REGULATORY REFORM

Routine use of cost-effectiveness analysis could dramatically improve transfer programs' effectiveness while saving taxpayers' money.

Evaluating Transfer Regulations

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HEN A FEDERAL REGULATOry agency issues a major regulation, the agency usually must provide a cost-benefit analysis that shows the monetized benefits of the regulation exceed the cost it imposes on industry. There has

been much debate about whether this practice has improved the quality of regulations, but few doubt that the quality of agencies' reasoning in formulating regulations has improved, and most commentators believe that cost-benefit analysis is a necessary first step toward improved regulation. Agencies, like businesses, are now expected to provide an accounting that shows their projects have a positive net present value. Although agencies, like businesses, can fudge the numbers a bit, regulatory impact statements provide more usable information about regulations than have statements accompanying regulations in the past, and that is a good thing for those who care about government transparency.

The regulations or proposed regulations that have been subjected to cost-benefit analysis are dominated by three areas: healthy, safety, and the environment. Notable recent examples include the Clinton-era arsenic and ergonomic regulations, which were withdrawn by the Bush administration when the analyses indicated that the regulations would produce a net loss for society. In those and other cases, cost-benefit analysis disciplines agencies by preventing them from justifying regulations based on speculative health or environmental benefits.

Cost-benefit analysis forces agencies to complete several valuable tasks: (1) quantify the effects of the regulation (e.g., the evidence either shows that the regulation will reduce cancer rates by a certain percent, or it does not); (2) monetize those effects (e.g., the monetary value of a life saved or a case of bron-

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chitis avoided is a certain amount of dollars); (3) discount future benefits (e.g., a case of bronchitis avoided today is worth more than a case of bronchitis avoided tomorrow); and (4) aggregate those amounts. Then the benefits can be compared to the cost of the proposed regulation and a decision can be made as to the regulation's net results.

Government agencies have intermittently used cost-benefit analysis from the very beginning, but it was in 1981 that President Ronald Reagan issued an executive order that directed all regulatory agencies to perform cost-benefit analysis of major rules. To the surprise of some people, President Bill Clinton issued an executive order that maintained the substance of the Reagan order, though there is some doubt whether his Office of Management and Budget enforced it as vigorously as Reagan's OMB did. Clinton's order remains in force today, and President Bush's OMB has reinvigorated it.

Both the Reagan and Clinton executive orders direct agencies to use cost-benefit analysis on all major regulations, with some exceptions of no interest here. Yet there is a large category of regulations that have escaped cost-benefit scrutiny: so-called "transfer" regulations that determine how money and other benefits are distributed to statutory beneficiaries. Unlike the regulations that normally are subject to cost-benefit analysis, transfer regulations do not solve market failures. Examples of them include guidelines for natural disaster relief, funds issued to victims of the September 11 attack, and payments from Medicare, Medicaid, and Social Security. Transfer regulations implement school lunch programs, research grants, and farm subsidies.

The regulatory impact statements accompanying transfer regulations rarely include cost-benefit analyses or anything resembling them. Annual OMB reports to Congress on the costs and benefits of federal regulation list the dozens of transfer regulations that are promulgated every year, but the agency excludes them from its evaluation of the costs and benefits of regulation. **Cost-effectiveness** Why are transfer regulations overlooked? Certainly not because they are unimportant. The regulations that are subject to cost-benefit analysis cost businesses tens or even hundreds of billions of dollars per year, but those amounts are smaller than the money distributed by transfer regulations. For instance, Medicare and Social Security payments exceeded \$700 billion in 2002, food stamps cost \$22 billion, and farm subsidies cost tens of billions of dollars per year.

The likely reason that agencies do not perform cost-benefit analysis on transfer regulations is that all such regulations would fail. A transfer regulation moves money from the taxpayer's pocket to the beneficiary's pocket while depleting administrative resources; thus, there must be a net loss. But cost-benefit principles can be used to evaluate transfer regulations. In particular, cost-effectiveness analysis is the proper decision procedure for evaluating regulations that have fixed benefit levels. That point is recognized by the same executive orders that direct agencies to conduct cost-benefit analysis; those orders direct agencies to conduct cost-effectiveness analysis when cost-benefit analysis is inappropriate. Yet, agencies rarely conduct costeffectiveness analysis of transfer regulations. When they do, the results are always crude and implausible.

The contrast between the sophistication of the cost-benefit analyses of ordinary regulations and the crudeness of the cost-effectiveness analyses of transfer regulations could not be greater, but there is no reason for that difference in practice. This raises the question, can agencies' evaluation of transfer regulations be improved?

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When an agency conducts a cost-benefit analysis of a proposed non-transfer regulation, it determines the monetary benefits and costs of the regulation and (in theory) approves it only if the benefits exceed the costs. For example, a well-designed pollution regulation will neither permit all pollution nor prohibit it completely, but permit factories to pollute up to the point at which health costs from additional pollution exceed the cost of preventing that pollution from entering the atmosphere. A non-transfer regulation that passes a cost-benefit analysis generates social welfare, usually by solving a market failure.

