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Washington Update

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WASHINGTON UPDATE:

The Presidential Race in Health Care

As of mid-April 2008, Senators Hillary Clinton and Barack Obama are still competing for the Democratic Presidential Nomination, while Senator John McCain is the Nominee-in-Waiting for the Republican Party. All three of the candidates have put forth their opinions and proposals for health care reform with varying degrees of complexity. Each generally advocates for raising the quality of patient care and chronic disease management, creating health care cost transparency, broadening the implementation of electronic health information technology, and ensuring drug costs and health care coverage are less tied to an individual's employer. However, this is where many similarities end.

Hillary Clinton has taken the position that affordable, accessible, and adequate health care is everyone's responsibility. Her plan would mandate that individuals buy into some form of health insurance with subsidies and tax credits tied to income to assist those who are otherwise unable to afford coverage on their own. Large employers would be required to either provide coverage or contribute to coverage for their employees. Small employers would be given tax credits, enabling them to provide coverage to their employees. Senator Clinton's plan would allow insured individuals either to maintain their current insurer or choose another insurance provider. Those who elect to obtain new coverage would be able to choose between new plans with private options modeled after the Federal Employee Health Benefit Program (FEHBP) and a public plan modeled after Medicare.

Barack Obama advocates towards the same goal of universal health care for all Americans. However, his plan only requires that children receive full coverage. His plan would also allow individuals to participate in their parents' health care plan until reaching 25 years of age. Senator Obama would further create a "new national health plan" with guaranteed eligibility for all Americans that would include benefits based on FEHBP. For individuals with lower incomes, Obama would seek to expand Medicare and the State Children's Health Insurance Program (SCHIP). His plan would also provide additional subsidies for those with higher incomes which would otherwise disqualify them from Medicaid and SCHIP. Senator Obama also advocates for more flexibility for states to institute reform and for federal health care initiatives targeting areas such as HIV/AIDS, autism, mental health care, and lead poisoning.

John McCain has been advocating for health care reform that provides for "personal . . . and economic freedom for everyone." McCain's plan includes tax credits of up to $2,500 for individuals and $5,000 for families, which will enable them to purchase insurance coverage independent of their employers. His plan also advocates for medical liability reform, especially to protect those physicians who follow clinical and safety protocols when treating patients. McCain has emphasized that families should have autonomy over medical decisions, so that they may genuinely consider financial constraints and the individual needs of their family members. Further, he advocates for health care cost transparency and the use of vehicles such as tax-exempt health savings accounts. Senator McCain's proposed individual responsibility would be bolstered by the increased competition created through the freedom for individuals to seek and for insurers to provide health care across state lines via the internet and other means.

The national elections are still many months away, and the candidates' diverse health care platforms will undoubtedly continue to develop as Election Day draws nearer.

Court Rules in Favor of FDA Preemption in Medical Devices

Preemption by Food and Drug Administration's (FDA) regulations has been a prominent issue before the Supreme Court in 2008. Specifically, this issue has arisen in the context of litigation against manufacturers of pharmaceuticals and medical devices. In Riegel v. Medtronic, 128 S. Ct. 999 (2008), the Court issued a decisive 8-1 decision ruling in favor of allowing FDA regulations to preempt certain state tort actions based on defective medical devices. Justice Scalia, writing for the majority, concluded that,if a medical device has passed the FDA's preapproval regulatory process, then it should not be subject to any further litigation in state courts for subsequent defects. The Court held that the Medical Device Amendments (MDA) of 1976 give the FDA exclusive power over the premarket approval process, and thus bar plaintiffs' from initiating common law negligence and strict liability claims in state courts which may impose duties of safety and effectiveness on manufacturers that exceed the scope of the FDA regulations. The Court relied on the FDA's administrative expertise in making final determinations on medical devices after weighting the associated risks and benefits, and reasoned that jurors cannot be trusted to accurately assess the same risks and benefits.

To date, the Court has not reached a consensus on whether FDA regulations should also preempt all common law personal injury suits against pharmaceutical manufacturers, The Court reached a 4-4 split in Warner-Lambert v. Kent, 128 S. Ct. 1168 (2008), the case addressing this issue. The decision did not issue an opinion, but essentially affirmed the Second Circuit's view that FDA regulations did not preempt this particular Michigan personal injury lawsuit against the allegedly defective drug Rezulin®. Notably, this may not be the ideal test case as it involved a rather narrow preemption issue.

