance on the LNT model often include three dubious arguments:

- The LNT model is easy to use.
- Even if the LNT model overestimates risks, this protects public health.
- There isn't a better, more plausible model.

Not one of these arguments is compelling; one of them is debatable and two of them are false.

Even advocates of the LNT model admit that it overestimates risks of low

doses of radiation delivered at low dose-rates. Some of them propose adjustments to LNT predictions to account for this inaccuracy. The appropriate magnitude of such an adjustment is itself the subject of debate and introduces complexity that mitigates the LNT model's simplicity.

The assertion that overestimating the risks from low-dose and low-dose-rate radiation exposure protects public health by building in a safety margin has been shattered by the real-world experiences of Chernobyl and Fukushima. In both cases the message, based on the LNT model, that there is no safe dose of radiation has permeated the public consciousness and led to irrational responses that unequivocally damaged public health.

In the strictest sense, the efficacy of the LNT model does not depend on whether or not a "more plausible" model exists. The LNT model either accurately describes the observed data on low-dose radiation effects or it doesn't. However, from a public health policy perspective, it is unlikely that regulators will finally abandon their misplaced reliance on the LNT model unless an alternative model gains favor.

Contrary to LNT advocates' assertions, several regulatory improvements have been proposed. These include melding the LNT and hormesis models to account for the uncertainty in the effects of low radiation doses, establishing a low-dose "stopping point" for ALARA, and the related idea of establishing a "de minimis" dose below which there would be no regulation. Unfortunately, so far regulators have steadfastly resisted these improvements.

All of these ideas have their merits and deserve honest, unbiased consideration and debate. Each alternative should be considered from a policy perspective that includes objective benefit-cost analysis and an assessment of public health outcomes.

It is well past time for our radiation regulation philosophy to evolve. The first steps are to unshackle ourselves from the LNT model that traps us in the past, and to begin developing a radiation regulatory strategy that reflects modern knowledge of low-dose radiation effects. R

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Would a U.S. Carbon Tax Change Things?

BY KENNETH W. COSTELLO

Michael Davis's recent *Regulation* article on a carbon tax raises questions that advocates should address before policymakers adopt such a tax. (See "Five Questions for 3,508 Economists," Summer 2019.) Both policymakers and analysts should seriously consider these questions by going beyond mainstream

economic theory to judge whether a carbon tax would have any detectable effect on climate change and society's well-being.

Government can use three different policies to combat carbon emissions and climate change:

- Make carbon-free energy cheaper with subsidies and government-funded research and development.
- Make carbon-intensive energy more expensive using such mechanisms as a carbon tax.
- Mandate a certain level of energy production from "clean" sources and "cap" carbon emissions using cap-and-trade mechanisms.

A carbon tax is the preferred choice for many economists because it would force emitters to contend with the full cost of producing a ton of carbon, instead of just the emitter's private cost. Burning carbon has an external cost because it produces a greenhouse gas (GHG) that accumulates in the atmosphere and risks unwanted climate change: higher global temperatures, greater climate variability, and possible increases in sea levels. Analysts and policymakers refer to this external cost as the social cost of carbon (SCC).

In economics, a carbon tax would be a Pigouvian tax on a negative externality. The tax would convey proper price signals to consumers and producers (e.g., the price level corresponds to the social cost of production that includes the damage from GHG emissions), stimulate R&D on clean

technologies, and avoid the use of such traditional policies as command-and-control regulation, subsidies, and other inherently inefficient schemes. It could also motivate actors to adopt cost-effective emissions mitigation, perhaps by using different energy technologies or avoiding emissions altogether. For these reasons, economists believe prices should reflect scarcity and the social value of a good or service.

A related argument offered by economists for a carbon tax is that it represents a market-oriented solution that corrects for market inefficiency or failure. It places the different energy sources on a level playing field, making low-carbon technologies and energy efficiency more attractive. Because non-clean energy currently receives an implicit subsidy by avoiding the social cost, a tax would undo or at least mitigate that subsidy. But, as discussed below, if the SCC is so speculative that we have little idea of its optimal value, there is the risk that an "excessively high" tax on carbon would result in the opposite problem: an inefficient subsidy to clean energy.

