



New Medicare Act Provides New Competitive Landscape for the Pharmaceutical Industry

by Stephen Paul Mahinka and Kathleen M. Sanzo

The principal provisions of the new Medicare Act¹ affecting the pharmaceutical and biotechnology industries properly balance the interests of consumers and the industry. In addition to providing what the Administration now estimates to be over \$530 billion for prescription drugs over the first decade of the Act's operation, the new 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 re-importation 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 new Medicare Act is the most significant new legislation affecting the pharmaceutical and biotechnology industry in several decades, and provides a new competitive landscape for industry companies. Important items in the new Medicare Act affecting the pharmaceutical and biotechnology industries include the following:

- An immediate increase in prescription drug funding, because, according to CMS estimates, the new Medicare discount card will fund \$2.4 billion to support drug purchases by low-income seniors during 2004 alone.
- 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 will be changed completely to reimbursement at average sales price (ASP) plus 6% (to cover 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 the Food and Drug Administration (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 patent), and providing for sharing of 180-day exclusivity among all ANDA applicants that file substantially complete applications on the first day; 180-day exclusivity also contains "use or lose" provisions for the first filer or filers who 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 judgement action, as explained below;



Mr. Mahinka is a Partner in the Antitrust and FDA/Healthcare Regulation Practice Groups, and Chair of the Life Sciences Practice at Morgan Lewis & Bockius, LLP, Washington, D.C.



Ms. Sanzo is a Partner in the FDA/Healthcare Regulation Practice Group and a member of the Life Sciences Practice at Morgan Lewis & Bockius, LLP, Washington, D.C.

- 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; and,
- 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 new Medicare Act codifies recent FDA regulations relating to these provisions.

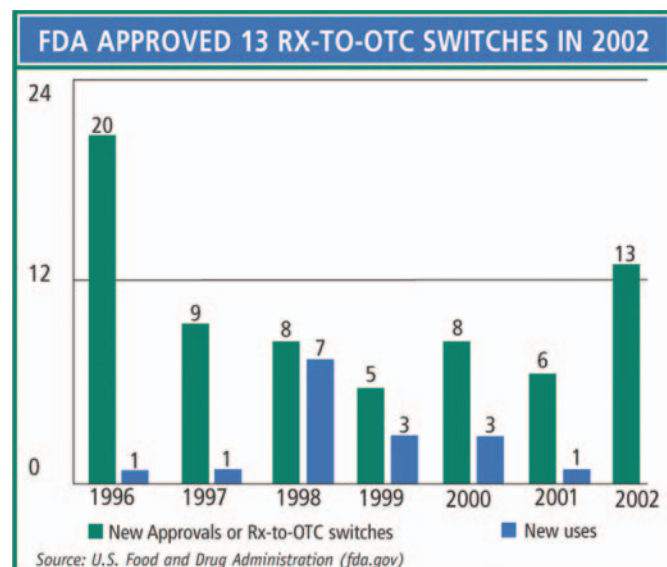
The new Act has several important implications for the pioneer pharmaceutical and biotechnology industry that will become increasingly apparent as total costs for the new prescription drug benefit increase over the next several years.

- It likely will result in a substantial shift of patients who are “dual eligibles” from Medicaid to Medicare; this shift likely will reduce the impact of state preferred-drug lists and of Medicaid rebates, because such “dual eligibles” constitute approximately 60% of the Medicaid prescription population.
- 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, and the therapeutic classification decisions will have to be monitored closely and reviewed by manufacturers.
- CMS intends to make a policy change under the new 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.
- Under a new interim CMS rule,² the Medicare drug discount card program will provide direct access to the negotiated prices for covered drugs offered by each card program. CMS intends for the requirement to promote informed consumer choice among the various programs. To avoid anticompetitive effects on pricing negotiations, however, the rule does not require that the card programs set out the percentage of discounts obtained that will be passed through to consumers, thereby

leaving consumers unable to make accurate comparisons. Drug manufacturers will need to be aware that the CMS rule will result in broad dissemination of the prices negotiated with drug discount price programs.

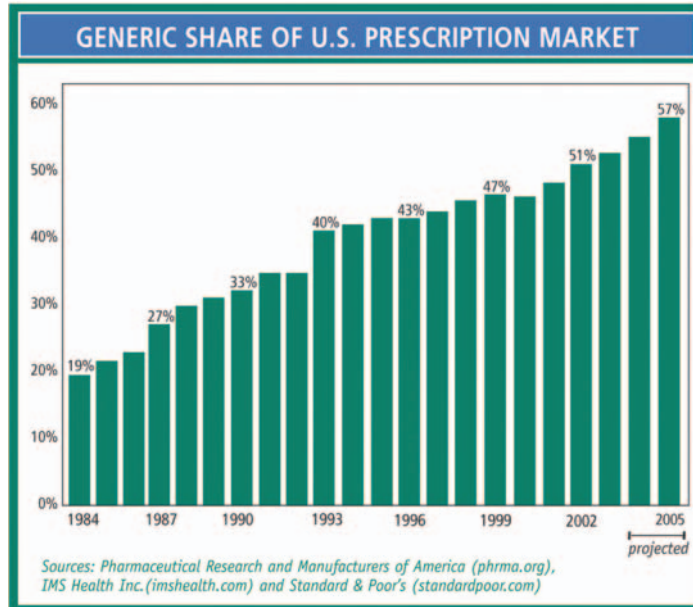
- The eventual movement to reimbursement calculation on the basis of ASP—coupled with other changes in the marketing of pharmaceuticals in response to new CMS, industry, and American Medical Association codes of conduct and litigation challenges—likely will lead to abatement in the private false claims 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, 2004.³)
- The absence of direct mechanisms for price restriction in the new Act may result in continuing pressure from healthcare purchasing entities to switch prescription (Rx) drugs to over-the-counter (OTC) status, and to include OTCs in the drug benefits provisions as another cost-controlling mechanism. The trend of Rx-to-OTC switches (*see* Table 1) is thus likely to increase.

Table 1



- The trend toward greater utilization of generics is likely to continue (*see* Table 2) as CMS and private insurers maintain 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 somewhat adverse financial effects on pioneer companies.

Table 2



- As part of the 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.
- The new 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 new 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.

- Because 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 if the total prescription drug benefit cost rises to levels currently estimated (the Congressional Budget Office estimates that the benefit will cost nearly \$2 trillion over the next two decades⁴), the potential 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 regarding 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 new Medicare Act thus changes the economic structure of the pharmaceutical and biotechnology industry in numerous significant respects. These changes in the competitive landscape must be assessed carefully by industry companies regarding their effect on strategies and operations. ▲

¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).
² Medicare Program; Medicare Prescription Drug Discount Card; Interim Rule and Notice, 68 Fed. Reg. 69,840 (Dec. 15, 2003).
³ FTC, Pharmaceutical Agreement Notification Filing Requirements, available at <http://www.ftc.gov/opa/2004/01/fyi0403.htm> (last visited May 21, 2004).
⁴ Statement by Douglas Holz-Eakin, Director, Congressional Budget Office, at a Heritage Foundation seminar, reported in MEDICARE REPORT (BNA), Dec. 12, 2003, at 1380.

