BRIEFLY NOTED

Helping Low-Latitude, Poor Countries with Climate Change

BY S. NIGGOL SEO

There is little evidence that low-latitude, poor countries will be greatly damaged by global warming if they adapt sensibly. Poor countries should strive to adapt to changes in climate on their own. They must not wait for international money from rich, industrial countries to do the magical work for them.

Climate funds to poor countries / A prevalent view in the global warming community is that low-latitude, poor countries will bear the brunt of global warming and climate change. This view leads to the idea that rich countries should financially help poor countries to cope with that change by financing the poor countries' adoption of low- or zero-carbon technologies and other adaptations.

This view has created a perennial divide in the global negotiations between rich and poor countries, most visibly so since the United States declared at the Copenhagen Conference in 2009—the first year of Barack Obama's presidency—that it will provide over $100 billion per year to assist poor countries in adapting to climate change. The U.S. financial commitment was interpreted as a political maneuver to avoid a new global climate "protocol" at that time that would be legally binding and apply to all countries without exception, described as "cutting the legs out" from under the messy United Nations framework on climate change.

After the Copenhagen meeting, global negotiations have deteriorated into a political deadlock between rich countries and poor countries with regards to when, how, how much, by whom, and where such funds should be delivered to the poor countries. Low-latitude, developing countries cannot afford to legally commit to any cut in greenhouse gas emissions, but they are still adamantly calling for financial assistance clauses to be explicitly written into a global agreement on climate change that is legally binding according to international laws as a pre-condition for the poor countries' participation in the treaty process.

Developed countries, on the other hand, have been sluggish and reluctant to make pledges to fund the international climate adaptation finance program known as the Green Climate Fund (GCF). By the end of July 2015, pledged and signed contributions amounted to $5.8 billion for the four-year initial period through 2020, which amounts to approximately $1.45 billion per year. There is no information available on how much money the GCF has actually received.

Devastation in poor countries? / The predominant perception that low-latitude, poor countries will be devastated by global warming is grounded on fragile assumptions.

First, it is assumed that agriculture will be the most vulnerable sector if the climate were to warm up, accounting for one-third of the total market and non-market damages that arise from global warming, even in the United States. (See Readings below.) Yields of major grains in the United States, such as corn and wheat, are predicted to suffer large losses if temperature increases.

Because agriculture is the most economically important sector in low-latitude, poor countries, employing more than 67 percent of the workforce in most African, South American, and South Asian countries, scientists reason that those countries are highly vulnerable to the effects of climate change. Scientists argue that the agricultural damage in those regions, relative to the current agricultural production or net income, will be at least twice as large as what is predicted in temperate developed countries like the United States.

In addition, low-latitude, poor countries are thought to lack the capabilities and capacities to adapt to climate change in the agricultural sector as well as in sectors besides agriculture; e.g., sectors affected by hurricanes, sea level rise, heat waves, monsoon rainfall, and diseases. As with agriculture, the damages in these sectors are routinely predicted to be more severe in the poor, low-latitude countries.

Perspectives on adaptation / Yet, let's step back for a moment and reconsider each of the above statements from the perspectives of adaptation motives, strategies, and capacities commonly found in the poor countries and the industrial countries.

The claim that U.S. agriculture will be severely harmed because of climatic changes is not sound if adaptation possibilities by farmers are carefully taken into account. Many of the past studies of climate change and agriculture concentrated on the economic effects on only a single crop or a few major crops. But U.S. farmers can transition from one portfolio of crops to another crop portfolio or to another system of agricultural and natural resource management—an adaptation strategy that cannot be accommodated in such studies.

Likewise, the notion that poor, low-latitude countries are condemned to far greater losses from climate change because their economies are heavily dependent on agriculture cannot be validated empirically. Low-latitude, tropical countries pride themselves on having a rich array of natural resources and ecological diversity because of the unique climatic characteris-

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tics found only there. Just look at the Amazon, the island of Sri Lanka, and the Congo River Basin. When the great diversity of natural and biological resources is taken into account, empirical studies suggest that global warming will create only minor damages if individuals and communities adapt sensibly in tandem with changes in ecosystems and ecological systems.

The argument that low-latitude, developing countries will be affected more adversely because of a lack of adaptation capacities and technologies is pervasive in the literature. That idea, however, needs to be qualified. A study of hurricane fatalities in Oceania indicates that the hurricane fatality rate has fallen sharply over the past five decades because of an increase in income in this historically remote and poor region. The growth of income has increased adaptation capacities in the region such as satellite observations, early warning systems, evacuation orders, global information-sharing networks, and hurricane path projection technologies. In Oceania, of all the hurricanes that made landfall, the hurricane fatality rate fell from 1.6 deaths per hurricane in the 1970s to 0.3 deaths per hurricane in the 2000s. Most hurricanes did not cause any deaths.

