Drug Discovery, Development and Commercialization, Winter 2013

Jan D. Hirsch, PhD
Pharmacoeconomics in Drug Development

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

Objectives

- Define basic types of pharmacoeconomic analyses
- Describe example value propositions for pharmaceuticals using direct cost, indirect cost and quality of life data
- Understand the role of pharmacoeconomics throughout the drug development process

Pharmacoeconomics

- Used by health care payers to compare the ***cost vs. benefit*** of alternative drugs for populations of patients
- Definition:

  Balancing *costs* and *consequences* (outcomes) of pharmaceutical *therapies* and *services*.

Bootman, Townsend, McGhan. Principles of Pharmacoeconomics. 3rd edition 2005.

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$$\frac{\textbf{Cost}}{\textbf{Outcome}} = \textbf{VALUE}$$

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Pharmacoeconomics

Health Economics, Outcomes Research

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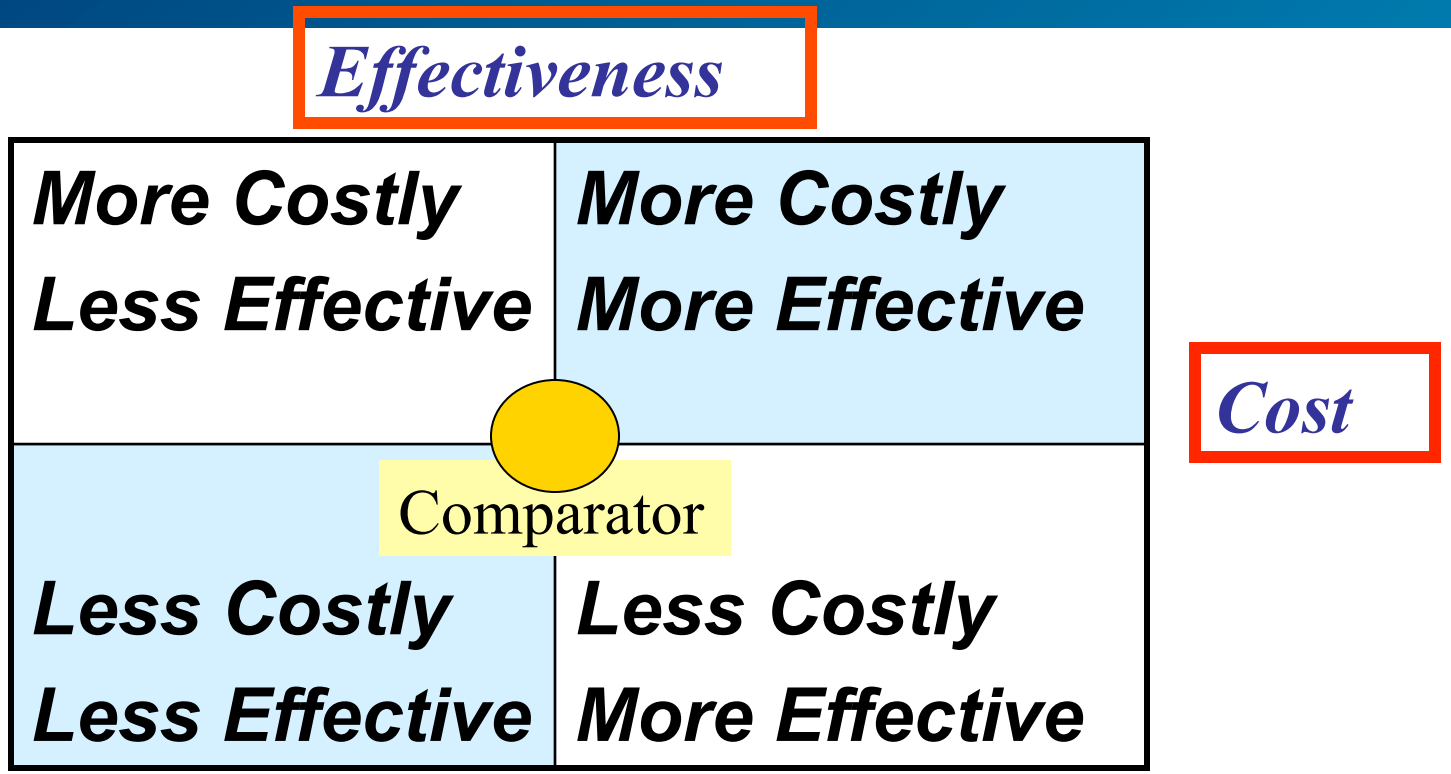
When Need Pharmacoeconomics?



