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Chapter 20

Medicare Act of 2003 Provides New Competitive Landscape for the Pharmaceutical Industry

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MEDICARE ACT OF 2003 PROVIDES NEW COMPETITIVE LANDSCAPE FOR THE PHARMACEUTICAL INDUSTRY

The principal provisions of the Medicare Act of 2003[1] affecting the pharmaceutical and biotechnology industries properly balance the interests of consumers and the industry. In addition to providing what the Food and Drug Administration (FDA) now estimates to be over $530 billion for prescription drugs over the first decade of the Act's operation, the Act expressly excludes the Centers for Medicare and Medicaid Services (CMS) from directly negotiating with pharmaceutical manufacturers for price discounts and provides for essentially no change from prior law regarding the reimportation of drugs. Congressional and state debate on reimportation continues, though with significant pressure to provide some mechanism to allow for direct consumer purchase of imported drugs.

The Medicare Act is the most significant legislation affecting the pharmaceutical and biotechnology industries in several decades, and provides a new competitive landscape for industry companies. Important items in the Medicare Act affecting the pharmaceutical and biotechnology industries include the following:

- An immediate increase in prescription drug funding, as the Medicare discount card will support drug purchases by low-income seniors.
- An altered structure of payment for reimbursed prescription drug products under Medicare Part B, mandating an immediate cut in reimbursement from average wholesale price (AWP) minus 5% to AWP minus 15%. In 2006, the pricing mechanism was changed completely to reimbursement at average sales price (ASP) plus 6% (to cover the indirect costs of providing the drugs).
- Changes in some of the exclusivity provisions of the Hatch-Waxman amendments, including:
  - Mandating only one 30-month stay of approval arising from a pioneer drug manufacturer's infringement action based on patents submitted to FDA before the abbreviated new drug application (ANDA).
  - Maintaining the award of 180-day exclusivity to the first ANDA filer for any patent, thus limiting it to one exclusivity period per product (not per patent), and providing

1. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (the Medicare Act or the Act).

for sharing of 180-day exclusivity among all ANDA applicants that file substantially complete applications on the first day. This 180-day exclusivity also contains "use or lose" provisions for first filers that fail to market within defined time frames.

- Requiring ANDA applicants to provide Paragraph IV notices to innovators within 20 days of an FDA mail notice of the "filing" of the ANDA. If the Paragraph IV notice asserts noninfringement, the ANDA applicant must provide the new drug application (NDA) holder/patent owner with a right of confidential access to the ANDA for the sole purpose of determining whether to file an infringement suit, or the applicant will be unable to file a declaratory judgment action as explained below.
- Providing authority for the ANDA applicant to seek a declaratory judgment as to whether a patent is valid, if the NDA holder does not file an infringement suit within its 45-day period. This authority may be challenged as unconstitutional on the ground that it lacks any case or controversy required for a federal court action.
- Providing that, if an infringement action is brought, the ANDA applicant may file a counterclaim seeking correction or deletion of patent information filed with FDA, although no damages ordinarily can be awarded.

For the most part, the Medicare Act codifies recent FDA regulations relating to these provisions.

The Act has several important implications for the pioneer pharmaceutical and biotechnology industries that will become increasingly apparent as total costs for the new prescription drug benefit increase over the next several years.

- It likely will result in a substantial shift of patients who are "dual eligibles" from Medicaid to Medicare: this shift will likely reduce the impact of state preferred-drug lists and of Medicaid rebates, because such "dual eligibles" constitute approximately 60% of the Medicaid prescription population.
- The delegation to the U.S. Pharmacopoeia, in consultation with pharmacy benefit managers (PBMs), of the power to develop therapeutic classes and categories of drugs that may be used by prescription drug plans will have a critical influence on the extent to which the plans can negotiate for discounts with drug manufacturers; the therapeutic classification decisions will have to be monitored closely and reviewed by manufacturers.
- CMS intends to make a policy change under the Act to limit reimbursement for off-label usage of certain oncology products (and eventually others), reportedly only to when such uses are listed in an official compendium or when relevant scientific data are published in qualified peer-reviewed journals. This policy change will put further focus and importance on access to the official compendia and scientific publications for drug manufacturers.

- The eventual movement to reimbursement calculation on the basis of ASP—coupled with other changes in the marketing of pharmaceuticals in response to new CMS, industry, and American Medical Association codes of conduct and litigation challenges—likely will lead to abatement in the private false claims litigation that had become a common feature of the historic AWP pricing mechanism. ASP submissions will be scrutinized closely and government enforcement focus likely will change to submission of false or inaccurate pricing certifications.

- The requirement that certain agreements between ANDA applicants that have filed Paragraph IV certifications and pioneer drug companies be filed with the Federal Trade Commission (FTC) and the Department of Justice, thus allowing for antitrust review of those agreements, will further increase the scrutiny of such agreements and the reluctance of pioneer manufacturers to enter into them. (The FTC issued a notice detailing the types of agreements that must be filed, effective January 7, 2004.[2])

- The absence of direct mechanisms for price restriction in the Act may result in continuing pressure from healthcare purchasing entities to switch prescription drugs to over-the-counter (OTC) status, and to include OTC drugs in the drug benefits provisions as another cost-controlling mechanism. The trend of prescription-to-OTC switches is thus likely to increase.

- The trend toward greater utilization of generics is likely to continue as CMS and private insurers increase their efforts to reduce costs, and PBM drug interchange opportunities are curtailed. The expansion of the overall prescription drug market by reason of the influx in funds mandated by the new Act, however, will mitigate the somewhat adverse financial effects on pioneer companies.

- As part of ongoing efforts to control drug costs, continued interest and increased energy will be directed toward the creation of mechanisms by FDA or through Congress to allow the introduction of generic biologics.

- The increase in federal government monies devoted to prescription drug purchasing should enhance the valuation of both pharmaceutical manufacturers and biotechnology companies, the attractiveness of initial public offerings, and the cost of acquisition or licensing agreements with biotechnology and other companies for drug candidates, especially for novel or first-in-class therapies.

- The proposed reimbursement coverage pathway and expected level of reimbursement will need to be expressly included as part of the valuation process in licensing agreements and acquisitions.

2. FTC, Pharmaceutical Agreement Notification Filing Requirements, at http://www.ftc.gov/opa/2004/01/fyi0403.htm (last visited May 21, 2004).

- The Act authorizes funding for the Agency for Healthcare Research & Quality to develop a research agenda regarding comparative clinical effectiveness of healthcare products and services. While the Agency is restricted in its scope under the Act, there is considerable interest in developing comparative cost-effectiveness data as a cost-control mechanism, and it can be expected that efforts will be made to expand the development and use of such data by FDA, CMS, and third-party payors.

- As the federal government will become the purchaser of nearly half of the prescription drugs sold in the United States (up from the current approximately 16%), and the total prescription drug benefit cost is estimated to total nearly $2 trillion over the next two decades (as estimated by the Congressional Budget Office), the risk of price restrictions—if not price controls—will greatly increase over the next several years. Any such price restrictions would have significant consequences not only with respect to industry profitability, but also with regard to the selection of therapeutic categories of interest for new drug candidates, the structure and scope of activities of pioneer pharmaceutical companies (including the degree to which current functions should be outsourced), the nature of cooperative agreements between drug manufacturers and biotechnology companies, and the focus by drug manufacturers on manufacturing and distributional efficiencies.

The Medicare Act thus changes the economic structure of the pharmaceutical and biotechnology industries in numerous significant respects. The effect of these changes in the competitive landscape on strategies and operations must be assessed carefully by industry companies.