In India, Bangladesh, and Sri Lanka, where a single hurricane tends to kill more than a thousand people, hurricane fatality rates have fallen sharply over the past three decades as a result of income growth and increased adaptation capacities. In India and neighboring countries, homes and other buildings have been made more resilient and shelters and bunkers along the vulnerable zones have become more common. Accordingly, hurricane fatalities fell from 2,441 persons per hurricane in the 1990s to 1,469 persons per hurricane in the 2000s, among the hurricanes that caused at least one fatality.

When it comes to the global warming that will unfold throughout this century, history suggests an encouraging future for low-latitude, poor countries. As their economies grow and their technological capacities increase, people and communities will find themselves more capable of withstanding natural disasters and climatic shifts. In low-latitude, developing countries, adapting to changes in climate optimally over a century-long time horizon will make them far more resilient and much less vulnerable than they are today.

Real help / Low-latitude, developing countries must not wait for the free money to flow from rich countries in order to prepare for climate change. They must realize that they should adapt on their own to the looming changes and should strive, based on that realization, to figure out and plan accordingly for the best ways their people and communities can adapt.

International aid often hurts the economic development of a recipient country if it works in a manner that weakens the country's people and the foundations of its institutions and markets. In the case of global warming funds, this pattern will prevail. The "free" climate change money will fall into the wrong hands and encourage mal-adaptations and no-adaptations, wreaking havoc on the economies and livelihoods in the climate-shifting world of the future. This is the real threat to low-latitude, poor countries. *R*

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CAFE and the Tension Between Optimization and Competition in Rulemaking

BY BRIAN F. MANNIX

Executive Order No. 12866, signed by President Bill Clinton, directs federal agencies to analyze the benefits and costs of regulations and to try to maximize the excess of the former over the latter. It is a sound principle, but it needs to be applied with an appropriate measure of humility. Regulators may be tempted to think that they can use cost-benefit analysis to determine what is "best" for the economy and then simply mandate it. Industry incumbents may encourage this approach; they often are willing to accept expensive regulation so long as it can be used to create barriers to entry that protect them from competition. The collateral damage to competition and innovation can easily turn an otherwise well-intentioned rule into an economic disaster.

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This problem can be illustrated by looking at fuel-economy standards jointly proposed this year by the U.S. Environmental Protection Agency and the Department of Transportation's National Highway Traffic Safety Administration. The rules will apply to companies that manufacture, sell, or import heavy-duty trucks, including tractor-trailer trucks. The proposed standards appear to have been developed in close consultation with industry incumbents, and incorporate prescriptive requirements that are likely to create barriers to entry. Rather than encouraging innovation, the standards are likely to make innovation very difficult. Even the proposed exemptions for small manufacturers incorporate production caps and grandfather features that appear to be designed to limit new entry and competition.

'Technology-forcing' / The EPA and NHTSA claim that, in the early years, the proposed standards can be achieved using existing technologies. In later years, however, the standards are technology-forcing—that is, the agencies assume future innovations will allow the industry to comply with standards that are not technically achievable today. Compliance with the standards will be determined through a complex array of computer modeling plus on- and off-road testing. Because of the cost and complexity of the testing, the standards will give manufacturers an option to comply by installing certain pre-approved technologies on their vehicles. In view of Volkswagen's current predicament over testing of its diesel-powered cars, truck manufacturers will likely feel compelled to install every safe-harbor technology the EPA specifies in the final rule.

As an example, consider cab-mounted fairings—the air deflectors mounted on top of the cabs of tractors in order to reduce the aerodynamic drag of the trailer in a tractor-trailer vehicle. These are commonly used in the industry, but the proposed standards will not allow just any old fairing. The Draft Regulatory Impact Analysis (RIA) goes into great detail on the advantages of a particular thermoplastic fairing design, Saudi Arabia Basic Industrial Corporation's (SABIC) Roof Fairing Technology, that delivers just the right combination of weight and aerodynamic performance. After 2018 it will be very difficult to put a truck on the road that does not include one of these fairings, and it will be illegal for any person to remove the fairing as long as the truck is in service.

Such regulatory specification of a particular technology can be especially dam-

Competition is the most important regulator of our economy. It works without a queue for licenses, an encyclopedia of rules, or an army of inspections.

aging when the technology is proprietary, because the law simultaneously locks out competitors and locks in customers. In this case the two agencies worked closely with SABIC to develop the standards. It seems likely that SABIC will patent the mandated design: the company "has passed the milestone of having more than 10,000 patents either issued or pending approval, making it the largest owner of intellectual property in the Middle East," according to a June 2014 *Arab News* report.

President Obama directed the two agencies to issue these standards in order to, in his words,

> drive down our oil imports even further. That reduces carbon pollution even more, cuts down on businesses' fuel costs, which should pay off in lower prices for consumers. So it's not just a win-win, it's a win-win-win. You've got three wins.

Certainly it seems to be a win for Saudi Arabia, which looks to gain a legally mandated virtual monopoly on a required part of American trucks.