Bootman et al 2005 page 109

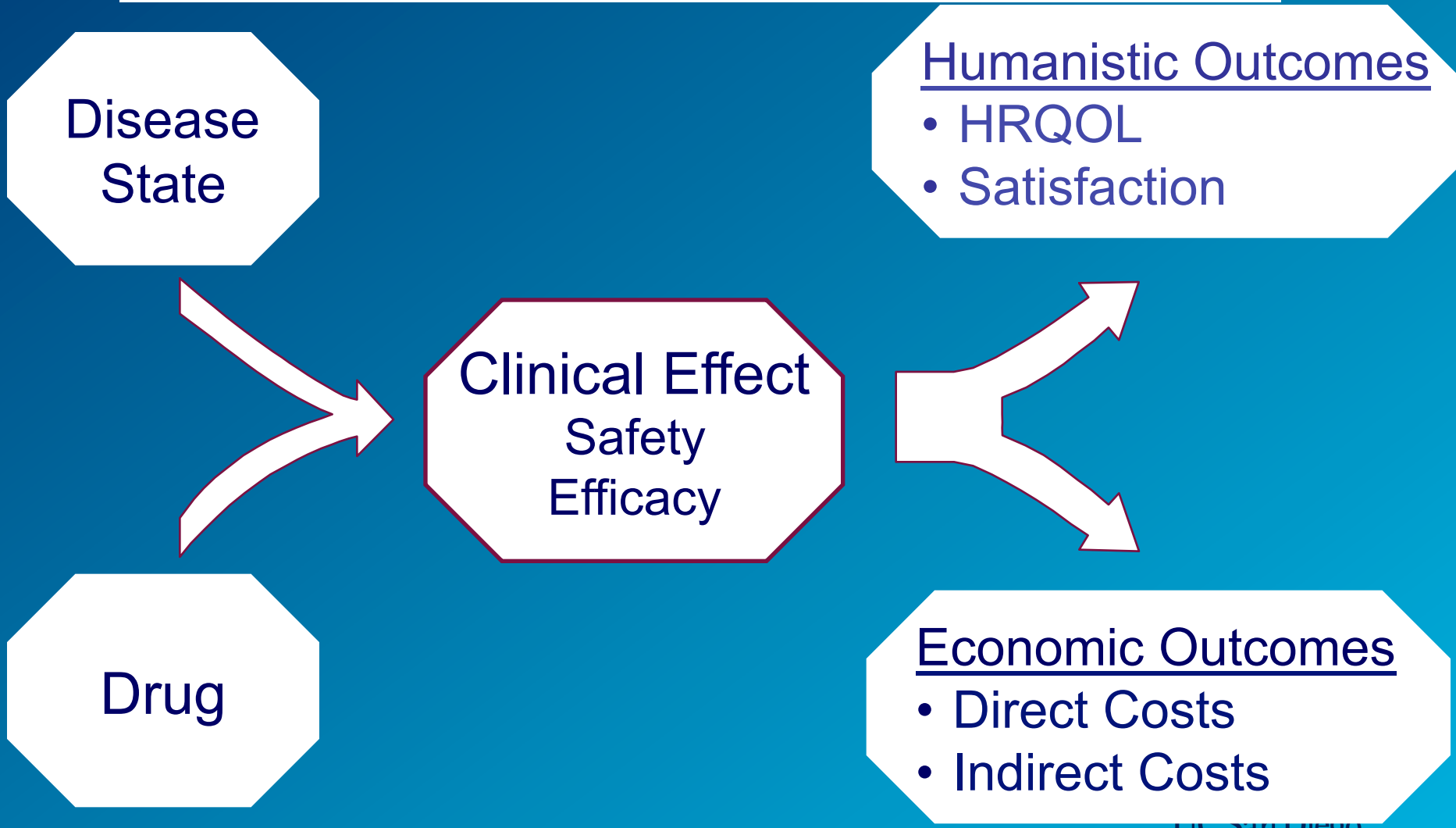
PE Requirements for Reimbursement

COUNTRY-SPECIFIC PHARMACOECONOMIC GUIDELINES

	Published PE Recommendations	PE Guidelines	Submission Guidelines
Africa	South Africa *2010*		
America-Latin		Brazil *2009* Cuba *2003* México *2008*	
America-North	United States *2009*	Canada *2006*	
Asia	China Mainland *2011*	Taiwan *2006* South Korea *2006*	Israel *2010* Thailand *2008*
Europe	Austria *2006* Denmark *1997* Hungary *2002* Italy *2001* Russian Federation *2010* Spain *2010*	Baltic (Latvia, Lithuania, Estonia) *2002* Belgium *2008* France *2004* Germany *2009* Ireland *2010* The Netherlands *2006* Norway *2012* Portugal *1998* Slovak Republic *2008* Sweden *2003*	England & Wales *2008* Finland *2009* Poland *2009* Scotland *2007*
Oceania		New Zealand *2007*	Australia *2008*

http://www.ispor.org/peguidelines/index.asp

Value of Pharmaceuticals
Framework



ECHO Model = Economic, Clinical and Humanistic Impact (Modified from Kozma et al)

Value of Pharmaceuticals Framework

Economic (Resource Utilization)	Clinical	Humanistic
Direct Costs e.g. Drug Physician visits Hospitalization Nursing time Transportation	**Safety** e.g. Headaches Nausea Stroke	**Quality of Life** Health-Related vs. Overall, Global
Indirect Costs Lost days of work Reduced Productivity Patient, Provider, System	**Efficacy** e.g. Reduced Symptoms Cured Patients Saved Lives Years Gained	**Patient satisfaction** e.g. With Treatment With Provider
		Patient preferences e.g. Treatment Mode Disease State

Value Proposition

- Examples
  - Direct Costs & Schizophrenia
  - Indirect Costs: Productivity & Migraine
  - Quality of Life & Migraine

Direct Costs

Direct Costs & Schizophrenia
Before vs. after risperidone therapy initiation

		Change in Hospitalization
No. patients	Months	↓ # Days/year
36	> 7 months	25% (5.7 to 4.2 days)

Carter C, Stevens M and Durkin M. Effects risperidone therapy on the use if mental health care resources in Salt Lake County, Utah. Clinical Therapeutics, Vol.20, no.2, page:352-363. 1998

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Direct Costs

Direct Costs & Schizophrenia
Before vs. after risperidone therapy initiation

		Change in Hospitalization
No. patients	Months	↓ # Days/year
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Change in Costs (mean per patient/yr)			
↑ Drug	↓ Hospital	↓ Other	↓ Total (%)
$1322 ↑ Risperidone $1889 ↓ Other psychotropic $567	$762	$868 Residential, day out patient, & case management	$308(3)

Carter C, Stevens M and Durkin M. Effects risperidone therapy on the use if mental health care resources in Salt Lake County, Utah. Clinical Therapeutics, Vol.20, no.2, page:352-363. 1998

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Productivity & Migraine

- Naratriptan treats migraine headaches when occur – not a prophylactic
- Modeled costs based on multinational trial: naratriptan vs. customary therapy
- One Year
- Canada

Caro JJ et al. Treatment of migraine in Canada with naratriptan: a cost-effectiveness analysis. Headache, Vol41: page 456-464: 2001

Indirect Costs

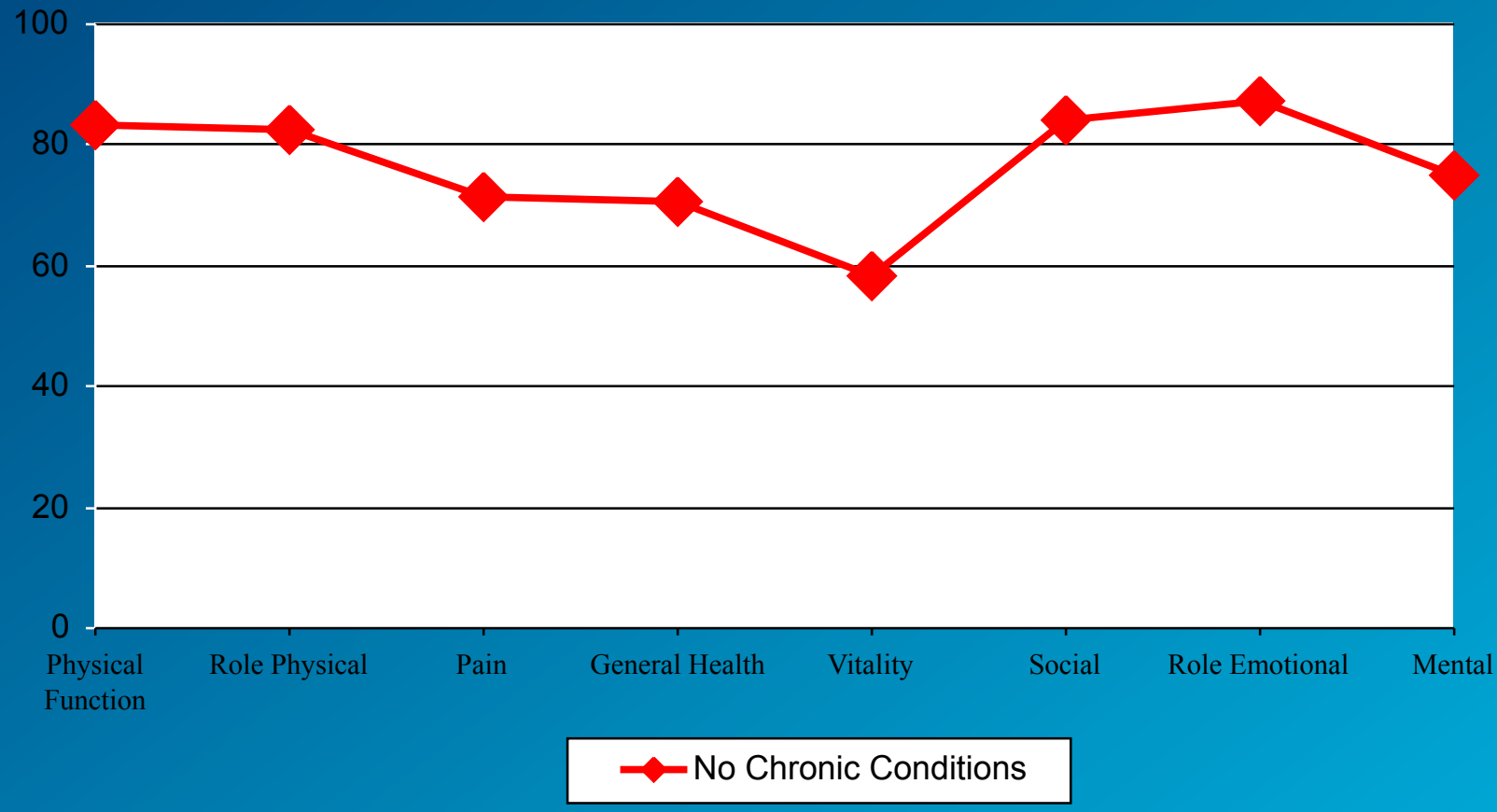
Productivity & Migraine

Mean	Customary	Naratriptan
# Attacks/pt	35.2	35.2
Duration (hrs)	608.4 hrs.	***383 hrs.***
Work time lost (hrs/ Can $)	51.4 hrs. ($851)	***32.8 hrs.*** ($544)
Unpaid work time lost (hrs/Can $)	19.9 hrs. ($228)	***12.6 hrs.*** ($145)
Leisure time lost (hrs/Can $)	46.2 hrs.($0)	***29.6 hrs.*** ($0)
Total	117.50 ($1,080)	***75.00*** ($689)

