

PHARMAC and Medication Funding - How difficult can it be?

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New medicines are important

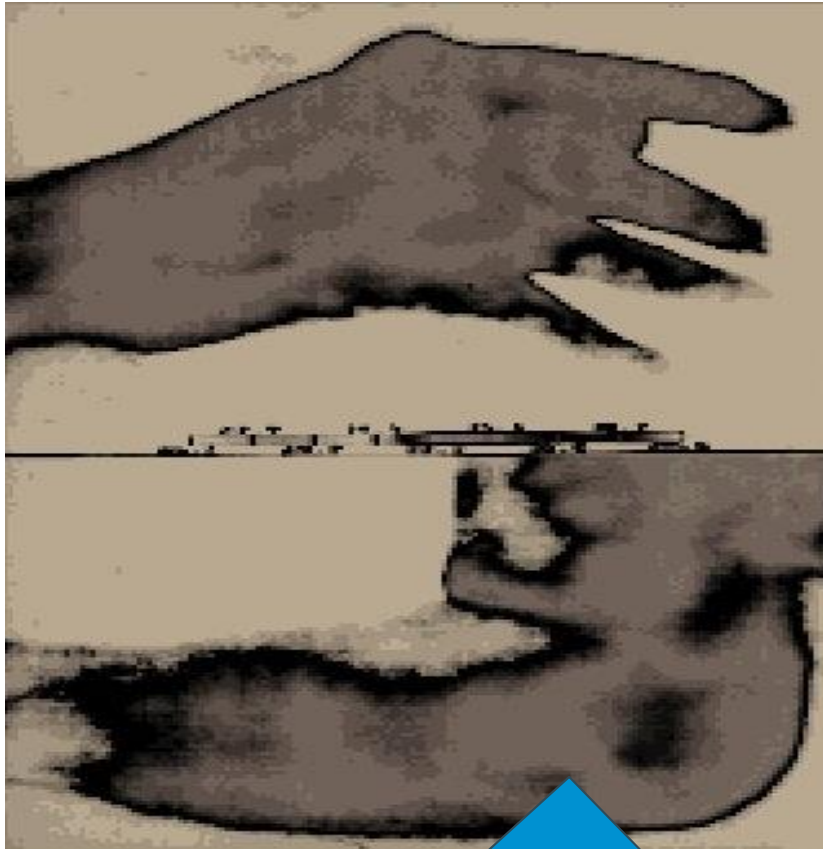
There are real **'game changers'**

- Hep C treatments, Rheumatology, Oncology

Bringing a medicine to market costs money/time/resources

Pharmaceutical companies are critical for bringing new medicines to the market

Controlling Rheumatoid Arthritis

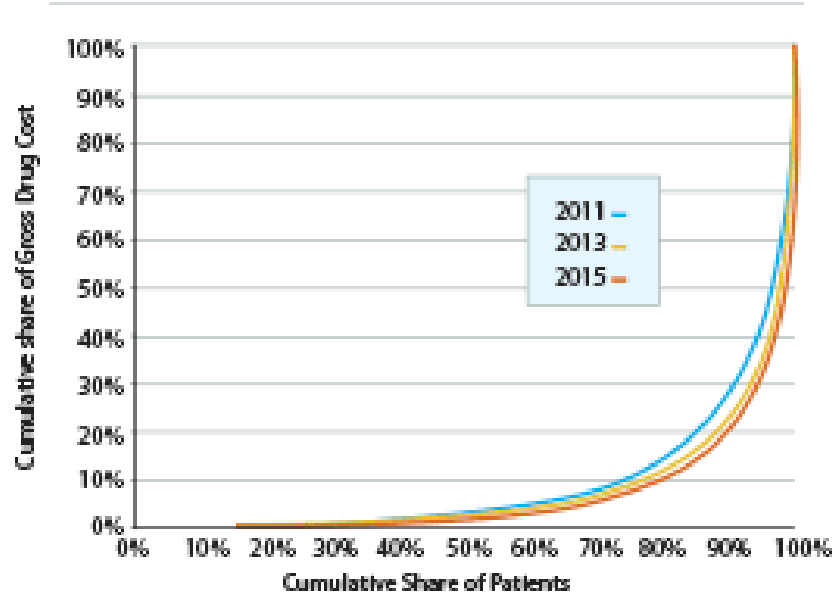


Thermal imaging of hand and elbow joints before.....