The EPA and NHTSA seem unconcerned about the danger to competition: "We are currently coordinating with SABIC on future efforts to determine feasibility and capability of this concept on additional areas of the tractor (e.g., bumper, hood, fuel tank/chassis skirt fairings, cab side extenders)," they announced in the RIA. The two agencies appear to be dramatically increasing U.S. dependence on Saudi proprietary intellectual property, even as, again in President Obama's words, "we take another big step to grow our economy and reduce America's dependence on foreign oil."

Whatever their particular mission, regulators need to be mindful that competition is the most important regulator of our economy. It is ubiquitous, ever vigilant, and ever faithful to the interests of consumers. It constantly pursues both lower costs and higher quality in the goods and services we produce and consume. At the same time, it is never rigid: it is always open to new entry and new ideas. It can be harsh, driving companies out of business without so much as a hearing; but it does so only when something better is there to replace them. It works without a queue for licenses, without an encyclopedia of rules, and without an army of inspectors.

The United States does have legitimate regulatory goals that require licenses and rules and inspectors. But we need to be very careful, when pursuing those goals, to not displace the competition that governs the larger marketplace. *R*

Transportation Cost-Benefit Analysis Can Be Highly Misleading

BY ROBERT KROL

Each year, state and local governments decide on which transportation infrastructure projects to build. Often, priority goes to projects directed at reducing highway congestion or air pollution.

The economic backbone of the decision process is supposed to be an objective cost-benefit analysis. However, calculating the costs and benefits of any major project is technically difficult. Cost estimates require a determination of labor and material quantities and prices. Benefit estimates require forecasting economic growth, demographic trends, and travel patterns in the region.

Clouding the analysis is the fact that this decision process takes place in a political environment. Politicians love the publicity they get at the opening of a high-occupancy vehicle lane or the expansion of a mass transit system. To voters, it may look as if their elected officials are doing something about a region's transportation problems. More often than not, however, the projects do little to mitigate transportation-related problems.

When it comes to estimating the costs and benefits of proposed projects, this environment creates incentives to cook the books. Because elected officials benefit from these projects, the incentive is to place pressure on analysts to underestimate costs and overestimate benefits so that the projects can move ahead.

Evidence / Academic researchers have examined the track record of cost-ben-

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TABLE 1

TRANSPORTATION PROJECT COST OVERRUNS

Project Type	Number of Projects	Average Cost Overrun
Rail	58	44.7%
Bridge or tunnel	33	33.8%
Road	167	20.4%
All Projects	**258**	**27.6%**

Source: Flyvbjerg et al. (2002), p. 283.

efit estimates of past transportation infrastructure projects. Bent Flybjerg, Mette Skamris Holm, and Søren Buhl, all affiliated with Aalborg University in Denmark, looked at the cost estimates for 258 transportation projects valued at $90 billion built in countries around the world during the 20th century. They found large cost overruns to be common, with an average overrun of almost 28 percent. (See Table 1.) Rail projects experienced the largest average cost overrun, at nearly 45 percent.

There is no evidence that transportation planners learned from their mistakes, as the size of the errors did not decline over time. This persistence suggests the errors are systematic, rather than random errors generated by unexpected shocks to the economy following the forecast.

In another paper, the same researchers looked at the accuracy of passenger and traffic flow forecasts for 210 rail and road infrastructure projects using data from 14 countries. Those projects were worth $58 billion and constructed between 1969 and 1998. Comparing actual vehicle or passenger flows in the projects' first year of operation to forecasted flows, the authors find transportation planners overestimated passenger flow for railroads and underestimated vehicle flow for roads. (See Table 2.)

For rail projects, passenger flows were overestimated by more than 50 percent. Nearly 85 percent of rail projects overestimated passenger flows by more than 20 percent, 40 percent of the errors exceeded 60 percent.

Because policymakers favor mass transit, we'd expect the political pressure to be reversed when it comes to estimating the benefits of additional roads. The findings suggest this may be the case, as the researchers found that road traffic flows (the forecast of benefits) were underestimated by about 10 percent.

Such errors do not only plague public projects; overestimating benefits also occurs in privately financed toll roads, tunnels, and bridges. Transportation finance researcher Robert Bain examined the record for 100 private projects built worldwide between 2002 and 2005. He found the average forecast overestimated traffic flows by 23 percent. We would think that private investors, risking their own funds, would produce a more unbiased forecast. While the errors are somewhat smaller, the results suggest that private promoters also provide overly optimistic projections of traffic demand, perhaps as a way to improve access to capital.

