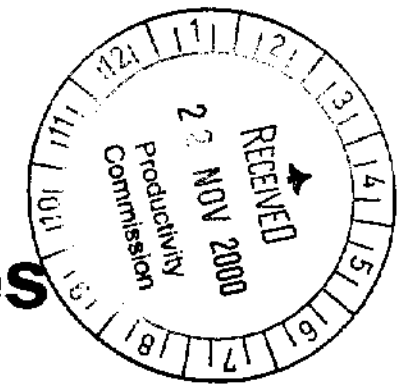
Presentation Outline

Cochlear

Cochlear Limited

Comparative Regulatory Agency costs

Therapeutic Goods Administration (TGA) fees and charges reduction arguments



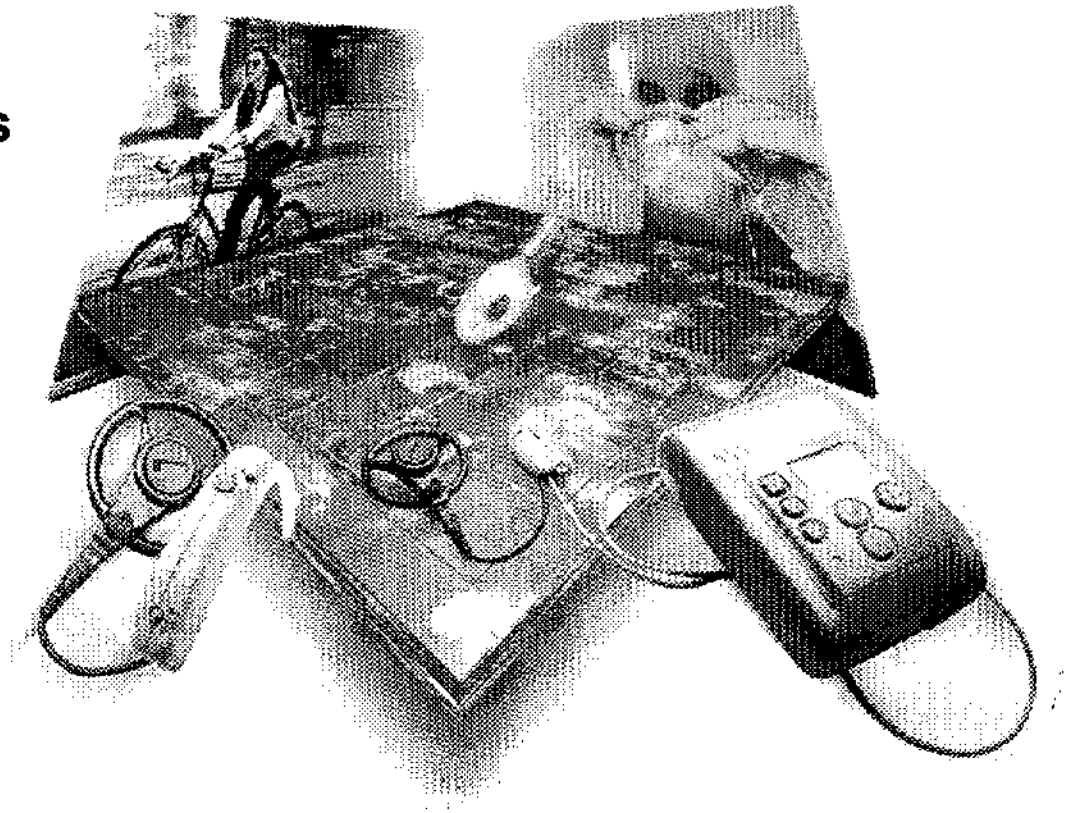
Johan M. Brinch
General Manager
Quality Assurance & Regulatory