Caro JJ et al. Treatment of migraine in Canada with naratriptan: a cost-effectiveness analysis. Headache, Vol 41: page 456-464. 2001

Quality of Life & Migraine *(SF-36)*

HRQOL



1998 General US Population: Ware JR, Kosinski M, Dewey JE. How to score version 2 of the SF-36 health survey. Lincoln, RI: QualityMetric Incorporated, 2000

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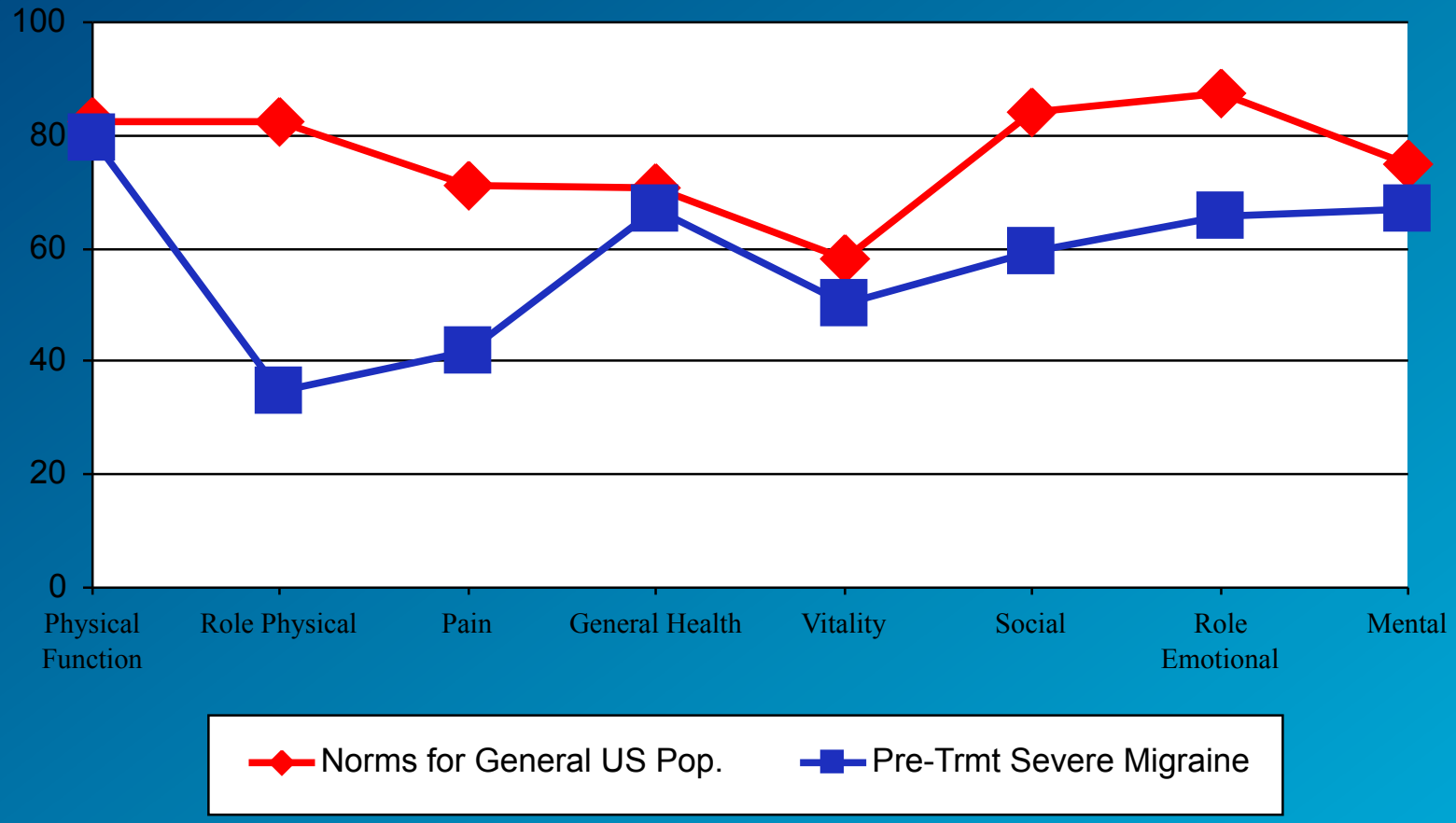

Pre/Post Trmt Severe Migraine - Quality of Life Assessment Among Migraine Patients Treated with Sumatriptan,Solomon, Skobieranda, Genzen, Headache 1995; 35: 449 -454

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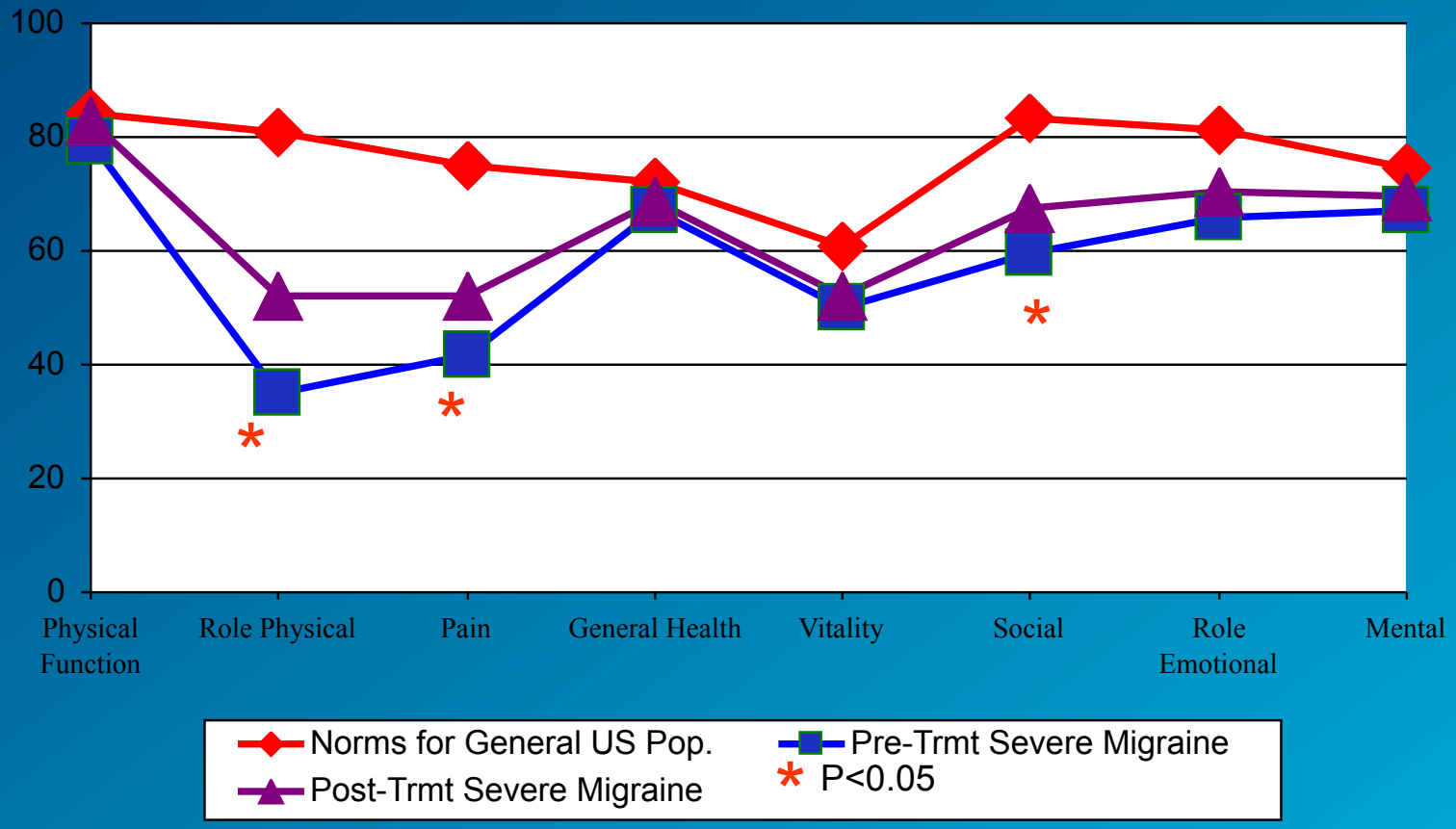