..and after Mab therapy

Medicine cost vs patient numbers



LAST YEAR MEDICINES
FOR **10%**
OF ALL PATIENTS

USED
80%
OF THE BUDGET



The funding environment

**PHARMACEUTICAL INDUSTRY
GETS HIGH ON FAT PROFITS**

BBC News

KALYDECO – TOO HIGH A PRICE TO PAY?

Milwaukee Sentinel

THE RACE TO CURE RISING DRUG COSTS

Financial Times

THE DRUG THAT IS BANKRUPTING AMERICA

Huffington Post

Health care wants exceed resources available...



... so choices need
to be made

Pharmaceutical funding decisions are complex



What makes the issue complex?

Environment:

- Competitive marketplace
- International medicine pricing
- Public expectations (internet and media)

The Evidence

- its more than the results

Spend more money?

Table 1. Life Expectancy and Health Expenditures Worldwide³

Country	Life Expectancy (female-years)	Total Expense per Person (US \$)	% of GDP
Australia	83	2,519	9.5
Canada	83	2,669	9.9
Ireland	81	2,860	7.3
Japan	86	2,662	7.9
Monaco	85	4,587	9.7
Singapore	82	964	4.5
Spain	83	1,541	7.7
Switzerland	83	5,035	11.5
United Kingdom	81	2,428	8.0
United States	80	5,711	15.2

Abbreviation: GDP, gross domestic product.

Shift the existing money around?

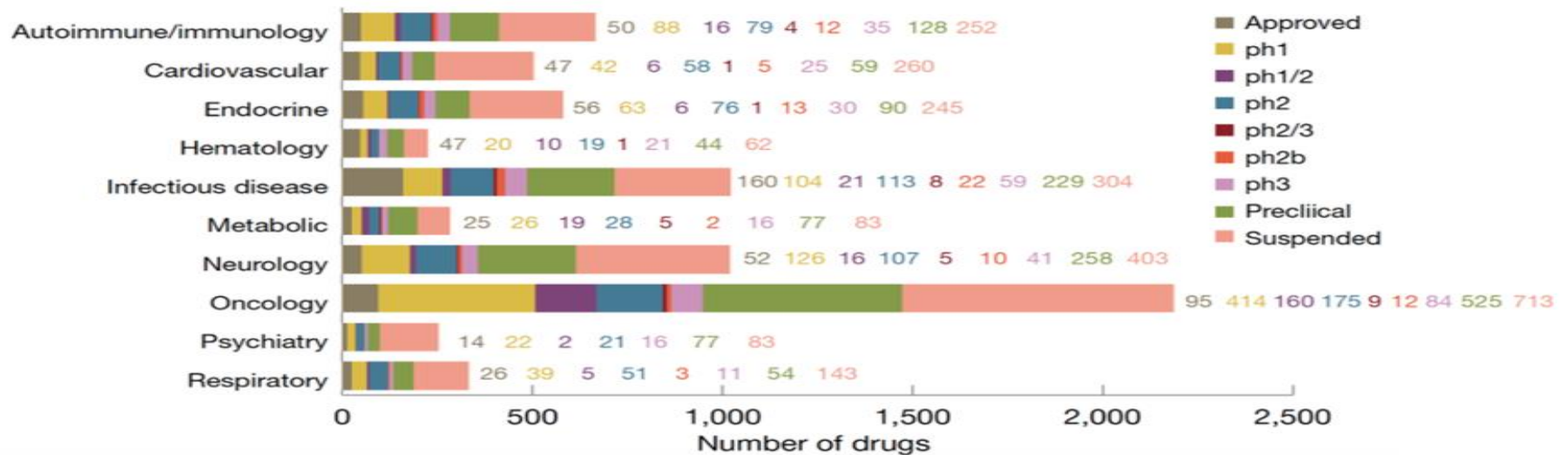
NZ Doctor

Shift gut money to
cancer, says gut doc

R&D is focused in certain therapeutic areas

Top ten disease groups by pipeline size

Oncology continues to dominate the drug pipeline



Intrinsic value – All benefit?

