how to counter antivaccinationists’ false and injurious claims. The scientific method must inform evidence-based decision making and a numerate society if good public policy decisions are to be made and the public health held safe. Syncretism between the scientific method and unorthodox medicine can be dangerous.

Fourth, we must enhance public education and public persuasion. Patients and parents are seeking to balance risks and benefits. This process must start with increasing scientific literacy at all levels of education. In addition, public–private partnerships of scientists and physicians could be developed to make accurate vaccine information accessible to the public in multiple languages, on a range of reading levels, and through various media. We must counter misinformation where it is transmitted and consider using legal remedies when appropriate.

The diseases that we now seek to prevent with vaccination pose far less risk to antivaccinationists than smallpox did through the early 1900s. Unfortunately, this means that they can continue to disseminate false science without much personal risk, while putting children, the elderly, and the frail in harm’s way. We can propose no Oslerian challenge to demonstrate our point but have instead a story of science and contrasting worldviews: on the one hand, a long history of stunning triumphs, such as the eradication of smallpox and control of many epidemic diseases that had previously maimed and killed millions of people; on the other hand, the reality that none of the antivaccinationists’ claims of widespread injury from vaccines have withstood the tests of time and science. We believe that antivaccinationists have done significant harm to the public health. Ultimately, society must recognize that science is not a democracy in which the side with the most votes or the loudest voices gets to decide what is right.

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ACOs and the Enforcement of Fraud, Abuse, and Antitrust Laws

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Hospitals and physicians are eagerly awaiting regulations for accountable care organizations (ACOs), which many observers view as the best hope provided by the Patient Protection and Affordable Care Act (ACA) for needed delivery system reform. Starting in 2012, health care providers in ACOs that furnish efficient, high-quality care to Medicare patients will share in Medicare’s savings. Providers are concerned, however, that in creating ACOs they risk violating fraud, abuse, and antitrust laws. To address these fears, the Department of Health and Human Services (DHHS), the Federal Trade Commission, and the Department of Justice, under the direction of the White House, are collaborating to provide waivers, safety zones, and guidance to providers.

An ACO, as defined by the ACA, is an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare patients for whom they provide the bulk of primary care services. ACOs must have defined processes for promoting evidence-based medicine, reporting data with which to evaluate the quality and cost of care, and coordinating care. ACOs that meet specified quality standards will receive a share of the savings if Medicare’s cost for the care of their assigned patients is below a certain benchmark. ACOs, along with bundled payments and other payment innovations, are intended to transform the health care delivery system both by replacing fee-for-service payments, which tend to increase utilization, and by boosting collaboration among providers so as to reduce costs and improve quality.

However, providers organizing ACOs may fear violating fraud-
Physicians and antitrust enforcers have focused primarily on the first question — whether a physician network is sufficiently integrated to rule out naked price fixing. Initially, enforcers sought to determine whether the network was at financial risk for its performance — for example, through a capitated contract — but they now recognize that physicians whose practices are integrated clinically, even if they don’t share financial risk, are not engaged in price fixing if their collaboration has potential for improving quality and reducing costs. Clinical integration, how-

The advent of ACOs increases the tension between fraud-and-abuse laws and providers’ desire to enter collaborative arrangements. Under current law, financial relationships designed to affect referrals and services are inherently suspect. But the success of ACOs hinges on their ability to use financial incentives to steer referrals to providers offering higher-quality, more cost-effective care. The ACA therefore authorizes the DHHS to grant waivers as needed to implement the ACO shared savings program — for instance, to permit ACOs to distribute to their physicians any shared savings they earn. But the agency must also consider when to waive the fraud-and-abuse laws for other types of payments — for example, incentives to use less costly medical technology or to refer patients to certain providers. These questions are difficult because although ACOs raise fewer concerns about overutilization than fee for service does, their financial incentives could theoretically result in underuse of services.

To remove unwarranted barriers to ACO formation, the DHHS should reverse its presumptions about the effects of financial relationships among providers, at least for DHHS-approved ACOs, and permit providers greater latitude to use financial incentives to improve quality and reduce costs. It should issue guidance outlining the types of arrangements that trigger concerns about inappropriate financial relationships and provide waivers for arrangements that have safeguards addressing such concerns. Because ACOs will have to report detailed quality and utilization data, enforcers will be able to evaluate whether the waiver requirements should be modified. The DHHS could also use such data to terminate waivers for arrangements that it perceives as threats to quality or abuse of Medicare.

