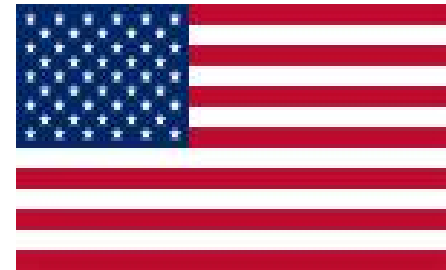
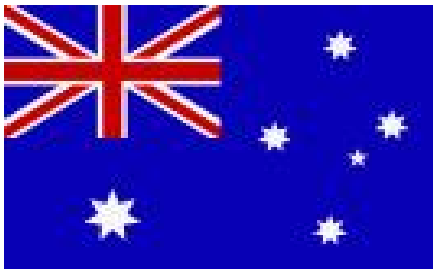


Australia's Cost-Effectiveness Requirements for Pharmaceuticals: Potential Implications for U.S. Patients



Collaboration

Pharmaceutical Research and Manufacturers of America

*Ph*ARMA

and

IMS Management Consulting



Purpose

- To evaluate whether cost-effectiveness data is an effective cost containment measure in the management of Pharmaceutical spending
 - To highlight the potential flaws inherent in coverage decisions based purely on a perceived cost/benefit relationship
 - To examine the standards Australia uses to grant reimbursement coverage for new medicines compared to the US process

Background

- The direct use of cost-effectiveness data for prescription drugs coverage remains a subject of debate among US policymakers
- Australia's Pharmaceutical Benefits Advisory Committee (PBAC) was among the first regulatory body to demand pharmacoeconomic evidence
- Utilization of Pharmacoeconomic data for policy and coverage decisions varies in the US compared to Australia

Background: The PBAC process - I

- Drug or technology must be considered safe and effective compared to other therapies
 - If approved the product is placed on the Positive List and covered for all Australian patients
 - Input provided by the Economics Sub-Committee and Drug Utilization Sub-Committee required
- Positive List inclusion requirements:
 - Evidence that the drug is safe and effective compared to other therapies
 - Use for conditions for which the drug has been approved in accordance with the Australian Register of Therapeutic Goods
 - Data to substantiate that the money spent on the product represents a cost-effective expenditure of taxpayers funds
 - Community need for the drug is “real”

Background: The PBAC process - II

- When recommended by the PBAC additional approval processes are required:
 - Consideration by the Pharmaceutical Benefits Pricing Authority
 - Pricing negotiations between the manufacturer and the Dept. of Health and Aging
 - Quality and availability checks
 - Consideration by government
- Listed medicines require other governmental reviews which can delay the process:
 - Not possible to say how long the process may take
 - Minimum time for these processes ~ 5 months
 - Negotiations regarding the listing details and costs can be complex
 - This process found to be slower in disseminating new drugs compared to the US

Methods: Analyses

- Estimated # of patients affected in the US if Australian approval process applied:
 - Identification of the total number of patients who use selected products of interest in 2003
 - Development of a sales volume forecasts through September 2008 based on IMS sales data
 - Calculation of the potential number of patients who may be impacted if the US were to implement the Australian framework

Methods: Data Assets

- Drug & Patient Estimation Methodology
 - National Prescription Audit Plus: NPA measures the outflow of dispensed prescriptions through all channels to consumers
 - National Disease & Therapeutic Index: NDTI provides information about disease and treatment patterns in office based practices in the US
- Various Forecasting Methods were applied to estimate the patients impacted for each therapy

Selected Products for Evaluation

IMS & PhRMA identified seven products which were excluded from reimbursement or reimbursed with stringent guidelines in Australia:

