



Australian Government

Department of Health and Ageing

Pharmacoeconomics & drug subsidy in Australia

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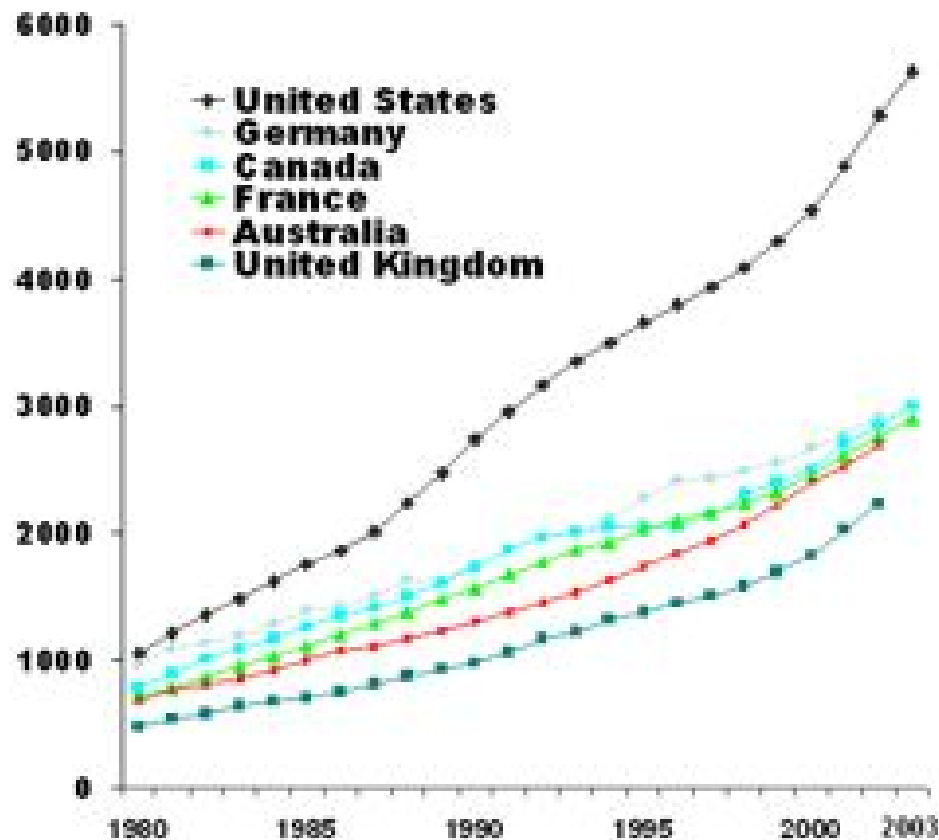
and

Principal Adviser, Pharmaceutical Policy Taskforce

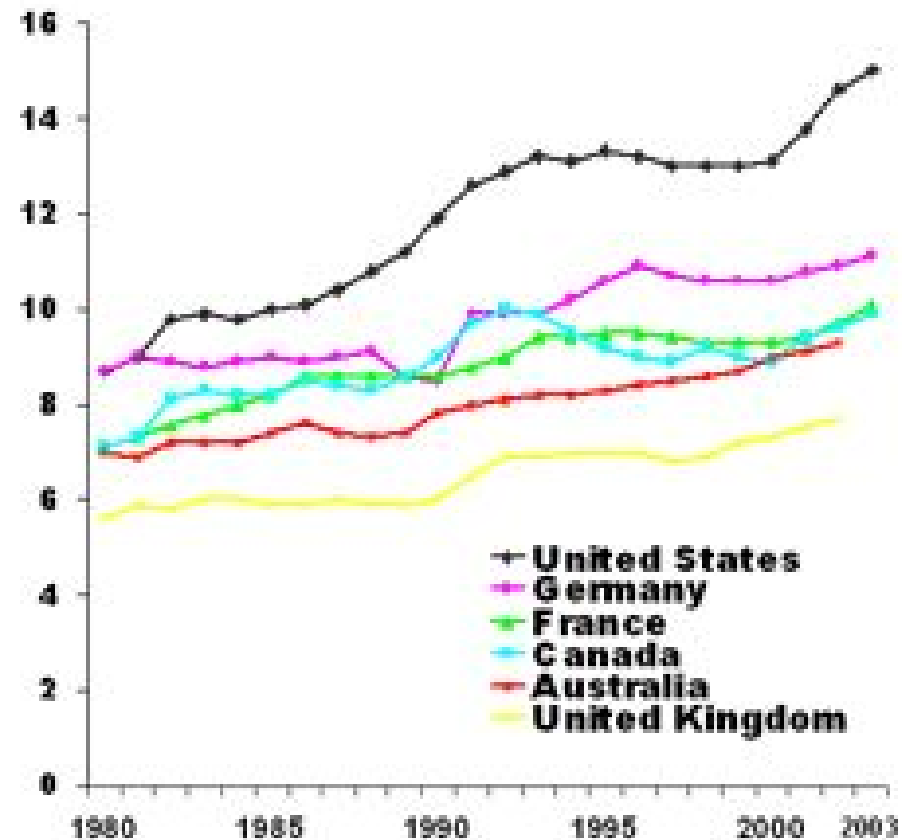
Department of Health and Ageing, Australia