Cochlear Limited

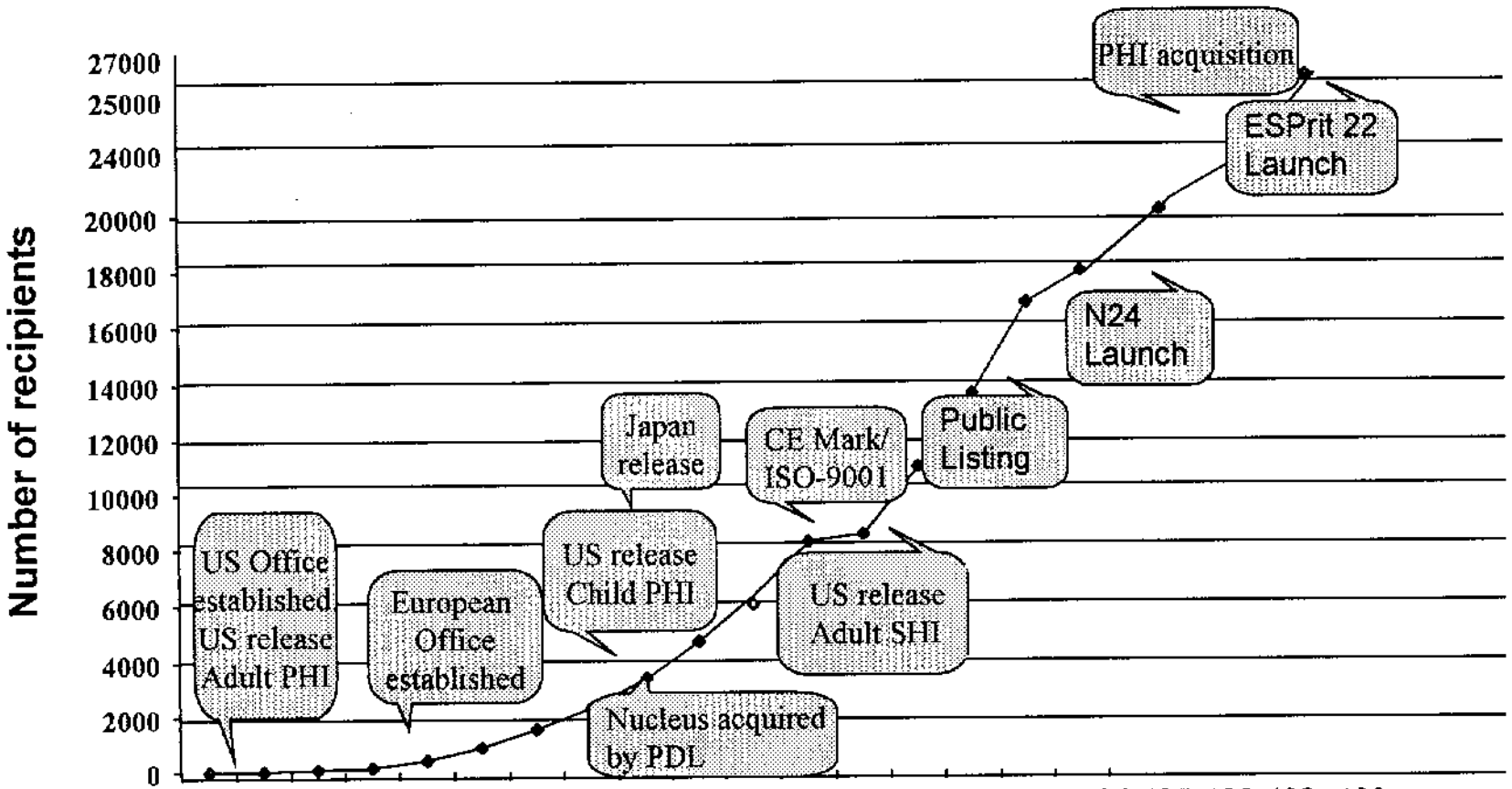
Cochlear

Publicly listed Australian company

We design and manufacture cochlear prosthesis systems and market them world wide



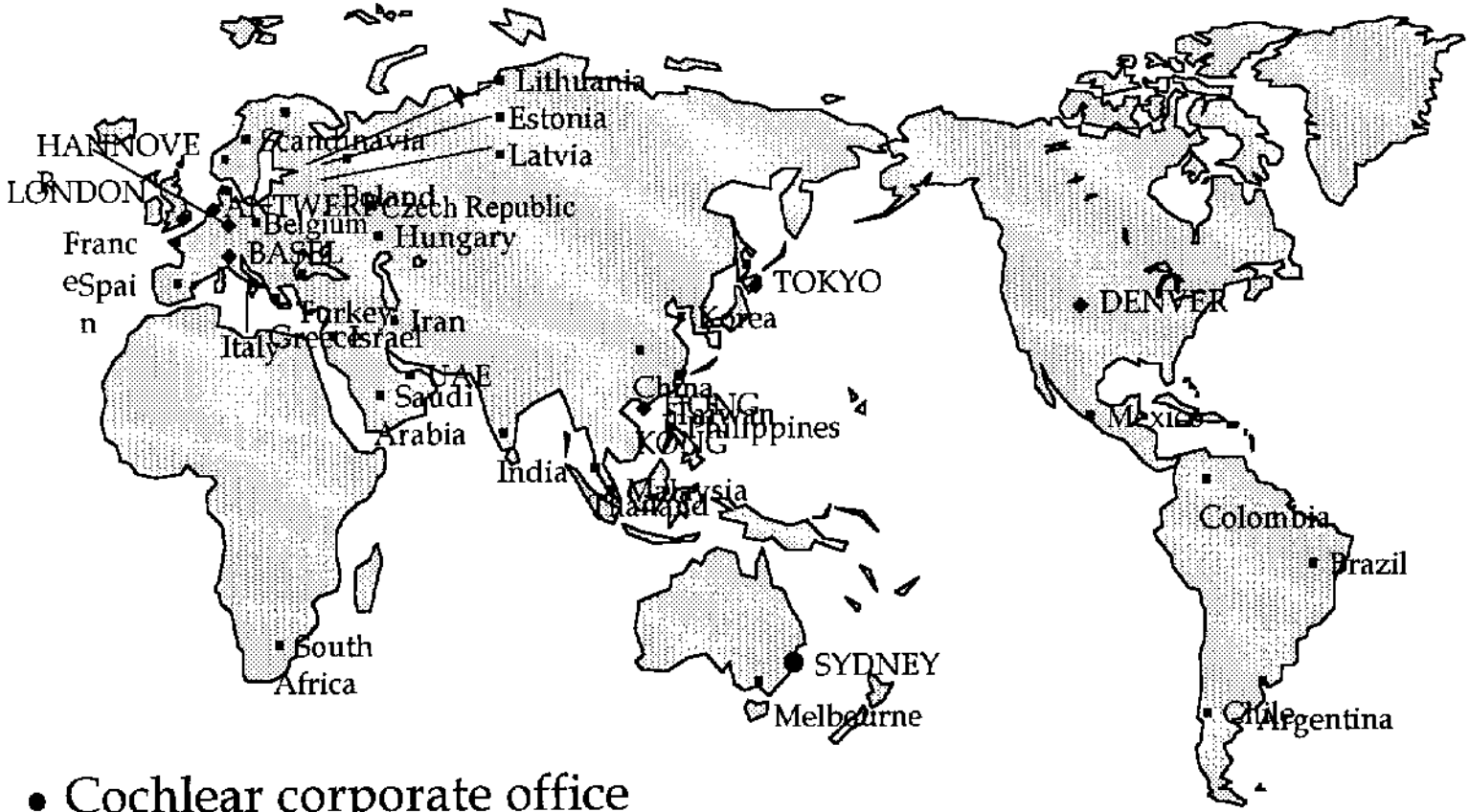
History of Cochlear



- 1967 Basic research (Professor Graeme Clark - University of Melbourne)
- 1978 First research implant
- 1981 Cochlear established as a division of Nucleus
- 1982 1st Cochlear implant surgery

Worldwide Distribution and Service to more than 50 Countries

Cochlear



- Cochlear corporate office
- ◆ Cochlear regional office
- ▪ Countries/ sites with Cochlear distributors

