

LAW & MEDICINE

Is It Time for Universal Health Coverage?

With Sen. Edward M. Kennedy (D-Mass.), a staunch supporter of patient rights and health care, now battling brain cancer, the subject of health care in our nation becomes all the more poignant. In a two-part series, we will consider this important issue.

Our present health care system is broken, and we need an updated model. A March 17, 2008, *Fortune* magazine article reported that the United States now has 47 million uninsured residents, and that, according to the Department of Health and Human Services, health care expenditures will double by 2017, to \$4.3 trillion. Insurance rates have jumped 72% since 2002 (according to the Henry J. Kaiser Family Foundation), Medicare is facing more red ink as baby boomers age, and fewer and fewer employers are offering health care insurance as part of an employment package. And even though the United States is the richest country in the world, the World Health Organization recently ranked it 37th in terms of health care quality and fairness.

Health care is a top-tier issue for our presidential candidates. The American electorate demands change in the health care system. This time, whoever takes the Oval Office must ensure that change comes about so that all Americans are provided adequate health care at affordable prices.

The first question to be answered is: Should all Americans be entitled to health care? It is a simple question but one that has produced considerable debate, because we as a nation have never considered health care to be a right. Should it be? If it should not become a fundamental right, should some Americans—such as children—have health insurance coverage guaranteed to them?

The permutations are many, but there is only one right and fair choice: All Americans, including those taking overt steps to become citizens, should be provided

health care as a matter of a new social policy. All Americans should be provided health care for many of the same reasons that led to Medicare's passage in 1965: The crisis is as widespread and pervasive today as it was in the years preceding Medicare's enactment, and some type of relief is warranted on a national level, but for all U.S. citizens—not just for seniors.

Additionally, as in the movie "The Perfect Storm," events and factors may come together during the next election cycle that rarely, if ever, do, increasing the chance that the existence of real health care reform may become a reality. These would include the make-up of Congress, the occupant of the White House, the existence of a crisis in providing medical care to all citizens, and the need to fix a broken-down system that, if fixed, would

enable all Americans to maintain, or regain, their health without being a burden on the economy in the long run.

Who should pay for that care is an important issue, but that should not be the engine that drives the car. Instead, we should declare that all Americans should have access to health care, and then figure out how to achieve that goal.

The two major-party presidential candidates, Sen. John McCain (R-Ariz.) and Sen. Barack Obama (D-Ill.) have very different approaches to the problem. Sen. McCain declares himself to be a free-market guy, believing that government intervention proposed in Democratic plans would be shackled with "inefficiency, irrationality and uncontrolled costs." He maintains that what voters want "[is] choice of doctors and health plans, and lower cost." A fundamental principle of his plan is that no American should be required to buy health insurance; he sees health insurance not as a right but as something that citizens choose to buy.

As noted in the *Fortune* article, Sen. McCain says his plan would "tax employer-

sponsored health insurance, and use the money to provide tax credits (up to \$5,000) for individuals and families to shop for coverage on their own," thereby "forcing insurance companies to compete" for customers" and ostensibly lowering prices. He has also proposed a creation of a Guaranteed Access Plan to help ill and high-risk patients obtain "coverage of last resort." He also would not require insurers to sell policies to those with preexisting medical conditions. His message makes for nice sound bites, but the devil is in the details.

The underpinning of McCain's plan involves the elimination of the tax break that employees now receive when their employer provides their health insurance. The employee would have to pay tax on the cost of an employer-provided plan for that employee or his family. With the federal dollars saved by eliminating the tax break, McCain would provide a \$2,500 federal tax rebate for individuals and \$5,000 per family that could be used toward the purchase of private health care policies. Sen. McCain expects that this would result in many fewer people opting for employer-sponsored health benefits, hopefully allowing employers to use the money they would have spent on health benefits to increase employee salaries.