The Court has expressed its interest in deciding the issue of whether FDA regulations preempt all pharmaceutical litigation, including defective design, inadequate warnings, and manufacturing defects. Indeed, in October of this year, the Court will hear the landmark case of Wyeth v. Levine, 128 S. Ct. 1118 (2008), and possibly preempt the entire realm of personal injury lawsuits against pharmaceutical manufacturers. In January 2006, the FDA issued a strong statement in the Federal Register supporting the preemption of all conflicting state

laws. The ultimate holding of Levine may well hinge on the amount of deference the Court is willing to yield to the FDA's expertise.

The Third Circuit's ruling in Colaccio v. Apotex Inc. in April 2008, a case brought by the families of two people who committed suicide while on antidepressants, provided a possible preview of the treatment of preemption in the drug industry. The court held that the drug manufacturer was shielded from liability under state law for failure to warn because of the preemption of established FDA rules.

Proposed Change to Physician Education about New Drugs

On March 12, 2008, the U.S. Senate Special Committee on Aging Chairman Herb Kohl (D-WI) held a hearing to propose changes to the current practice of pharmaceutical companies educating physicians about their own pharmaceuticals. Chairman Kohl and Senator Dick Durbin (D-IL) plan to introduce legislation this spring which will seek to ensure that physicians receive unbiased information about new pharmaceuticals. The bill will include the provision of grants to fund the dissemination of neutral information to physicians through educational materials and medical professionals' personalized visits to physicians' offices.

This proposed legislation may negatively affect the pharmaceutical industry's current marketing strategy since an integral component of many companies' marketing schemes relies upon the company's direct distribution of product information to physicians. Nonetheless, in the hearing, Chairman Kohl emphasized the importance of academic detailing, and stated that, "[w]ithout academic detailing, physicians may not have access to information about the full array of pharmaceutical options, including low-cost generic alternatives. However, research has shown that when they do, doctors prescribe the best drug — not just the newest one — and health care spending is lowered."

The March 2008 hearing was conducted as follow-up to a hearing held in June 2007 in which the Committee evaluated the current relationships between physicians and drug companies. During the preceding hearing, Chairman Kohl and Finance Committee Ranking Member Senator Charles Grassley (R-IA) proposed the Physician Payment Sunshine Act (S. 2029), which requires manufacturers of pharmaceuticals, medical devices, and biologics to provide information about money they spend marketing their products to physicians. The pharmaceutical industry has opposed the Physician Payment Sunshine Act, claiming that it impedes the industry's ability to provide information to physicians about these medical resources.

Updating the Family and Medical Leave Act

The Family and Medical Leave Act (FMLA), enacted in 1993, allows eligible employees to take up to 12 weeks of unpaid leave due to a serious medical condition or to care for a new child. After the fifteenth anniversary of the law's enactment, the Senate Committee on Health, Education, Labor and Pensions (HELP) held a hearing on February 13, 2008 to discuss the future of FMLA. Senator Chris Dodd (D-CT), Chairman of the HELP Subcommittee on Children and Families and drafter of FMLA, discussed a new bill that would provide paid leave to employees and new FMLA regulations recently proposed by the Department of Labor (DOL).

The DOL has proposed several regulations to amend FMLA. One proposal would reverse the current provision allowing employees the leeway to call their employers for up to two days after an absence, eliminating a provision which protects employees facing unpredictable and sudden family medical emergencies. The new regulations would also allow employers to ask for documentation regarding the medical conditions of their employees twice a year, regardless if the employees' medical conditions are chronic or permanent.

In addition to the proposed changes related to employees, the DOL also seeks public comments on a new bill related to veterans (H.R. 3556). This bill would amend the FMLA to allow eligible employees to take up to 26 weeks of leave to care for an ill or injured family member who is on active duty or has active duty status. The proposed changes also include at least one pro-employer provision, which would allow employers to deny perfect attendance awards or benefits to employees that utilize FMLA leave days.

Proposed Legislation Aims to Provide "Sunshine" in Industry Relationships

House and Senate bills titled the "Physician Payments Sunshine Act of 2008" appear to be moving swiftly through Congress. The legislation (H.R. 5605 and S. 2029), sponsored in the Senate by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI), require quarterly reporting of all transfers of value in excess of $25 between manufacturers of drugs and devices, including compensation, gifts, speaking and consulting fees, and physician ownership or investment interests. The bills make an exception for product samples that are intended for a patient. The legislation provides for delayed reporting of clinical trials. Penalties for noncompliance include a fine between $10,000 and $100,000. Some manufacturers, such as device maker Zimmer, have provided support for the bills. The legislation is partly a response to recent media attention to industry sponsored drug studies where compensation reports have not been properly disclosed. Senator Grassley believes that "a little bit of sunshine will go a long way" in promoting the best interests of patients in a fair market health care sytem.

Biswajit Chatterjee, Chandana Kolavala, Thomas B. Sparkman, and Rebecca L. Wolf contributed to this column.