Blackboard economics / The takeaway from Davis's article is that, though economists like to work in an idealized world with stylized facts—one in which a Pigouvian tax simply resolves the carbon emissions problem—policymakers must consider the context and details of the politics and measurement problems with the SCC. Because a tax would lower GHG emissions, the tendency is to think that we could then devote less effort toward adaptation to climate change, say, in agricul-

ture or water-management planning. As discussed later, adaptation may be more effective and economical than reducing GHG emissions.

A carbon tax could have negative net benefits (assuming a reasonable discount rate): costs are incurred now but benefits from such reductions are in the distant future and highly uncertain.

Under specific conditions, a quantity-based measure such as a cap-and-trade mechanism would be preferred to a carbon tax. For example, in comparison with a tax, tradable emissions permits reduce the uncertainty in attaining a specified level of carbon in the atmosphere. This is because the responsible governmental agency controls the number of emissions permits that it issues.

Implementation issues relate to the size of the tax and how soon it should be imposed. For example, how large would a carbon tax have to be to reduce U.S. carbon emissions by 30%? There is much uncertainty over how economic actors would respond to such a tax and, thus, on the amount of carbon emissions reduced.

Even with a carbon tax, climate advocates would surely also want more stringent (inefficient) regulations on energy production and use. They would never agree to a carbon tax unless it was extremely high. Even then, the world would likely fall short of the 2°C limit on global warming advocated by climate activists; meanwhile, such a high tax rate would face strong opposition from the political right and center. We know from the past that when governmental action leads to higher energy prices, often there is a public outcry. We also know that environmentalists are generally skeptical of market-based approaches; their preferences are for subsidies for clean energy technologies and caps on emissions. The trouble with subsidies is that they reflect heavy-handed regulation and require policymakers with imperfect information to choose specific technologies for preferential treatment.

Proposals for a carbon tax almost always specify how the resulting revenues should be allocated. Proposed uses include

reducing the national debt and cutting taxes, funding R&D of clean energy technologies, and distributing lump-sum rebates to households. One argument for the last option is that it would compensate low-income households for the regressive outcome from a carbon tax. It would also supposedly garner wider political support than the other options. Some have argued that if a carbon tax can help eliminate or reduce distortionary taxes (e.g., income and payroll taxes)—which is a big if—society would be better off when government revenues derive from Pigouvian-type taxes (i.e., taxes on a negative externality) rather than from other taxes.

Some advocates of a carbon tax argue that it would be easier to undo a tax—if that became necessary—than other policy approaches. But we know from experiences with other taxes that beneficiaries (e.g., clean energy producers) will exert strong political opposition to the abolition of a tax.

Setting the tax / In theory, a carbon tax should equal the SCC. But there are a number of problems with turning that simple theory into reality.

For one thing, estimates of the SCC are wildly speculative and vary within a wide range. Some analysts argue that climate change will be moderate, will occur in the distant future, and will have only a small effect on the economies of most countries. This would imply that the SCC is small, perhaps only around \$10 per ton of carbon dioxide emissions. Others argue that without an immediate and stringent GHG abatement policy, there is a reasonable chance of substantial temperature increases that could have a catastrophic economic effect. If so, the SCC is large, perhaps as high as \$200 per ton of carbon dioxide. The SCC is extremely sensitive to parameters that are subjective—“garbage in, garbage out.” One can come up with an SCC that best advances one’s agenda; for example, the SCC is especially sensitive to the discount rate because most climate change scenarios predict major damages only after several decades have passed.

Another problem is the United States would experience only a small part of the global harm from climate change, even though a ton of U.S. emissions produces the same warming as a foreign ton. As a result, Americans might only accept a low carbon tax, which would have only a small effect on change in global temperature.

Also, it is questionable whether a carbon tax would have even a detectable effect on climate change. If the demand for “dirty” energy is highly inelastic, people may be willing to pay the tax and continue emitting carbon. This undermines the position of those who believe that even if a carbon tax fails a benefit–cost test, it can still act as a form of “insurance” by preventing “worst case” scenarios (or “fat tails,” in the literature) of climate change. The overall



effect is the government collecting huge tax revenues while showing little effect on global temperatures.