Our prescription drugs are the **third leading cause of death** after heart disease and cancer.

Based on the best research I could find, I have estimated that psychiatric drugs alone are also the third major killer, mainly because antidepressants kill many elderly people through falls.

What makes this tragedy particularly absurd is that the vast majority of the deaths can **easily be prevented**.

Pills, pills!
The magical fruit.



Ask your doctor if pills are right for you.

Environment

+

Evidence

New Medication is Expensive

As **clinical leaders** - need to be aware of extent of the issues .

There are real **'game changers'**

- Hep C treatments, Rheumatology, Oncology.

Financial toxicity

- 'patient-level impact of high cost oncology drugs' (Abernathy + Zahar')

New Medication is Expensive

Eculizumab: Paroxysmal nocturnal hemoglobinuria (PNH):

- \$576,000 per patient.
- 400 in Australia – \$280 million per year.

New Hep C Meds:

- 50000-60,000 Euros per year per 12 week course
- *756 times cost production in France

Oncology Meds :

- Australian PBS 2000: \$65million , 2012: \$466 million
- US 7-10% growth yearly: 2020 Est: \$150 billion

Cost Pressures

Most commodities depreciate over time

Medicine is unique- cost increase each year.

- Daraprim available 5 decades parasites in HIV – US13.50 per tablet to \$750 US per tablet
- Epi-pen: 2007: US \$123, 2016 US \$799 – 16 fold increase. Since company take-over
- Imatinib(Leukaemia): \$30,000 2001, US \$92,000 in 2012

USA:

50% global pharmaceutical market – key bearing on medication cost in rest of world:

- **Medicare prescription Drug, Improvement and Modernization Act (2003)**
- Prohibits Medicare from negotiating medicine prices.
- Price determined entirely by industry – based on ‘what the market can bear’

Cost effective

Not necessarily

- Defined: QALY < \$50,000 per QALY gained
- 2003 and 2013:
New oncology meds increased overall survival average: 3.43 months
- 16% of 134 anti-cancer meds Europe 2009 to 2016 showed survival >3 months.
- Oncology meds cost increased 10 times in last 10 years ?
commensurate increase in effectiveness – challenge!

Research & Development

Justification: cost of research and development

- Cost new medicine development
 - \$2.6 billion 2014, up from \$802 million 2003
- Contested – some authors <\$100million.

Why:

- Cost of failed medicines can be (80%) put into calculation.
- Independent verification difficult
- Overlook public funding:
 - tax credits
 - non-profit
 - university
- Accounts for 84% of basic research .

Effect

- **Patient** – access to medication esp. long term therapy.
- **Companies:** high price – more likely to develop second generation medicines on existing meds rather than novel new class.