Incentives and reforms / Government analysts and consultants conducting the cost-benefit analyses are under pressure to bias the projections in a way that favors the goals of the officials who employ the analysts. If widening a bridge will garner enough additional votes to win the next election, a politician may apply pressure to ensure that cost and benefit estimates place the project in the best light. A consultant's future project opportunities or the salary of a staff analyst likely depends

TABLE 2

TRANSPORTATION TRAFFIC FORECAST ERROR SIZE AND DISTRIBUTION

	Rail	Roads
Average Error (%)	51.4%	–9.5%
Percentage of projects with inaccuracies beyond +/– 20% of projections	84%	50%
Percentage of projects with inaccuracies beyond +/– 40% of projections	72%	25%
Percentage of projects with inaccuracies beyond +/– 60% of projections	40%	13%

Source: Flyvbjerg et al. (2006), p. 11.

on how willing he or she is to play along. While reputation serves as a constraint on how far an analyst would massage a forecast, the evidence from actual projects suggests political forces dominate the decision process.

While it is not possible to completely eliminate the political pressure to cook the books, there are a number of reforms that would improve the estimates of the costs and benefits of transportation projects. First, specialists who are not directly involved in the project should review the analysis. This kind of review process has improved forecasts made by the Congressional Budget Office. Second, Flyvberg suggests comparing the cost and benefit estimates of proposed projects to those of completed projects with similar characteristics. If there are enough comparable projects, past outcomes can put a lid on overzealous estimates of benefits and underestimates of cost. Transparency is important. Making the results of these comparisons public would allow taxpayers to judge the viability of a given project. Third, cost and benefit estimates should be made using a range of economic assumptions. For example, what would happen to rail ridership if the economy grew 1 percent slower? How robust are the estimates? Finally, the salary of the analyst or consultant could be tied to the accuracy of an estimate. This would counteract political pressures to bias transportation project forecasts.

CONCLUSIONS

Taxpayers and investors need to be careful when it comes to projections of the costs and benefits of transportation infrastructure projects. They are likely to be biased to favor projects politicians want. This bias should give pause to any supporter of high-speed rail or any public megaproject in the United States or abroad.

A finding that the biases are large but, once built, the projects still produce a (small) net benefit does not mean there is no reason for concern. There are opportunity costs associated with low-return projects. Alternative non-transportation projects or tax cuts would have made taxpayers better off. Flyvbjerg and his coauthors conclude that politicians sell the projections as scientific, but they turn out to be "strategic misrepresentations" that end up being financial disasters that often provide negative net returns. *R*

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What Regulatory 'Ossification'?

BY SAM BATKINS AND IKE BRANNON

The notion that the regulatory process is broken, and that valid and necessary rules take far too long to implement because of an onerous bureaucratic process, has become an oft-repeated claim these days. This has led to calls for reforms that would speed up rulemakings.

Numerous anecdotes are used to support the notion that the system deters rulemaking. For instance, a recently issued U.S. Environmental Protection Agency regulation required five years of analysis before it became a final rule; a worker safety rule sat at the Office of Information and Regulatory Affairs (OIRA) for three years; and a food safety regulation from 2011 is currently being held up by legal issues, although the Obama administration still hopes to implement the rule.

However, argument by anecdote can lead us astray. Broader data reveal that the regulatory mechanisms currently in place work just fine and regulatory ossification is hardly a government-wide problem.

The problem with the regulatory state has never been that it places too many barriers in front of bureaucrats who are making new regulations. If there is any bias in the process, it errs in the direction of *hastening* regulations—a point we've made in these pages previously ("Explaining Delays in Regulatory Publication," Winter 2014–2015). Decisionmakers at federal regulatory agencies have every incentive to make regulations because that is their currency to promotions, notoriety, and the praise of their "stakeholders." Agency economists are motivated to provide cost-benefit analyses that support their agency's actions and not rock the boat. And OIRA, the ostensible gatekeeper of regulations, often has a difficult time convincing the White House politicos to expend political capital to push back on an ill-thought-out regulation that may create a public relations firestorm, no matter how counterproductive the rule may be.

The data / To determine whether the ossification bogeyman has any credence, we reviewed 361 regulations deemed "major" and "economically significant" (defined as a rule with an effect on the economy of $100 million or more, thereby rendering it automatically subject to scrutiny from

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OIRA) issued by the federal government between 2005 and 2014. The regulations in our universe came from 71 different federal agencies and sub-agencies.

We note in our analysis when each rulemaking first made an appearance in the Unified Agenda, which is how regulators officially notify the public that they are working on a new rule. We then recorded when the final rule was published in the Federal Register and measured the total time of the rulemaking. In some instances our methodology might underestimate the length of a rulemaking because regulators can begin work on a regulation before it is published in the Unified Agenda. At the same time, there are occasions where little work has been completed on a rule before it appears in the Unified Agenda.

Our method measures the time until formal publication in the Federal Register, not when OIRA receives the final rule. As we detailed in our article last year, there can be a sizeable gap between the time when OIRA informally releases a rule and when it reaches final publication; in some cases it has exceeded six months. We include this publishing delay as part of "regulatory ossification" even though the rule is final, affected parties are on notice, and the agency's work is largely finished aside from potentially needing to defend the rule in court.

