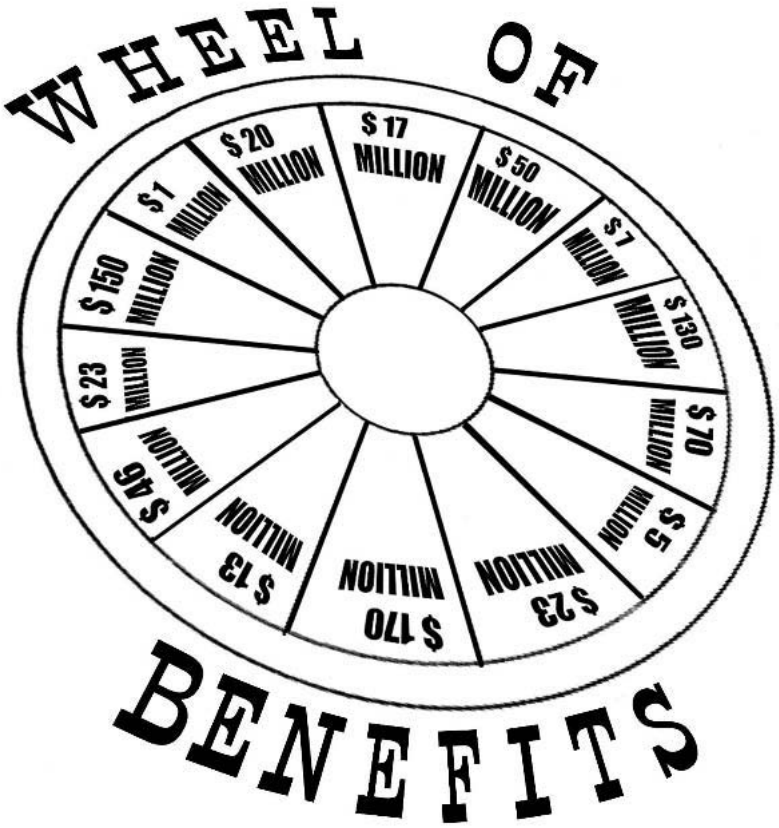
The **Mercatus Center** at George Mason University is an education, research, and outreach organization that works with scholars, policy experts, and government officials to bridge academic theory and real-world practice. The center's Regulatory Studies Program works within the university setting to improve the state of knowledge and debate about regulations and their impact on society. More information about the center can be found on the Web at www.mercatus.org. For the latest federal regulatory developments, visit www.regradar.org.



KEVIN TUMA (3)

Annual Report to Congress on Regulation

STATUS: OMB accepting comment until May 20.

In mid-February, the Office of Management and Budget released a draft of its annual report to Congress on the costs and benefits of federal regulation. As in years past, the report tallies agency estimates of the monetized costs and benefits of economically significant regulations issued over the previous fiscal year, with no independent assessment of the quality or usefulness of agency analyses. And, as in years past, the figures will be reported in the press without caveat, even though the report states that the "citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates."

According to the draft report:

- The annual benefits of regulations issued in FY 2003 range from $1.6 billion to $4.5 billion.
- Annual costs for regulations issued in FY 2003 are $1.9 billion.
- For regulations issued over the last 10 years (October 1, 1993 to September 30, 2003), annual benefits range from $62.1 billion to $168.1 billion, and annual costs range from $34.2 billion to $39.0 billion.

The benefits and costs for fiscal year 2003 are based on agency estimates for only six regulations, or 1/10th of one percent of the final rules published in the *Federal Register* during the year. By definition, an economically significant or major rule has an annual impact of $100 million or more, yet costs are presented for only 15 percent of those rules. If each of the 31 economically significant rules not included in the OMB's total imposed the minimum cost of $100 million per year, then total costs would be understated by $3.1 billion.

The upper end of the benefit range for the 2003 fiscal year is driven by a Food and Drug Administration rule requiring food manufacturers to include information on trans fat content on standardized nutrition labels; the FDA estimates the rule will provide annual benefits of between $234 million and $2.9 billion per year. The cost estimate is dominated by a Department of Transportation rule limiting the hours a commercial truck driver can be on duty ($1.3 billion per year).