Yet another problem is that, while assuming a zero value for the SCC may be wrong, it may be better (i.e., reduce welfare losses by less) than to assume some grossly high level for a carbon tax. Also, estimates of the SCC require forecasts of climate change to relate, for example, economic welfare losses to global temperature change. As of today, those forecasts are highly speculative, diminishing their use for setting the tax. One final problem is that a carbon tax would do little to reduce

carbon emissions outside the United States, where the climate-change battle will be won or lost. While it has long been noted that the United States was the largest (and now second-largest, after China) producer of GHG, over 85% of carbon emissions originate outside the United States.

Policy implications / Given the problems with the Pigouvian tax on GHG, we should give more consideration to adaptive strategies, which can evolve over time in response to new information. The best scientific evidence shows that warming of the Earth’s atmosphere will occur gradually, allowing ample time for adaptive measures to mitigate the effects of climate change. As we learn from basic economics and other contexts, people adapt when

change implies a need to reoptimize.

Adaptation can involve adjusting planting dates and crop locations, building and strengthening seawalls, and urban and rural flood management. Adaptation does not require international cooperation, which, as discussed below, is highly difficult to achieve. Arguably, this is a more effective, less costly, and more practical strategy than futilely trying to limit global emissions in order to achieve a stringent temperature-change target.

A U.S. carbon tax by itself would accomplish little in reducing global temperature. Deep decarbonization to achieve strin-

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gent temperature-change limits (e.g., no more than 2° C) requires collective action between countries. One country, even one as big as the United States, cannot do it alone with a carbon tax. But it is hard to reach an effective agreement on limiting emissions even if it is in the world's common interest because of free-riding or countries understating their willingness to pay the costs for climate-change mitigation. (The rise of populism has also aggravated the difficulty for international cooperation.) Internal costs of these poli-

cies for individual countries could be significant, but benefits are unclear, distant, and broadly spread across all countries. In effect, countries see potentially high costs of actions that primarily benefit others.

Lastly, a carbon tax would meet with strong political opposition: the left wants more draconian measures like the Green New Deal while the right would oppose any tax at all. Although a favorite of many economists, we are unlikely to see an effective U.S. carbon tax unless the political and economic dynamics radically change. **R**

The FDA Needs More Accountability, Not More Independence

BY HENRY I. MILLER

Should the U.S. Food and Drug Administration, which currently resides organizationally within the Department of Health and Human Services, become an independent agency? A few academics recently argued that “partisan political interposition has grown increasingly worrisome. As the sole arbiter standing between a New Drug Application and a potential public health calamity, the FDA can hardly afford to be buffered by undue political interference,” and should, therefore, become an independent agency. A group of former heads of the agency have made a similar recommendation.

In fact, political meddling at the FDA has been extremely rare in recent years, in no small part because of the agency's 17,000-plus employees, more than 99.9% enjoy civil service protection from political influence or retaliation. And although there have been some real problems with the formulation of policies and their implementation, they have been largely self-inflicted wounds that might have been avoided with more, not less, oversight.

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Regulators and risk / The FDA is ubiquitous in Americans' lives, regulating products that account for more than \$1 trillion annually—25¢ of every consumer dollar. Regulation of those goods provides some measure of reassurance and tangible benefits, to be sure, but it has massive costs, direct and indirect. Regulation that is wrong-headed or that merely fails to be cost-effective actually costs lives, both directly by withholding life-saving products and indirectly by diverting societal resources to gratuitous regulatory compliance.

There is widespread belief among the public and their representatives that more-stringent regulation is synonymous with greater public well-being. In fact, net benefit to patients is often compromised because of a regulatory anomaly: the asymmetry of outcomes from the two types of mistakes that regulators can make. A regulator can commit an error by permit-

ting something bad to happen (approving a harmful product like a drug with unrecognized side effects), or by preventing something good from becoming available (not approving a beneficial product in a timely way). Both outcomes are bad for the public, but their consequences for the regulator are very different.

The first kind of error is highly visible, causing the regulators to be attacked by the media and patient groups and investigated by Congress. The second kind of error—keeping a potentially important product out of consumers' hands—is usually a non-event, eliciting little attention. As a result, regulators make decisions defensively, tending to unnecessarily delay or reject new products of all sorts, from cancer drugs to vaccines and painkillers. That's bad for public health and for physicians' and consumers' freedom to choose among a variety of products.

