

## Healthcare Reform Law: Impact on Pharmaceutical Manufacturers

April 15, 2010

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law, or Law), will have a number of direct and indirect effects on pharmaceutical manufacturers, ranging from the imposition of an annual tax starting in 2011 to potentially affecting research and development through the availability of new grants and tax credits. The following summarizes a few of those potential effects on the industry.

### Annual Fee Imposed on Pharmaceutical Manufacturers

In contrast to the significant analysis and coverage of the impact on the insurance industry, the effect of the Healthcare Reform Law on pharmaceutical manufacturers has not been quantified. As a result of the increased number of insured consumers with a drug benefit, manufacturers may expect demand for products to increase. However, manufacturers of branded drugs face a significant annual fee under the new law. The Healthcare Reform Law imposes an annual fee on any “covered entity engaged in the business of manufacturing or importing branded prescription drugs” beginning in 2011. Branded prescription drugs and biologics covered include (i) any prescription drug approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act; and (ii) any biological product for which an application was submitted under section 351(a) of the Public Health Service Act.

“Covered entity” is defined broadly, and includes “any manufacturer or importer with gross receipts from branded prescription drug sales.” This annual fee, for any individual pharmaceutical manufacturer (or importer), is based on a calculation intended to reflect the market share of the manufacturer.

“Branded prescription drug sales” is defined to include sales of branded prescription drugs to specified government programs (Medicare, Medicaid, the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the TRICARE retail pharmacy program under 10 U.S.C. § 1074g) or “pursuant to coverage under any of those programs.”<sup>1</sup> Significantly, based on the statutory language and application to only “branded” drugs, sales of generic drug products will not affect the calculation of the annual fee.

In determining the annual fee, the government programs that either purchase or provide coverage for the branded drugs (i.e., Medicare, Medicaid, VA, and DOD/TRICARE) will provide a yearly report to the Department of the Treasury, indicating the prior year’s sales (or units of drugs dispensed to beneficiaries and corresponding payment amount) for each branded drug for all manufacturers covered by the

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<sup>1</sup> Patient Protection and Affordable Care Act, Title IX, Subtitle A, Section 9008.

program. Dividing the industry into tiers of branded sales, the Secretary of the Treasury will calculate the annual fee for each pharmaceutical manufacturer or importer based on reports from other specified federal government agencies based on a ratio of its branded drug sales to the branded drug sales of all covered entities for the prior year (i.e., market share).<sup>2</sup> The annual fee is a step-wise annual increase, starting at \$2.5 billion in 2011, increasing to a maximum of \$4.1 billion in 2018, and decreasing to \$2.8 billion in 2019 and onward.

### **Changes in Generic Drug Approval**

Section 10609 of the Healthcare Reform Law is intended to increase access to lower-cost generic drugs by preventing brand name manufacturers from delaying approval of generic products by making label changes to the brand name or listed drug. Prior to the Law, the labeling of a generic drug was required to match the labeling of the referenced brand name or listed drug, or would not be approved.

Under the Healthcare Reform Law, a generic application can be approved despite last-minute changes to the labeling of the listed drug, so long as the labeling change to the listed drug is approved 60 days prior to the date of expiration of the listed drug's patent or exclusivity period, and provided that the labeling change does not affect the "Warnings" section of the listed drug's labeling.

### **Research-Related Provisions**

The Healthcare Reform Law contains a number of provisions that could shift the focus of certain research and development efforts in the pharmaceutical industry.

#### *Therapeutic Discovery Project Credit*

Section 9023 of the Healthcare Reform Law provides a tax credit to small companies (250 employees or fewer) to encourage new therapies. These credits will be available for 50% of investments made in **2009 and 2010** in "qualified investments," which include projects to conduct preclinical or clinical research to support marketing approval for a new drug; projects that develop molecular diagnostics, affecting therapeutic decisions; and the development of drug-delivery technologies. Note that the provision applies retroactively, meaning that the credit may be available for projects that occurred in 2009, pending approval through the process described below.

Despite the fact that "qualifying therapeutic discovery projects" under this section are limited to the development of products and diagnostics generally regulated by the Food and Drug Administration (FDA), the responsibility for making the determination as to whether a project is eligible for the tax credit is placed on the Treasury. The provision requires that, within 60 days of enactment, the Secretary of the Treasury work with FDA to "establish a qualifying therapeutic discovery program to consider and award certifications for qualified investments eligible for credits under this section." As a component of the program developed by the Treasury (with the help of FDA) through which projects will be reviewed to determine eligibility for the credit, the Treasury must consider whether the project has the potential to result in new therapies to treat unmet medical needs, reduce healthcare costs, advance the goal of curing cancer, create new jobs, or generally advance U.S. competitiveness.<sup>3</sup> It seems likely that, well after the

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<sup>2</sup> Health Care Education Affordability Reconciliation Act of 2010, Title 1, Subtitle E, Sec. 1404, amending the Patient Protection and Affordable Care Act (PPACA).

