latory pathways are too slow (even as the FDA adds ever more ways to approve or provide access to investigational therapeutics more quickly).

Add to the mix a dose of stem cells, and one has a recipe for more medical tourism, fed by clinics seeking profits and patients seeking cures. When older gene-editing technologies were used to engineer intestinal stem-cell organoids in the search for cystic fibrosis treatment,[4] a headline on futuremedicine.com read, "Fixing stem cells via genome editing: hope for cystic fibrosis?" If new is better, then new-squared, with two high-profile fields combined to address chronic, degenerative, and fatal diseases currently lacking cures, may be well nigh irresistible to patients and to clinics that would abuse their trust.

It will take a concerted effort by researchers, journal editors, companies, investors, and the media to find the fine line between hope and hype and to keep explaining why the best way to find safe, effective cures is through the careful steps of clinical trials and treatment monitoring. Editors need to ensure that headlines are more carefully written, scientists need to be careful about how they allow themselves to be quoted, and regulators need to collaborate with one another and with patient groups, so that misleading claims on the Internet can be checked or withdrawn. On the research side, national academies of science and medicine in Europe, Asia, and the United States have begun projects examining potential applications, regulatory pathways, and means to predict and measure precision, accuracy, and off-target effects. And proposals are being made regarding educating patients before any gene-editing–therapy trial begins.[5]

Participation in responsibly designed research is not at odds with promoting innovative medicine; it provides the data needed to confirm that innovative methods are effective. Nor is it at odds with compassion or an awareness of the different risk–benefit balance at play in terminal illnesses, which is why regulators provide pathways for access to investigational products. But the absence of good research undermines any effort to separate real from illusory therapeutic claims. Patients may be tempted by Willie Nelson, who "can't wait to get on the road again," but real progress is more like the Beatles' "long and winding road."

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Toward Lower Costs and Better Care — Averting a Collision between Consumer- and Provider-Focused Reforms

Elliott S. Fisher, M.D., M.P.H., and Peter V. Lee, J.D.

Over the past 20 years, two major approaches to slowing the growth of health care costs have emerged. One focuses on the delivery system, encouraging physicians, hospitals, and others to improve the way they deliver care. The other targets consumers, hoping to turn patients into more price-sensitive shoppers. Although both have had some success, it's increasingly clear that these approaches are on a collision course: poorly structured benefit designs will sharply limit the effectiveness of efforts to promote higher-value care through payment and delivery-system reform. But a crash is not inevitable.

Interest in reforming care delivery grew out of observations regarding the relative efficiency of integrated medical group practices, growing concern about variation in quality of care, and evidence that the greater use of specialist and hospital-based care in high-cost U.S. regions and health systems did not translate

into better quality or superior health outcomes.[1] Reform initiatives focused on both support for practice transformation and changing payment systems to reward better care and lower costs — now widely referred to as "value-based payment." One example of these efforts is the patient-centered medical home (PCMH) model, which has been broadly adopted, with millions of patients now receiving care through practices certified by the National Committee on Quality Assurance. Another is the recent growth of accountable care organizations (ACOs), which now provide care to more than 26 million Americans. These approaches are rooted in the notion that improved delivery of effective primary care and better coordination of patient care over time are essential to improving quality and reducing costs.

California's example suggests that it's possible to avoid a collision between consumer- and provider-focused efforts to improve care and reduce cost growth.

The consumer-focused strand of activity largely emerged from the private sector. These efforts were spurred by the Rand Health Insurance Experiment, a randomized trial that demonstrated that cost sharing reduced utilization (and thus spending) with no apparent adverse health effects on the average participant but with potential negative effects on low-income participants with chronic illnesses.[2] Because benefit design as a lever for constraining health care spending has been readily accessible to both large, self-insured employers and health plans serving small businesses, cost sharing has increased dramatically. Since 2006, the proportion of Americans with employer-sponsored coverage involving deductibles of over $1,000 has increased from 10% to 46%, and many of these enrollees must fully meet their deductible before receiving any coverage for primary care. In addition, 93% of covered workers must pay a portion of the costs for primary care visits in the form of either coinsurance or copayments, with copayments now averaging $24.[3]