The Environmental Protection Agency's estimates of the benefits and costs of its regulations comprise over 60 percent of the total benefits and costs reported for the 10-year period (and over 75 percent of the reported upper bound benefits). It is interesting to note that the majority of the EPA's benefits derive from reductions in exposure to a single pollutant — particulate matter.

In addition to the benefit and cost estimates, the draft includes an interesting literature review and discussion of the relationship between regulation, freedom, and economic growth. The conclusion, that less-regulated countries are freer and more prosperous than countries with more regulation, is encouraging. It also requests suggestions for regulatory reforms relevant to the manufacturing sector, particularly small and medium-sized firms. While the federal government should not impose unnecessary burdens on any sector of the economy, there is evidence that the manufacturing sector may be particularly hard hit by regula-

tion. A recent Mercatus study found that in 2000, U.S. manufacturers spent an average of $2.2 million to comply with federal workplace regulations, or roughly $1,700 per employee. Small and medium-sized firms (less than 100 workers) bore a greater burden, with costs of $2,500 per employee — 68 percent higher than the costs of larger firms with 500 or more employees.

CAFE Standards

STATUS: NHTSA accepting comment until April 27.

For years, the National Highway Traffic Safety Administration (NHTSA) has been criticized (and even sued by the Competitive Enterprise Institute) for undermining its Traffic Safety mission by forcing consumers into smaller, less safe cars with its Corporate Average Fuel Economy (CAFE) Standards. It has now proposed to "fix" the standards so that consumers no longer pay a safety penalty, drawing in part on a 2001 report from the National Academy of Sciences. (See "Bringing JAVA to the CAFE," Fall 2001.) The Advanced Notice of Proposed Rulemaking, "Reforming the Automobile Fuel Economy Standards Program," can be found at *www.nhtsa.dot.gov/cars/rules/CAFE/rulemaking.htm*.

In contrast to the Energy Department's energy efficiency standards for appliances, NHTSA's CAFE standards do not ban particular models of automobiles. Instead, they constrain each automaker's "fleet average" fuel economy, forcing the automakers to cross-subsidize smaller vehicles with the profits on larger vehicles so that consumers can be persuaded to buy what the government tells the automakers they must sell. But distortions of the market are not so easily contained. In adopting CAFE standards, Congress did not intend to deprive people who needed heavy vehicles for hauling and towing, so heavier trucks were exempt. The result: In order to escape the standards, more people bought heavier vehicles than they would have preferred absent the government's interference. And those who did not, bought cars that were smaller and less safe than they would have preferred.

"Not what we intended at all," cry the regulators! So now NHTSA proposes to include more of the heavier vehicles in the CAFE program, while at the same time "weighting" the standards in such a way that consumers will not pay a safety penalty. It is unclear how this will work out but, based on experience, we can predict that it will not be what consumers would prefer and it will not be what the regulators intended.

Meanwhile, the Congressional Budget Office released a study in December 2003, "The Economic Costs of Fuel Economy Standards Versus a Gasoline Tax." It found that a 10 percent reduction in gasoline consumption could be achieved more efficiently through a gasoline tax than through fuel economy regulations, because the tax produces fewer distortions and acts more quickly. But it also notes that gasoline is already subject to federal and state taxes at a level that exceeds the fuel's "social premium" as calculated by the 2001 National Academy study. As a result, not only will tighter CAFE standards reduce consumer welfare in a variety of unintended dimensions, they are also likely to reduce welfare through the intended effect of saving gasoline. We can only hope that "repeal" is among the "reform" options that NHTSA will consider.

