The US pharmaceutical industry is heavily and appropriately regulated by the Food and Drug Administration (FDA) regarding the safety and efficacy of new and generic drug approvals, and pharmaceutical promotional and marketing practices. However, the US is one of the last major countries without government price controls. Comparisons between the US and Canada or western Europe are inappropriate, because in the US the majority of the population receive healthcare from private insurance, as opposed to governmentsponsored programmes in the other countries.

The pharmaceutical market in the US is moving away from a fee-for-service model, where pharmaceutical manufacturers target prescribers who have had autonomous decision-making power over selection of drugs. Under the growing managed care model, the plan pharmacy and therapeutics committees make drug coverage decisions for participating staff or community physicians. The physicians receive negative reinforcement when they prescribe non-formulary drugs, and positive reinforcement to prescribe covered medications. They are unable to separate prescribing practices for managed care and their dwindling private-pay population, and soon begin writing plan formulary drugs for all patients. Thus, the influence of managed care formularies goes beyond the directly covered plan membership as a result of this ‘spill-over’ effect. Although this is difficult to measure, it has been estimated that an enforced managed care drug prescription can influence an average 2.7 additional prescriptions in highly prescribed therapeutic categories (M.Z. Holubiak, personal communication).

In the past decade, managed care membership has flourished in the US, and now represents over 80 million in health maintenance organisations (HMOs) and preferred provider organisations (PPOs). This trend suggests that by the year 2000, most of the insured US population may be covered by a managed care healthcare plan. National healthcare analysts, encouraged by President Clinton’s ‘managed competition’ theme, believe a migration of state Medicaid and federal Medicare members into managed care will also increase the growth of managed care.

1. Basis for Pharmaceutical Price Controls

There are 2 fundamental reasons given to justify pharmaceutical price controls: (a) according to the US Bureau of Labor Statistics, the US spends almost 13% of its gross domestic product (GDP) on healthcare; and (b) the Consumer Price Index (CPI) for Drugs has been twice that for all goods over the past 5 years. Pharmaceutical price regulation is also politically attractive, and therefore likely to become a recommendation in President Clinton’s comprehensive healthcare reform.

Unfortunately, the federal government has contributed to recent drug price increases by enacting the OBRA 1990 legislation, which was designed to
reduce Medicaid drug costs by requiring pharmaceutical manufacturers to provide their current ‘best price’ (often given to managed care plans) to state Medicaid programmes (Fulda & Hass 1992). The reaction of manufacturers was to reduce the value of discounts to all purchasers and increase prices dramatically on key drugs prior to January 1993, when a manufacturer’s overall price increases must average no more than the CPI for drugs. Exceptions to the ‘best price’ provision include the Veterans Administration and the military depot system.

Novel drugs and delivery forms contribute to pharmacy programme cost increases. It is my understanding that in 1992, nicotine patches alone represented 5% of several managed care pharmacy budgets, prompting implementation of controlled access procedures (Managed Care Drug Class Report 1992). Other newly released drugs for treatment of several chronic diseases, including hypertension, depression, arthritis, and hypercholesterolaemia, contributed to increasing costs in 1992. It is important to emphasise that several of the drugs launched during 1992 in these therapeutic categories were less expensive on a cost-of-therapy basis than existing products, but that the overall therapeutic category costs increased because of an overall increase in drug utilisation, attributable to increased promotional pressure supporting new product introductions. Figure 1 demonstrates the average prescription cost increases from January 1989 to August 1992 at Health Net, an 885,000 member health plan in California. The rate of increase clearly accelerated during 1991 and 1992 for the aforementioned reasons. The Group Health Association of America pharmacy subcommittee reported similar experiences in several large managed care organisations (R. Jones, personal communication).

It is myopic to blame new technology for increasing near-term pharmacy programme costs, without considering the long term cost-effectiveness of successfully treating greater numbers of patients. It is this lack of understanding of the value of pharmaceuticals that leads to reactionary price controls and access limitations. However, the drug use evaluation (DUE) programmes of many managed care systems routinely discover a high level of inappropriate use and patient noncompliance. As a result, managed care systems that have successfully implemented strategies to control drug acquisition and reimbursement costs are now dedicating clinical pharmacists and DUE resources to interact with physicians to promote the most appropriate use. Appropriate utilisation is a critical component in cost-effectiveness.

2. Pharmaceutical Manufacturers’ Response

In its defence against price controls, the Pharmaceutical Manufacturers Association (PMA) has argued that the average cost of developing and marketing a new drug exceeds $US250 million, and high prices are justified to support continued research and development. The PMA points to a paucity of new chemical entities emerging from price-controlled countries. However, this is a spurious argument, because the pharmaceutical industry is a global business, and companies systematically develop an international market for drugs when a desired price and volume can be achieved, or to sustain local operations in countries with more stringent price controls. The industry must shift the focus of its argument to the value of pharmaceuticals. If it is accepted, this model will redefine the manner in which drugs are evaluated, and their cost-effective contribution to healthcare costs.

3. The Value of Pharmaceuticals

There is a clear and important distinction between cost containment and economic efficiency. Although managed care decision-makers may be very effective at controlling the pharmacy budget, they may be doing so at the expense of true economic efficiency. As an example, the access limitations imposed by many managed care plans, through prior authorisation procedures, on 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors, may reduce drug expenses, but may also reduce the plan’s ability to achieve greater