Congressional oversight is supposed to provide a check on regulators' performance, but rarely does it focus on gratuitous delays in product approvals. A premature or mistaken approval makes for more exciting hearings, with injured patients and their families paraded before the cameras. There is no reason to expect that congressional oversight would be more conscientious if the FDA were to become an independent agency.

These perverse incentives for FDA regulators yield a host of negative consequences for public welfare, ranging from disincentives for product research and development (and inflated costs for them), to significant threats to public health. The detrimental effects of FDA delays in approving certain new drugs already available in other industrialized countries are well documented.

An example is the long delay before the FDA's 2015 approval of Fluvad, a flu vaccine that contains an adjuvant that boosts immune response. It is used primarily in the elderly, whose immune response to flu vaccines typically is poor. According to the Centers for Disease Control,

It has been estimated that between 71 percent and 85 percent of seasonal flu-

related deaths have occurred in people 65 years and older and between 54 percent and 70 percent of seasonal flu-related hospitalizations have occurred among people in that age group.

Fluad had been used in Italy since 1997 and approved in more than three dozen countries. The 18-year delay in availability in the United States undoubtedly resulted in many avoidable hospitalizations and deaths. Another example was the delay in approval of a much-needed meningitis B vaccine.

Yet another egregious example of the



harm from the FDA's excessive risk-aversion is the drug pirfenidone. It is used to treat a pulmonary disorder called idiopathic pulmonary fibrosis (IPF), which used to kill tens of thousands of Americans annually. The FDA unnecessarily delayed approval of the drug for years, although it had already been marketed in Europe, Japan, Canada, and China. During the delay, more than 150,000 patients died of IPF in the United States, many of whom could have benefited from the drug.

These examples illustrate the endemic problem at "gatekeeper" regulatory agencies, which must grant an affirmative approval before a product can be legally marketed. Their timidity can be lethal.

Labeling and advertising / The FDA also has authority over the accuracy and integrity of food labeling. Although this isn't generally an issue on the same life-or-death scale as drug approvals, it is important to informing consumers' choices in a free market. It also offers examples of regulators' distorted priorities and poor judgement.

Consider one example: In 2017, the FDA sent a formal Warning Letter to a Massachusetts bakery for including "love" in its ingredient list. "'Love' is not a common or usual name of an ingredient, and is considered to be intervening material because it is not part of the common or usual name of the ingredient," it stated.

But while the FDA finds time to police inconsequential violations at small bakeries, it has been giving a pass for decades to the \$47-billion-a-year organic industry's blatantly false and deceptive advertising claims. Consider the Whole Foods website, which explicitly claims that organic foods are grown "without toxic or persistent pesticides." In fact, organic farmers rely on both synthetic and natural pesticides to grow their crops, just as conventional farmers do, and organic products can contain residues of numerous synthetic as well as

natural chemicals.

In addition to such blatant untruths, food marketers are masters at subtly misleading consumers. A favored technique is the "absence claim": asserting a meaningless distinction between products in order to make theirs seem superior. The feds would never allow an orange juice producer to label its product "fat free," for example, because that would imply the product is healthier than other orange juice when, in fact, no orange juice contains fat. Generally, the FDA comes down hard on such behavior. But some get a pass: Tropicana labels its orange juice "Non-GMO Project Verified" and Hunt's labels its canned crushed tomatoes "non-GMO," even though there are no

genetically engineered oranges or tomatoes on the market. In fact, absence claims about GMOs are never enforced: I was unable to find a single FDA warning letter or other enforcement action against deceptive "non-GMO" labeling.

The Non-GMO Project's butterfly label appears on more than 55,000 organic and nonorganic products on supermarket shelves today, many of which have no GMO counterpart or couldn't possibly contain GMOs. The clear purpose of these labels, as one peer-reviewed academic study found, is to "stigmatize food produced with conventional processes even when there is no scientific evidence that they cause harm, or even that it is compositionally any different." The labels and anti-genetic-engineering propaganda are effective: another study found nearly half of consumers avoid GMO-labeled foods.

The FDA's years-long inaction is all the more surprising inasmuch as they published explicit guidance on this issue in 2015:

Another example of a statement in food labeling that may be false or misleading could be the statement "None of the ingredients in this food is genetically engineered" on a food where some of the ingredients are incapable of being produced through genetic engineering (e.g., salt).