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Value of an Intervention

Outcomes/Benefit		**Cost**
Direct Cost Savings		
Productivity Increase	>	$$$$$
QOL Improvement		

Several Types Pharmacoeconomic Analyses

$$\frac{\textit{Cost}}{\textit{Outcome}} = \textit{VALUE}$$

Pharmacoeconomic Analyses

Analysis Type	*Cost*	*Outcome*
Cost of Illness (COI)	$ or Natural Units	
Cost Minimization (CMA)	$	Equal (no denominator)
Cost Effectiveness (CEA)	$	Natural Units (e.g. % cured)
Cost Benefit (CBA)	$	$
Cost Utility (CUA)	$	Quality Adjusted Life Years (QALY's)

Drug A: $80, 60% cured Drug B: $120, 80% cured

CEA: A: $80/.60 = $133/cured pt, B: $120/.80=$150/cured pt

$$\frac{\$120 - \$80}{0.80 - 0.60} = \frac{\$40}{0.20} = \$200 \text{ each additional cured patient}$$

CBA:

A: $80/$ value of curing 60% patients (60% pts x $1,000/yr)

C/B

A: $80/$600=$0.13 B: $120/$800=$0.15

B/C

A: $600/$80=$7.5 B: $800/$120=$6.7

QALY = Quality Adjusted Life Year

* CEA Registry: Tufts New England Medical Center, Institute for Clinical Research and Health Policy Studies

Drug A: $80, 60% cured Drug B: $120, 80% cured

CUA: A: $80/ # QALYs Gained

A: 60% pts x 10 yrs x 0.7 QOL= 4.2 QALYs

B: 80% pts x 15 yrs x 0.6 QOL= 7.2 QALYs

A: $80/4.2 QALYs = $19/QALY

B: $120/7.2 QALYs = $17/QALY

BENCHMARK of "GOOD VALUE" = $50K - $100K*

ALL ANALYSES – have to consider all COSTS and BENEFITS over time

QALY = Quality Adjusted Life Year

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Building Value Evidence across the drug development process

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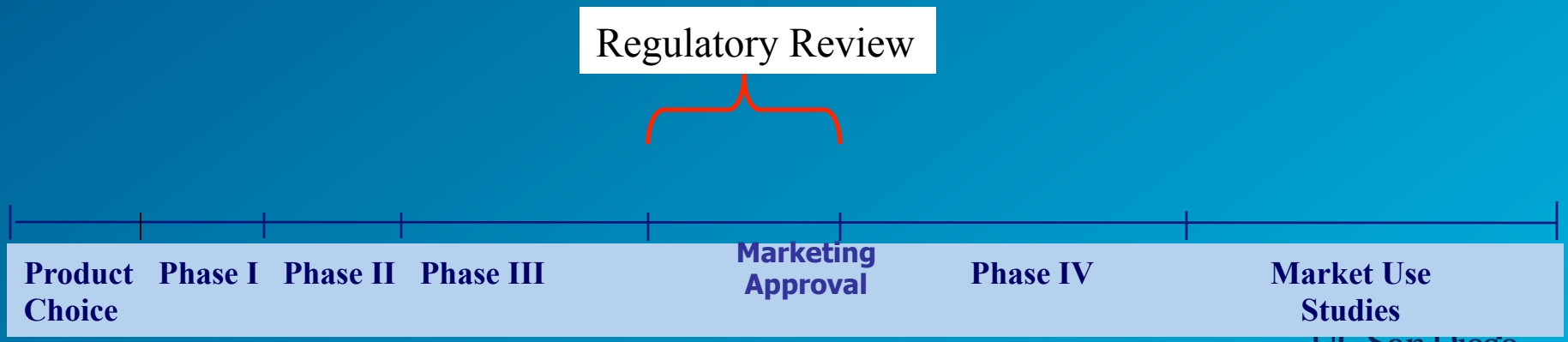
Building Value Evidence



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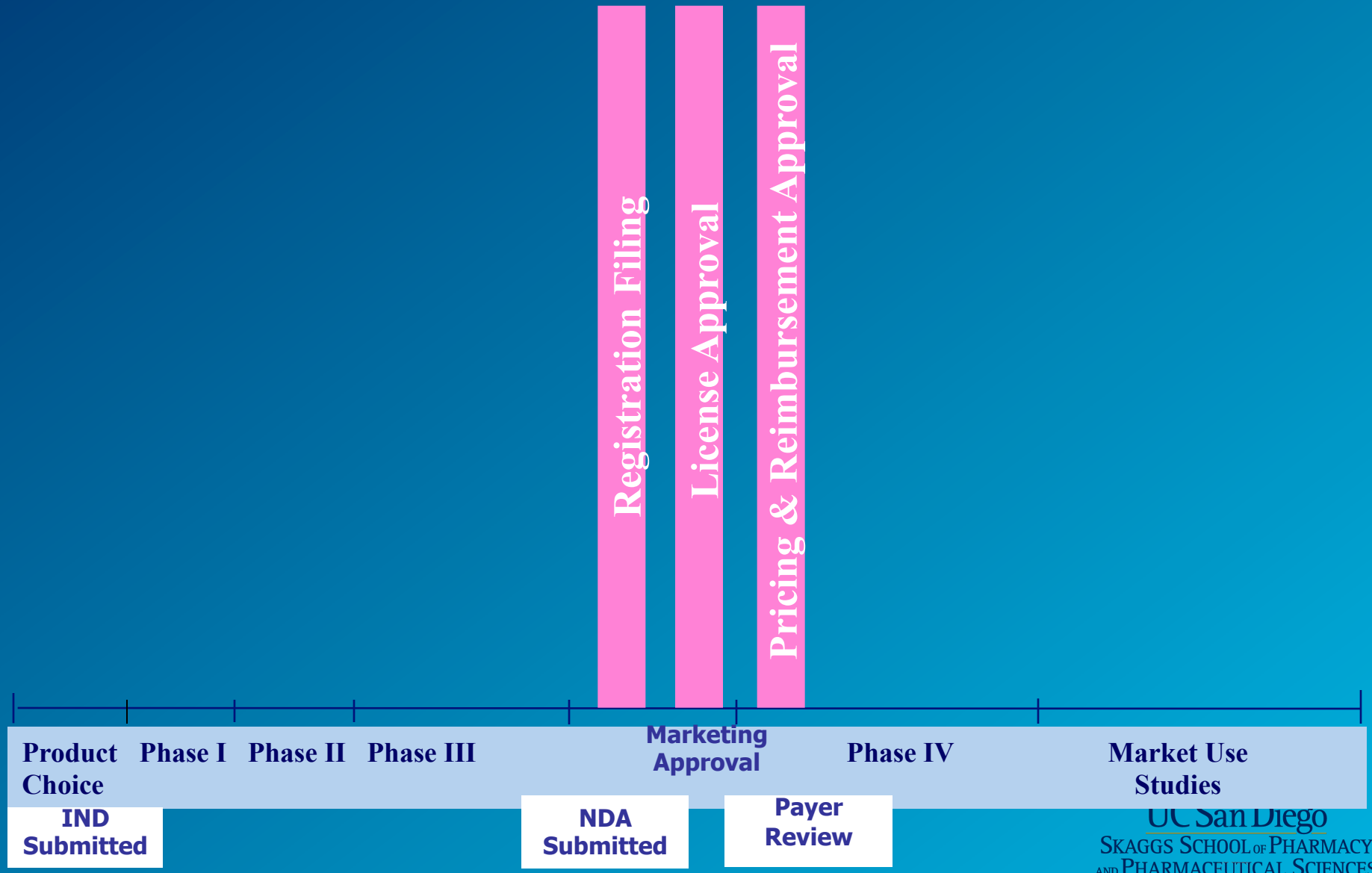