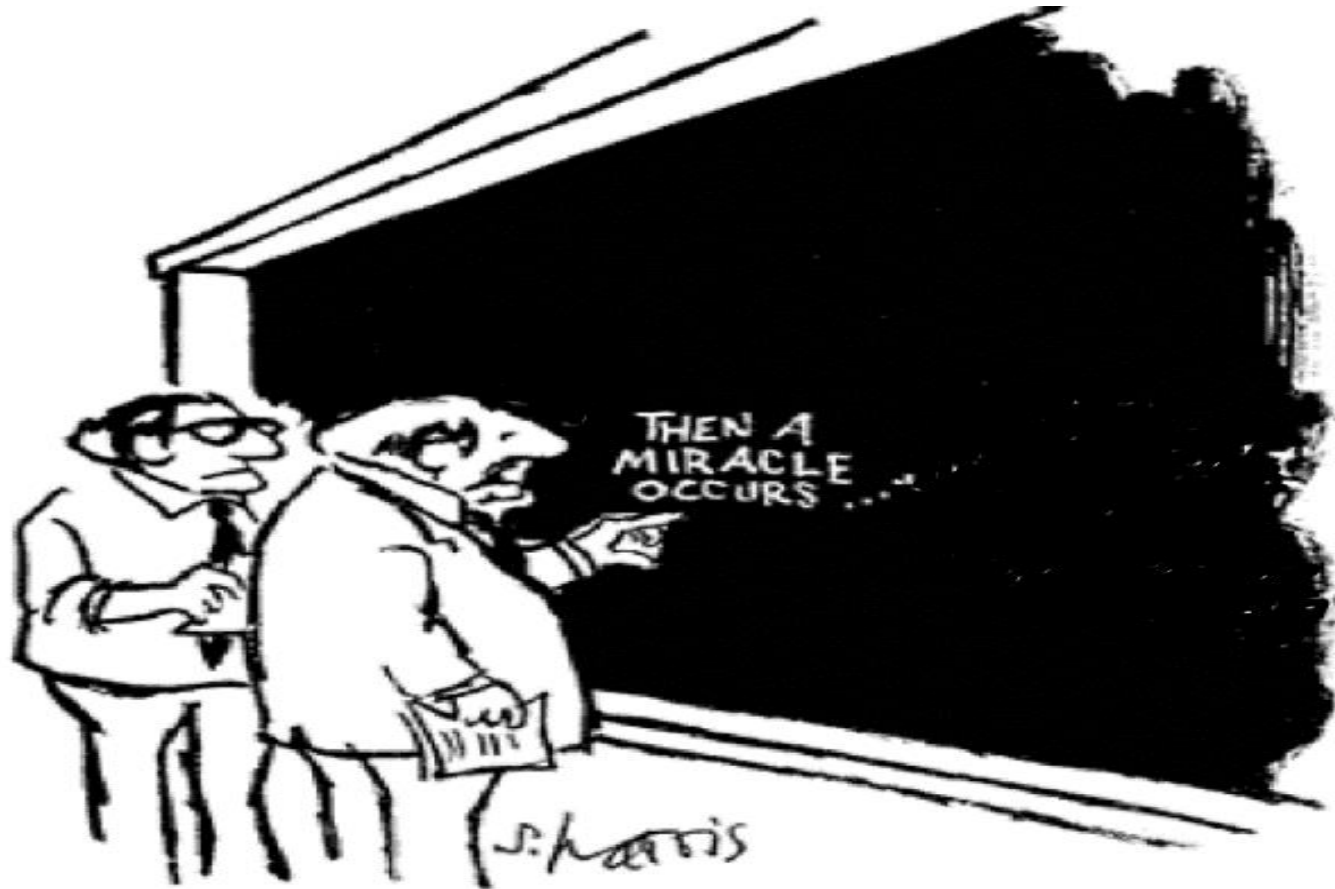
Role:

- Government agencies
- Health professional – questioning prescription behavior
- Professional bodies – guidelines.

Regulation:

- Transparency
- Focus: Tension between early access weighed against pricing.

Issues with Evidence



"I think you should be more explicit here in step two."

Study Design

1. Quality and design of a study are more important than the results of a study
 - **As Doctors we're more interested in the results** - read the heading, then go straight to the conclusion!!
2. Primarily studies are designed to get drugs onto the market, not to give optimal use, place in treatment paradigm or relative value
3. A tension exists between then need to do something for my patient versus the true benefit of the intervention

Studies: Analysis Issues:

Assessments often based on derived , modelled estimates, not measured improvements in survival:

- Modelled consistently greater than measured gains
- Modelled make assumptions or adjust for post study estimates.

Unrepresentative populations

- Survival benefits occur in un-representative populations
- Often younger, less co-morbidity
- When applied to real world small benefit 'disappears due to balance/risk

Studies: Particular challenges – Analysis and results

The more the data is cut the more likely a positive result

How are **the results reported** :

- Rosuvastatin JUPITER study, 2010.
- Healthy individuals with statin
- High HsCRP – surrogate marker.
- RR: 44%

Critique:

- Absolute Risk reduction: 0.2 to 0.6%
- Stopped after 1.9 years – extrapolated out to 5 years
- Patient group - relevant?

Use of **surrogate** ('proxy' 'substitutes') markers

Surrogate Outcomes

- Surrogates often used as proxies for hard clinical outcomes.
 - Does the endpoint = real outcome
- Surrogate outcomes (PFS) poorly correlated to survival.
- Few have good evidence
- Post marketing studies rarely validate efficacy and safety.