The conflict between these two approaches is clear. The success of provider-focused reform strategies, such as ACOs and PCMHs, depends directly on having patients engaged with their care team — usually a primary care practice. Early evidence suggests that ACOs achieve their substantial successes in improving quality (including improvement on measures of patient experience, clinical outcomes, and readmission rates) by ensuring that primary care patients receive needed preventive and chronic disease care.[4] Their modest successes in controlling costs appear to be generated by more effective referrals (for commercial populations) and better care coordination (for high-cost Medicare beneficiaries). Substantial or poorly targeted cost sharing could easily undermine these approaches. Numerous studies have shown that cost sharing is a blunt instrument, causing patients to cut back on both needed and wasteful care. A recent study showed that the adoption of a high-deductible health plan in a relatively high-income population led to a 10% reduction in the use of preventive services and an 18% drop in physician visits, with the greatest reductions occurring in the sickest quartile of patients.[5]

Although trends in benefit design are worrisome, the Affordable Care Act (ACA) set some important requirements for health plans offered in both the employer and individual markets, including mandatory coverage for medical and mental health care and provision of free preventive care services. In the employer market, however, the ACA largely leaves benefit designs unregulated, aside from imposing minimum value requirements. The individual insurance marketplaces, dominated by the state-based and federal exchanges, go a few steps further: products must fall into one of four tiers of actuarial value, ranging from "platinum" products with comprehensive benefits but high premiums, through "gold" and "silver," down to "bronze" products with thinner benefits but low premiums. Though all products must include a defined set of essential health benefits and none may impose cost sharing exceeding a defined annual maximum for in-network care, states can determine how much flexibility to allow health plans in setting deductibles, copayments, and coinsurance.

Because most exchanges do not standardize the benefit designs health plans can offer, consumers face a confusing array of products, many of which will undermine initiatives in delivery-system reform. For example, in Colorado

— whose exchange gives health plans free rein on benefit designs — Denver residents can choose from 35 different silver products offered by eight health plans. Of these products, 15 require the consumer to meet the deductible before insurance kicks in to cover outpatient care. In 2015, for example, the lowest-cost silver plan had a premium for a 30-year-old of $183 per month, half as much as that of the most expensive silver product. In the lowest-cost plan, however, all outpatient services other than the required free preventive services and generic drugs are subject to a $3,900 deductible.

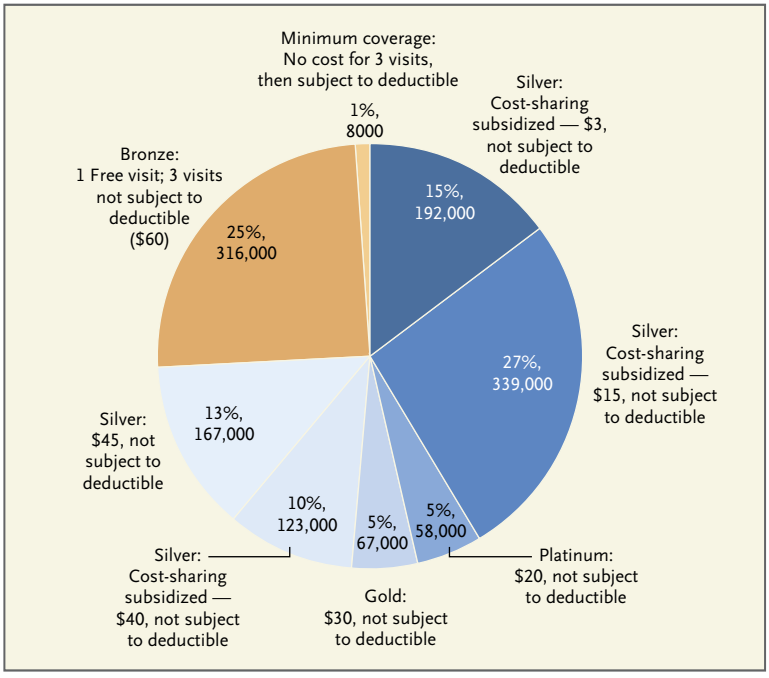
California has taken a different approach. As an active purchaser, Covered California, the state's insurance exchange, opted to standardize the designs of deductibles, copayments, and other cost sharing for all its contracted health plans within each of the four tiers. The aim is to enable consumers to make apples-to-apples comparisons among plans based on cost and network composition (rather than hard-to-interpret differences in deductibles and copayments) and to ensure that consumers do not face undue financial barriers to receiving primary and other high-value care.