Under that setup, the net effect for the employee would be that he would take the extra salary, less the tax on it, plus Sen. McCain's credit, and use that money to buy private health insurance. Added to all this is the Health Savings Account, which would allow a family to put away \$5,800 yearly toward medical care and treatment, before taxes.

In addition, Sen. McCain would allow the individual to purchase the health plan that best fits his or her stage in life, allowing insurers to offer an array of plans, with various benefits, copays, and deductibles. As one writer has observed, however, the downside is that "he risks leaving the poor and sick behind" (although one McCain lieutenant says the tax credit would be increased for that patient population).

Sen. Obama describes his plan as providing affordable and portable health coverage for all and lowering costs by modernizing

the health care system. Specifically, he would require that no American be turned away from any insurance plan because of an illness or a preexisting condition. Americans would receive benefits similar to those that Sen. Obama and other members of Congress receive through the Federal Employees Health Benefits Program. He also calls for a National Health Insurance Exchange to assist individuals who wish to purchase a private insurance plan.

Employers that do not offer or make a "meaningful" contribution to the cost of quality health coverage for their employees would be required to contribute a percentage of payroll toward the costs of a national plan, although some small employers would be exempt from that requirement. Parents would be required to provide coverage for their children. States whose health reform plans are equally as generous as a national plan would not be preempted, and eligibility for Medicaid and the State Children's Health Insurance Program programs would expand. Sen. Obama says private insurance premiums would drop by \$2,500 per year per family under this scenario.

For physicians, Obama's plan would strengthen comparative effectiveness research by establishing an independent institute to guide reviews and studies, giving physicians and patients up-to-date clinical information. Another part of his plan would strengthen antitrust laws to prevent insurers from overcharging physicians for their malpractice insurance and would work to improve systems that eliminate errors in patient care and safety. Again, nice bullet points, but crafting all his points into a workable solution for a majority of Congress will take some doing; he predicts passage no later than 4 years from now.

In our next column, we will look at what U.S. history and health plans in other countries can teach us about health reform. ■

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BY MILES J. ZAREMSKI, J.D.

FDA Proposes Changes to Pregnancy Information on Labels

BY ELIZABETH MECHCATIE
Senior Writer

The system that uses letters of the alphabet to categorize drugs' pregnancy and lactation risks will be eliminated and replaced by a more consistent format designed to be more comprehensive and useful to health care professionals and patients who are of childbearing age, pregnant, or breast-feeding, the Food and Drug Administration recently announced.

The proposed rule would change the content and format of the pregnancy and lactation in-

formation that is included in the labeling of human drugs and biologics. Under the proposal, the drug label "would explain the potential benefits and risks for the mother, and the developing baby or fetus, and how these risks may change over the course of pregnancy," Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs, said during a media briefing.

Established in 1979, the current category system uses the letters A, B, C, D, and X to indicate degrees of risk associated with a drug or biologic during pregnancy. The system has been criticized by many in the medical community

as providing an inaccurate and oversimplified view of the information available on a drug, and has caused difficulty in updating specific labels as new information on drugs becomes available.

Under the proposed rule, labels would also include "relevant clinical information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and/or lactation," according to the FDA.

The letter system would be replaced by a pregnancy section, which would contain three subsections:

► The "Fetal Risk Summary"

would summarize known risks of the drug for a fetus and, in the event of a risk, would explain whether that risk is based on human and/or animal data.

► "Clinical Considerations" would include information about the effects of a drug taken by a woman before she knows she is pregnant.

► "Data" would provide details on the available human and animal data found in the fetal risk summary on the effects of the drug.

The pregnancy section would also contain information about available pregnancy registries of women exposed to specific drugs.

There would also be a lactation section, which would include the same three subsections used in the pregnancy section.

The section on labor and delivery, which is included in current labels, would be eliminated; information on a drug used during labor and delivery would be included in the pregnancy section.

Once the rule is finalized, the new format would be required for the labels of newly approved drugs. Manufacturers of drugs that are already approved would be required to comply over a certain number of years or when another change is made to the label. ■