That FDA guidance went further, explaining that GMO absence claims can also be "false and misleading" if they imply that a certain food "is safer, more nutritious, or otherwise has different attributes than other comparable foods because the food was not genetically engineered." But this (in addition to violating the "standard of presence" criterion) is exactly what the Non-GMO Project's butterfly labels are all about. Its website, considered by the FDA to be a part of its labeling, describes certain foods as being at "high risk" of "GMO contamination."

Fortunately, the regulatory landscape for labeling may be changing. Guidance issued in March indicates that the FDA recognizes these widespread deceptive

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practices. It remains to be seen whether regulators will follow up this guidance with long-overdue enforcement action or continue to give a pass to the politically favored organic industry.

Greater accountability needed/ Earlier this year, a blog post on *Health Affairs'* website by three distinguished former federal officials raised valid objections to making the FDA an independent agency. Quoting from their post:

- The [U.S.] president's program—which is conceptualized and implemented through accountability to cabinet secretaries and the [Office of Management and Budget]—is important for directing the activities of the FDA. For example, presidential initiatives to lower drug prices bear on the rapid approval of generics but also on how such products are purchased by Medicare and Medicaid. In addition, policies to address the opioid crisis draw on the expertise and regulatory structure of the FDA, as well as many other federal agencies—inside and outside of HHS. FDA coordination and expertise [are] invaluable in formulating this program and can best be incorporated when the FDA is part of the vibrant debate that goes on among HHS operating divisions.
- An independent FDA would be able to represent its views in litigation without reference to well-established policies of the Department of Justice (DOJ). (Agencies within HHS, on the other hand, must follow DOJ policies.) Failure of the FDA to follow the DOJ's central rules on matters such as jurisdiction, standing, immunity, and remedies could leave the court system with inconsistent positions being taken by different parts of the US government. This phenomenon is also potentially present if the FDA was to adopt a different view on points related to foreign policy than the Departments of Defense or State, or the US Trade Representative.

- There are benefits to be secured from working within the HHS and OMB structures to make sure that the tools and techniques of economic analysis are consistently applied to rulemaking involving similar matters. The OMB's Office of Information and Regulatory Affairs may seem cumbersome to the leader of an HHS operating division, but it has consistently been a highly useful check on the risks of excessively expensive regulation. It's also a way that Congress and the president can ensure consistency across government in the application of expertise in regulatory policy

The post's authors were charitable enough not to mention that the FDA has had some terrible commissioners over the last three decades. Even the meager existing oversight and management of them has been something of a check on their worst inclinations.

What the FDA needs is not more independence and freedom from accountability, but better management and more conscientious oversight. There is a role both for Congress, which must demand greater perspicacity and discipline from regulators, and for the HHS, which should restore responsibility for the FDA's performance to the assistant secretary for health, who once had authority over the agency. R

What Does the OMB Memo Mean for Review of Independent Agency Actions?

◆ BY SAM BATKINS AND IKE BRANNON

For decades, scholars have debated whether the Office of Information and Regulatory Affairs should review the rulemaking of independent agencies, which would include the Securities and Exchange Commission, Commodity Futures Trading Commission, and Federal Communications Commission. At the start of the Trump administration there was intense speculation OIRA would decide that it could compel independent agencies to submit regulations for review. However, months passed without any such announcement.

On April 11, 2019, Russell Vought, acting director of the Office of Management and Budget, issued a memo that could eventually result in the executive review of independent agency actions—or merely serve as a footnote to President Trump's regulatory legacy.

The memo uses the Congressional Review Act (CRA) as a way to compel independent agencies to submit proposed “major” rules to OIRA. Section 804 of the

CRA defines a major rule as any measure that OIRA determines could result in an economic effect of \$100 million or more, cause a major increase in prices to consumers, or have significant adverse effects on competition.

It is far too early to tell what effects the memo will have on independent agency actions. Since the regulatory output is historically low under the Trump administration, the dearth of new rules provides an obstacle to discerning the effects of the Vought memo.

