

cause the FDA is holding supplements to the same safety standards as food additives — which was not Congress's intent when drafting DSHEA. Industry advocates are correct insofar as DSHEA does not hold established (pre-1994) supplement ingredients to the same safety standards as food additives: a chemical preservative sprayed inside a can of tomato soup or the purple dye in Jell-O requires much more evidence of safety than ingredients used in supplements. However, the industry's argument is flawed with respect to new supplement ingredients. The FDA's legal authority over new products is generally greater than that over established products,<sup>5</sup> and this also applies to supplements. DSHEA explicitly requires the FDA to assess the reasonable expectation of safety of new ingredients, and it is impossible to do so scientifically without experimental data.

If the FDA succumbs to industry pressure, the public health consequences will be significant, as hundreds of thousands of Americans continue to turn to new supplements to sustain their health and treat their ailments. By insisting on scientific evidence to demonstrate the expectation of safety, the FDA will not only improve the safety of new supplements but also create a database of evidence that scientists, physicians, regulators, and consumers can tap to help make informed decisions about the use of supplements in the future.<sup>5</sup> But even if the guidance is strengthened and aggressively implemented, fundamental flaws in DSHEA, such as the lack of a preapproval review process for all supplements, will continue to limit the FDA's ability to ensure that dietary supplements are safe.

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## Improving Childhood Vaccination Rates

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Recently, the mother of a young child confessed to me that she didn't know any parents who were following the recommended immunization schedule for their children. She said that when she told her pediatrician she'd like to follow an alternative schedule, the physician had simply acquiesced, leading her to assume that the recommended schedule had no advantage over the one she suggested.

Despite the phenomenal success of childhood vaccination, thousands of U.S. parents refuse selected vaccines or delay their administration. Some choose not to vaccinate their children at all.

These parents are not a homogeneous group: some object to immunization on religious or philosophical grounds, some are avoiding an apparently painful assault on their child, and others believe that the benefits of at least some immunizations don't justify the risks. Since parents today have little or no experience with vaccine-preventable diseases such as polio, *Hemophilus influenzae* type b, or measles, they can't easily appreciate the benefits of vaccination or the risks of not vaccinating.

In 2010, California reported over 9000 cases of pertussis — more than the state had seen

since 1947. Of these, 89% occurred among infants younger than 6 months, a group too young to be adequately immunized and largely dependent on herd immunity for protection from infection. Ten of these infants died from their infection.

At first glance, U.S. vaccination rates appear reasonable: coverage among children entering kindergarten exceeds 90% for most recommended vaccines. A closer look, however, reveals substantial local variation. In Washington State's San Juan County, for example, 72% of kindergartners and 89% of sixth graders are either non-compliant with or exempt from

vaccination requirements for school entry. Only 52.5% of kindergartners and 4% of sixth graders were adequately immunized against pertussis for the 2010–2011 school year.<sup>1</sup> Not surprisingly, the county also has one of the state's highest incidence rates of pertussis.

Continued outbreaks of pertussis, measles, and *H. influenzae* type b indicate that U.S. vaccination levels are inadequate. Some physicians have taken matters into their own hands, refusing to see children whose parents won't allow them to be vaccinated. Others encourage alternative vaccine schedules in an effort to accommodate worried parents. Neither of these represents an adequate solution.

Because parents who oppose vaccination on the basis of personal beliefs will probably remain opposed despite the best efforts of clinicians and public health experts, the most effective way to increase vaccine coverage is to improve immunization rates among children whose parents either are open to vaccination but encounter barriers to obtaining vaccines or hesitate because of fears and concerns about safety. Health care professionals, health care organizations, and state and federal policymakers all share responsibility in this endeavor.

First, socioeconomic barriers and disincentives to vaccination should be eliminated. Even small copayments or administration fees pose substantial barriers for some families. Referral to a public health clinic is one option, but attending such clinics requires extra effort, travel, and time away from work — all disincentives to following through. Removing barriers to vaccination is an obvious first step to improving coverage. Some countries,

such as Australia, have gone further, offering incentives for vaccinating children on time. Incentives can take several forms, including reduced insurance rates, tax rebates, or direct payments.