Earnings Growth of Cochlear

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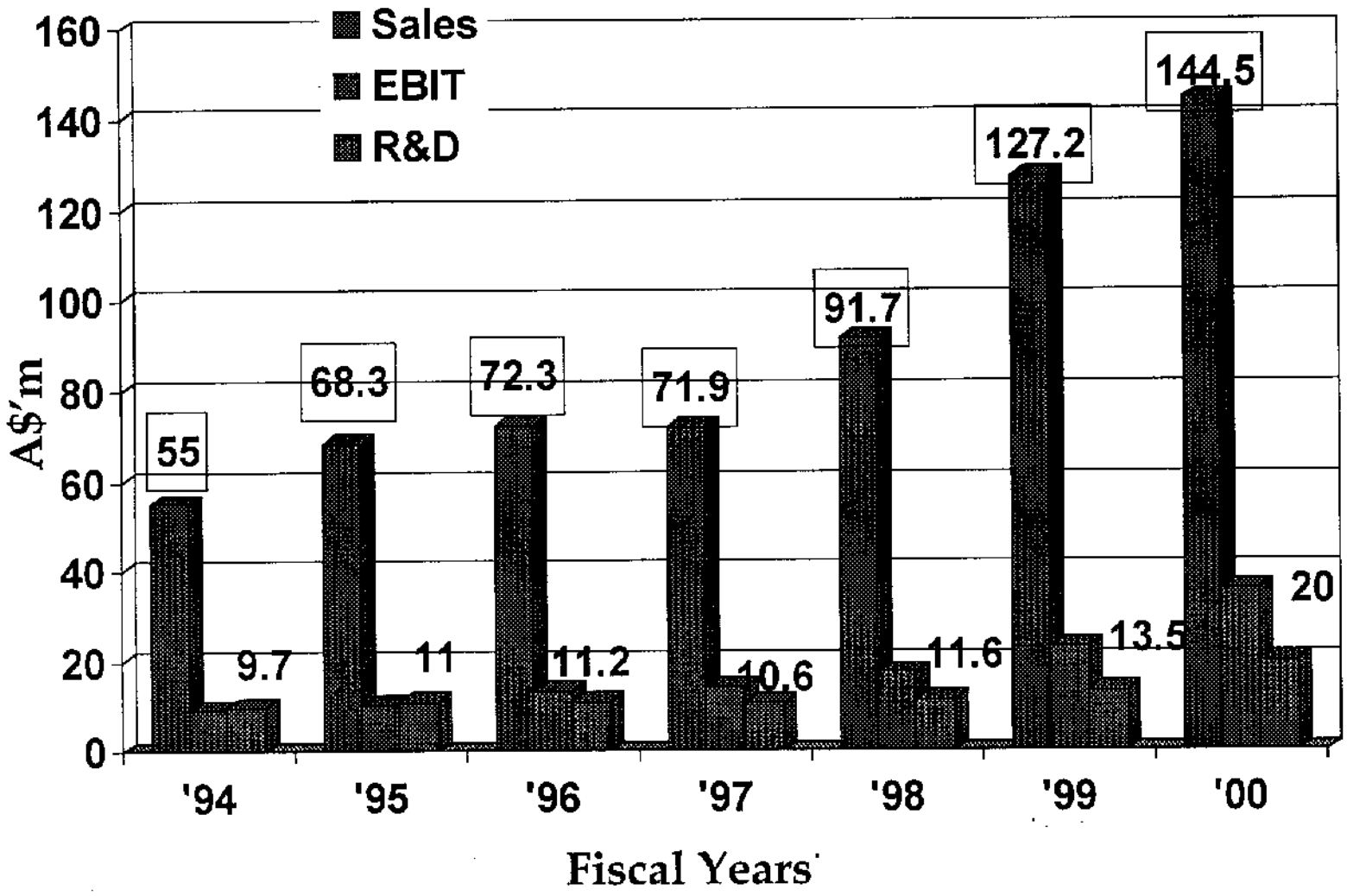