However, cost-benefit analysis is not the appropriate procedure for evaluating transfer regulations, because transfers distribute resources rather than solve market failures. A typical authorizing statute says that such-and-such amount of money will be distributed to certain beneficiaries — victims of a natural disaster, for example — and the agency must determine, by regulation, how different types of people qualify to receive the transfer. Like in the pollution case, the statute leaves open many different possible approaches to regulation: Should people get cash or low-interest loans? Should funds be distributed to people who did not take reasonable precautions against the disaster? How much evidence of financial loss should be required?

Cost-benefit analysis cannot be used to answer those questions, but cost-effectiveness analysis can. The difference between cost-benefit analysis and cost-effectiveness analysis is that the latter takes the benefit as fixed and evaluates the cost of achieving that benefit through various alternative regulations.

Consider a regulation to implement a school lunch program. Congress appropriates \$1 billion and directs the U.S. Department of Agriculture to ensure that the money is used for lunches for needy children. The USDA then must develop transfer regulations — regulations that determine how the money will be spent. It confronts numerous basic design choices: Should the money go directly to children, perhaps in the form of vouchers issued to impoverished parents; or should the money go to schools, or school districts? If it goes to school districts, how should the districts be required to spend the money? Should the money go to all school districts or only those that have a certain proportion of poor students? How should the agency ensure that school districts provide accurate information about the poverty rate among their students? Should the agency dictate the contents of the lunches or allow flexibility, so that regional tastes can be accommodated?

Alternative regulations can be compared using cost-effectiveness analysis. Suppose, for example, that regulation A provides for vouchers to parents and regulation B provides for grants to school districts. Each regulation is designed to exhaust the appropriation, but they involve different levels of administrative cost for the USDA. Because regulation B delegates much of the paperwork to school districts, the USDA is able to supply 200 million lunches — that is, \$5 per lunch. Under regulation A, the USDA is able to supply only 180 million lunches — that is, about \$5.50 per lunch. So, at first sight, regulation B is more cost-effective than regulation A.

But the agency should also take account of the administrative costs incurred by schools, parents, and others. Suppose that the school districts would incur another \$150 million in administrative costs under regulation B, whereas the parents' costs under regulation A would be negligible. That would add 75 cents per lunch in administrative costs to regulation B, and now it is no longer as cost-effective as regulation A.

There might be other differences between the regulations. Suppose that regulation B would result in many non-poor children obtaining free lunches because the schools have inadequate information about the income of parents, but regulation A would result in fraud and abuse because parents would sell the vouchers rather than give them to their children to obtain lunches. The cost-effectiveness analysis would need to handle those problems; the simplest way would be to count only those lunches that make it to poor children, and not those that are consumed by non-poor children. Then the dollar per lunch figures would be recalculated and compared. Although this issue and similar issues cannot be dealt with in a mechanical way, a little bit of creativity and pragmatism is all that is needed.

No alternative Some people might wonder why such studies are not carried out now. Without such analysis, how can agencies determine if their programs are having the desired effect and if they can be improved? What is the alternative decision procedure? Those same questions can be asked about agencies' evaluation of ordinary regulations before they used cost-benefit analysis.

It is hard to know how to answer those questions. Agencies are required by law to explain why they design a regulation in one way rather than another, but usually they have provided only vague generalities. It seems likely that some combination of moral, economic, and political reasoning has informed agencies' decisions, but this is only speculation.

The bottom line is that cost-effectiveness analysis is simple and straightforward, and there are no reasonable alternatives. It should not be a controversial technique for evaluating projects and regulations whose benefits are fixed by statute.

An example Adequate cost-effectiveness analysis is performed rarely on transfer regulations. Despite the executive orders that direct them to use cost-effectiveness analysis, agencies routinely do not do so, or else they provide a perfunctory and unpersuasive cost-effectiveness analysis.

A real-world example is the regulation by the Department of Health and Human Services (HHS) that authorized Medicare coverage for self-management training programs for diabetics. The simple idea behind the regulation and its authorizing statute is that it might be cheaper for Medicare to cover the cost of training diabetics to manage their disease instead of covering the cost of treating the various symptoms that result when people do not engage in self-management. That idea certainly seems sensible, but one cannot know whether the idea is correct, or whether it can be implemented successfully, without doing a cost-effectiveness analysis.

This is a case where the agency issued an inadequate costeffectiveness analysis rather than ignoring the requirement alto-

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gether. The HHS began by noting that there were 4.5 million diabetic beneficiaries at the time of the rulemaking. Not all of those patients would need to be covered by the self-management regulation; some of the beneficiaries already had been trained in self-management, others would not benefit from training. The HHS estimated that about 2.25 million beneficiaries would be eligible. Training would take 10 to 12 hours, so Medicare would have to pay for 22.5 to 27 million hours of training.

At that point, the HHS should have stated the cost of training per hour, and multiplied that amount by the total hours of training, and then discounted the product to present value. Instead, the agency stated the total expenditures as a flow over the next five years: \$150 million in 2001, rising steadily to \$280 million in 2005. One can infer the average hourly cost of training from those numbers, but that is only part of the information that one needs. The HHS should have, and could have, disaggregated the costs so that one would know how much would be spent on training programs, whether that varies by region, how much is going to administrative costs, and so forth. It should also have discounted the total amount to present value rather than listing the stream of payments over five years.