Finally, we want to avoid conflating the notion of regulatory ossification with delays from litigation. Our intent is to measure the outcome of the regulatory process itself; lawsuits are, we argue, external to this system. Of course, potential litigation does inform regulatory behavior to some degree: the agencies issuing regulations keenly want to avoid court fights, which can have an unpredictable outcome and also consume agency resources and attention better spent elsewhere. Because litigation is generally unwanted, often unanticipated, and has a duration that's inherently unpredictable, we exclude its effect in our analysis.

Results / The median time it takes to move from initial notice of a proposed rule in the Unified Agenda to final publication is 401 days. Given what's entailed in a final rule—which involves giving official notice to affected parties, an economic analysis, a review by OIRA, an opportunity for stakeholders to meet with the agency and OIRA and to provide their own critique of the rule, and (typically) approval by the White House—13 months does not seem excessively long.

There are a few outliers in our data set that do provide a degree of *prima facie* evidence for regulatory ossification. For example, six rulemakings (1.7 percent) took more than 10 years to complete and another 34 rules (9.4 percent) took more than five years. However, those are outliers:

The median time it takes to move from initial notice to final publication is 401 days. Given what's entailed, 13 months doesn't seem excessively long.

167 rulemakings (46.3 percent) needed less than a year from the time they were proposed until they became a regulation, more than four times the number that languished for five years.

Focusing on a relatively few "outliers" gives a misleading impression of the situation. The degree to which regulations spend an excessive amount of time in the system is specific to certain agencies and not a problem endemic within the federal government. For instance, the EPA's Office of Air and Radiation typically needs 2.5 years to complete a significant rule, while the Centers for Medicare and Medicaid Services (CMS) needs just over one year for its median rulemaking. The Occupational Safety and Health Administration issues far fewer rules than the CMS and EPA, but OSHA's rules are almost invariably bound to create significant industry pushback. OSHA anticipates this and proceeds at a very deliberate pace; the agency promulgated just four rules over the period we examined, but the rules on average took a decade from proposal to completion.

The 13-month median length also reflects a few "instantaneous rulemakings": agencies published 22 final rules without a proposed rulemaking and before the first appearance in the Unified Agenda. For example, the rule establishing preventative coverage for group health plans under the Affordable Care Act appeared in the fall 2010 Unified Agenda, but the agency had issued an interim final rule the previous July. Excluding those rules doesn't significantly alter the results, boosting the median time from 401 to 440 days.

While the instantaneous rulemakings have a slight effect on our results (mitigated by our examination of the median length rather than mean), they reveal a great deal about the regulatory process. In many instances, stakeholders, industry, or economists have little notice that economically significant measures are looming. The Obama administration has published 12 economically significant rules without first issuing notice in the Unified Agenda; many of those were interim final rules implementing the Affordable Care Act, which was obviously a White House priority.

Matter of priority / When an administration wants a rule to move quickly through the process, it does so. Legal and statutory battles can complicate those efforts, but after we examined the implementation of the Dodd-Frank Act and the Affordable Care Act, we became convinced that regulators can grease the skids when they want to.

From the end of 2010, shortly after President Obama signed both laws, until the end of 2012, the administration ushered through 26 major Dodd-Frank final rules and 35 major Affordable Care Act final rules. For those 61 major rules, the supposedly ossified regulatory process sped up considerably. Congress didn't finish both laws until the summer of 2010, but just two years later the federal govern-

ment had formulated regulatory plans, proposed rules, taken public comment, and finalized the rules—an urgency no doubt exacerbated by the 2012 presidential election.

This haste does not always lead to good policy. The faster a rule moves through the regulatory process, the more the analysis suffers—a phenomenon that the Mercatus Center has thoroughly demonstrated and one that comports with common sense. Regulators should get rules right the first time, not leave flawed rules to review by federal courts. Most recently, the Supreme Court vacated the EPA's mercury rule because of cost-benefit concerns. In the words of Justice Antonin Scalia, "No regulation is 'appropriate' if it does significantly more harm than good."

Overstated barriers / If a regulatory process that needs 13 months to propose, analyze, discuss, and issue the typical major rule is symptomatic of an ossified regulatory system, then progressives have won the debate. But we argue that there are currently *too few* barriers in place to prevent agencies from promulgating ill-thought-out rules, and we see no pressing need to remove further constraints on rulemaking.

The discussion on the length of the rulemaking process has been driven largely by hyperbole and anecdote, and rarely from an analytical perspective. Policymakers should be less concerned about the speed of rulemaking and more focused on whether there is a compelling government need to regulate. The long-term effect of finalized regulations—which gets precious little attention these days—should matter much more to agencies, OIRA, and Congress than how long it takes to issue those regulations. R

Pharmaceutical Marketing, the FDA, and Free Speech

BY THOMAS A. HEMPHILL

Last August, the U.S. District Court for the Southern District of New York decided that the Irish drugmaker Amarin, manufacturer of the triglyceride-lowering drug Vascepa, could tout the drug's apparently beneficial effects on a wider class of patients than what the U.S. Food and Drug Administration had approved. The wider benefit has not been demonstrated by full FDA trials, but Amarin has sufficient experimental evidence of that benefit, the court ruled; informing health care providers of those results would be truthful and non-misleading speech in accordance with First Amendment court decisions involving "commercial speech."