Figure 1. International Comparison of Spending on Health, 1980–2003

Average spending on health per capita (\$US PPP*)



Total expenditures on health as percentage of GDP



* PPP = Purchasing power parity — an estimate of the exchange rate required to equalize the purchasing power of different currencies, given the prices of goods and services in the countries concerned.

Source: Organisation for Economic Co-operation and Development (OECD) Health Data, 2004.



National Medicines Policy

- Medicines meeting appropriate standards of quality, safety and efficacy
- Timely access to the medicines that Australians need, *at a cost individuals and the community can afford*
- Quality use of medicines
- Maintenance of a responsible and viable medicines industry



Pharmaceutical Benefits Scheme

Providing *timely, reliable and affordable access* for the Australian community to *necessary and cost effective* prescription medicines for >50 years

- Pharmaceutical benefits for war veterans from 1919
- 1946 Constitution amended to allow the Commonwealth Government to introduce a national subsidy system
- National Health Act (1953) established the PBS, PBAC
- Formulary selection on basis of clinical need
- Requirement for consideration of value-for-money introduced in 1988



PBS - overview

- Federal government program, all Australian residents eligible
- In community, not in public hospitals
- Comprehensive formulary
- Two levels of *fixed* co-payments based on income; safety nets protect against catastrophic expenditure
- In 2004-05, 170 million prescriptions reimbursed costing AUD 6.47 billion (around USD 4.7 billion); ~ USD 250 per person
- PBS 16.5% of the total federal health budget,
- ***A demand driven program with an uncapped appropriation***
- Nominal growth in PBS expenditure averaged > 12% over 1999-00 to 2003-04



Basis for subsidy

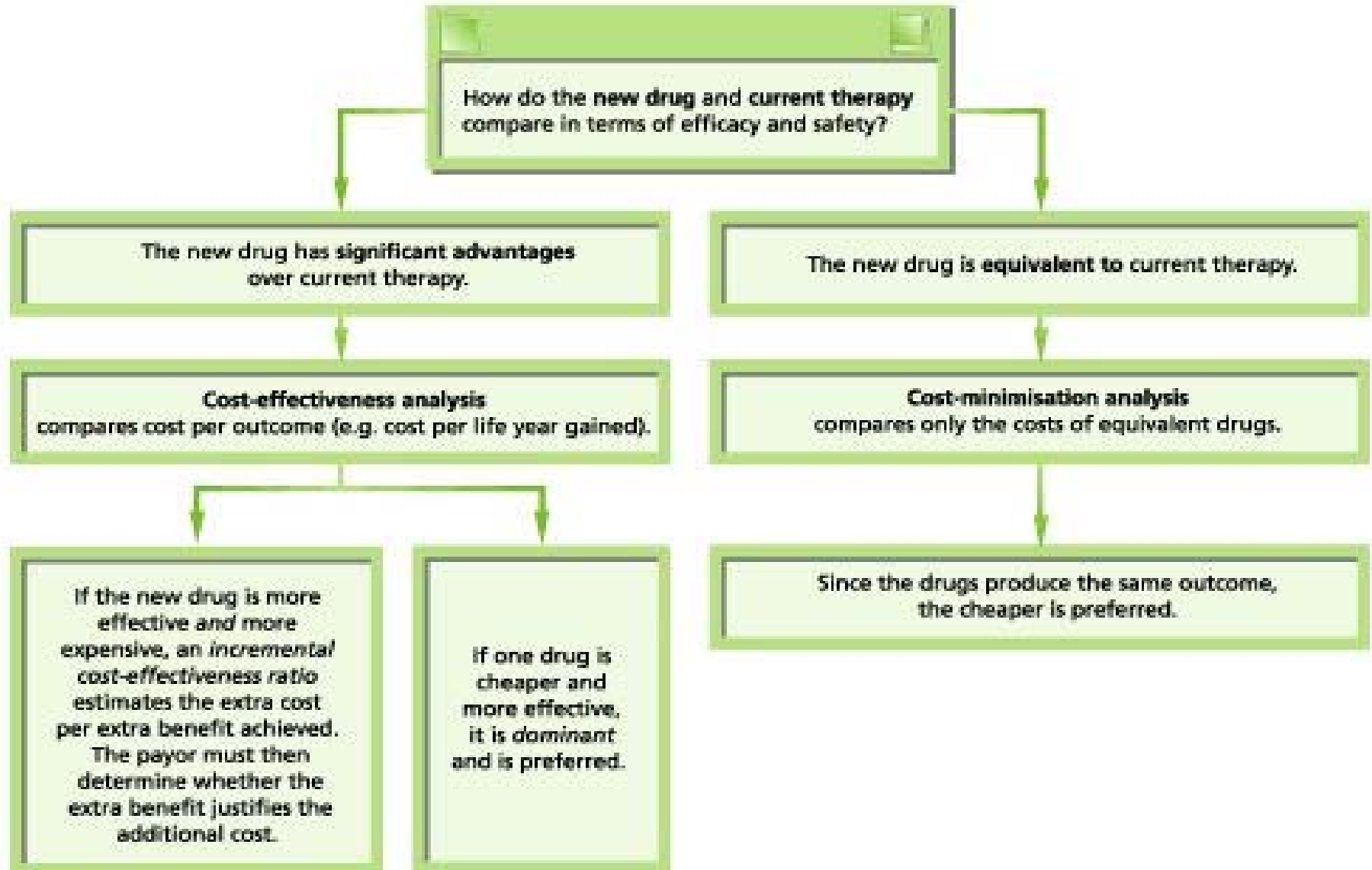
- Drug must be registered; only registered indications may be considered for subsidy
- Subsidy considered on the basis of comparative effectiveness and cost
- Under the legislation a medicine substantially more costly than alternatives cannot be recommended unless for some patients it provides additional benefit
- Ministerial decision but *Minister cannot list without positive recommendation from Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert advisory committee*
- All policies stem from principle of “*purchasing outcomes*”