The CRA and independent agencies/ Since the advent of the CRA in 1996, the Government Accountability Office has recorded 1,576 major rules. Only 457 major rules were generated by independent agencies

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(29% of the total), but 40% of those have come since 2010, owing largely to the implementation of the 2010 Dodd–Frank Act. Some scholars believe that it is not uncommon for independent agencies to put their finger on the scale and fail to certify formal rules or regulatory guidance that should properly be certified as “major” and thus subject to review.

Despite the large number of major independent agency actions, Congress has only invalidated four of those regulations: two rules from the Consumer Financial Protection Bureau, one from the SEC, and one from the FCC.

Although the language of the CRA appears to give OIRA the power to determine whether a rule is major, independent agencies rarely rely on OIRA to make that determination. As a result, there are, in our estimation, an untold number of “major” rules published in the *Federal Register* lacking such a designation and that went into effect immediately, as opposed to the statutory 60-day delay that is standard for major rules.

The CRA as a sword / Rather than issue a new executive order or memo to enable OIRA review of independent agency actions, the Trump administration opted to use the CRA as the vehicle. Legally, this seems to be the safest approach because both the Paperwork Reduction Act and the CRA contemplate some interaction between independent agencies and the executive branch—for example, independent agencies must also submit paperwork collection requests for OIRA review. The administration opted to, in effect, use the CRA to appropriate a bit more authority over the rest of the administrative state.

The Vought memo lays out a series of procedures for independent agencies to follow, not unlike the formal strictures of an executive order that would have ushered in a formal review of all agency actions. The requirements for independent agencies are:

- Agencies must notify OIRA of pending rulemakings, likely through submitting notification of planned rules.

- OIRA will inform the agency within 10 days if it agrees with the determination that a rule is not major.

- For major rules, the agency must submit a CRA determination for review by OIRA at least 30 days before publication in the *Federal Register*.

- Agencies must include a regulatory analysis with each rule, consistent with OMB Circular A-4. (It’s notable that many independent agencies do not typically follow A-4 precisely.) Failure to conduct a rigorous analysis may delay OIRA’s determination and ultimately block the rule.

- OIRA is to make a judgment under Section 804 of the CRA.

- After any designation, the agency can send the rule to the GAO, but if it is major the agency must delay the effective date by 60 days to satisfy the CRA.

There is little doubt that the regulatory analysis requirement is the most consequential for independent agencies. Previously, many agency actions not subject to review contained sparse analyses or omitted them altogether, but the Vought memo effectively demands that all agencies in the federal government follow Circular A-4. The memo’s utility is that it relies on the CRA to demand a thorough benefit–cost analysis rather than a separate executive order that some agencies could fight in court. The Vought memo has yet to be challenged in court, and because of the dictates of Section 804 of the CRA, any legal challenge will likely face an uphill climb.

Beyond rules both major and minor, the Vought memo also applies to guidance documents, statements of general policy, and interpretive rules. There are countless guidance documents that agencies have never submitted through the formal CRA process that will now undergo review by both the agency and OIRA, while also giving Congress a chance to scrutinize major guidance under the CRA.

What’s next? / The key to determining the efficacy of the Vought memo will be to

observe if there is an increase in independent agency actions sent to Congress and the GAO, and if the regulatory analyses at agencies prove to be more rigorous. However, given the paucity of regulatory output from the Trump administration, a verdict will take some time. Nonetheless, during the next few months we should be able to examine major actions from independent agencies to determine if they are actually following the memo.

The bigger question is whether the Vought memo will fundamentally change independent agency behavior or the relationship between the executive branch and the agencies. The spirit of the memo certainly contemplates a sea change, even if it does not explicitly demand strict performance through a formal executive order.

It is also possible that this memo could engender a showdown between independent agencies and OIRA. Under this administration, it is easy to imagine a scenario where an agency decides it needs to fast-track a rule; if OIRA takes issue with the agency’s benefit–cost analysis and objects, what would occur? Or what would happen should OIRA hold a rule pending a more formal analysis, but the agency objects? What recourse would OIRA have if an agency decides to bypass OIRA review altogether and submit a rule for formal publication? Could OIRA demand the Government Printing Office refuse to publish the rule?