<sup>3</sup> PPACA, Title IX, Subtitle B, Sec. 9023.

development of the initial “qualifying therapeutic discovery program” by the Treasury and FDA, the Treasury may require continued support from FDA in order to implement several of these criteria.

Although the provision has retroactive effect (i.e., projects in 2009 may be deemed eligible for the credit), this need for coordination between the Treasury and FDA to establish the qualifying therapeutic discovery program (and, potentially, to make case-by-case determinations of eligibility) can be expected to result in some level of delay of the availability of the credits.

### *Cures Acceleration Network*

Section 10409 of the Healthcare Reform Law establishes the Cures Acceleration Network (CAN). Administered by the National Institutes of Health (NIH), CAN is intended to support (through the awarding of grants and contracts) “revolutionary advances in basic research” and “the development of high need cures, including through the development of medical products and behavioral therapies.” NIH will deem a product to provide a “high need cure” if it “is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition,” and if it is a product “for which the incentives of the commercial market are unlikely to result in its adequate or timely development.” In furthering its mandate to accelerate the development of high need cures, CAN is also tasked with supporting private, institutional, and governmental agencies in their development efforts, and with facilitating FDA’s review of the high need cures for which CAN has provided funding or support by helping the recipient to establish protocols that comply with FDA’s requirements at all stages of development.<sup>4</sup> Grants authorized under this provision may not exceed \$15 million per project per fiscal year, and are available to any government, private, or nonprofit entity, which could include pharmaceutical manufacturers.

### *Coverage of Clinical Trial Costs*

Under Section 10103 of the Healthcare Reform Law, “health plans” (defined as group health plans or insurance issuers offering group or individual health coverage) may not deny coverage of certain routine patient costs associated with participation in “approved clinical trials,” which are clinical trials for the prevention, detection, or treatment of cancer or other life-threatening disease or condition. The Healthcare Reform Law also prohibits health plans from discriminating against individuals for participating in clinical trials. The routine patient costs to be covered under this provision of the Healthcare Reform Law do not include the investigational product itself (whether drug, device, or service), or services that are either rendered solely in connection with collecting data about the investigational product or are inconsistent with the standard of care for the condition being studied.<sup>5</sup>

In addition to potentially encouraging participation in clinical research, generally this provision is significant to manufacturers in that it likely will affect clinical trial agreement negotiations. Although clinical trial budgets based on protocol-required assessments sometimes include standard-of-care assessments required under the study protocol, mandated insurance coverage for those standard-of-care costs may warrant the exclusion of these costs from payments to investigational sites. Moreover, the new requirement to provide insurance coverage for standard-of-care assessments may impact clinical trial agreement provisions regarding “subject injury” costs, depending on whether injuries sustained by study subjects are attributable to standard-of-care assessments.

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<sup>4</sup> PPACA, Title X, Subtitle D, Sec. 10409.

<sup>5</sup> PPACA, Title X, Subtitle A, Sec. 10103 (amends Subpart I of Part A of title XXVII of the Public Health Service Act).

## *Offices of Women's Health*

The Healthcare Reform Law also places new emphasis on women's health issues, mandating the creation of several new offices within the health-related federal agencies (including the Department of Health and Human Services, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and FDA). Among these, the Healthcare Reform Law directs the establishment of the Office of Women's Health Issues within the FDA Commissioner's Office, with the purpose of that office being to "consult with **pharmaceutical, biologics, and device manufacturers**, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on administration policy with regard to women."<sup>6</sup> Based on its placement within FDA, the creation of this office may result in an increased focus by FDA on therapies targeted to women.

## *Pain Research*

The Healthcare Reform Law also incorporates several initiatives designed to further research and development in the area of understanding and treating pain. The provisions call for the Institute of Medicine Conference on Pain Care, which includes the mandate to increase awareness of pain as a significant public health problem, to identify barriers to treating pain, and to improve pain-related research, education, training and clinical care. The Healthcare Reform Law provides continued support for the Pain Consortium at the NIH, encouraging the NIH to implement a comprehensive program by facilitating collaboration among government agencies, healthcare providers, and patient groups on the topic. In addition, the Healthcare Reform Law allows for the awards of grants to both public and private entities to provide education and training to healthcare professionals in pain care.<sup>7</sup> Grants will be available under this provision only where the grant recipient agrees that the program carried out with the award will include "information and education" relating to the following:

- (1) Recognized treatments and assessments related to pain and pain management, including the medically appropriate use of controlled substances
- (2) Applicable laws and policies on controlled substances, including education regarding instances in which such laws may inadvertently create barriers to patient access
- (3) Interdisciplinary approaches to the delivery of pain care, including the utility of specialized pain management centers
- (4) Cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations
- (5) Recent findings, developments, and improvements in the provision of pain care

## **Making Prescription Drug Advertising More Consumer Friendly**

Section 3507 of the Healthcare Reform Law requires FDA to determine whether the addition to promotional labeling and print advertisements for prescription drugs of standardized tables or other easily recognizable tools summarizing the risks and benefits for the prescription drugs (e.g., similar to "Drug Facts" on over-the-counter products) would "improve healthcare decision-making by clinicians and patients and consumers."