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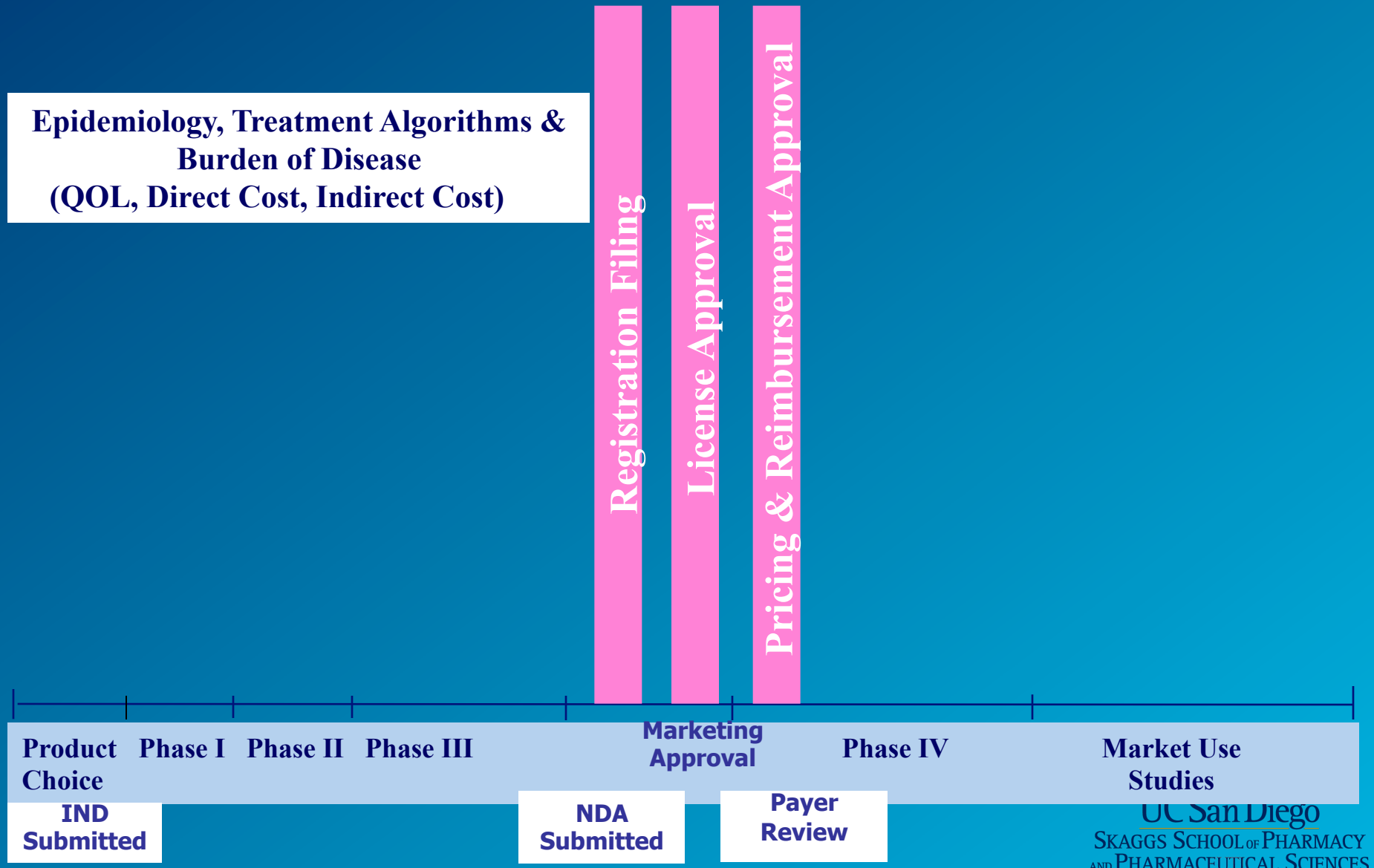
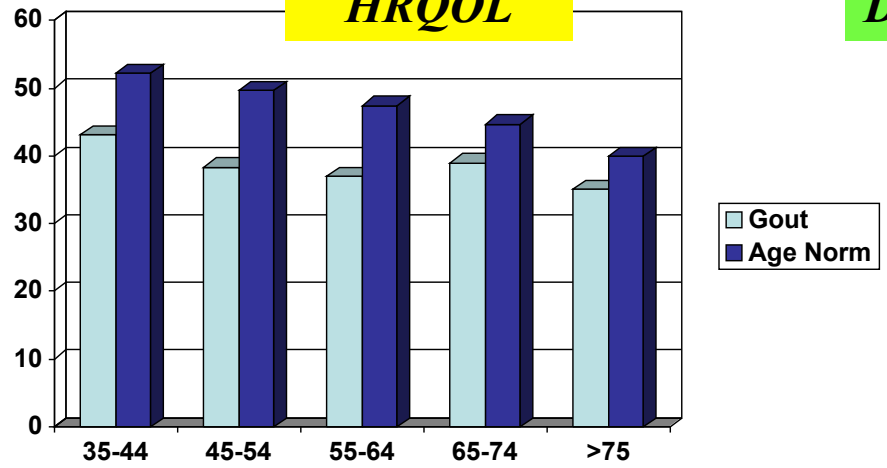


Burden of Disease: Gout

HRQOL



Direct Costs

	% ≥ 1 visit		
	With Gout	No Gout	Risk Ratio
Inpatient	6.34	3.56	1.6
ER	6.21	3.18	1.5
Outpatient	99.4	93.8	1.1

Indirect Costs

	Mean Days Lost		
	With Gout	No Gout	Sig.
Sick Leave	6.34	3.56	<0.001
Short-term Disability	6.21	3.18	0.0003

QOL: SJ Lee et al, Direct Costs: Wu et al, JMCP 2008, Indirect Costs: Kleinman etal AMCP 2005