Contact Lens Prescription Release

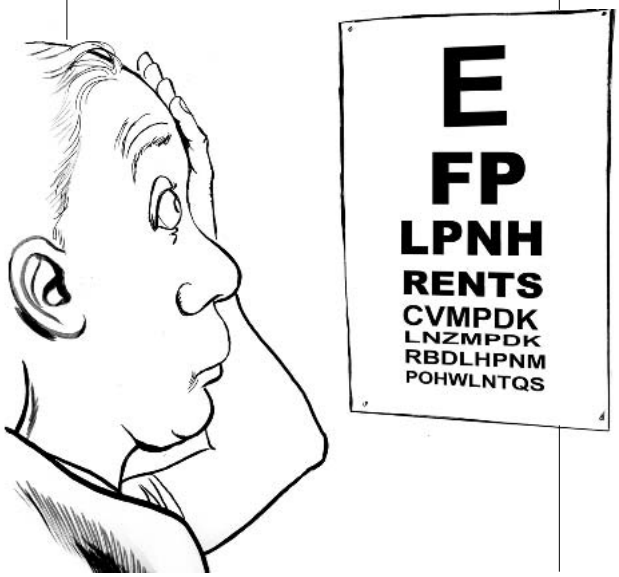
STATUS: FTC comment period closes April 5.

The Federal Trade Commission proposes to require that optometrists and ophthalmologists must give contact lens prescriptions to consumers once the process of fitting lenses has concluded, instead of being able to withhold that information. Congress required this new regulation (similar to existing FTC regulations of eyeglass prescriptions) in the Fairness to Contact Lens Consumers Act, signed by the president last December 6. The new rule would also prohibit eye doctors from requiring consumers to purchase contact lenses from them as a condition of performing the eye exam, and it would prevent them from charging separately for providing a copy of the prescription. Selling lenses without a prescription would now be a clear violation of federal law.

Most interesting is a requirement that eye doctors must provide and/or verify the prescription when a consumer seeks to purchase replacement contact lenses from anyone else, be it a competing doctor, a discount retailer, or an Internet-based lens merchant. Indeed, the principal political impetus for the legislation was mail-order and Internet lens sellers, along with their customers, who expressed frustration that some eye doctors would not provide or verify prescriptions.

Optometrists often sell a lot of contact lenses, so they have natural incentives to withhold the prescription information. But because eye doctors compete with each other, they also have incentives to release prescriptions if that is important to consumers. Lens sellers produced examples of instances in which doctors declined to release or verify prescriptions, and doctors produced examples of instances in which sellers shipped lenses without properly verifying the prescription. It is not clear how big each problem is, but Congress decided neither side could be trusted — hence the legislation.

One item still subject to debate



involves the length of time the lens seller has to wait before it can presume the eye doctor has verified a prescription. (Verification is necessary if the customer does not furnish a copy or fax of the original prescription.) The law states that the eye doctor can be presumed to have verified the prescription if the doctor makes no response eight "business hours" after being contacted by the lens seller. But it is up to the FTC to define what "business hours" are. The FTC proposes that "business hours" are between 9 AM and 5 PM, Monday through Friday, excluding federal holidays. That means if a consumer tried to order lenses at 10:30 AM on a Saturday, the seller would not have to ship them until Tuesday… or Wednesday if Monday happened to be a holiday.