Cochlear's Regulatory Environment

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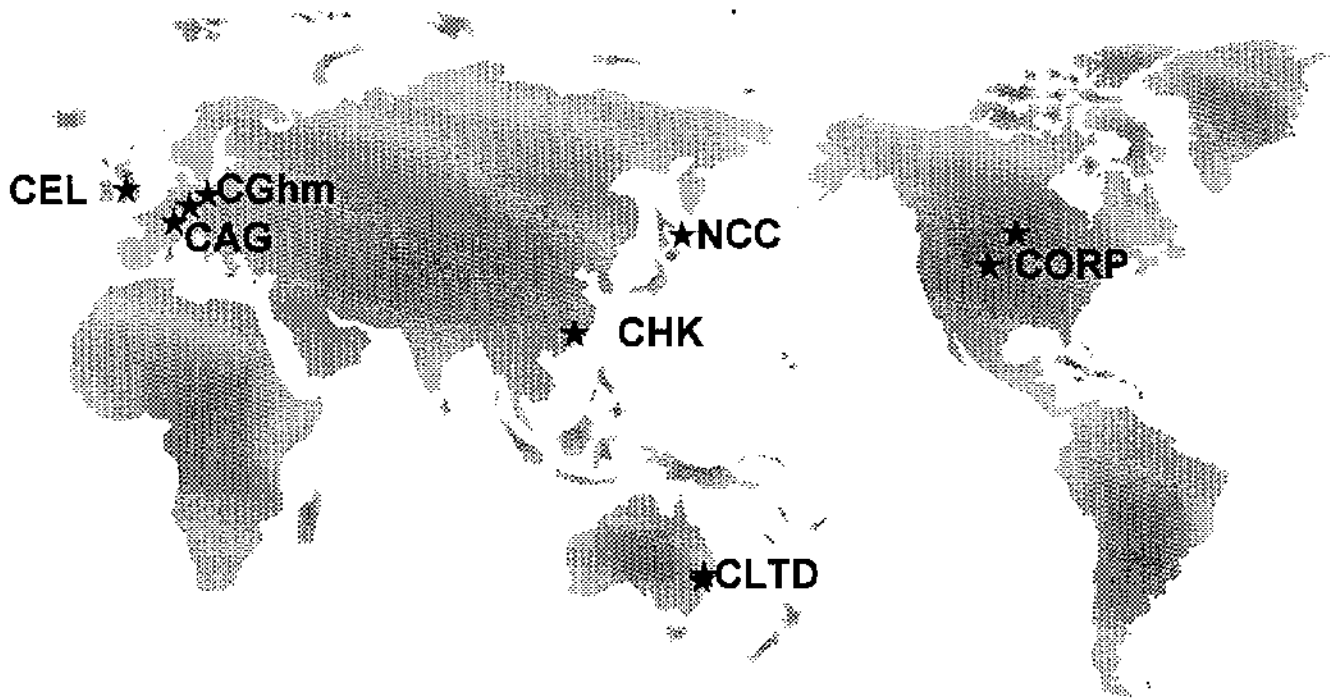

Therapeutic Goods Administration (TGA)	- Australia
Food and Drug Administration (FDA)	- USA
Medical Device Bureau (MDB)	- Canada
Medical Health and Welfare (MHW)	- Japan
European Commission (EC)	- Europe

Regulatory Costs and Markets

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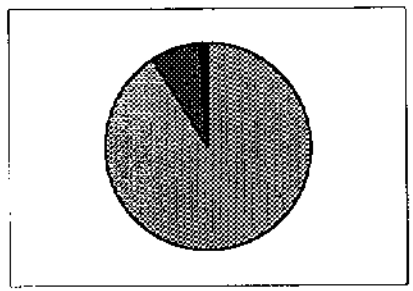
Illustration of the difference in fees and charges for a "High Risk" medical device and the relative market sizes

Country	Regulatory Agency	Fees $A June 1998	Fees $A Aug 1998	Fees $A May 2000	Relative market size[1]	Recovery Relativity factor[2]
Australia	TGA	$41,000	$59,000	$76,000	1%	760
Canada	TPP	$15,800	$15,800	$19,800	3%	66
Europe	TUV	$8,500	$8,500	$12,800	26%	4.1
USA	FDA	Nil	Nil	Nil	41%	0
Japan	MHW	$8,700	$8,700	$11,100	18%	6.2

1. Medical device market estimates made by Health Industry Manufacturers Association USA in 1993.
2. A relativity factor based on the regulatory fees divided by the size of the markets as an indicator of degree of difficulty to recoup regulatory expenses.



