

es could affect safety or efficacy. Tracking adverse events associated with the use of reference and biosimilar products will be difficult if the specific product or manufacturer cannot be readily identified, and appropriate strategies must be developed to ensure the implementation of robust, modern pharmacovigilance programs for biologics.

Under the BPCI Act, biosimilars will also have the opportunity to meet a higher standard of similarity to a reference product — “interchangeability,” reflecting an FDA assessment that pharmacists can make substitutions between biologics without the prescriber’s intervention. A biologic will be considered interchangeable with a reference product if the developer demonstrates that it can be expected to pro-

duce the same clinical result in any given patient and that the risk associated with alternating or switching between the two products is not greater than that involved in continuing to use the reference product.

The FDA will carefully consider what data will be necessary for this purpose and translate that assessment into effective regulatory standards. The agency will also develop standards to ensure that products not deemed interchangeable are not inadvertently substituted for a reference product without the prescriber’s consent. But even without interchangeability, recognition that two products are biosimilar will give clinicians far more information than the mere knowledge that they were developed for the same indication.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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1. Biologics Price Competition and Innovation Act, 2009. (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf>)
 2. Emerging health care issues: follow-on biologic drug competition. Washington, DC: Federal Trade Commission, 2009. (<http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>)
 3. Woodcock J, Griffin J, Behrman R, et al. The FDA’s assessment of follow-on protein products: a historical perspective. *Nat Rev Drug Discov* 2007;6:437-42.
 4. Guideline on similar biological medicinal products. London: European Medicines Agency, 2005. (<http://www.emea.europa.eu/pdfs/human/biosimilar/043704en.pdf>)
 5. Draft: guideline on similar biological medicinal products containing monoclonal antibodies. London: European Medicines Agency, 2010. (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/11/WC500099361.pdf)
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Redesigning Employee Health Incentives — Lessons from Behavioral Economics

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Buried as Section 2705 of the Patient Protection and Affordable Care Act (ACA) is a provision of potentially momentous importance. Beginning in 2014, employers may use up to 30% of the total amount of employees’ health insurance premiums (50% at the discretion of the secretary of health and human services) to provide outcome-based wellness incentives. Such rewards can “be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or co-

insurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.”

This provision represents an attempt to rein in health care costs, to which health conditions associated with unhealthy behaviors, such as smoking, overeating, and not exercising, are major contributors. Projections that the provision would reduce costs arose, in part, from claims that Safeway Supermarkets had achieved flat health care costs from 2005 to 2009 by tying employees’ health insurance premiums to outcome-

based wellness incentives.¹ It later became clear, however, that Safeway’s program began in 2008 — too late to deserve credit for flat costs starting in 2005.²

Although it may seem obvious that charging higher premiums for smoking (or high body-mass index, cholesterol, or blood pressure) would encourage people to modify their habits to lower their premiums, evidence that differential premiums change health-related behavior is scant. Indeed, we’re unaware of any health insurance data that have convincingly demonstrated such effects.

Enabling employers to vary premiums on the basis of employees' health-related behaviors or health outcomes could undermine some of the ACA's intended benefits. The law aims at universal coverage, partly to spread the costs of addressing health risks across the population and partly

behaviors and outcomes that may not be completely under their control.

The hope behind this ACA provision is that it will improve health-related behavior and reduce the prevalence of chronic disease caused by unhealthy lifestyles. Our research and that of other

interventions involve immediate costs (the inconvenience of taking a drug or undergoing a preventive medical procedure) with delayed and often uncertain benefits of better health years later. From this perspective, attempts to motivate behavior change through annual premium adjustments are unlikely to be maximally effective because the consequences are delayed. Ideally, incentives should provide small but tangible and frequent positive feedback or rewards. A program that promotes exercise with a year-end rebate for gym attendance or a small year-end reduction in one's health insurance premium is far less likely to succeed than one providing incentives, and symbolic encouragement, at every visit. Similar concepts apply to most health-related behaviors, such as smoking or medication adherence, for which incentives might bring immediate and frequent attention to otherwise delayed benefits.

Another relevant behavioral economics concept is mental accounting, which reflects how people tend to categorize monetary receipts and payments. For instance, the effect of rewards (or punishments) diminishes when they're bundled into larger sums of money: a \$100 discount on premiums may go unnoticed, whereas a \$100 check in the mail may register as an unexpected windfall. Increases or decreases in insurance premiums that are deducted from periodic paychecks will probably be less salient and effective than similar financial incentives provided separately.