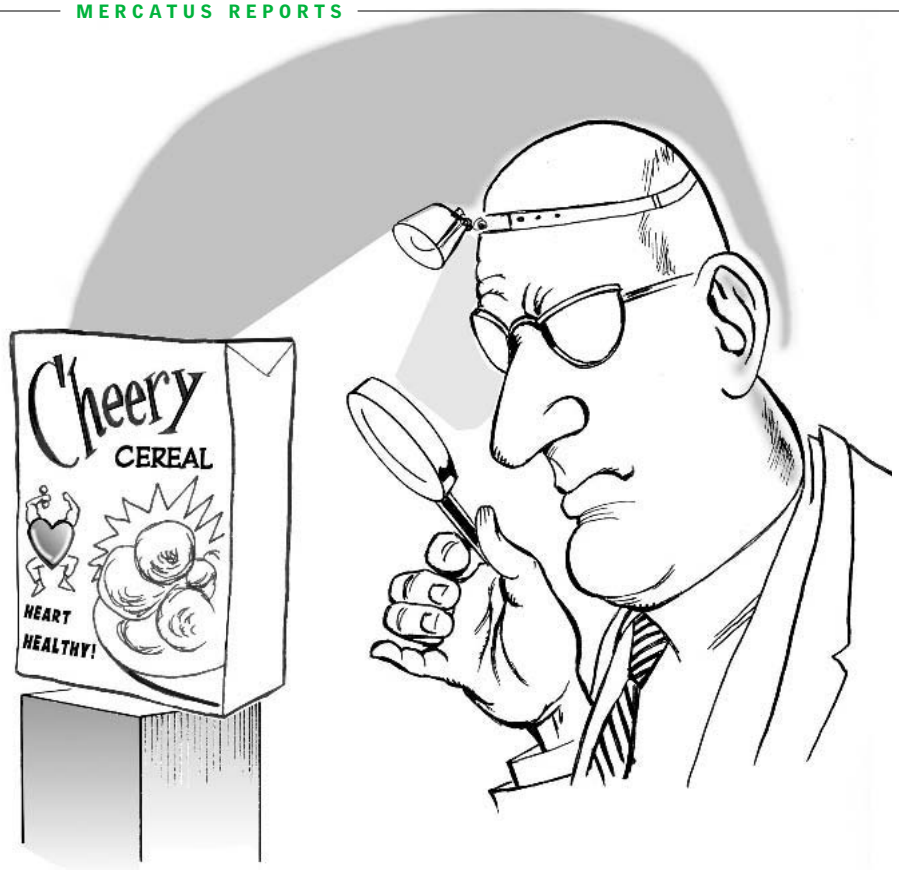
Whew! It would be a lot easier to let consumers decide whether they want a state-licensed medical professional to determine whether and what kind of lenses they need. But that option is not on the table, and something like this rule may be the next best thing. If a consumer has to pay for a prescription, at least the regulation will guarantee that the prescription is the consumer's property.

Qualified Health Claims for Food

STATUS: FDA is reviewing comment.

The Nutrition Labeling and Education Act (NLEA) of 1990 gave the Food and Drug Administration authority to permit health claims on food labels. A "health claim" is a labeling claim that links a substance to a disease or health-related condition, e.g., "25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease." With this authority, the FDA began approving only health claims that the agency determined were supported by "significant scientific agreement," as outlined in the NLEA.

However, the FDA was forced to reexamine its health claims approval process when makers of dietary supplements sued the agency for rejecting their health claims. The courts held that



the FDA's outright bans on the companies' health claims violated their First Amendment commercial speech rights. The courts also told the FDA that if a less restrictive and reasonable approach to regulating health claims was available, it was to choose it. In addition, they suggested that the FDA should permit producers to make "qualified" health claims — claims for which there may be some scientific evidence, but not significant scientific agreement — and allow the use of disclaimers to disseminate the information in a truthful and non-deceptive way.

As a result of the cases, FDA Commissioner Mark B. McClellan established a Task Force on Consumer Health Information for Better Nutrition, which published a report and two guidance documents outlining the process for evaluating qualified health claims. Next, the agency issued an advanced notice of proposed rulemaking, seeking comment on three options for permitting qualified health claims. The options were also described in one of the guidance documents.

Under Option 1, a producer would petition the FDA for permission to make a specific claim, and the FDA would determine the appropriate disclaimer by assessing the strength of the scientific evidence underlying the claim. This option would codify the process that the agency is currently using to review qualified health claims. Under Option 2, each health claim would undergo full notice-and-comment rulemaking to determine whether the wording of the claim accurately reflects the underlying scientific evidence. Under Option 3, producers would be free to make qualified health claims without prior FDA approval, but the agency would investigate suspect claims to ensure that they are not false or misleading.

Based on the available information, Option 3 appears to be the alternative that best promotes consumer welfare by giving consumers the timeliest access to truthful health claims while protecting them from false and misleading claims. Option 3 would also satisfy the courts' directive to the FDA to find an alternative that addresses its consumer welfare concerns without imposing unnecessary restrictions on the producers' right to commercial speech. R