Though doctors already could prescribe Vascepa to those patients as an "off-label use," Amarin (and other drug companies with products having off-label benefits) wasn't allowed to discuss such use with either doctors or patients. In the District Court's opinion, that prohibition "paternalistically interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions."

Amarin follows a seminal 2012 Second Circuit Court of Appeals decision, *U.S. v. Caronia*, vacating the 2008 conviction of pharmaceutical sales representative Alfred Caronia. (The Second Circuit includes the Southern District of New York.) Caronia had promoted the Jazz Pharmaceuticals drug Xyrem, FDA-approved for treating narcolepsy, as also effective for treating insomnia, fibromyalgia, and other maladies. There is scientific evidence supporting those off-label uses, but the FDA has not granted approval for them. Because he gave that information to health care professionals, Caronia was convicted of violating the Food, Drug and Cosmetics Act (FDCA), but he appealed on free speech grounds. In finding for Caronia, the Second Circuit concluded, "The government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."

The FDA decided not to appeal Caronia's victory, fearing that a loss before the U.S. Supreme Court would extend the Second Circuit's ruling nationwide. The U.S. Justice Department and state attorneys general have repeatedly used the threat of prosecutions like Caronia's to wring billions of dollars in settlements, fines, and civil damages from drugmakers (e.g., $2.3 billion from Pfizer in 2009, $1.4 billion from Eli Lilly in 2009, $1.6 billion from Abbott Laboratories in 2012, $3 billion from GlaxoSmithKline in 2012, $2.2 billion from Johnson & Johnson in 2013), and didn't want to risk the loss of that cash cow. But now the drugmakers are seizing on the Second Circuit decision to block future extractions; Amarin's suit is just the first of what should be vigorous drug industry pushback.

Amarin's *effect* / In *Amarin*, the Justice Department argued that the drugmaker's appeal was a "frontal assault" on the FDA's drug approval regulatory framework. If Amarin's arguments were adopted by the court, claimed the government, then pharmaceutical manufacturers would skip the FDA approval process for new uses ("indications" in medical jargon) of an FDA-approved drug.

The *Amarin* court was unmoved by this argument. It noted that the *Caro-*

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BRIEFLY NOTED

nia decision offers an "alternative, less speech-restrictive means for the FDA to achieve its objectives" of protecting public health and safety, and that the Justice Department had elected not to petition for certiorari or seek an *en banc* review of *Caronia* (which was decided by a three-judge panel). If the FDA truly believes that cases like *Caronia* and *Amarin* are a threat to its duty to protect the public, it hasn't made much effort to combat that threat, the court reasoned.

Going forward / The FDA and Justice Department are now likely weighing two courses of action: (1) appeal *Amarin*, and (2) encourage drugmakers to voluntarily work with the FDA even though they have growing freedom to promote non-FDA-approved uses. Those actions are not mutually exclusive, and interestingly both could benefit consumers—but not the federal government.

Concerning an appeal of *Amarin*, the FDA and Justice Department are now in a similar position to where they were following *Caronia*. They could elect not to appeal, allowing the decision to stand in the Southern District of New York and have a circumscribed effect on the pharmaceutical industry's prescription drug marketing and advertising efforts. Or they could appeal, but the case would go to the Second Circuit—an unwelcome prospect for the government. So a decision to appeal would likely be a choice to go all the way to the U.S. Supreme Court, which has of late been receptive to First Amendment claims by corporations.

A loss at the Supreme Court would mean the FDA would lose a big chunk of its nationwide regulatory authority over off-label marketing and advertising.

A loss at the Supreme Court, of course, would mean the FDA would lose a big chunk of its nationwide regulatory authority over off-label marketing and advertising of pharmaceuticals. The FDA would still have authority to investigate and enforce civil and criminal remedies against untruthful and misleading commercial "speech." But a loss on appeal would significantly reduce the number of billion-dollar criminal and civil settlements by the Justice Department against pharmaceutical companies who honestly promote off-label uses of their drugs. That would be a loss for the government—but, of course, a big win for both the pharmaceutical industry and consumers.

What of voluntary cooperation between drugmakers and the FDA? The *Amarin* court recognized that its decision does weaken the need for the FDA's approval process for a new pharmaceutical indication (but obviously does not impinge on the need for an original indication to be approved). Perhaps in an effort to "split the baby," the court recommended that drug manufacturers submit to the FDA the "speech" that they intend to use in promotional material and adverting for a non-approved use, along with an explanation for why the "speech" is truthful and non-misleading.