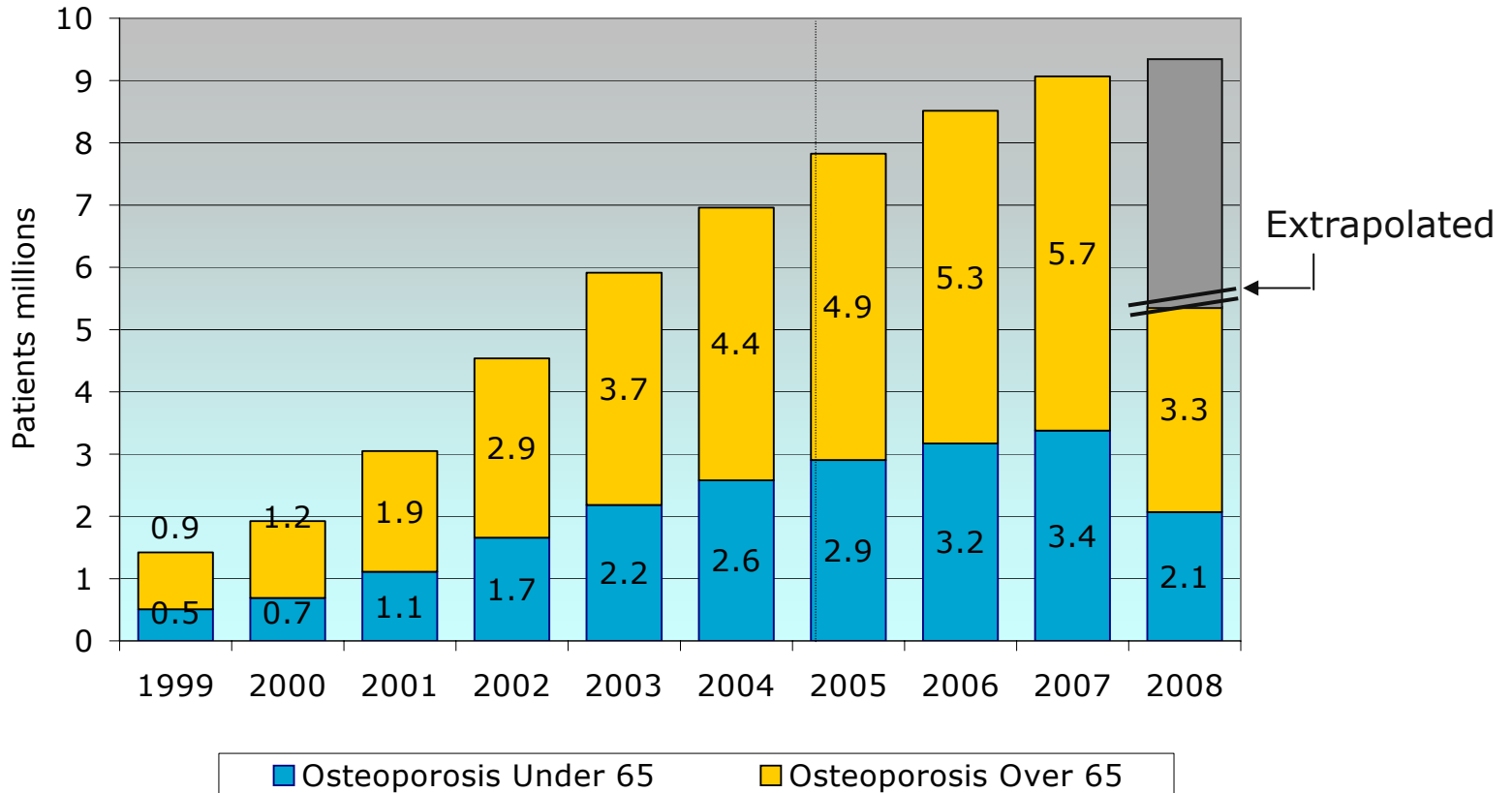
- Osteoporosis Therapies
 - Actonel (risedronate)
 - Forteo (teriparatide)
 - Fosamax (alendronate)
- Alzheimer's Therapies
 - Namenda (memantine)
 - Reminyl [Razadyne] (galanamine)
- Rare Disorder Therapies: (Thrombocythemia & Pulmonary Hypertension)
 - Agrylin (anagrelide)
 - Tracleer (obsentan)

Results: Osteoporosis

- Affects 44 million Americans
- Burden of Illness – \$17 B in human & economic costs
- These agents are not approved for primary prevention
 - Reimbursed only for treatment of patients who have suffered a fracture (secondary prevention)
- Currently this is an underserved market
 - By 2007 - 9.1 M pts in the US with Osteoporosis could be affected were PBAC guidelines implemented.
 - This is relevant especially for those at risk for developing osteoporosis (US) compared to those who must first suffer fractures before treatment is made available (Australia)

Results: Osteoporosis

Patients forecast to be impacted in the US in the Osteoporosis therapy area 1999 to 2008