Key observation is the relativity factor in the ability to recover the costs

Cochlear Regulatory Costs

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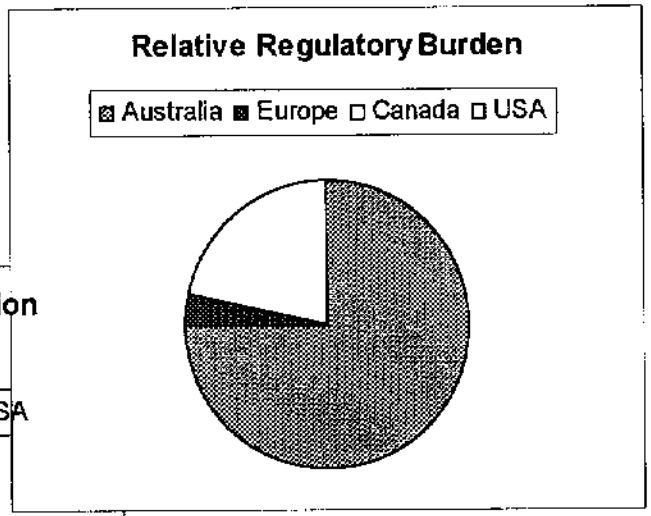
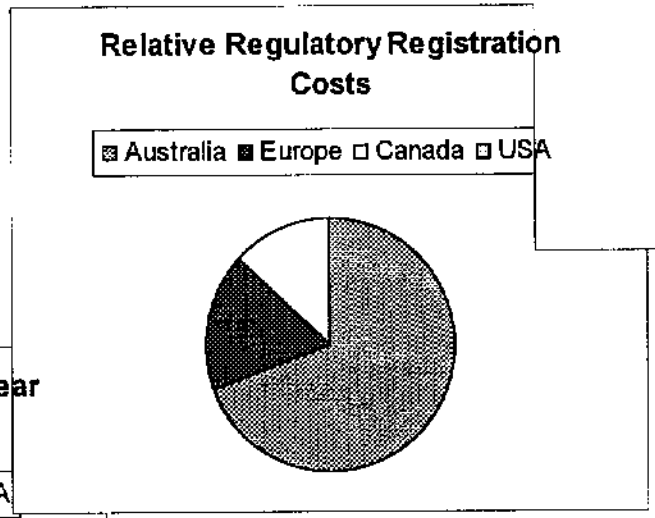
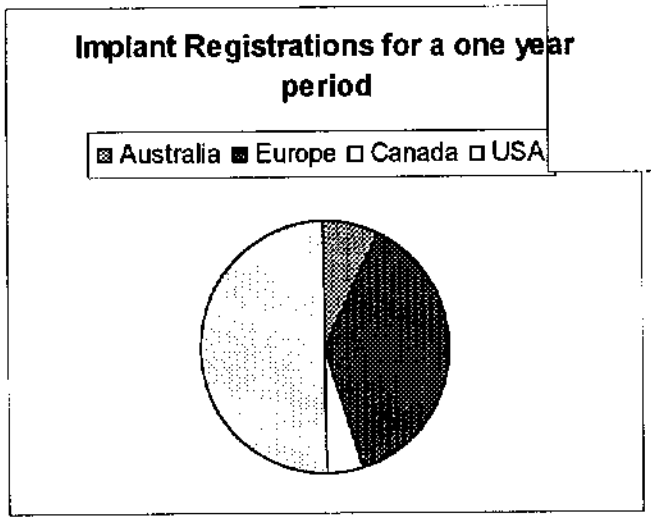
Relative cost per sale in Australia is much higher than in Canada, Europe and USA







Australia is by far the most costly for Cochlear

Cochlear sales in Australia are much lower than Europe and USA

Effect on Cochlear

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Product Offering

Cochlear is not intending to register two implant models in Australia.

Pricing

Cochlear adjusts prices to recover costs

Competition

Cochlear is in a privileged position because we can afford it

Cochlear's position

Cochlear

TGA's fees and charges, being the highest in the world as a result of the Government's 100% cost recovery policy, are unacceptable because we believe:

- **They are a barrier to trade**
- **They potentially stifle competition**
- **They create undue burden on start-up companies**
- **They prevent the public from access to medical devices and higher quality health care**

In short business and the public are losers, and interestingly, the net effect on Government revenue is at best neutral.

Cochlear's position

Cochlear

Cochlear believes that TGA's fees and charges should be dramatically reduced resulting in:

- Removal of the negative effects mentioned
- Stimulation of the Medical Device industry in Australia
- Benefits of better public access to the latest in medical technology and quality health care

Win – win on all fronts

Conclusion - Reduction of TGA fees and charges

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The time is right for change

TGA regulation is changing to harmonise with Europe and the Global Harmonization Task Force Model for Medical Device regulations (FDA, MDB, TGA, MHW, EU)

Mutual Recognition Agreements will demand that TGA becomes competitive with other medical device evaluation bodies.