



ML Strategies Update

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Health Care Update

- **Judge Rules Against 340B Drug Authority:** A federal judge in the DC District Court [ruled](#) that the Department of Health and Human Services (HHS) does not have the authority to implement regulations related to provisions in the Affordable Care Act (ACA) to expand the 340B drug discount program to rural and cancer hospitals. The regulation would have allowed certain health care facilities to access 340B discounts on orphan drugs for non-orphan indications. Safety Net Hospitals for Pharmaceutical Access [released](#) a statement expressing its disappointment in the ruling. This may have significant implications for the much anticipated 340B “mega-rule” that is currently under review at the White House and was expected as soon as this month. Most analysts believe that the ruling is limited to the orphan drug issue because the ACA did not direct HRSA to make exceptions for orphan drugs. However, if the court ruling is interpreted to be broader, then Congress would have to step in via legislation to reign in possible overuse of the program. For more information on the ruling, please read our [Mintz Levin Health Policy Law Matters Blog](#).
- **FDA Approves Skin Infection Drug:** On May 23rd, the Food and Drug Administration (FDA) approved the drug Dalvance, an antibacterial to treat adult skin infections. The approval comes as policymakers and regulators show increasing concern that, given the recent rise in infectious diseases, fewer antibiotics are being approved. Reflecting this concern previously lawmakers have put forward legislation, such as the Generating Antibiotic Incentives Now (GAIN) Act, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act, and the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act—all designed to increase R&D incentives to the biopharmaceutical community and promote FDA regulatory reforms. Having gained approval under the FDA Qualified Infectious Disease Product Designations (QIDP) program—enacted under the Food and Drug Administration Safety and Innovation Act (FDASIA)—Dalvance will enjoy an added five years of market exclusivity. Several other drugs have received QIDP designations in recent months, including: Astellas’ Isavuconazole, Actelion’s Cadazolid, and SCYNEXIS’ Antifungal Agent SCY-078.

Implementation of the Affordable Care Act

IRS Prohibits Dumping into ACA Exchanges: The IRS has [ruled](#) that an employer payment plan cannot include an arrangement in which employers provide a tax-free contribution for their employees to purchase plans on the ACA exchanges.

FOIA Suit Filed Against HHS over MA: The Center for Public Integrity has [sued](#) HHS under the Freedom of Information Act (FOIA) seeking records related to the oversight of Medicare Advantage (MA) health insurance plans and allegations that HHS is overpaying the privately-run plans.

WH Argues Slow Growth in Health Costs Continuing: In a blog post, the White House [argued](#) that underlying slow growth in health care prices is continuing, despite an increase in health spending as coverage expanded due to the ACA.

Half of Uninsured Eligible for Financial Assistance: A new report from the Robert Wood Johnson Foundation and the Urban Institute [found](#) that over half of the uninsured were eligible for financial assistance with health insurance through the ACA. In states that expanded Medicaid, 68% of uninsured were eligible for assistance, while only 44% of uninsured were eligible for assistance in states that did not expand Medicaid.

Senators Question Subsidies' Accuracy: Senators Mitch McConnell (R-KY), Orrin Hatch (R-UT) and Tom Coburn (R-OK) [wrote a letter](#) to the HHS Inspector General urging him to examine reports that more than 1 million Americans may be receiving incorrect subsidies on the ACA exchanges.

Other Federal Regulatory Initiatives

Hagel Orders Military Health System Review: Defense Secretary Chuck Hagel has [ordered](#) a comprehensive review of the military health system to assess the safety and quality of care in military facilities and in health care purchased from civilian providers.

President Obama Highlights Youth Concussions: President Obama [highlighted](#) concerns about youth concussions at the Healthy Kids and Safe Sports Concussion Summit at the White House, where he discussed efforts to combat concussions and highlighted new funding for concussion research.

NIH Launches Pain Research Database: The National Institutes of Health (NIH), along with five other agencies, [launched](#) the Interagency Pain Research Portfolio, a database which will provide information about pain research and training activities.

Tavener Defends Data Release: Centers for Medicare and Medicaid Services (CMS) Administrator Marilyn Tavenner [defended](#) the release of data about physicians and health care providers in an article in the New England Journal of Medicine and that CMS plans to release more data.

Medtronic Pays \$9.9 Million to Resolve Kickback Claim: Medical device manufacturer Medtronic Inc. [paid](#) \$9.9 million to resolve claims by the Department of Justice that it paid illegal kickbacks to physicians to induce them to implant Medtronic pacemakers and defibrillators.

FDA Reclassifies Sun Lamps: The FDA has [issued](#) a final order reclassifying ultraviolet tanning lamps from class I to class II, which require manufacturers to submit a pre-market application and require them to carry warnings that they should not be used by those under the age of 18.

PCAST Report on Systems Engineering: The President's Council of Advisors on Science and Technology (PCAST) [issued](#) a new report recommending the use of systems-engineering principles in health care to improve

the efficiency and quality of care. To do so, they recommend eliminating the fee-for-service payment model.

Other Congressional and State Initiatives

Approps Committee Urges Analysis of Drug Labeling: The House Appropriations Committee has [released](#) report language for its Agriculture appropriations bill, which includes a request that the Food and Drug Administration (FDA) conduct a new economic analysis of the generic drug labeling rule.

Senators Request Lung Cancer Screening Coverage: Forty-four senators led by Dianne Feinstein (D-CA) and Johnny Isakson (R-GA) [sent a letter](#) to CMS Administer Tavenner requesting that CMS provide coverage for a new form of lung cancer screening which they argue is more effective at detecting cancer early.

Other Health Care News

NCHC Launches Campaign on Sovaldi Pricing: The National Coalition on Health Care (NCHC) [launched](#) the “Campaign for Sustainable Rx Pricing” to highlight unsustainable and abusive medication pricing. The campaign specifically highlighted the hepatitis C drug Sovaldi, which costs \$1,000 per pill.

Health Care Sector Worst at Cybersecurity: BitSight Technologies [released](#) a report which found that the healthcare sector was worse than the financial, utilities, and retail sectors at responding to cybersecurity threats and had the slowest response time to threats.

Discrimination Alleged Against FL Insurers: The AIDS Institute and the National Health Law Program have [filed](#) a complaint with the Office of Civil Rights at HHS alleging that four Florida insurers discriminated against those with HIV/AIDS by structuring their prescription drug policies in a way that discourages them from applying.

Upcoming Hearings and Markups

The House is in Recess.

Senate

On June 5th, the Senate Veterans' Affairs Committee will hold a [hearing](#) on pending legislation including veterans' health care, education, job-training and other benefits.

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