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HOT TOPICS IN HEALTH CARE REFORM

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The Patient Protection and Affordable Care Act (ACA), colloquially known as Obamacare, is in full effect and its impact is palpable throughout the drug development industry. Enacted on March 23, 2010, and modified soon thereafter by the Health Care and Education Reconciliation Act of 2010, this hotly contested legislation which amends the Public Health Service Act includes programs and provisions squarely focused on clinical research. Of particular interest to trial sponsors, researchers and sites – the Act allows for 1) the establishment of a streamlined U.S. Food and Drug Administration pathway for the approval of generic biosimilars; 2) a concerted effort to increase minority representation in clinical trials; 3) the creation of the Cures Acceleration Network, a translational research initiative at the National Institutes of Health; and 4) the launch of the Physician Payments Sunshine Act, intended to promote transparency regarding recompense for research participation.

Let's take a broad look at each applicable legislative component.

SECTION 7002 — APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS

According to market research by Datamonitor, global sales of biosimilars are expected to reach $3.7 billion this year compared to $243 million in 2010 – largely due to impending patent expirations for more than 30 blockbuster biologicals with estimated annual sales of $51 billion. The Biologics Price Competition and Innovation (BPCI) Act of 2009 establishes a new abbreviated pathway for FDA licensure of biosimilars, defined as protein-based biologicals that are similar to or interchangeable with reference biologicals already authorized for use, with no meaningful difference in terms of quality, safety or efficacy.

For patients, the BPCI Act may mean greater access to safe, effective and lower-cost drug alternatives. From the drug manufacturer's perspective, however, it can mean higher up-front costs and longer time to market. The U.S. Federal Trade Commission estimates that biosimilars cost between $100 million and $200 million and take 8 to 10 years to develop. By comparison, generics cost between $1 million and $5 million and take 3 to 5 years to develop. Many logistical questions and concerns persist as well, including determining an appropriate reference product; ensuring comparable quality between the reference product and biosimilar; and supplying sufficient data to support a biosimilar application, namely, clinical data which may require additional, costly clinical trials.

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Under the ACA, a biosimilar may not be approved until 12 years after the reference product was first licensed under the Public Health Service Act. This 12-year exclusivity period comprises an initial 4-year data exclusivity period, during which the approval application for the biosimilar drug cannot be filed with the FDA. This is followed by an 8-year period of market protection, when the application may be filed and provisionally approved. Final approval is not granted until this second period has passed.

Due to the complexity and cost of biosimilar development, collaboration is a growing trend in the industry with alliances between pharma and pharma, pharma and manufacturer, and pharma and CRO. The latter represents the newest collaborative model, as CROs move from merely supplying clinical and regulatory support to being key stakeholders.

As of September 17, 2013, no biosimilars had been licensed under the new law. However, 17 Investigational New Drug Applications for biosimilar development had been submitted to the FDA.

SECTIONS 10334 AND 4302 — MINORITY HEALTH EQUITY

Disparate access to quality health care and disproportionately low participation in clinical research have long plagued ethnic minorities in America. But under health care reform the Department of Health and Human Services (HHS) Office of Minority Health is striving to mitigate these issues by, among other things, analyzing subpopulation data and promoting increased clinical trial participation among minority patients and minority health professionals.

Section 4302 requires the HHS to ensure that any “ongoing or federally conducted or supported health care or public health program, activity, or survey” collects and reports data on the race, ethnicity, and primary language of applicants, recipients, or participants.” Conversely, Section 10334 establishes Offices of Minority Health within six key HHS agencies, and directs the HHS Secretary to award grants to public and nonprofit private entities in communities of color to improve the health status of racial and ethnic minorities.

The Act also reauthorizes and expands scholarships available through the Centers of Excellence (COE) program – a congressionally mandated initiative established to help ease the health burden in underserved populations. Through research training and faculty development, COE endeavors to widen the pool of investigators, disseminate health information, and increase clinical trial participation among members of these populations. To date, the program has funded clinical research studies within numerous disease areas, including breast, prostate, and pancreatic cancers; cardiovascular disease; HIV; and human papillomavirus.

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SECTION 10409 — CURES ACCELERATION NETWORK

Gene therapy, immunotherapy and nanomedicine are expected to dominate the next few decades of new drug development. Yet bringing these treatments – any treatment – to market costs an estimated $350 million. Enter the Cures Acceleration Network (CAN), established within the Office of the Director of the National Institutes of Health (NIH), to help quicken the pace of discovery and market availability.