Given that President Trump has installed many of his allies to run independent agencies, such scenarios are not near-term certainties, but there is nothing stopping agency heads from ignoring the Vought memo or attempting to bend the rules to avoid real scrutiny. Since this administration has previously claimed it has always had the authority to review independent agency actions, perhaps agency heads should be grateful this process is guided more by the CRA than by a formal review process under Executive Order 12866, which can easily scuttle rulemakings in perpetuity.

Thus far, there has been no notable uptick in the number of independent agency actions arriving at the GAO. Then

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again, there appears to be no public way to track review of independent agency actions. By contrast, all notable executive branch rules under review are listed on OIRA's website, including meeting notices with outside parties lobbying on the rule-making. It is worth noting that since the Vought memo became effective, the GAO reports no independent agency actions have been submitted under CRA review—including major rules.

Conclusion / For years, myriad regulatory

policy scholars have urged OIRA to rein in independent agency actions under executive review, reasoning that it makes little sense to have one set of regulatory standards for one part of the government and a far more lax set of procedures for the other. When the Trump administration arrived, many expected an executive order that would have claimed authority over independent agency actions. By using the CRA as a statutory vehicle, OIRA has been able to provide some level of oversight to independent agency actions. R

rency manipulation. For example, if the Fed pushes down interest rates, American investors will invest more in foreign countries with higher interest rates, which will push down the relative value of the dollar. Another example: Scott Sumner of the Mercatus Center suggests that a tight fiscal policy—by, say, the German government—could reduce the domestic price level and thus encourage exports and discourage imports. (This explanation still does not apply to Italy, where there is no chance of a government budget surplus.)

Such macroeconomic policies are, for better or worse, generally recognized as falling within the purview of national governments. As for intentional competitive devaluations, they should be avoided, as the early 1930s showed. This suggests not engaging in a currency war even if some other government starts it. One thing is pretty sure: it does not make much sense to accuse a country of currency manipulation if it does not have its own currency.

China, of course, has its own currency. In its May report, the Treasury Department declined (once again) to label the Chinese government a currency manipulator. But three months later, on August 5th, the Treasury changed its mind, explaining that the yuan had dropped suddenly. This drop was most likely a direct market consequence of President Trump's announcement of new tariffs and the fear this move stoked in financial markets.

Trump himself has advocated or implemented a number of policies that have devalued the dollar. His 2017 tax cuts, by stimulating the American economy and increasing incomes, likely had the indirect effect of increasing imports, which, *ceteris paribus*, put more dollars on currency markets and devalued the U.S. currency. His pressures on the Fed to push down interest rates will have a similar effect on the dollar, and many indicators suggest that this is exactly his intention. Who is the currency manipulator?

The Chinese government isn't the only one failing to behave according to White House diktats. The Treasury report hectors the German government about the need

The Pursuit of Nuttiness

BY PIERRE LEMIEUX

In a recent post on his blog *The Grumpy Economist*, Hoover Institution senior fellow John Cochrane criticized a May 2019 Treasury report on currency manipulation as “institutionalized nonsense” or “*institutionalizing nuttiness*” (his emphasis). This characterization might seem too strong, but alas it isn't.

The report, “Macroeconomic and Foreign Exchange Policies of Major Trading Partners of the United States,” extended the list of countries the United States government deems possible “currency manipulators.” It now includes three Eurozone countries—Germany, Italy, and Ireland—that do not have a currency to manipulate. They use the euro, a currency controlled by the European Central Bank, which is independent of any particular national government.

Currency nuts / Currency manipulation typically occurs when a national government or its central bank uses the domestic currency to buy a foreign currency with the purpose of causing a devaluation of the former. If, for example, the U.S. government bought a large quantity of Chinese yuan on world currency markets, the price of the yuan in dollars would increase

or, what amounts to the same, the price of dollars in yuan would decrease. This would make American goods cheaper for Chinese importers because the dollar is worth less, favoring American exporters. Conversely, the price of Chinese goods would rise for American importers because the yuan is worth more. Such a “competitive devaluation” is prohibited by international trade rules because it is equivalent to a general tariff.

The Treasury Department did not think it was necessary to explain how a government can manipulate its currency when it does not have one. It is like accusing Texas of being a currency manipulator. This led George Mason University economist Don Boudreaux to conclude on his *Cafe Hayek* blog, “We Americans are today governed by imbeciles.”

