be how states approach the interactions between the insurance exchanges and Medicaid; adults with incomes close to 133% of the federal poverty level may not know which program they should apply to, and states should take steps to prevent uninsured adults from falling through the cracks. Other approaches to streamlining Medicaid enrollment will also need to be considered. The natural experiment of having 50 different states with highly variable participation rates offers ample opportunity for exploring the policy options.

The impending Medicaid expansion will be the single biggest change in the program since its inception in 1965. The success of health care reform in improving access to care will largely depend on whether newly eligible individuals enroll in Medicaid and remain enrolled. Though the details of enrollment outreach, application processes, and renewal procedures may not be glamorous, they hold the key to success in expanding health insurance coverage to millions of needy Americans.

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Pharmaceutical Marketing and the New Social Media

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Facebook and Twitter, the largest social media Web sites, have more than 350 million users worldwide, and surveys indicate that 60% of Americans turn first to the Internet when seeking health-related information.[1] It is therefore surprising that the pharmaceutical and medical-device industries have been slow to establish a social media presence. The drug industry allocated less than 4% of the more than $4 billion it spent on direct-to-consumer advertising to Internet outlets in 2008, and only a tiny fraction of that was for social networking sites.[2] In the next year, however, the proportion may change substantially.

Since the Pure Food and Drug Act was passed in 1906, control by the Food and Drug Administration (FDA) over drug labels has been one of its most powerful tools for protecting the public's health. To encourage appropriate use of prescription drugs, the FDA has sought to ensure that promotional statements make claims about approved indications only and neither overstate the benefits nor understate the risks. A major concern has been finding ways to ensure "fair balance," with adequate attention given to information about risks as well as benefits. When this balance is not achieved, inappropriate promotional statements can contribute to misuse of drugs, with dangerous consequences.

As communications media have evolved, manufacturers have tended to wait for the FDA to establish explicit codes of acceptable marketing practices before devoting substantial resources to a new medium. Direct-to-consumer advertising in print media proceeded tentatively until the FDA issued a guidance document in 1985 establishing a standard format for providing a "brief summary" of risks.[3] Prescription-drug advertising in broadcast media was similarly minimal until the FDA's guidance revised the definition of "adequate" risk information in 1997, and again in 1999, to permit broadcast media to include references to a toll-free number or Web site where consumers could obtain more detailed descriptions of a product's adverse effects. In the wake of these FDA actions, spending on direct-to-consumer advertising mushroomed from $579 million in 1996 to $1.3 billion in 1998 and to over $4 billion in 2008.

In November 2009, the FDA

convened a public hearing to discuss pharmaceutical promotion through Web-based social media,[4] which present some new challenges. First, it is unclear how to provide fair balance in the dynamic and expanding matrix of networked media — not to mention in a 140-character Twitter post. For static Web sites, manufacturers had been using a "one-click rule," ensuring that risk information was no further away than a single tap of the finger. This approach remains controversial; in April 2009, the FDA issued warning letters to 14 manufacturers who sponsored search-engine ads for prescription drugs in which there was no obvious connection to a statement of risks. In addition, there is growing concern about the effectiveness of the strategy: the mere possibility of access to risk information does not necessarily translate into a realistic presentation of risks.

Another important consideration regarding Web-based social media is that manufacturers may lose control over the content of the promotional message. Companies may intend to draw a line dividing their own media (such as a company Web site or a company-initiated chat area) from other online discussions of their products. But even if such a distinction were feasible, it would still be possible for manufacturers to support third-party bloggers, posters, and Twitter users who make flattering claims and discredit negative claims about their products in online discussions. Furthermore, the proposed distinction may no longer be technically possible, since entrepreneurs have effectively blurred the line between company-controlled Web sites and the general blogosphere. Google, for instance, with its "Sidewiki" application, can layer a social network of commentary onto any existing static Web site, with or without the site owner's consent.

The FDA may reasonably conclude that fair balance in Web-based social media cannot be implemented in a way that is compatible with public health needs, and it may try to ban pharmaceutical promotion entirely from these media. If, as media analysts predict, the agency instead issues new guidance, there will probably be an explosion of marketing in online social media, as there was in print media in the 1980s and broadcast media in the 1990s. We believe there are three aspects of pharmaceutical promotion in new social media to which physicians should pay special attention.

First, there is a dearth of research on the clinical and public health impact of communication about drugs. Such work should not be led solely by entities with financial interests in its outcome. Since the FDA hearing last November, an industry-funded, Internet-based social network called #FDASM has been maintaining an active Twitter feed and has been actively soliciting empirical research to justify recommendations for FDA-sanctioned Web 2.0 promotional activity. As medical messages on social media become increasingly available to patients, clinicians will need to better understand the impact of these media, especially in terms of product promotion.

Second, it is crucial to address the problem of disclosure of financial interests in social media. Although most Internet users can often (but not always) find data on drugs' risks and benefits within a few keystrokes, it is hard to determine whether the source is credible and disinterested. It is now recognized that the ghostwriting of medical research articles can have important public health implications; financial disclosures should be just as explicit for leading providers of social media content as for authors of articles in peer-reviewed journals.

Third, physicians and consumers should hold the FDA and pharmaceutical manufacturers responsible for maintaining credible information in social media regarding the benefits and risks of therapeutic products. One suggestion that emanated from the FDA hearing was a call for a digital FDA "seal of approval" that would identify FDA-reviewed content in posts and discussion threads and provide a hyperlink to pages with FDA-approved content. But this approach would address only a fraction of potential therapy-related claims, and the FDA lacks the resources to police all health-related marketing in social media. Manufacturers are in a better position to monitor online discussions about their products: most U.S. companies that depend on copyright and trademark recognition currently engage in brand-protection activities through aggressive surveillance and litigation.

Debate over the regulation of these new media harkens back to days when a different seal of approval — that of the American Medical Association (AMA) — was placed in medical journals next to drug advertisements that had met rigorous informational standards. The AMA's Seal of Acceptance program ran from 1929 to 1955 and became the strongest tool for regulating pharmaceutical promotion during that period. Social media of the 21st

century are far more complex. Given the potentially important health implications of drug promotion in these media, regulators and manufacturers will have to share the responsibility for oversight.

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