The process

The sponsor lodges a submission, prepared according to detailed guidelines on how to collate and present evidence of comparative effectiveness and comparative cost effectiveness

- The submission undergoes detailed evaluation
- The sponsor provides comment
- The submission is considered by technical subcommittees of PBAC
- The sponsor provides further comment The submission is considered by the PBAC who makes a decision – to recommend, reject, or (rarely) defer
- *The whole process takes 17 weeks (cf NICE)*





Economic evaluation

- Cost Minimization Analysis - used when drugs have the same outcome - need to ensure that the new drug is no worse than comparator
- Cost Effectiveness Analysis - clinical advantage measured in natural units ie incremental cost per incremental unit of effect
- Cost Utility Analysis - health outcomes rated by preference strength (eg healthy years or quality adjusted life years - QALY). Output is incremental cost per incremental unit of preference state.
- Cost Benefit Analysis - rarely used, and not encouraged



Decision-making

- No simple decision rules, but careful weighing of relevant factors
- What is an acceptable ICER? There is no fixed threshold
 - PBAC considers AUD 50K/QALY “on the high side”
 - but has rejected drugs with lower ICERs and accepted drugs with higher ICERs
 - seems broadly consistent with NICE
- Many other factors including the disease context, severity, other treatment options, uncertainty in the ICER, equity, total cost etc



Restrictions

- Used to target drugs to indications, patient groups or clinical settings which achieve the optimum clinical and cost effectiveness - CE is context-dependent!
- Evaluation of cost effectiveness based on data from controlled clinical trials BUT is that cost effectiveness reproduced in practice?
- Listings may be
 - Unrestricted
 - Restricted Benefit
 - limiting the subsidized use to specific indications, patient groups or clinical settings
 - Authority Required
 - prior approval to prescribe required for an individual patient