This idea had previously been advanced by the drug industry's chief trade association, the Pharmaceutical Research and Manufacturers Association (PhRMA). In its 2008 *Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines* (2008), PhRMA recommended:

> Companies devote substantial time and effort, and often ask for input from FDA, to ensure that DTC [Direct to Consumer] communications are accurate, fairly balanced, and meet all applicable legal requirements. PhRMA member companies will engage in a dialogue with FDA to maximize opportunities for FDA review of DTC advertising prior to release, consistent with these Principles and the Agency's priorities and resources.

This cooperation could be a benefit to consumers and drugmakers while giving the FDA some input into off-label marketing. If the agency truly has expertise in identifying clear and accurate marketing language, the manufacturers and their customers should welcome that expertise to their marketing efforts. Drugmakers and consumers would retain the important freedom to communicate with each other about new, scientifically supported uses for already approved drugs, while the FDA could improve that communication's quality. R

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Reinforcing Reproducibility: What Role for the Federal Government?

BY RANDALL LUTTER AND DAVID ZORN

A bedrock principle of scientific inquiry is the independent reproducibility of scientific results. Publication of irreproducible results threatens the reliability of scientific publications and the integrity of scientific inquiry, and can lead to questions about the merits of science-based regulations to reduce risks. Yet, recent examinations of empirical research published in prominent academic journals have found a disturbingly high number of irreproducible results. There is now a growing agreement that the entire scientific community must help remedy this serious problem and many journals are requiring authors to provide access to data, computer codes, and lab specimens.

One stark exception to this important trend is the many influential journals published by U.S. government agencies. Although federal agencies have adopted policies to promote reproducibility, e.g., through data transparency, we find that nine of the top 10 federal journals (as measured by the h-index, a measure of productivity and citation impact), lack policies to promote data access and sharing.

This needs to change. The White House's Office of Science and Technology Policy (OSTP), in conjunction with the Office of Management and Budget (OMB), should direct federal journals to adopt policies for public data access that are at least as strong as the private journals *Science* and *Nature*.

Data access / Those two journals, and others, have adopted policies requiring data access. *Science*, for example, requires that

> all data necessary to understand, assess, and extend the conclusions of the manuscript must be available to any reader of *Science*. All computer codes involved in the creation or analysis of data must also be available to any reader of *Science*.... Large data sets with no appropriate approved repository must be housed as supplementary materials at *Science*, or only when this is not possible, on an archived institutional Web site.

Public access to data and code has improved reproducibility in economics research. In the 1980s, William Dewald, Jerry Thursby, and Richard Anderson tried to replicate results of empirical research in economics that had been published in a respected journal. Writing in the *American Economic Review* (AER) in 1986, they reported that "inadvertent errors in published empirical articles are commonplace rather than a rare occurrence." As a result, the *AER* implemented various data access policies and, importantly, investigated the reproducibility of published papers after implementation of its current data access rules. After analyzing data and code placed as required in repositories for published papers, the *AER*'s replication researchers concluded that "all but two of the articles (95 percent) could be replicated with little or no help from the author(s)."

These findings may well hold in other fields. Economists' analytic methods involve complicated statistical analyses of large non-experimental datasets, techniques broadly similar to those used in epidemiological and some medical research. In psychological research, a major cooperative effort recently found that while 97 percent of original studies reported statistically significant results, the researchers endeavoring to replicate those studies found statistically significant results in only 36 percent of replications. The researchers did not address how or whether greater data access might improve reproducibility.

Federal journals / The federal government has already taken important steps to promote reproducibility. In 2002, the OMB directed agencies disseminating "influential scientific, financial, or statistical information" to "include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."

However, as noted above, the federal government has not acted to promote data access in the scientific journals that it manages. We have examined the editorial policies of the peer-reviewed federal journals that accept submissions from non-government authors. In particular, we searched the U.S. Government Printing Office, websites of the cabinet-level departments and agencies, and the SCImago Journal and Country Rank portal for federal journals and found information on their rankings and h-indices to identify the most prominent. Information on the 10 federal journals with the highest h-indices appears in Table 1. With one exception, none have posted policies to promote, let alone guarantee, access to data or code needed to replicate the research that they publish.

The exception, the *Social Security Bulletin*, has a "requirement" for researchers: "If your paper is accepted for publication, you will be asked to make your data available to others at a reasonable cost for a period of three years (starting six months after actual publication)." This modest step is inadequate. Bryan Drew, Romina Gazis, Patricia Cabezas, et al. reported in a 2013 *PLoS Biology* article that less than 3 percent of researchers voluntarily share data and code sufficient to allow for reproducibility, even if many had said they would share data and code upon request. Similarly, requirements for authors only to make data available upon

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request have been shown to be ineffective.

Some federal journals are important. Four (*Environmental Health Perspectives, Emerging Infectious Diseases, Morbidity and Mortality Weekly Report*, and the *Journal of Rehabilitation Research and Development*) are ranked among the top 10 journals in their areas of specialization based on the 2014 data in the SCImago Journal and Country Rank portal. All of these journals enjoy taxpayer support, and thus the editors-in-chief have a special duty to ensure sound management.