There exist indirect ways to manipulate one's currency, which is perhaps what the Treasury subliminally meant. Keynesian policies (monetary or fiscal) aimed at cooling down or stimulating the economy can have effects similar to a direct cur-

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to “make use of existing fiscal space”—that is, to increase its public expenditures and reduce its budget surplus. It complains about Italy’s “weak social outcomes” (whatever that means) and “the long-term sustainability of its public finances,” as if the U.S. government is in a position to lecture on budget deficits.

A wide pursuit? / The Trump administration’s nuttiness is not limited to the May Treasury report.

Underlying all that is its trade-deficit obsession, reminiscent of the mercantilist sermons of the 17th and part of the 18th century. A trade deficit or surplus depends on many economic factors other than tariffs. Other Trump policies besides tax cuts and lower interest rates have the effect of *increasing* the trade deficit. Defying logic, Trump seems to want both *A* and $\sim A$.

Since the administration started making protectionist noises in 2017 and then implemented many waves of tariffs in 2018 and 2019, the U.S. trade deficit has increased. The trade deficit in goods, which was \$749 billion in 2016, increased to \$805 billion in 2017 and \$887 billion in 2018. Available data suggest that this trend is continuing in 2019. The deficit on goods and services follows a similar trend.

Even with China, the trade deficit on goods increased from \$347 billion in 2016 to \$419 billion in 2018, as exports decreased more than imports. Many of the goods previously imported from China are diverted to more costly suppliers, which contributes to increasing the global trade deficit. (Evaluating the data is complicated by transshipments meant to avoid American tariffs and the fact that data from China may be unreliable.)

Chinese retaliation for the U.S. tariffs further fueled the trade deficit. “Trade wars are good and easy to win,” President Trump memorably tweeted on March 2,



2018. This wishful pronouncement flies in the face of a few centuries of economic analysis and trade experience.

In a *Forbes* article, John Hopkins University economist Steve Hanke explained that the American trade deficit is homegrown, notwithstanding “Trump’s trade rubbish.” The Trump administration has only intensified the homegrown factors. It increased the federal budget deficit and created trade uncertainties, driving foreign investors to U.S. bonds and stocks, pushing up the dollar. A higher U.S. dollar, in turn, pushes imports up and exports down, thus increasing the trade deficit.

The vast majority of economists would agree that trade deficits, especially bilateral trade deficits, are meaningless. The increase in the trade deficit over the past two years is only significant because it results from the inconsistent policies of a government ostensibly intent on reducing it.

Another illustration of the pursuit of nuttiness is Trump’s refusal, along with his official trade adviser, Peter Navarro, to admit what happens in all but exceptional cases: that U.S. consumers pay these tariffs in the form of higher prices, reimbursing the importers who have previously paid the tariffs to the Treasury. Economics students know this from basic courses on international trade. Many recent studies, data, and frequent examples reported by the press have confirmed this. Yet Trump and

his mouthpieces have repeatedly claimed that tariffs are paid by Chinese exporters. After several rounds of tariffs and after announcing more of them, Trump tweeted on August 3rd, “So far our consumer is paying nothing.”

Ten days later, Trump expressed unusual doubts about his trade policy, probably caused by stock market resistance. Announcing a suspension of his new tariffs against China until December 15th, he declared, “We’re doing this for Christmas season, just in case some of the

tariffs would have an impact on U.S. customers.” If he had serious doubts, he would fire Navarro. But then, he could change his mind the next day and announce new tariffs by tweet.

New and not newer / That politicians, whatever their party, are incentivized to be illogical and incoherent, and then to cover up in public statements, is not news. But the phenomenon usually remains within certain limits. In November 2013, Barack Obama admitted that he was wrong when he said that his health care law would allow people to keep their doctors and health care plans. Disregarding any constraint set by personal morality, politicians’ main limit is that their fabrications must not be too glaring, even to rationally ignorant voters facing whole baskets of complex policies with unknown future consequences. Politicians have an interest in retaining some credibility. They do not want to be seen as nuts.

Why this minimal constraint does not seem to work anymore—why nuttiness is becoming institutionalized—may have something to do with this era’s seeming retreat from reason, the substitution of wacky information sources for more credible ones, the intensification of blind partisanship, and the lure of raw government power. Those are features of populism on the right and left. R