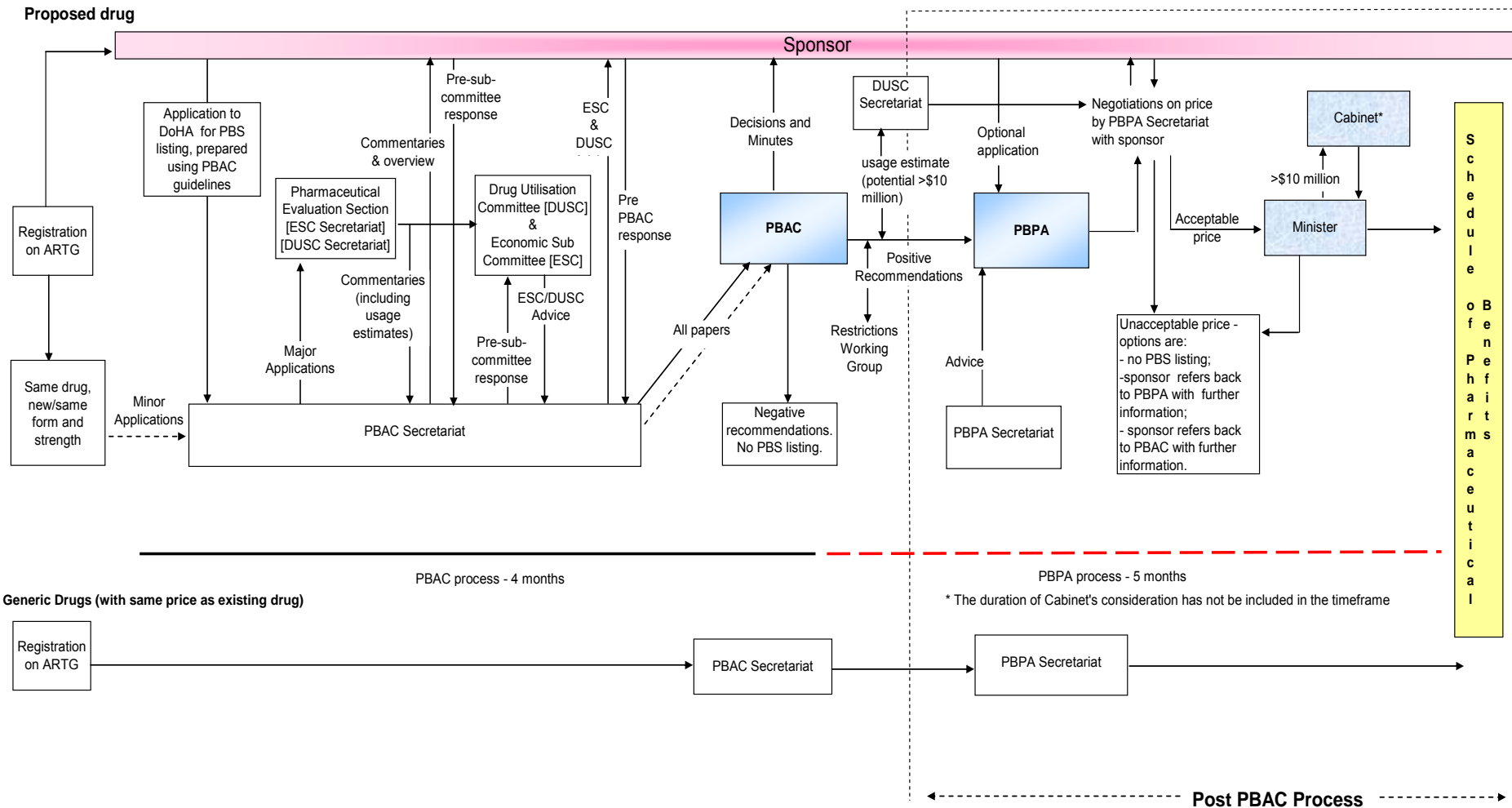
Eligibility and continuation criteria

- May involve step therapy to initiate Rx (eg TNF- α 's in rheumatoid arthritis prior treatment algorithm) + subjective/objective measures of patient response
- Cholinesterase inhibitors in dementia - use of changes MMSE scores
- Gleevec in CML - evidence of Ph+ or *bcr-abl* for initiation of Rx, + major cytogenetic response (MCR) for continuation
- Tracleer – survival registry (ie similar to coverage with evidence development)



Figure 1

Process to gain PBS listing for registered drugs





Exploding some myths

➤ **Myth #1 - “The Government is setting prices”**

- The Government does not set the price (cf Canada)
- The price is proposed by the sponsor and accepted if supported by evidence of comparative clinical benefit and cost effectiveness
- Principle of purchasing outcomes underpins (internal) reference pricing paradigm
- Patent status is irrelevant – many patented medicines are reference priced to off-patent drugs (patent doesn't confer any clinical benefit)
- This leads to
 - Prices for “me-too” drugs significantly lower than US
 - BUT prices for truly innovative drugs often HIGHER
 - *An outcomes-based rewards system for innovation?*



Exploding some myths (2)

- **Myth #2: “The PBS processes are a mechanism for restraining spending on pharmaceuticals!”**
 - If they are then they’re not working!
 - It’s a mechanism for ensuring the taxpayers get reasonable (NB not best) *value for money*