Surrogates: Statistics cannot remedy basic problem of extrapolation in the face of incomplete knowledge

Surrogate:

- Evidence a drug increases High Density Lipoproteins (HDL), to the belief the drug will lower risk of cardiovascular disease.
- Ezetimibe: Improves lipid profiles, increases carotid intima-medial thickening- complicated to interpret?
- Example: PVCs as surrogate for CVD mortality in anti-arrhythmics.
- Rosiglitazone

Issues with Trials:

- Marginal benefit
- Few patient centered outcomes
- Weak surrogate markers
- Cost of R&D

Tension...

‘Findings underline the importance of decisions...be made through appropriate health technology appraisal. **Only then best decisions to ... maximize value for ... patients and society as whole**’

Richard Sullivan, Professor Cancer and Global Health Kings College

‘Support rigorous evaluation, it’s essential **new system offers fast access to innovative and exciting drugs...** to ensure patients not denied the most promising treatments because of their cost’

Paul Workman, chief executive of Institute of cancer Research London.

How do we manage the pharmaceutical funding issue?



PHARMAC's value add

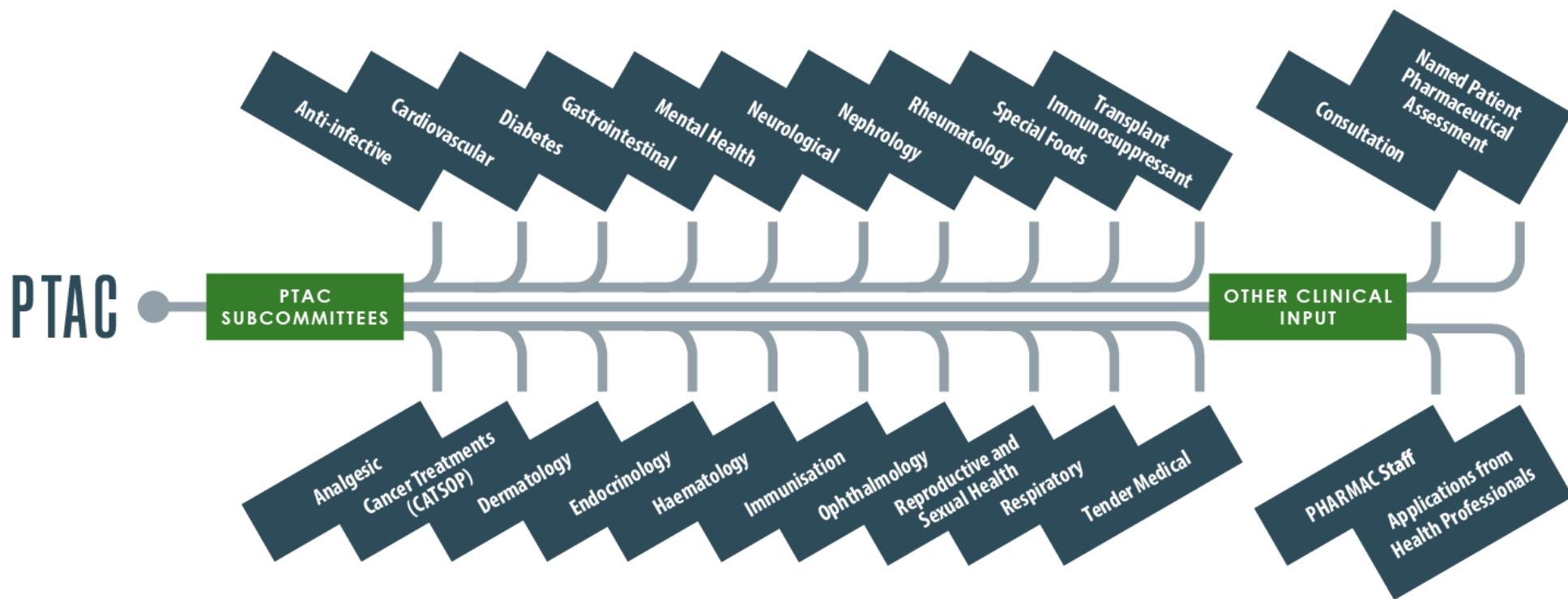
Appraise the evidence

Seek expert advice

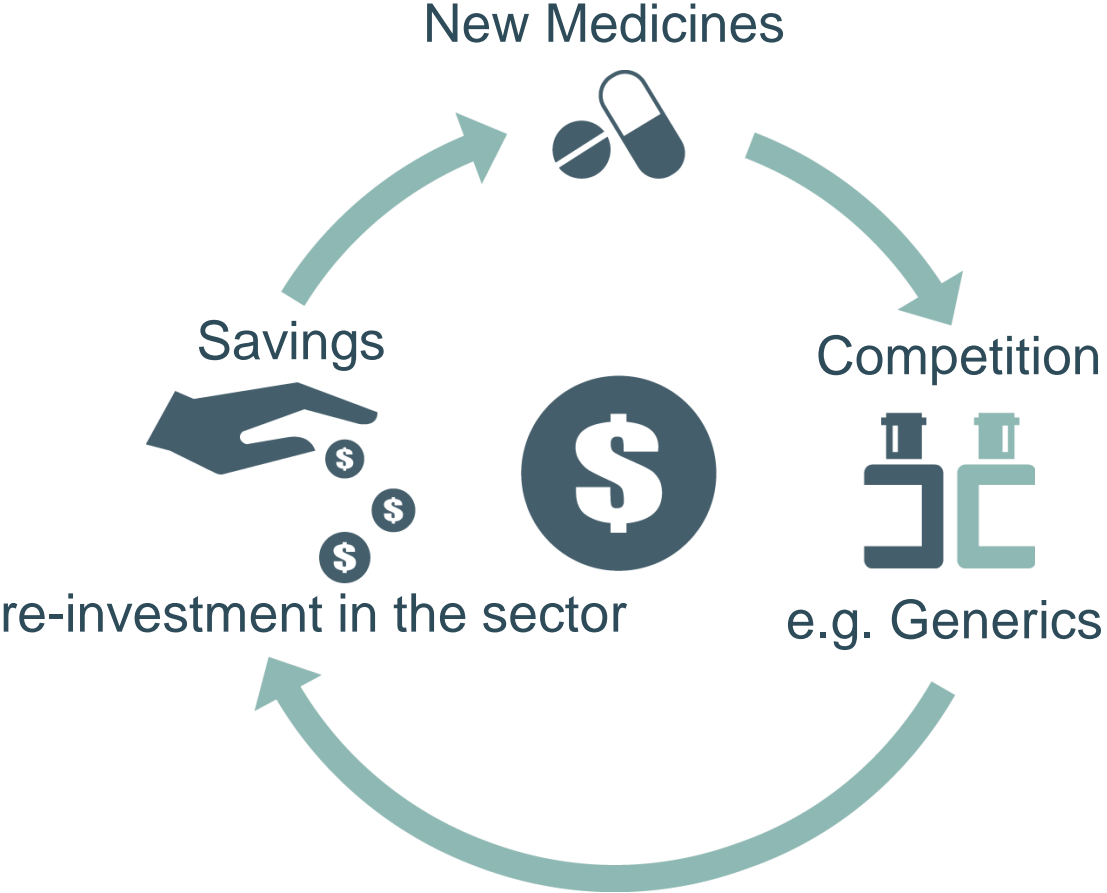
Commercial negotiation

Target funding

Getting clinical advice into our decision-making



PHARMAC's management model



1. Clinical advice appraisal – independent
2. Health Economics
3. Prioritization and Commercial Negotiation
4. Capped Budget

Key figures 2015 – combined pharmaceutical budget

\$795 MILLION
YEARLY DHBS' COMBINED
PHARMACEUTICAL EXPENDITURE
(ON BUDGET)