Functions of the CAN include conducting and supporting "revolutionary advances in basic research, translating scientific discovery from bench to bedside." More specifically the network awards grants and contracts to eligible entities to support development of high need cures, defined as a drug, biological product or device determined to be:

A. a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and
B. for which the incentives of the commercial market are unlikely to result in its adequate or timely development

In a letter to the Senate Appropriations Committee, signed by more than 75 advocacy organizations, the CAN is described as a "vital new approach to moving high need medical cures through the development pipeline faster – giving hope to millions of patients and their families throughout the country."

Entities eligible to receive CAN grants include biotech and pharmaceutical companies, research institutions, patient advocacy organizations, and universities. The awards may be up to $15 million and can be supplemented in successive years. These awards will generally require a match of one private dollar for every three federal dollars. All grants are awarded competitively.

SECTION 6002 — PHYSICIAN PAYMENTS SUNSHINE ACT

One of the most controversial provisions in the Affordable Care Act, the Physician Payments Sunshine Act, requires doctors and academic researchers to publicly disclose gifts and payments from drug and device makers totaling $10 or more. Similarly, drug and device companies must also report gifts and payments to doctors and academic researchers, including speaker's fees, event tickets, medical conference accommodations, stock options, and more.

Collection of payment data commenced August 1, 2013, and the first reports are due to the Centers for Medicare & Medicaid Services (CMS) by March 31, 2014, and annually thereafter. Records must be kept for 5 years. Data submitted in March will be available for public consumption Sept. 30, 2014, on the CMS website. Subsequent reports will be posted on June 30 each year.

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To be reportable, the research-related payment must also be made pursuant to a written agreement or contract between the drug or device manufacturer and the entity conducting the research. Such agreements or contracts may include unbroken chains of agreement between the sponsor, contract research organization (CRO) or site management organization (SMO), and the covered recipient. For example, an agreement between a manufacturer and a CRO, a CRO and an SMO, and then an SMO and a teaching hospital constitutes a continuous chain that necessitates reporting.

Physicians will have 45 days to review and dispute data contained within the report before it goes live on the CMS website in September. Sponsors will have an additional 15 days to resolve any disputes and submit updated, finalized information to CMS. If a dispute cannot be resolved during this period, the claim will be published as submitted and remain in dispute. Disputes resolved outside the stated time periods will not be reflected on the public website until the next update of the website.

Supporters of the Sunshine Act say, contrary to some perspectives, being listed on the website is not indicative of any malfeasance or conflict of interest. Rather, the rule provides patients greater visibility to compensation arrangements between researchers and trial sponsors. Those who fail to report as required face fines of up to $150,000 annually. This penalty can rise to $1 million for willful, repeated noncompliance.

Critics of the law lament that it stifles innovation by dissuading doctors to participate in clinical research for fear of reprisal. In a 2010 survey conducted by the Association of Contract Research Organizations and the Academy of Physicians in Clinical Research, 13 percent of respondents said they would be “less likely to participate” or “would not participate at all” in future clinical trials given the open payments rule. Further, at an estimated cost of $269 million this year and $180 million annually thereafter to enforce compliance, research budgets are expected to take a profound hit.

Dr. Faith A. Coleman, a contributor to Imperial’s writing team and a doctor of family medicine, explores this issue in greater depth in *The Promise and Peril of the Open Payments Act*. Click here to read now.

Other components of the Affordable Care Act have ramifications for researchers, including requiring insurance coverage of some standard care administered during trial participation, and establishment and funding of the Patient Centered Outcomes Research Institute focused on comparative effectiveness research.

To read the Affordable Care Act in full text or section by section, visit the U.S. Department of Health and Human Services online at www.hhs.gov/healthcare/rights/law/

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Felicia leads brand messaging and content development for DAC's corporate and client collateral, including print and digital material targeted to patients and clinicians. She is a widely published writer with 23 years of journalism and corporate communications experience, including seven years with DAC. Her writing talents have garnered 11 awards, including two International Hermes Awards and three International AVA Awards since 2010, alone. Felicia was a contributing writer and editor for two industry books: "Global Issues in Patient Recruitment and Retention," and "International Patient Recruitment Regulatory Guidelines, Customs and Practices."

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