The general lack of policies regarding data access for federal journals contrasts sharply with the data access policies of the highest-ranked non-federal journals publishing in the same subject areas. The *Journal of Geophysical Research* requires authors to post their data. *Immunity*, the *Journal of Clinical Microbiology*, the *Canadian Journal of Fisheries and Aquatic Sciences*, and *Health Technology Assessment* require authors to commit to making all data available upon request. *Immunity, Clinical Infectious Diseases*, the *Journal of Infectious Diseases*, *Marine Ecology—Progress Series*, and the *Journal of Experimental Biology* require authors to deposit sequence and microarray data in publicly accessible databases. The *Journal of Geophysical Research* and the *Journal of Clinical Microbiology* require that computer code necessary to reproduce the results be made available, with the *Journal of Geophysical Research* requiring that such computer code be posted for download.

The adoption of data access policies by these higher-ranked journals shows their value. Indeed, the head of the National Institutes of Health commended *Science* and the other journals of the American Association for the Advancement of Science for requiring data and code access for its publications.

Data access policies are low cost, since so many non-federal journals could not otherwise have adopted them. Further, one federal journal, the *Journal of Fish and Wildlife Management*, published by the Fish and Wildlife Service, already has a strong data access policy, requiring "as a condition for publication, that data ... be provided either directly in the paper, in the associated supplemental materials, ... or archived in an appropriate public archive."

Journals of international agencies also fail to promote data access. For example, the *World Bank Research Observer*, *World Bank Economic Review*, and the World Health Organization's *WHO Bulletin* are all published without any announced policies on data access.

The policies of federal journals have been managed on a decentralized basis, with little formal interagency coordination. An initiative to promote reproducibility through mandatory public access to data and code could be managed centrally, however, either by the OMB (which oversees the journals' budget requests) or the OSTP. Such an initiative would not only promote reproducibility of articles published in federal journals, but may spark the adoption of similar best practices among non-federal journals that now lack strong data access policies. R

TABLE 1

TOP 10 FEDERAL JOURNALS BY H-INDEX

Federal Journal	Sponsoring Agency	Area of Specialization (rank within area)
Emerging Infectious Diseases	Centers for Disease Control and Prevention	▪ Epidemiology (3) ▪ Microbiology—medical (4) ▪ Infectious Diseases (8)
Environmental Health Perspectives	National Institute of Environmental Health Sciences	▪ Health, Toxicology, and Mutagenesis (1) ▪ Public Health, Environmental, and Occupational Health (1)
Fishery Bulletin	National Marine Fisheries Service	▪ Aquatic Science (55)
Journal of Rehabilitation Research and Development	Veterans Affairs Office of Rehabilitation Research and Development	▪ Rehabilitation (10)
Marine Fisheries Review	National Marine Fisheries Service	▪ Aquatic Science (111) ▪ Agronomy and Crop Science (121)
Monthly Labor Review	Bureau of Labor Statistics	▪ Organizational Behavior and Human Resource Management (32) ▪ Management of Technology and Innovation (44) ▪ Strategy and Management (70)
Morbidity and Mortality Weekly Report	Centers for Disease Control and Prevention	▪ Health Information Management (1) ▪ Health—social science (2) ▪ Health, Toxicology, and Mutagenesis (3) ▪ Epidemiology (6) ▪ Medicine—miscellaneous (44)
Preventing Chronic Disease	National Center for Chronic Disease Prevention and Health Promotion	▪ Health Policy (33) ▪ Public Health, Environmental, and Occupational Health (119)
Public Health Reports	U.S. Public Health Service	▪ Public Health, Environmental, and Occupational Health (46)
Social Security Bulletin	Social Security Administration	▪ Public Administration (53) ▪ Social Sciences–miscellaneous (175)

READINGS

- "Estimating the Reproducibility of Psychological Science," by the Open Science Collaboration. *Science*, Vol. 349 (2015).
- "Irreproducible Experimental Results: Causes, (Mis)interpretations, and Consequences," by Joseph Loscalzo. *Circulation*, Vol. 125 (2012).
- "Lost Branches on the Tree of Life," by Bryan T. Drew, Romina Gazis, Patricia Cabezas, et al. *PLoS Biology*, Vol. 11 (2013).
- "NIH Plans to Enhance Reproducibility," by Francis S. Collins and Lawrence A. Tabak. *Nature*, Vol. 505 (2014).
- "Public Availability of Published Research Data in High-Impact Journals," by Alawi A. Alsheikh-Ali, Waqas Qureshi, Mouaz H. Al-Mallah, et al. *PLoS One*, Vol. 6 (2011).
- "Replication in Empirical Economics: the Journal of Money, Credit, and Banking Project," by William G. Dewald, Jerry G. Thursby, and Richard G. Anderson. *American Economic Review*, Vol. 76 (1986).
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- "Reproducibility," by Marcia McNutt. *Science*, Vol. 343 (2014).

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