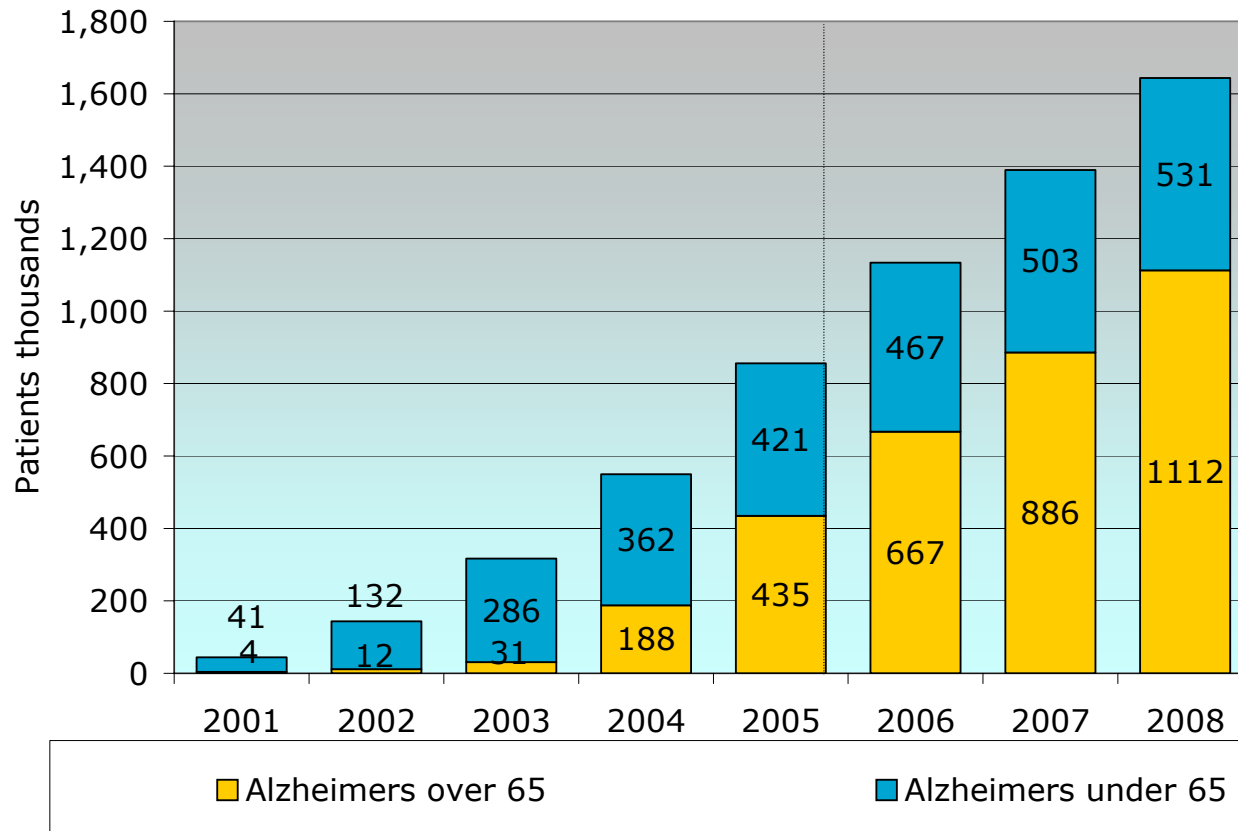


Results: Alzheimer's Disease

- 4.5 M Americans suffer from the disease in this underserved market
- Prevalence will increase due to increasing age and longevity of the US population ~ 13.2 M by 2050
- Burden of Illness – direct and indirect \$100 B.
- By 2010 Medicare costs are estimated to be ~ \$50 B
- Medicaid expenditures will increase 80 % to \$33 B by 2010
- PBS guidelines would impact 400,000 Americans were they applied to the US health care system
 - Overall 1.6 M patients could be affected if US were to adopt the Australian system

Results: Alzheimer's Disease

Patients forecast to be impacted in the US in the Alzheimer therapy area 2001 to 2008