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<sup>6</sup> PPACA, Title III, Part III, Subtitle F, Sec. 3509 (amends Part A of title II of the Public Health Service Act (42 U.S.C. §§ 202 *et seq.*), Sec. 1011), emphasis added.

<sup>7</sup> PPACA, Title IV, Subtitle C, Sec. 4305.

In fulfilling this mandate, the Healthcare Reform Law directs FDA to consider research in the areas of social and cognitive psychology, and to consult manufacturers and consumers, “experts in health literacy, representatives of racial and ethnic minorities, and experts in women’s and pediatric health.” Within one year of enactment, FDA must submit a report to Congress outlining its determination. If FDA ultimately determines that adding these types of standardized risk/benefit summary statements (or tables) to advertising and promotional labeling for prescription drugs would improve healthcare decision making, it has three years from submission of the report to Congress to promulgate proposed regulations setting forth such requirements.<sup>8</sup> The provision, however, does not include any penalty or “hammer provision” to hold FDA to this three-year deadline for promulgating these rules.

### **Other Issues of Interest to Manufacturers**

A number of the changes included in the Healthcare Reform Law will have significant impact on pharmaceutical manufacturers, including the following:

- **Comparative Effectiveness:** Drug manufacturers should keep abreast of comparative effectiveness research activities initiated under the Healthcare Reform Law and assess whether their products may be impacted. The law creates a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research priorities, establishing a research project agenda, and contracting with entities to conduct the research in accordance with the agenda. Research findings published by the Institute will be publicly disseminated. However, the law imposes restrictions on CMS’s ability to use such findings to make decisions related to coverage, reimbursement, or incentive programs. Additional information on comparative effectiveness will be available in a forthcoming Morgan Lewis LawFlash.
- **Fraud and Abuse:** Drug manufacturers also will be affected by Healthcare Reform Law amendments related to fraud and abuse, including amendments to the Anti-Kickback Statute, False Claims Act, healthcare fraud criminal statute, and program integrity provisions. Additional information on these amendments is available in our March 31, 2010 LawFlash, “Healthcare Reform Law: Healthcare Fraud and Abuse and Program Integrity Provisions,” available at [http://www.morganlewis.com/pubs/WashGRPP\\_PrgmIntegrityProvisions\\_LF\\_31mar10.pdf](http://www.morganlewis.com/pubs/WashGRPP_PrgmIntegrityProvisions_LF_31mar10.pdf).
- **Transparency Initiatives:** Drug manufacturers will need to establish systems and controls to ensure compliance with new transparency provisions, which require reporting of (1) payments and other transfers of value to physicians and teaching hospitals for values of \$10 or more (or \$100 aggregate in a calendar year), and (2) physician ownership of or investments in drug manufacturers. The statutory language is limited to applicable manufacturers of devices, drugs, biologics, and medical supplies for which “payment is available” from certain designated federal healthcare programs and does not appear to include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format. Additional information on the new transparency requirements is available in our March 29, 2010 LawFlash, “Healthcare Reform Law Delivers New Transparency Requirements for the Health Industry,” available at [http://www.morganlewis.com/pubs/WashGRPP\\_FDA-TransparencyRequirements\\_LF\\_29mar10.pdf](http://www.morganlewis.com/pubs/WashGRPP_FDA-TransparencyRequirements_LF_29mar10.pdf).

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<sup>8</sup> PPACA, Title III, Part III, Subtitle F, Sec. 3507.

- **Biosimilars:** The Law authorizes FDA to create a new regulatory pathway for biosimilar biological products, allowing licensure of biological products as biosimilar or interchangeable to products with current licenses. Innovator manufacturers of reference biological products are granted 12 years of exclusive use before biosimilars can be approved for marketing in the United States. Because it establishes a new regulatory pathway for biosimilars, this aspect of the Healthcare Reform Law will have a broad impact on industry activities for both innovator and follow-on biological products. Additional information on the new transparency requirements is available in our April 15, 2010 LawFlash, “Healthcare Reform Law: A New Regulatory Pathway for Biosimilar Biological Products,” available at [http://www.morganlewis.com/pubs/WashGRPP\\_RegulatoryPathForBiosimilarBiologicalProducts\\_LF\\_15apr10.pdf](http://www.morganlewis.com/pubs/WashGRPP_RegulatoryPathForBiosimilarBiologicalProducts_LF_15apr10.pdf).

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Kathleen M. Sanzo** (202.739.5209; [ksanzo@morganlewis.com](mailto:ksanzo@morganlewis.com)), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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