The next step would be to compare the cost of self-management training with the alternative, which here is the status quo — no self-management training. (There are other alternatives as well; for example, more or less than 10 to 12 hours of training per week, and so forth.) The goal is to pay for medical care sufficient to provide the beneficiary with a certain level of well being; the cost-effectiveness analysis addresses the question of whether the training regulation is better than the status quo program of paying for the treatment of symptoms as they appear.

The question can be answered only by estimating the effect of the self-management training programs. Do they really reduce or ameliorate symptoms and, if so, by how much? If \$150 million of training in 2001 will not reduce symptoms to the extent that at least \$150 million of traditional Medicare coverage costs are avoided — for all of the beneficiaries of the training in 2001, over the rest of their expected lives, discounted for the time value of money — then the self-management regulation is not cost-effective for 2001. Yet, the HHS provided no information about the effectiveness of the training, or the cost savings for the Medicare program given the expected effectiveness of the training. Instead, the agency said that the benefits of self-management — avoiding blindness and the other symptoms of diabetes, delaying death, and so forth — could not be monetized.

That is an old strategy of the agencies, one that has been subjected to increasing pressure by cost-benefit analysis. If you read regulatory impact statements accompanying non-transfer regulations issued 15 or 20 years ago, you will find agencies listing the costs of the regulation but refusing to monetize the benefits — insisting instead that an environmental regulation, for example, produces nonquantifiable health and environmental benefits. Today, an agency is more likely to estimate those benefits using medical costs and valuations of statistical lives for health benefits, and contingent valuation surveys for

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environmental benefits. Those techniques can be used for transfer regulations as well.

Returning to the diabetes regulation, the first point is that, from a budgetary perspective, the HHS just needs to compare the cost of covering the training and the cost of covering the treatment of the symptoms that self-management prevents. If the cost of the training is less than the cost of treating the symptoms, then covering training is cost-effective. If the cost of training is not less than the cost of treating the symptoms, it is still possible that the regulation is cost-effective, but one must factor in the enhanced well being of people who do not experience symptoms because of self-management. The HHS is wrong to say that the benefits of self-management cannot be monetized. benefit test, and evaluating agencies' performance in annual reports to Congress. The OMB has also developed helpful guidelines that give the agencies instructions about how to perform cost-benefit analysis. The guidelines provide step-by-step recipes and information about discounting and valuing hardto-measure goods such as human lives.

The OMB could do the same thing for cost-effectiveness analysis, and there is some evidence that it has begun to do so. Its current draft guidelines for regulatory review emphasize cost-effectiveness analysis somewhat more than in the past, though the instructions about how to conduct cost-effectiveness analysis are not nearly as thorough as the cost-benefit instructions. In at least one recent case, it has returned a reg-

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They can use valuations routinely used by the Environmental Protection Agency and other agencies when they apply costbenefit analysis to non-transfer regulations. If self-management training costs the HHS \$150 million, saves \$120 million in coverage of symptoms, but also produces other health benefits valued at \$40 million by beneficiaries, then the regulation is costeffective relative to the status quo.

Cost-effectiveness analysis, like cost-benefit analysis, often relies on complex assumptions, but that is true for any decision procedure. The chief virtue of cost-effectiveness analysis and cost-benefit analysis is that those assumptions are made explicit so that interested people can criticize and debate them. The HHS's reasoning, by contrast, is opaque.

IMPROVING COST-EFFECTIVENESS ANALYSIS

It is tempting to say that agencies could improve their evaluations of transfer regulations simply by complying with the relevant executive order, which directs them to perform costeffectiveness analysis on regulations that have an economic impact of \$100 million or more. But the problem is that the executive order is already in force, and has been for many years, but it has had no influence on agencies' behavior.

History teaches us something here. It is not enough to issue an executive order; the executive also must take steps to enforce it. Forcefully during the Reagan years, and somewhat more sporadically afterwards, the OMB has pressured agencies to conduct cost-benefit analysis, and to do so in a relatively sophisticated way. The earlier cost-benefit analyses were no better than cost-effectiveness analyses today, but over time the agencies have acquired sophistication, and when the OMB exerts pressure, the agencies have generally been responsive. The OMB has exerted pressure by issuing return letters that tell agencies to reevaluate regulations that appear to fail the costulation to an agency because of an inadequately performed cost-effectiveness analysis of a transfer regulation. And the HHS appears to be getting serious about applying cost-effectiveness analysis to Medicare regulations. Earlier this year, the agency announced that it would apply cost-effectiveness analysis to prescription drug benefits, so that Medicare coverage would be denied to a prescription drug that costs \$5 when another drug that has identical effects is available for \$4. A similar policy would apply to tests and other medical procedures.

The only question is why such an obvious reform was not implemented decades ago, and much more broadly across the entire system, and by other agencies as well. The OMB will need to put more pressure on agencies, and provide more leadership, before substantial change will occur.

READINGS

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