Second, school-entry requirements should be strengthened and enforced. Such requirements effectively boost immunization rates for school-age children, but they vary widely by state, in terms of both the kinds of exemptions allowed and the ease of obtaining an exemption. All states allow exemptions for medical reasons, 48 for religious reasons, and 20 for philosophical reasons. Exemption rates vary widely, from less than 0.1% among kindergartners in Mississippi to 6.2% among those in Washington State.<sup>2</sup> Moreover, within Washington State, 2010–2011 exemption rates for K–12 students varied significantly by county, ranging from 1.2% to 25.4%.<sup>1</sup>

Although eliminating exemptions for religious and personal beliefs may seem logical, such efforts would encounter substantial resistance and probably increase antivaccinationist fervor. Some states might improve immunization rates by addressing the ease of obtaining exemptions and enforcing school-entry requirements. The exemption process should not be easier or less costly than the vaccination process. Obtaining a religious or personal-belief exemption should at least require a visit to the physician's office, including counseling on the risks posed by remaining unvaccinated; insurance should pay for such visits. States could also require that exemption requests be signed by both parents (if both possess legal decision-making authority). Although such measures wouldn't change the stance of the most resistant

parents, they would eliminate many exemptions sought because of convenience rather than conviction. Finally, lax enforcement of school-entry requirements sends the message that vaccination is merely a bureaucratic requirement, rather than a prerequisite for school attendance and a mechanism for ensuring students' safety.

Third, misinformation regarding vaccines must be addressed promptly and aggressively. False or misleading information about vaccination is widely dispersed by a few influential individuals, self-described vaccine-safety advocates, and some clinicians. Public health officials and professional organizations should respond swiftly to dishonest or unbalanced portrayals of vaccination.

Fourth, clinicians, health care organizations, and public health departments must learn to use the tools of persuasion effectively. In *The Art of Rhetoric*, Aristotle argued that persuasion requires not only a reasonable argument and supporting data, but also a messenger who is trustworthy and attentive to the audience and a message that engages the audience emotionally. Data and facts, no matter how strongly supportive of vaccination, will not be sufficient to compete with the opposition's emotional appeals. The use of a compelling story about a single victim of vaccine-preventable illness is far more likely than data to move an audience to action.<sup>3</sup>

Physicians represent the best opportunity to influence the vaccine-hesitant. Most parents trust their primary care providers and look to them for information and advice. Parents will be most receptive to considering vaccination if they believe their provider is primarily motivated by the welfare of the individual child rather

than an abstract public health goal. Demonstrating a willingness to listen respectfully, encouraging questions, and acknowledging parental concerns are essential elements of this strategy. Providing accurate information about both risks and benefits is crucial to maintaining trust; interactions should include discussion of risks associated with both remaining unvaccinated and delaying certain vaccines and a reminder that vaccinations are important in part because effective treatments do not exist for most vaccine-preventable diseases.

Effective communication requires understanding parents' reasons for resisting vaccination. Physicians should approach such reluctance as they would any diagnostic challenge. "Diagnosing" the reasons for hesitancy will permit a more effective discussion and approach. Parents concerned about the number of shots at a given visit or the side effects of a single vaccine require a different strategy from parents who believe vaccines weaken the immune system, cause autism, or contain

mercury. The Centers for Disease Control and Prevention, the American Academy of Pediatrics, and the American Academy of Family Physicians recently produced resources to assist clinicians in identifying communication strategies, enhancing trust, and providing reliable information ([www.cdc.gov/vaccines/conversations](http://www.cdc.gov/vaccines/conversations)).

Even with optimal communication strategies, some parents will remain hesitant to vaccinate their children. Maintaining the patient-provider relationship despite disagreement conveys respect, builds trust, and affords additional opportunities to discuss immunization. Asking parents who refuse to vaccinate their children to seek medical care elsewhere is counterproductive: it rarely gets a child vaccinated, it undermines trust, and it eliminates opportunities for continued dialogue about vaccination.<sup>4</sup>

Finally, clinicians must set an example. We're unlikely to achieve optimal vaccination rates until health care professionals comply with vaccine recommendations for themselves and their children.

The unwillingness of many clinicians to submit to influenza vaccination each year is disgraceful, sets a poor example, and gives patients reason to question the safety and efficacy of vaccines. A logical place to begin increasing public confidence in vaccines is with the example we set.

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## Keeping Score under a Global Payment System

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It is widely acknowledged that continued growth in health care spending is threatening the viability of the U.S. health care system. Although there are no clear comprehensive solutions to this problem, most observers see payment reform as the next best hope for reining in out-of-control costs. Our current fee-for-service payment system provides incentives to physicians to increase the delivery of services, which results in excessive utilization. Moreover, neither individual physicians nor

the patients receiving the services bear the brunt of these utilization decisions. Rather, they're reflected in ever-rising health insurance premiums or tax-financed government expenditures shared by all. Many observers are therefore calling for fundamental redesign of the ways in which physicians and hospitals are compensated for the care they provide. Most options call for bundling payments to physicians; specific approaches range from prospective payments for discrete episodes

of care (e.g., coronary-artery bypass surgery) to global payment or risk-based models of care.

Global prospective payments became prevalent during the heyday of managed care in the 1990s. Such so-called capitation payments were common in many markets, whereas in others physician organizations were actively preparing themselves for a coming tide of capitation that never materialized. In a fast-growing economy, both patients and physicians bridled at the restrictions of choice and ac-