- **Myth #3: “The PBAC doesn’t always consider hospitalization costs and other cost offsets”**
 - It most certainly does. This is clearly laid out in the Guidelines
 - PBAC considers budget impact on PBS but cost effectiveness perspective is that of the health care system as a whole (with the addition of patient co-payments)



Exploding some myths (3)

- **Myth #4: “Australian patients are missing out on advances in medical care”**
 - No substantive gaps in the formulary
 - Strong community and professional support for the processes and the program

- **Myth #5: “The Australian system is slower to provide dissemination of new drugs than the US ”**
 - How?
 - US makes no attempt to ensure dissemination other than through the regulatory process
 - No dissemination at all to the uninsured
 - Regulatory processes in Australia no slower than in US
 - Lack of PBS listing does not preclude private prescription and PBS has no reach on prices in private market



Exploding some myths (4)

- **Myth #6: “The Australian Government is a lazy monopsony that is applying unfair market power”**
 - Government is acting like any rational large purchaser in the market would do
 - Prices are not set arbitrarily but accepted if the therapeutic value of the drug justifies the price requested
 - Government is acting like any well informed consumer would/could/should do.



Subsidy options – the system could subsidise...

- all registered pharmaceuticals at the price requested (the preferred industry option)
- all drugs at price requested but cap the total drug budget
- all drugs at price requested but with total cost of drug/drug class capped
- all drugs at a fixed proportion of the requested price eg 50%
- only one drug of a class at a tendered price, or
- evaluate cost vs benefit in an uncapped system

Which option provides greatest equity and recognition of opportunity cost in health care?



Drug-Coated Stent Case Highlights Problem of Health Care Costs

The question of whether the benefits of drug-coated stents outweigh the risks is "a nearly perfect example of what's wrong with our health care system.

"The problem is that there's nobody whose job it is to say no. .. no federal agency or medical group takes action when an expensive form of treatment becomes far more common than it needs to be -- which is a big reason that health care spending is rising so rapidly...Economic incentives for doctors to choose the most aggressive treatment certainly play a big role (however) to save real money, reform can't simply be about taking profits away from doctors or insurers ...

...it will also have to involve an acknowledgement that, sometimes, Medicare or an insurance policy should nudge people away from the latest, greatest treatment"

(Leonhardt, *New York Times*, 12/13).



Clinical Fracture Arm of the Fracture Intervention Trial				
Fracture/ population	Alendronate	Placebo	RD (95% CI)	RR (95% CI)
Any clinical #				
- CFA	272/2214 (12.3%)	312/2218 (14.1%)	-1.8% (-3.8, 0.2)	0.87 (0.75, 1.02)
- CFA T _≤ -2.5	107/819 (13.1%)	159/812 (19.6%)	-6.5% (-10.1, -2.9)	0.67 (0.53, 0.83)
Morphometric Vertebral #				
- CFA	43/2057 (2.1%)	78/2077 (3.8%)	-1.7% (-2.7, -0.6)	0.56 (0.39, 0.80)
- CFA T _≤ -2.5	22/757 (2.9%)	44/763 (5.8%)	-2.9% (-5.0, -0.8)	0.50 (0.31, 0.83)
Non-vertebral #				
- CFA	261/2214 (11.8%)	294/2218 (13.3%)	-1.5% (-3.4, 0.5)	0.89 (0.76, 1.04)
- CFA T _≤ -2.5	101/819 (12.3%)	150/812 (18.5%)	-6.1% (-9.7, -2.7)	0.67 (0.53, 0.84)
Hip #				
- CFA	19/2214 (0.9%)	24/2218 (1.1%)	-0.2% (-0.8, 0.4)	0.79 (0.44, 1.43)
- CFA T _≤ -2.5	8/819 (1.0%)	18/812 (2.2%)	-1.2% (-2.6, 0.0)	0.44 (0.20, 0.98)
Wrist #				
- CFA	83/2214 (3.7%)	70/2218 (3.2%)	0.6% (-0.5, 1.7)	1.19 (0.87, 1.62)
- CFA T _≤ -2.5	34/819 (4.2%)	38/812 (4.7%)	-0.5% (-2.6, 1.5)	0.89 (0.57, 1.39)
Other* #				
- CFA	182/2214 (8.2%)	227/2218 (10.2%)	-2.0% (-3.7, -0.3)	0.80 (0.67, 0.97)
- CFA T _≤ -2.5	71/819 (8.7%)	111/812 (13.7%)	-5.0% (-8.1, -2.0)	0.63 (0.48, 0.84)



The price tag on progress

“As a society, we are reluctant to systematically deny access to expensive treatments that extend life by a few weeks, but the morality of refusing to make deliberated choices is itself questionable”

D Schrag, NEJM July 2004



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Thank you

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