Antitrust concerns, for their part, focus on whether providers will exercise market power to raise prices above competitive levels. Typically, enforcement of antitrust law has targeted physicians’ negotiations with health plans. Joint negotiations by competing physicians are assessed under the Sherman Act in three steps. Step 1 examines the degree of economic integration among the physicians. Joint negotiations by completely independent practices are condemned summarily as “naked” price fixing, because they cannot result in any efficiencies that could benefit consumers. But if the physicians are economically integrated — for example, sharing financial risk for improving quality or reducing costs — their conduct cannot be dismissed as price fixing lacking any redeeming value. Instead, the joint negotiations are examined in step 2 to see whether they are reasonably necessary to achieve efficiencies. If they are, the collaboration is evaluated in step 3 under the “rule of reason” to assess its effect on competition.

Collaborations that give physicians the market power to raise rates above competitive levels are unlawful, even if they involve substantial integration. It is assumed, however, that entities with market share below 30 to 40% are unlikely to have such power. Rule-of-reason analysis places a heavy burden on antitrust enforcers, who must persuasively define relevant geographic and product markets that render market share too high or prove that prices (after adjustment for quality improvements) have increased as a result of joint negotiations.
ever, is difficult to define. Because enforcers feared that providing a simple checklist of criteria would deter innovation, they have described only general attributes of clinical integration. These attributes include the selective choice of network members, mechanisms to ensure compliance with clinical protocols, and investment in infrastructure, such as shared electronic health records and staff to evaluate practice patterns. Until recently, antitrust discussions have centered on providers’ questions about how much clinical integration is enough to avoid having their arrangements condemned as price fixing. Antitrust enforcers are concerned that if the bar is set too low, providers may create arrangements to give them antitrust cover without achieving important cost or quality goals. Antitrust inquiries have not focused extensively on the more difficult question of whether an integrated physician network may nevertheless be unlawful because it has too much market power.

The ACA may change all that. Its requirements for ACO programs closely track the antitrust agencies’ description of clinical integration, so ACOs that meet DHHS requirements will probably be viewed as clinically integrated for antitrust purposes. In the long run, defining clinical integration may be less important if payment reforms that offer incentives for collaboration take hold, because provider networks that don’t achieve meaningful clinical integration will probably not receive shared savings from Medicare (or similar rewards from private health plans), and most will ultimately fail.

Instead, as physicians continue merging their practices, seeking employment by hospitals, and forming networks, antitrust enforcers will shift their focus to the challenging question of whether such efforts result in undue market power. Over the past two decades, these agencies have wrestled with similar issues raised by hospital mergers. To assess a merger’s competitive effects, a market must be defined, and the effect on competition considered in light of the efficiencies to be created. The agencies have had limited success in challenging hospital mergers, since courts have defined geographic markets broadly (reducing the estimated market share of the merging hospitals) and concluded that mergers could reduce wasteful duplication, improve quality, and result in substantial savings.

Physician collaborations raise even thornier issues, since separate markets must be defined for each specialty. For example, cardiac surgeons compete in much broader geographic markets than do obstetricians. Moreover, high market shares for physicians may be necessary to ensure adequate coverage in rural areas or for specialty care. In such situations, antitrust enforcers have suggested that market-power concerns are alleviated if physician networks are nonexclusive, allowing physicians to participate in other networks or contract directly with health plans. But exclusivity may help ensure physicians’ commitment to an ACO and reduce the possibility that other networks will get a free ride on its initiatives by benefiting from the ACO’s improved care without paying for its associated costs. Thus, in places with many physicians, exclusivity should be encouraged, as long as market shares are low enough to allow several competing networks to coexist.

Federal Trade Commission Chair Jon Leibowitz recently said that his agency was considering new safe harbors and expedited reviews for organizations wishing to qualify as ACOs. Insofar as ACOs confine themselves to the Medicare shared savings program, they won’t raise substantial antitrust issues, since they won’t be negotiating payment terms with the DHHS, but such issues can arise if ACOs also seek to contract with private health plans. Safe harbors and guidelines, especially if linked to ACO certification by the DHHS, along with transparency by enforcers regarding their analysis of arrangements, will afford providers more guidance on creating collaborations likely to survive antitrust scrutiny.

But these first steps probably won’t address difficult market-power questions. For those, the agencies will need to undertake fact-specific inquiries, which could involve weighing the benefits gained from broader networks against concerns about potential anticompetitive results of consolidation. That step will necessitate informed, sophisticated antitrust assessment by the enforcers and the courts.

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