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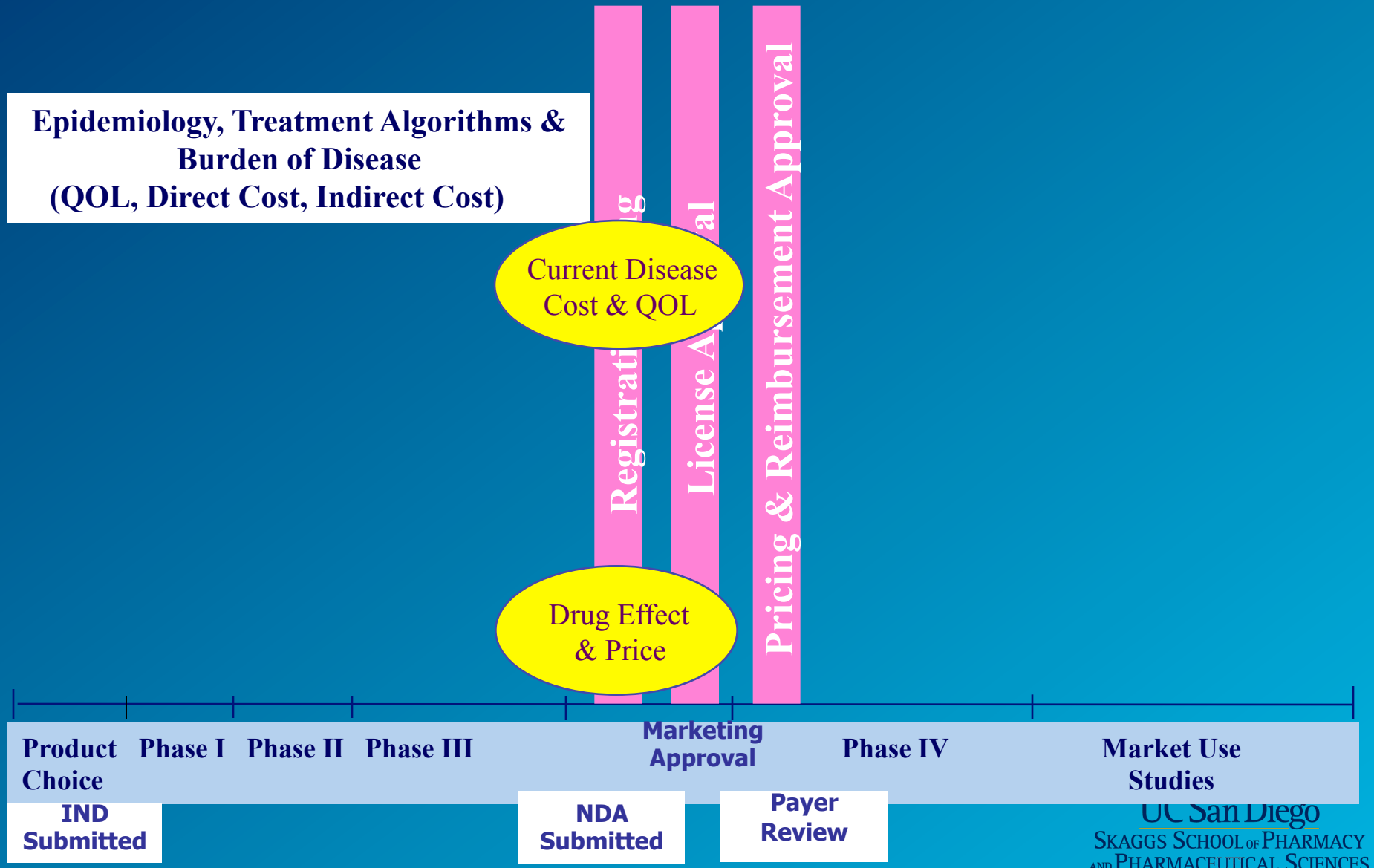
Building Value Evidence



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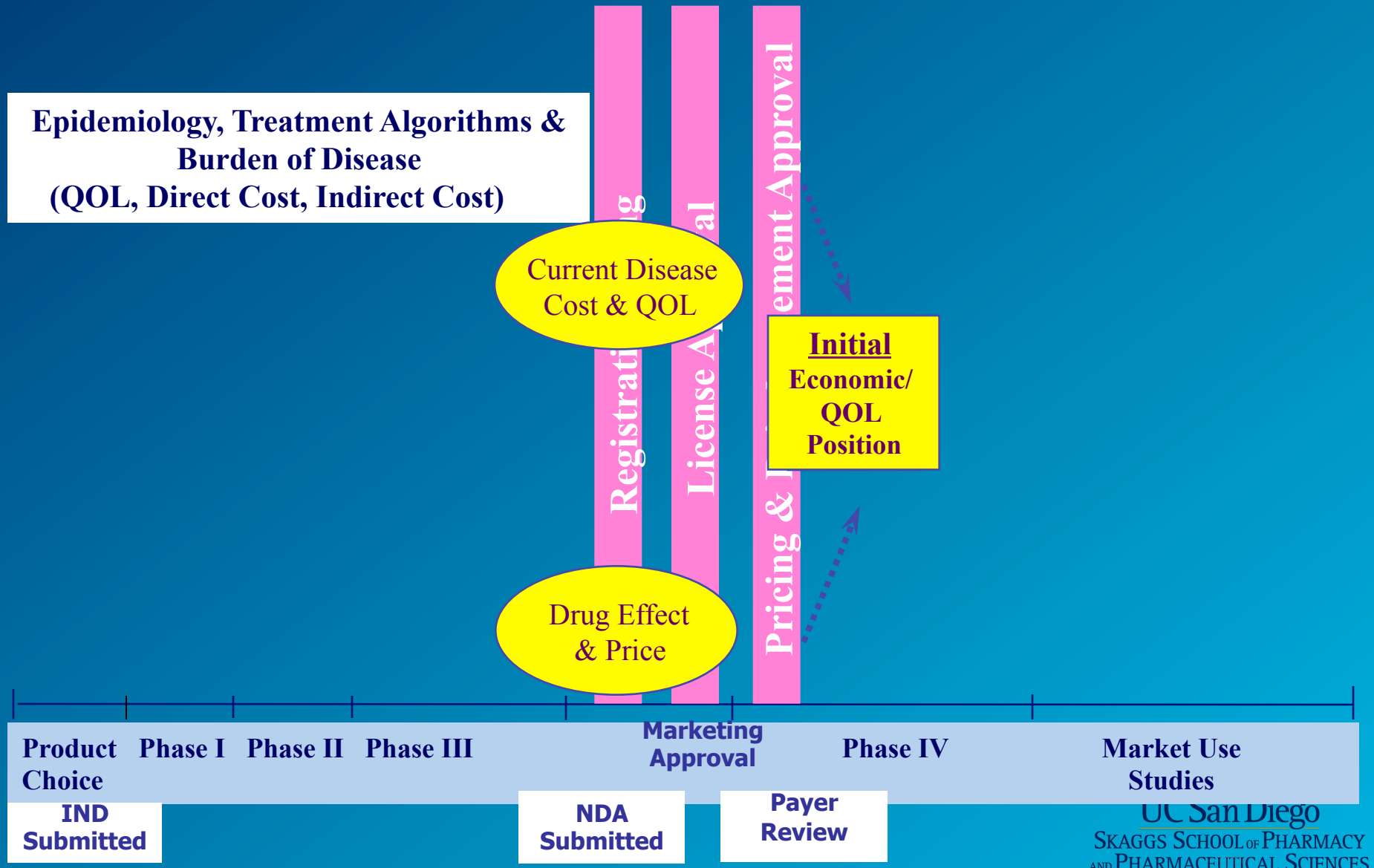
Building Value Evidence