The pie chart shows the levels of cost sharing for the exchange's 1.3 million enrollees. Those who select a silver product face no deductible and modest copayments for physician visits and other outpatient services; subsidies further reduce copayments for lower-income enrollees. Anyone selecting a bronze plan receives one free primary care visit and three visits that are not subject to the annual deductible.

Other elements of California's approach include encouraging plans to support PCMH and ACO models. For instance, Covered California currently requires plans to report the percentage of enrollees receiving their care from either type of organization and intends to require increasing use of such integrated delivery systems in coming years. Many of the exchange's consumers are therefore enrolled in ACOs and PCMHs that have multiple public and private ACO contracts.

A few other states — including Connecticut, Oregon, and Massachusetts — have adopted standardized benefit designs, and the federal marketplace recently indicated that it's starting down this path by making a standardized design voluntary for plans in 2017. The exchanges, however, cover only 10.2 million Americans, or 4% of the population under 65 years of age. If meaningful health care reform is to reach a critical mass, more employers will need to partner with health plans to engage their employees in more integrated delivery models.[4]

California's example suggests that it's possible to avoid a collision between consumer- and provider-focused efforts to improve care and reduce cost growth. Benefit designs encouraging utilization of high-quality, accessible primary care that's supported by an effective organizational structure should help consumers better manage their health risks and chronic conditions and more effectively navigate the challenges of serious illness. At the same time, carefully designed cost sharing may help motivate patients to work in partnership with their primary care physician and others to make wise decisions about what discretionary care they truly need and want.



Costs to Covered California Enrollees for Primary Care Visits, June 2015.

The blue segments represent enrollees (75% of the total) who can obtain primary care without being subject to a deductible. Numbers and percentages have been rounded.

Whether we can slow the growth of health care spending while improving both health and health care is far from certain. This outcome is much more likely, however, if leaders in the public and private sectors strive to align benefit designs with delivery-system reforms.

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The Physician Payments Sunshine Act — Two Years of the Open Payments Program

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The Physician Payments Sunshine Act, part of the Affordable Care Act, requires public reporting of payments made to physicians and teaching hospitals by medical product manufacturers and group purchasing organizations.[1] In the Open Payments program, we at the Centers for Medicare and Medicaid Services (CMS) receive reports from industry on relevant financial interactions and make the information available on a public website. The first round of data, released on September 30, 2014, included financial interactions from August through December 2013. These payments totaled $3.4 billion, from 1347 companies to more than 470,000 physicians and 1019 of the approximately 1200 U.S. teaching hospitals. The second round, published on June 30, 2015, included all reported payments for 2014 — about $6.5 billion from 1444 companies to more than 600,000 physicians and 1100 teaching hospitals (see Table 1).

Table 1. Details of Open Payments Data Reported in 2013 and 2014.*

Variable	2013 (August–December)	2014
General financial interactions	$972 million	$2.56 billion
Research-related financial interactions	$1.55 billion	$3.23 billion
Ownership or investment interest	$908 million	$703 million
No of companies reporting data	1347	1444
No. of physicians covered	470,000	607,000
No. of teaching hospitals covered	1019	1121
Research interactions withheld from public release	$454 million	$1.3 billion

* Research interactions withheld from public release are in addition to the publicly released data, as of July 2015; information on about 4300 payments from 2013, totaling about $39 million, that was initially withheld from public reporting per program specifications was allowed by the 81 reporting companies to be published in 2014.

Industry–physician financial relationships have garnered much attention in recent years. A 2007 Institute of Medicine report, citing concern about potential conflicts of interest, called for a national transparency program, as have reports from the Medicare Payment Advisory Commission.[2,3] Several states have required public reporting of financial relationships for years, and others are implementing or considering policies for augmenting Open Payments. Several countries are considering similar policies.

Much of the work done to date on financial relationships and conflicts of interest has lacked context on the type and scope of the interactions. In deploying the Open Payments program to fill this gap, CMS has prioritized three strategic goals. First, we seek to assemble a complete, unbiased database to inform public analyses and discourse. CMS