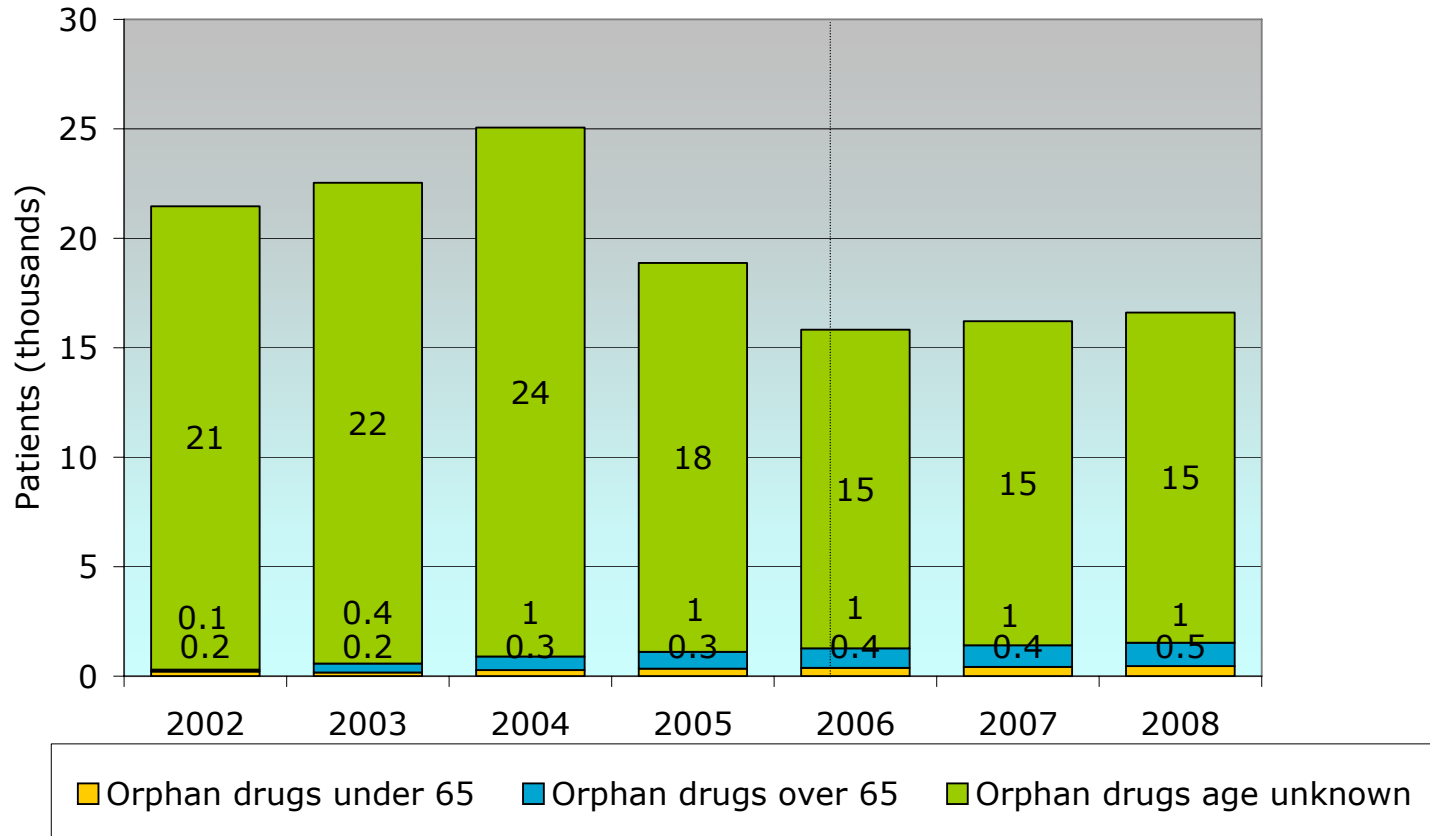


Results: Orphan Drugs

- Less prevalent diseases such as:
 - Essential Thrombocythemia and related Myeloproliferative Diseases
 - Pulmonary Arterial Hypertension
- 25,000 people with orphan diseases would have difficulty being treated if these guidelines were implemented in the US

Results: Orphan Drugs

Patients forecast to be impacted in the US in the Orphan Drug therapy area 2001 to 2008



Summary

- If Cost Effective standards similar to those in Australia were applied to the US:
 - Millions of patients would face significant new barriers to obtaining medicines they are now receiving to treat serious and life threatening diseases.
 - The impact on the Medicare population would be significant
 - Patients affected would include a minimum of:
 - 9.1 million patients with Osteoporosis
 - 400,000 Alzheimer's patients
 - Thousands of patients with rare disorders (e.g. Pulmonary Artery Hypertension & Essential Thrombocythemia)

Considerations

- The “single payor” Australian and the US “open market” are different systems with different incentives and drivers
- Despite the lack of formal cost-effective criteria the US has instituted value based formulary controls as it relates to prescriber choice and patient access
- Mandatory controls such as prior authorization in the US have not been cost-effective
 - Costs have outweighed the benefits
 - Most MCO have abandoned this strategy except for the most expensive drugs
- Most MCOs and PBMs have instituted formulary management & specialty pharmacy activities & to control costs and support appropriate use of newer drugs via the following:
 - Incentives to use generics first
 - Mail & specialty pharmacy service options
 - Patient cost-sharing: copay and deductibles
 - Drug utilization review activities
 - Disease & Population management programs
 - Formulary Drug rebates from Manufacturers

Conclusions

- Australia is one of the few countries in the world to employ mandatory cost-effective requirements for reimbursement
- The impact of this approach could have implications for millions of US patients
- Access to new innovative technologies is important to improve clinical, economic and patient-centered outcomes.
- Policymakers should consider the overall impact of applying “mandatory” cost-effective standards to prescription drug reimbursement policies