becoming popular, they were protected by patents. This means that the drugs were much more expensive (although generally covered by insurance). It also means, however, that the pharmaceutical companies were willing to spend significant resources providing information about the drugs to physicians and patients through expenditures on promotion. Metformin is no longer covered by patent and is made by several generic producers, so there is relatively little money to be made from promoting it, so no one has much incentive to do so.

Because of the lack of promotion, many physicians may be unaware of the preventative uses of the drug. (Anecdotally, I have found this to be true. I have taken the drug for several years and whenever I see a new physician I must convince him or her that I am not a diabetic.) Moreover, many physicians are biased against drugs and prefer to recommend their patients simply follow a regimen of “diet and exercise,” a proposal that is easy for doctors to prescribe but hard for patients to follow. Of course, diet and exercise is a sensible recommendation, especially since the same evidence that indicates metformin is useful also indicates that diet and exercise is more effective. However, if a physician observes that a patient is not getting any thinner and blood sugar remains elevated, metformin should be (but often is not) the alternative.

The U.S. Food and Drug Administration has approved metformin for diabetes treatment, but not prevention. Physicians are allowed to prescribe an approved medicine for any condition, so the lack of FDA approval does not mean the drug cannot be used for prevention. However, firms are not allowed to advertise or promote a medicine for an unapproved use. That lack of promotion means that physicians are significantly less likely to understand the benefits and prescribe the drug. Moreover, because the drug is not protected by patent, no one has the incentive to spend the resources needed to convince the FDA to approve the drug for prevention, even when—as in metformin’s case—the evidence is solid.

Suggestions If you are a person with somewhat elevated blood sugar, ask your physician to prescribe metformin. If the doctor refuses, you may want to seek another physician. Use of this drug can increase length and quality of life, and is worth the bother of seeing another doctor.

If you are a doctor, consider prescribing metformin for your patients with elevated blood sugar, particularly if previous suggestions to lose weight and increase exercise have not worked. After the third or fourth unsuccessful admonition to lose weight, another approach is needed.

If they can find a way, FDA officials should seriously consider approving this drug as a diabetes preventative. Moreover, the drug is sufficiently beneficial and safe that it should be considered for over-the-counter sale. A public health campaign promoting the drug as a preventative could improve and lengthen many lives. It is said that there is a significant remedy for a condition that is often described as an “epidemic” and yet our regulatory institutions are such that no one is making an effort to use it.

Tight Budgets Constrain Some Regulatory Agencies, But Not All

BY SUSAN E. DUDLEY AND MELINDA WARREN

Regulations are an increasingly important aspect of modern American life, and yet measuring regulatory activity is challenging. The cooperative effort between the George Washington University Regulatory Studies Center and Washington University in St. Louis’s Weidenbaum Center on the Economy, Government, and Public Policy to track the trends in federal regulatory agencies’ expenditures helps monitor one component of the impact of regulation: the direct taxpayer costs associated with developing, administering, and enforcing federal rules and regulations. Each year we examine the President’s Proposed Budget of the United States to identify the outlays and staffing devoted to developing and enforcing federal regulations. This “regulators’ budget” report covers agencies whose regulations primarily affect private-sector activities and expressly excludes budget and staffing associated with regulations that govern taxation, entitlement, procurement, subsidy, and credit functions.
Our most recent report examines the requested budget outlays in fiscal year 2015 as well as estimated outlays for FY 2014. It also provides 56 years of data on annual outlays and staffing, from FY 1960 to the present. Those data reflect the on-budget costs of regulation and cannot inform analysts about the benefits regulations may convey. They also do not reflect full costs, as regulations impose social costs beyond the direct tax dollars spent to write and enforce them. An assessment of the full cost would not only calculate businesses’ and individuals’ costs associated with compliance, but also the loss of economic opportunities and choices available to individuals and organizations.

Despite those limitations, the time-series data on expenditures and staffing of federal regulatory agencies presented in the regulators’ budget report offer a useful proxy of the size and growth in regulations that American businesses, workers, and consumers must follow. This information can serve as a barometer of regulatory activity, providing policymakers and analysts with useful insights into the composition and evolution of regulation over time.

Overall, this year’s report finds that the regulators’ budget continues to grow at a modest pace. The proposed budget for regulatory activities in FY 2015 is $60.9 billion (in nominal dollars), a real (inflation-adjusted) increase of 3.5 percent above estimated FY 2014 outlays. (See Figure 1.) The FY 2014 regulators’ budget of $57.8 billion is 2 percent larger than FY 2013 regulatory agencies’ outlays of $55.9 billion. The proposed budget also requests an increase in federal regulatory agency personnel of 0.8 percent in FY 2015, following an estimated 2.0 percent increase in FY 2014. (See Figure 2.)

One of the most interesting (though not surprising) findings of our analysis is that, while tight budgets are constraining regulatory spending at many federal agencies, those that are at least partially funded by fees on the entities they regulate are able to support substantial increases in regulatory outlays and staffing. For example, while the Environmental Protection Agency’s outlays shrank by almost 4 percent in 2014, the Food and Drug Administration’s budget grew by more than 29 percent. The Consumer Financial Protection Bureau’s spending increased 33 percent in 2014 and outlays of both the Patent and Trademark Office and the Securities and Exchange Commission grew by more than 10 percent. The growth in spending and staffing at those agencies appears to reflect not only the increased scope of their regulatory activities, but a greater ability to finance those activities from revenue sources that are less affected by congressional spending limits.

This year’s analysis also documents some interesting long-term shifts in regulatory spending patterns, including a trend in which overall outlays devoted to economic regulatory activities, including price, quality, and entry regulation, are increasing at a faster rate than those aimed at social regulatory activities such as environmental, safety, and health issues. This reverses a trend that began in the 1970s away from economic regulation of private-sector activities, and would likely be more dramatic if our data included agencies of the Department of Health and Human Services that pursue economic regulation of health insurance markets pursuant to the 2010 Patient Protection and Affordable Care Act. While the staffing and outlays devoted to these regulations do fit the criteria for inclusion in the regulators’ budget report, the 2015 proposed budget did not allow us to distinguish between resources devoted to regulations that affect private-sector behavior (covered in the report) and those that affect entitlement spending (not included). This trend is worth watching because economic theory and empirical evidence suggest that the costs of economic types of regulation often outweigh the benefits.