Finally, although there's generally wider support for programs that reward people for healthy behavior than those that penal-

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to discourage insurers from trying to enroll only the healthiest (and lowest-cost) individuals. Although the health benefits achievable through wellness incentives may be greater in lower-income than in higher-income populations — both because lower-income people would place greater value on the same level of incentive and because their rates of poor outcomes tied to behaviors such as smoking tend to be higher — a system linking premiums to health outcomes would probably lead to higher premiums for lower-income individuals and families. If some employers or insurers started reducing rates for healthier people and raising them for the less healthy, healthier people would gravitate toward firms with such policies, and other employers and insurers would feel pressure to follow suit. Although employers and payers increasingly see personal accountability as fair and as an important aspect of effective health care reform, many people would end up paying higher premiums for be-

havioral economists shows that this premise cannot be assumed. The effectiveness of incentive programs depends critically on how the incentives are timed, distributed, and framed,³ and several factors might make insurance-premium adjustments, the most common implementation mechanism, less effective dollar for dollar than other approaches.

Findings of behavioral economics suggest that the same decision errors that contribute to poor health-related behaviors can be used to “supercharge” incentive programs so that they motivate behavior change more effectively than simple premium adjustments do.⁴ For example, in making decisions, people place more weight on the present than the future — they're more attracted by immediate than delayed benefits and more deterred by immediate than delayed costs. Many behavioral patterns that undermine health involve immediate benefits and delayed costs (eating provides immediate gratification but may cause later obesity) and many

ize them for unhealthy behavior, issues of perceived efficiency and fairness often cause the former to be transformed into the latter. Efficiency favors penalty programs because they effectively target people who could benefit from changing their behavior, whereas reward programs may expend resources on people who are already performing targeted behaviors (e.g., not smoking) or, if they target behavior change, could motivate people to adopt the undesired behavior so as to reap rewards through cessation. Many people may favor penalty programs because they find it distasteful to reward people for behaviors that are in their own self-interest. However, reward programs are more likely than penalty programs to convey a sense of cooperation between employer and employee in seeking a mutually beneficial goal — employees' health. Data are scarce on whether reward or penalty programs are more effective — a critical question that may override philosophical preferences.

Our experience with implementation of a program following the completion of a randomized, controlled trial in which \$750 incentives resulted in a tripling of smoking-cessation rates, from 5.0% to 14.7%, after 9 to 12 months in a large-employer setting highlights some of the limitations of a straightforward application of concepts from be-

havioral economics.⁵ Once the company decided to implement an incentive program based on the study findings, feedback from nonsmoking employees led to the replacement of the \$750 reward with a \$625 penalty for smokers. Nonsmokers believed that their colleagues shouldn't be rewarded for "something I did myself without any reward." In addition, for practical reasons, the penalty was tied into health insurance premiums: incorporating it into payroll deductions was far simpler administratively than setting up a separate system for financially penalizing smokers. The anticipated difficulty of collecting money from smokers who didn't quit suggests that whereas reward systems can be made more effective by being separated from paychecks, that approach probably isn't feasible for penalties. Providing rewards outside the premium framework would make them taxable, and it's unclear whether a taxed but more salient reward is more effective than a premium adjustment.

In general, the effectiveness of outcome-based wellness incentives is uncertain, and their use raises concerns about distributional equity; nevertheless, these approaches are gaining momentum because of rising health care costs and payers' belief that incentives should work in health care as they do in other spheres. Lessons from behavioral eco-

nomics could improve incentive-program design, but real-world implementation challenges may lead to substantial deviation from theoretically optimal design. Developing and testing a variety of programs between now and 2014 will generate the data needed to determine how best to use this new approach to improve health.

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1. Burd S. How Safeway is cutting costs. *Wall Street Journal*. June 12, 2009:A15.
2. Hilzenrath D. Misleading claims about Safeway wellness incentives shape health-care bill. *Washington Post*. January 17, 2010:G01.
3. Haisley E, Volpp KG, Pellathy T, Loewenstein G. Promoting completion of health risk assessments with lottery incentives. *Am J Health Promot* (in press).
4. Volpp KG, Pauly MV, Loewenstein G, Bangsberg D. P4P4P: an agenda for research on pay-for-performance for patients. *Health Aff (Millwood)* 2009;28:206-14.
5. Volpp KG, Troxel AB, Pauly MV, et al. A randomized, controlled trial of financial incentives for smoking cessation. *N Engl J Med* 2009;360:699-709.

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