3.5 MILLION
NEW ZEALANDERS
RECEIVING FUNDED MEDICINES

43.1 MILLION ^{Rx}
NUMBER OF FUNDED
PRESCRIPTION ITEMS FILLED
(3.2% INCREASE)

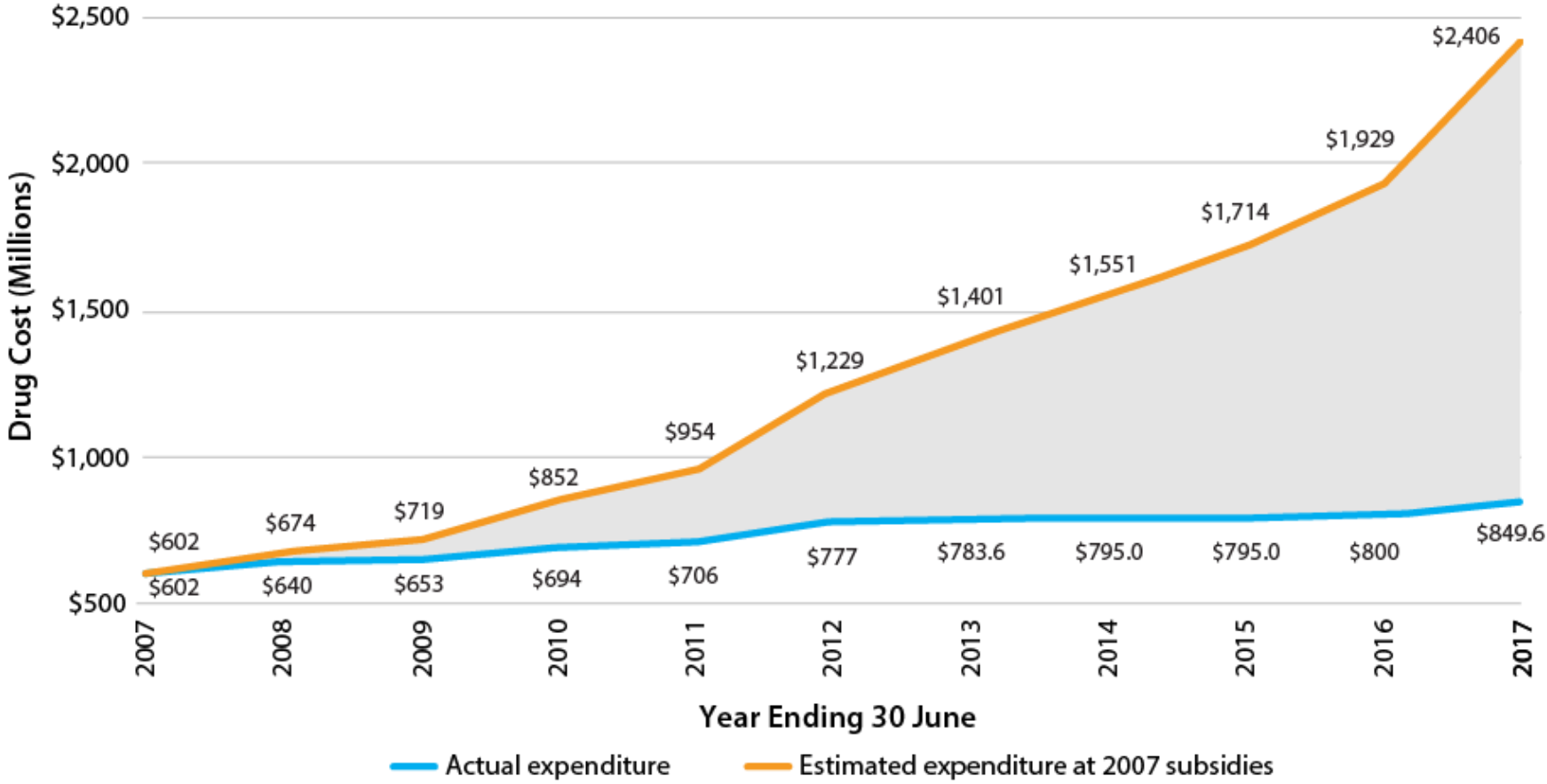
\$52.7 MILLION
IN SAVINGS ACHIEVED

21 NEW MEDICINES
FUNDED

AND
20 MEDICINES HAD
FUNDED ACCESS
WIDENED

70,685
NEW ZEALANDERS
BENEFIT FROM NEW FUNDING
DECISIONS

PHARMAC's long-term impact



Why PHARMAC Exists: The Patient



QUESTIONS