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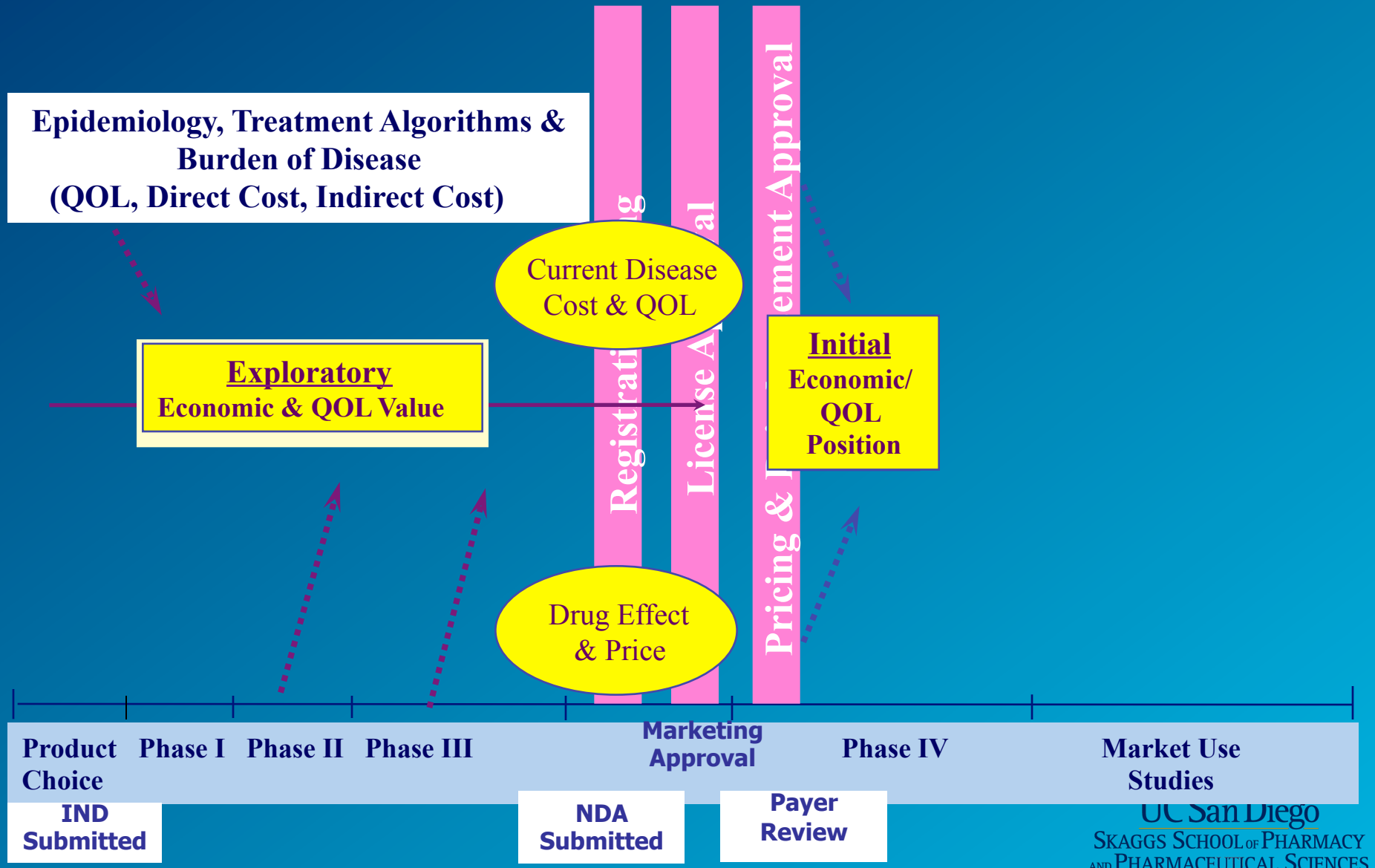

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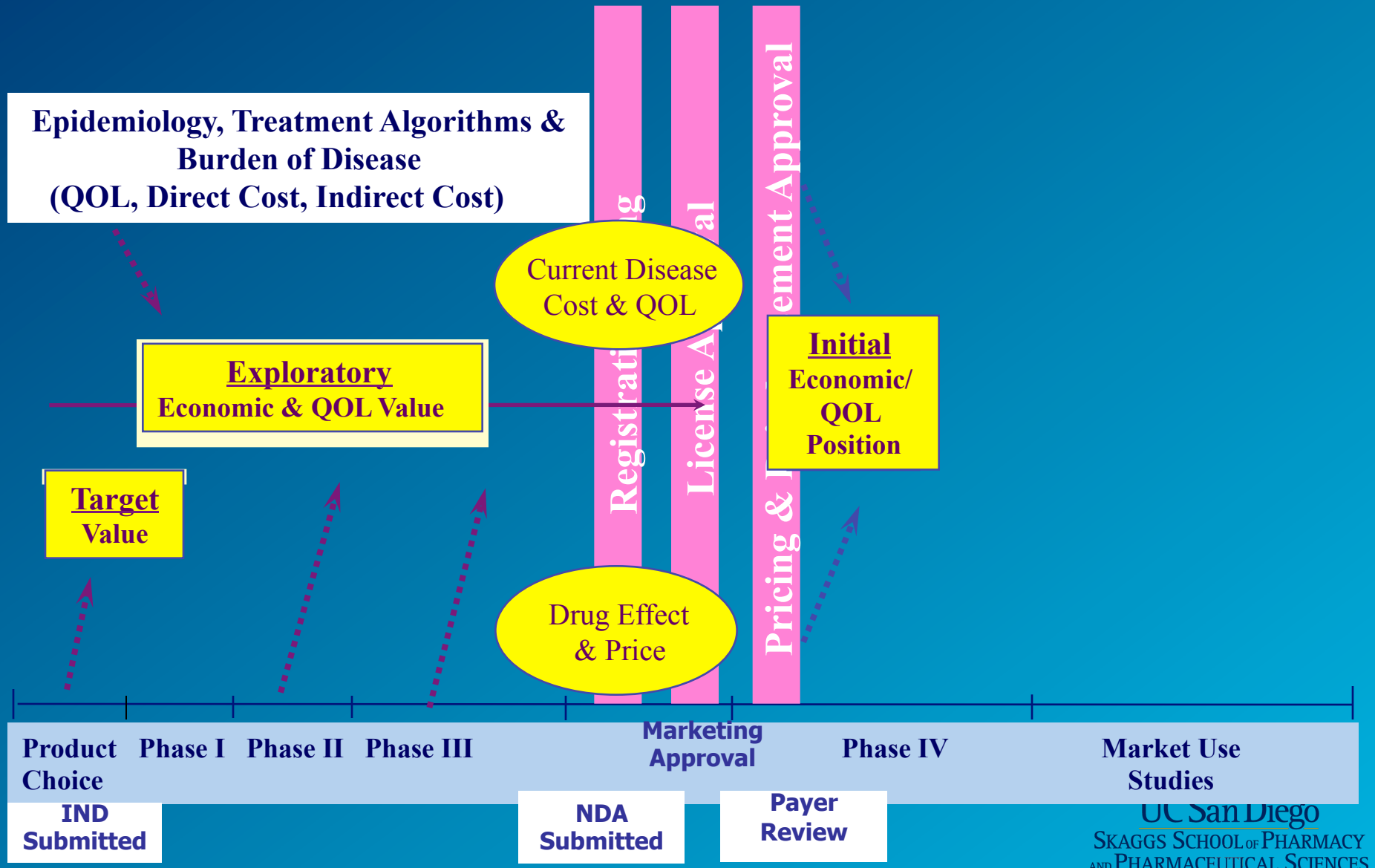

