Obama Team Brings ‘Consumerist,’ Public Interest Attitude to Drug Issues

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Drug industry concerns will be flying fast and furious through the Washington air this year as health care reform and resurrection of the FDA take center stage. The Obama health care team, finally fully in place and notable for its lack of business experience—in the drug industry and elsewhere—will bring its “consumer-centric” and public interest sensibilities into play. The top officials at the Department of Health and Human Services (DHHS), the FDA, the Federal Trade Commission (FTC), and the Justice Department will be willing lieutenants in General Obama’s campaign to impose key health reform goals such as reducing the cost of prescription drugs and providing competition to health insurers.

The Obama team is stacked with former government officials. Margaret Hamburg, MD, a former New York City health commissioner and DHHS official during the Clinton administration, is the new FDA Commissioner. Her expertise is in the area of bioterrorism and public health, having gotten kudos for her campaign against tuberculosis in New York City in early 1992. Her top deputy, Joshua Sharfstein, MD, was chosen for the number two position at the FDA, in part because he once worked on Capitol Hill for Representative Henry Waxman (D-Cal.), chairman of the powerful Energy & Commerce Committee, which has jurisdiction over the FDA. Mr. Waxman is a long-time antagonist of the brand-name pharmaceutical industry. Dr. Sharfstein was in the running for the top job but was apparently nixed because of opposition from large drug companies. He is clearly the power behind the throne at the FDA. And he, like Mr. Waxman, has a certain antipathy for the brand-name drug industry, reflected by the fact that he worked early in his career for Public Citizen’s Health Watch. He has also been a frequent critic of the drug industry’s marketing practices.

Both Drs. Hamburg and Sharfstein report to Kathleen Sebelius, DHHS secretary, formerly the insurance commissioner and governor of Kansas. Her claim to fame—which she touted in her confirmation hearings—is that she pushed her state to adopt a patient-protection bill and then, in her words, “took the unprecedented step” of blocking the sale of Blue Cross and Blue Shield of Kansas to the health care holding company of Anthem of Indiana. She did that to avert increases in health insurance premiums.

It is not a great leap from opposing big health insurance companies to opposing big pharmacy benefit managers (PBMs). In that regard, Ms. Sebelius, Jon Leibowitz, JD, and Christine Varney, JD, may be birds of a feather. Jon Leibowitz is the new chairman of the FTC, and Ms. Varney is Assistant Attorney General in charge of antitrust matters; as the top antitrust regulators, they will both have something to say about Express Scripts’ acquisition of Wellpoint’s PBM. The National Community Pharmacists Association not only is pushing for the Obama administration to either disallow the acquisition or place significant restrictions on it but also wants Jon Leibowitz to revisit the FTC’s approval in 2007 during the Bush administration of the CVS–Caremark merger. He has a clear, pro-competition streak. Last February, for example, he called Solvay’s attempt to protect its monopoly of its testosterone product AndroGel “yet another example of pharmaceutical companies turning competition on its head.” He is not likely to be a big fan of PBM consolidation either.

Jon Leibowitz objected to Solvay’s payments to generic competitors because the company blocked cheaper, generic versions of AndroGel. “Generics” will be the watchword of the Obama health care team. Republicans in Congress, often allies of the brand-name drug industry, have no problem with this conceptual goal. That was reflected by the first question asked of Dr. Hamburg during her confirmation hearing by Senator Mike Enzi (R-Wyo.), the top Republican on the Senate Health, Education, Labor, and Pensions Committee. He wanted to know whether he and the Democrats he is working with could count on her support when they reintroduce bipartisan legislation, creating a regulatory pathway at the FDA for approval of “biosimilar” drugs. Sometimes known as “biogenerics” or “follow-on biologics,” these protein-based drugs are essentially pharmaceutical preparations based on a biologically active substance for which the patent has expired. The brand-name precursors of these drugs are extremely expensive. Dr. Hamburg quickly assented but echoed a point made by Mr. Enzi: in allowing for FDA approval of biosimilar drugs, the FDA would have to keep alive the incentives for innovator companies to create those products while at the same time making it easier for biogenerics to come to market because of their considerably lower prices.

Dr. Hamburg will also be pushing hard to win faster approval of conventional generics. The FDA’s proposed $3.2 billion budget for 2010 is a whopping 19% increase over that for 2009, but $295.2 million of the $510.6 million increase represents budget authority; the remainder represents increases in industry user fees. When he appeared before a House Appropriations subcommittee in May, Dr. Sharfstein explained that the FDA’s big initiative in the drug area was getting congressional approval for new user fees that would be paid by generic companies in exchange for faster FDA approval. The FDA wants to raise $36 million from the industry in 2010 for that program.

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Kathleen Jaeger, President of the Generic Pharmaceutical Association, says that her industry “remains open” to a generic user fee program as long as there are guarantees that the fees would result in the timely review and approval of generic applications.

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