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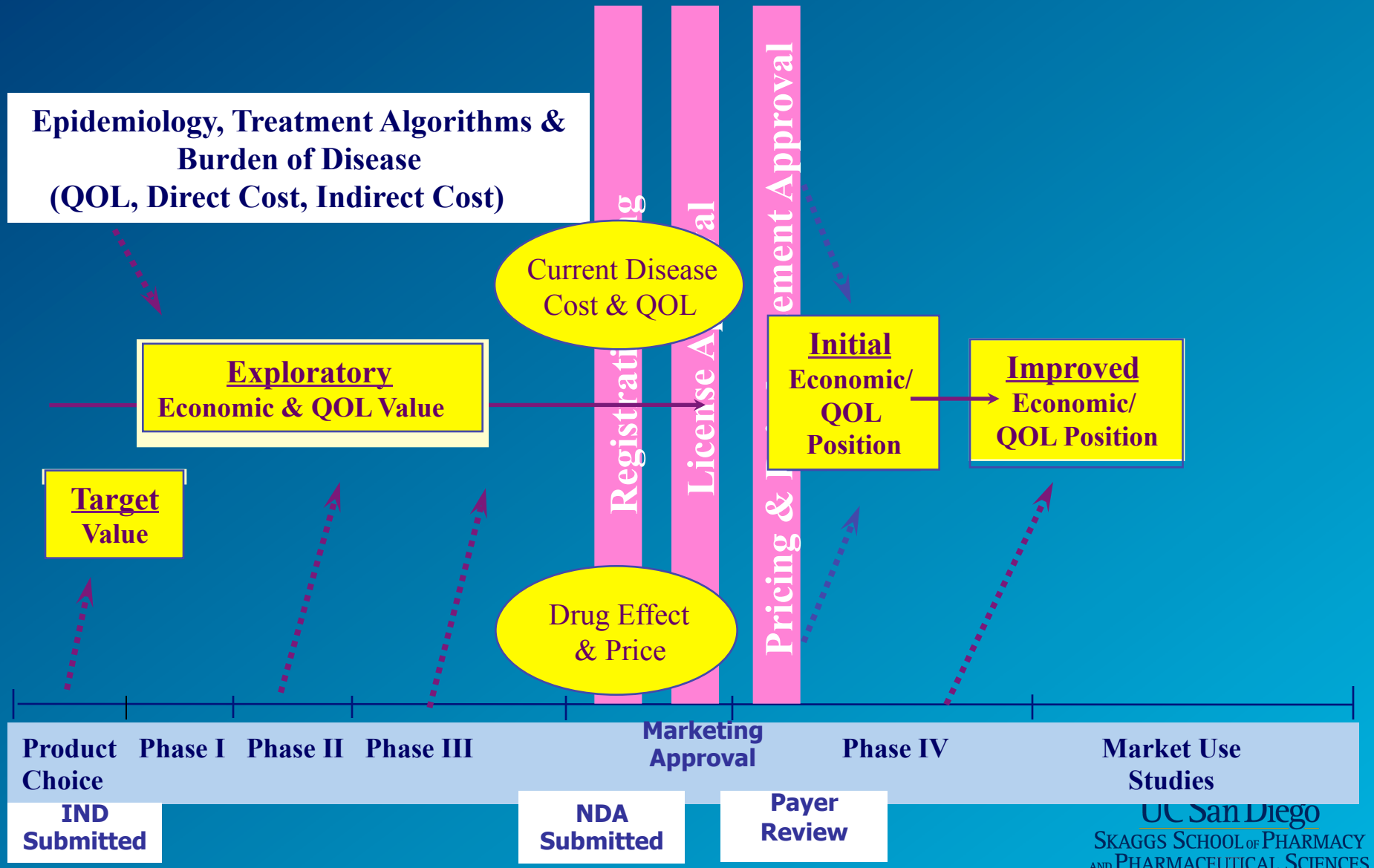

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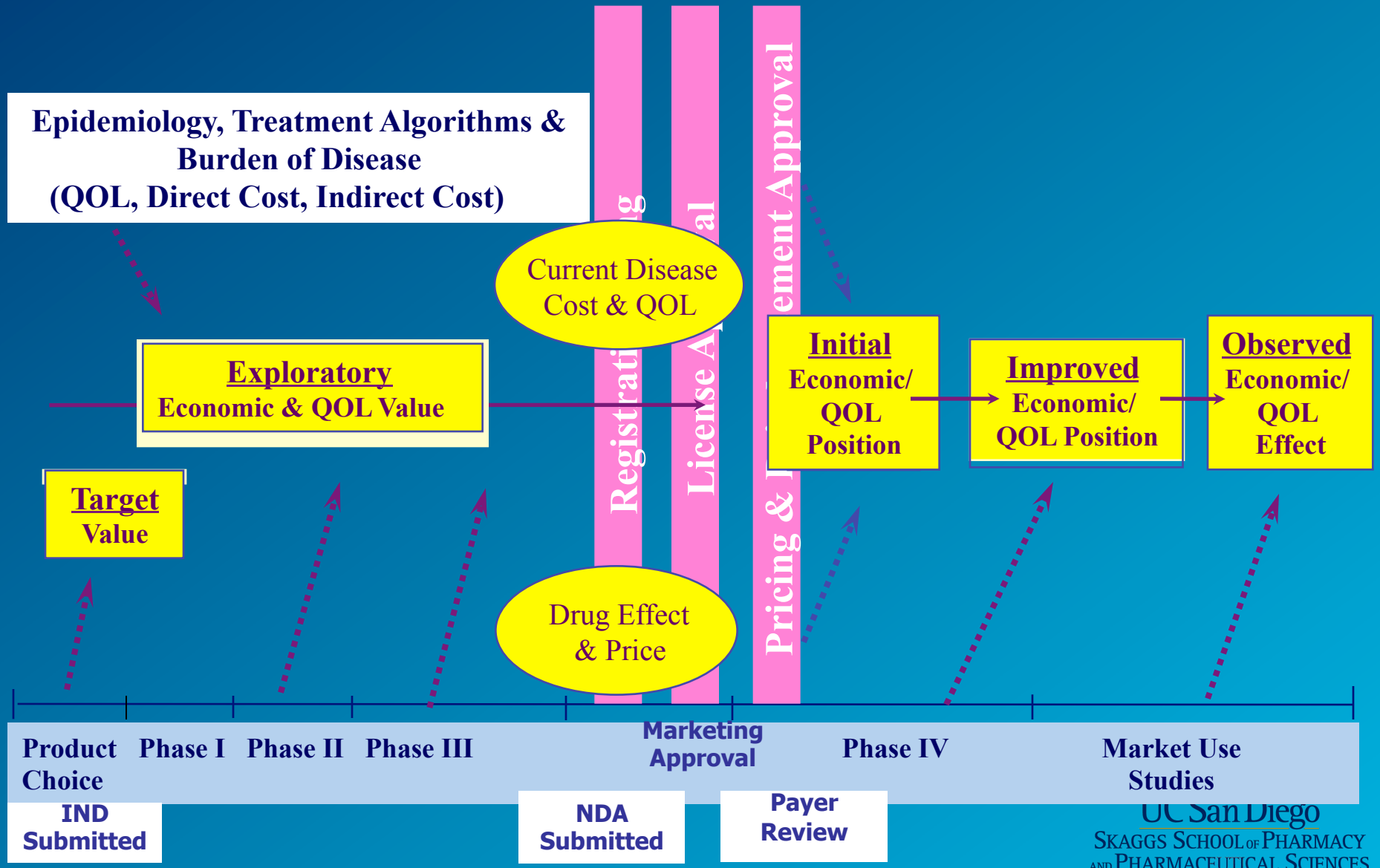

Building Value Evidence – Summary

- Target Value - based on future products - should drive product choice
  - "Back of the Envelope" modeling early stages
- Many studies – within & outside of clinical trials - needed over many years
  - Build value evidence in published literature
  - Build "methods" for Epi, Econ & QOL in literature
- Resource intensive
  - Within company & outside experts needed
  - Study Funding (within & outside clinical trials)

Complications…

Just a Few

PE Submission Requirements Differ

	U.S.	Canada	France	Australia
Comparator	Best available	Most Used or Lowest Cost	Most Used or Likely Future Product	Most Used
Analysis Type	CEA or CUA	CEA,CUA, CMA, CBA, CCA	CEA,CUA, CMA, CBA, CCA	CEA,CUA, CMA, CBA
Costs	All relevant	Medical, social services, patient & family	All relevant, indirect separate	Medical, social services: productivity not encouraged
Effectiveness or Efficacy	Either	Effectiveness	Effectiveness	Effectiveness

Different Value Dossier each Country &/or Payer

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Value equation differs by country

Outcomes/Benefit		**Cost**
Direct Cost Savings		
Productivity Increase	>	$, ,
QOL Improvement		

Different Currency, Relative Value Medical Resources, Treatment Algorithms, Expectations…

Complications – A few more…

- Communication Strategy - Critical
  - Levels of Audience Expertise
    - Expert review, clinicians, policy makers
  - Timing – before vs. after launch – competitors?
  - Venues – must be medical peer-reviewed
  - International reach – e-journals, internet
- Product price: first vs. future indications – C/E differs
- New competitor – new price – new C/E bench mark