



AmCham Workshop on pharmaceuticals and the U.S. market GENERIC MARKET OPPORTUNITIES

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KNOWLEDGE IS KEY

Some historians have called the era from the development of the first antibiotics, the 1940s, through the 1990s “the golden age of medicine.” But scientists predict that even that period will pale in comparison to the achievement of the 21st century, the “Platinum Age.”

SESSION I

THE GENERIC INDUSTRY IN THE U.S

KEY DATA

- ❑ Estimates from IMS Health place the global market for human drugs at \$602B.
- ❑ The US leads with over 47 percent of global market, followed by Europe (EU) (30.0%) and Japan (10.7%).
- ❑ In the 12 months period leading to June 2006, the U.S. sales were just shy of \$189 billion, a 5 percent increase.
- ❑ Staggering...compared to \$38.5B in 1990.

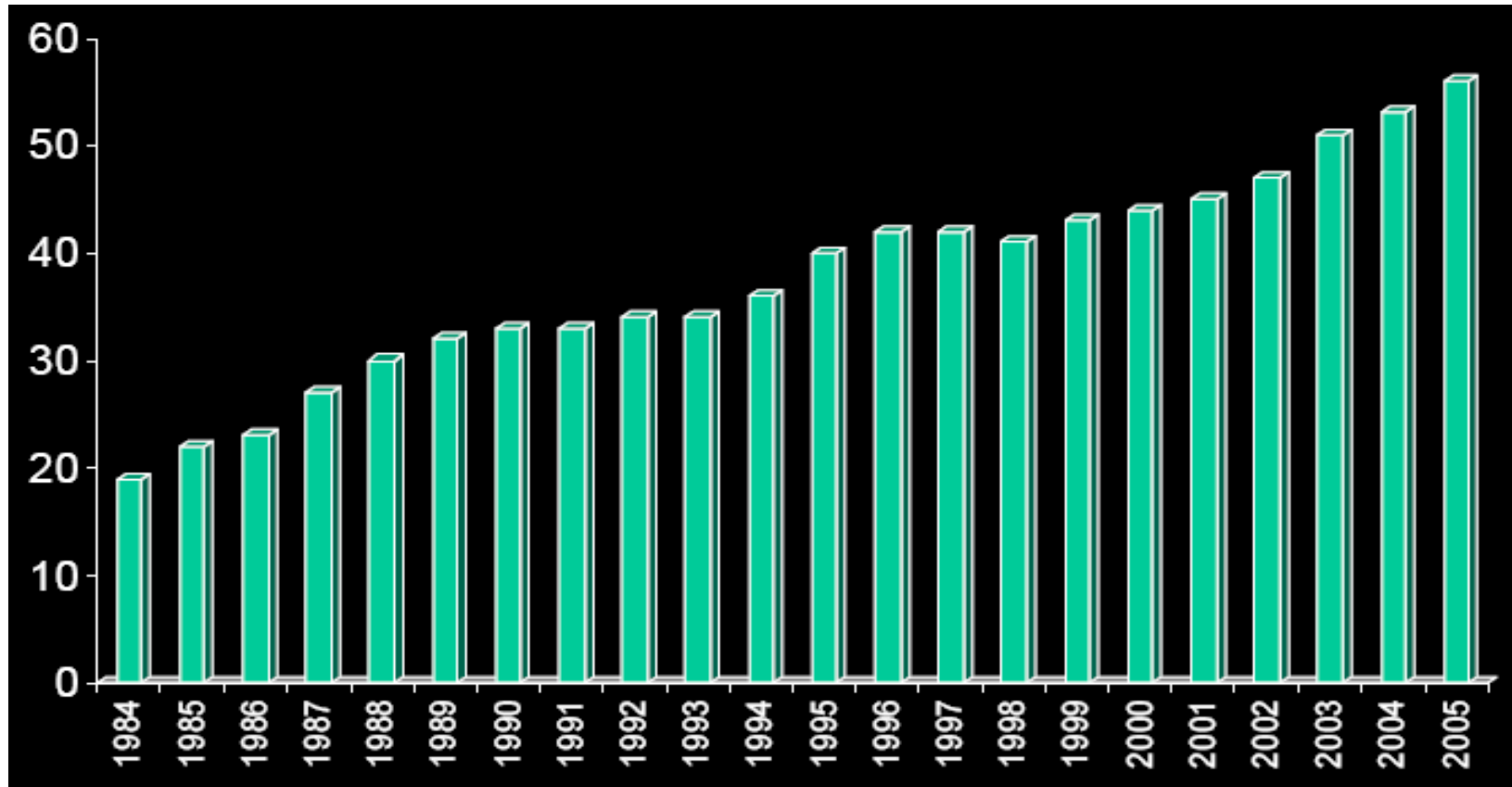
IGNITION: TOO MUCH COST

- ❑ The healthcare industry includes prescription drugs as well as other medical products, nursing homes, hospitals, and physician services.
- ❑ The healthcare industry is a \$1.6 trillion.
- ❑ It is expected to reach 17.4% of the nation's economic output by 2010.
- ❑ It could exceed 20% by 2040.
- ❑ It averaged \$5,035 per capita in 2001, is expected to reach \$6,926 in 2007, and could exceed \$9,216 by 2011.
- ❑ The U.S. spends more on healthcare as a percentage of GDP than other industrialized countries -- 8% to 10%.

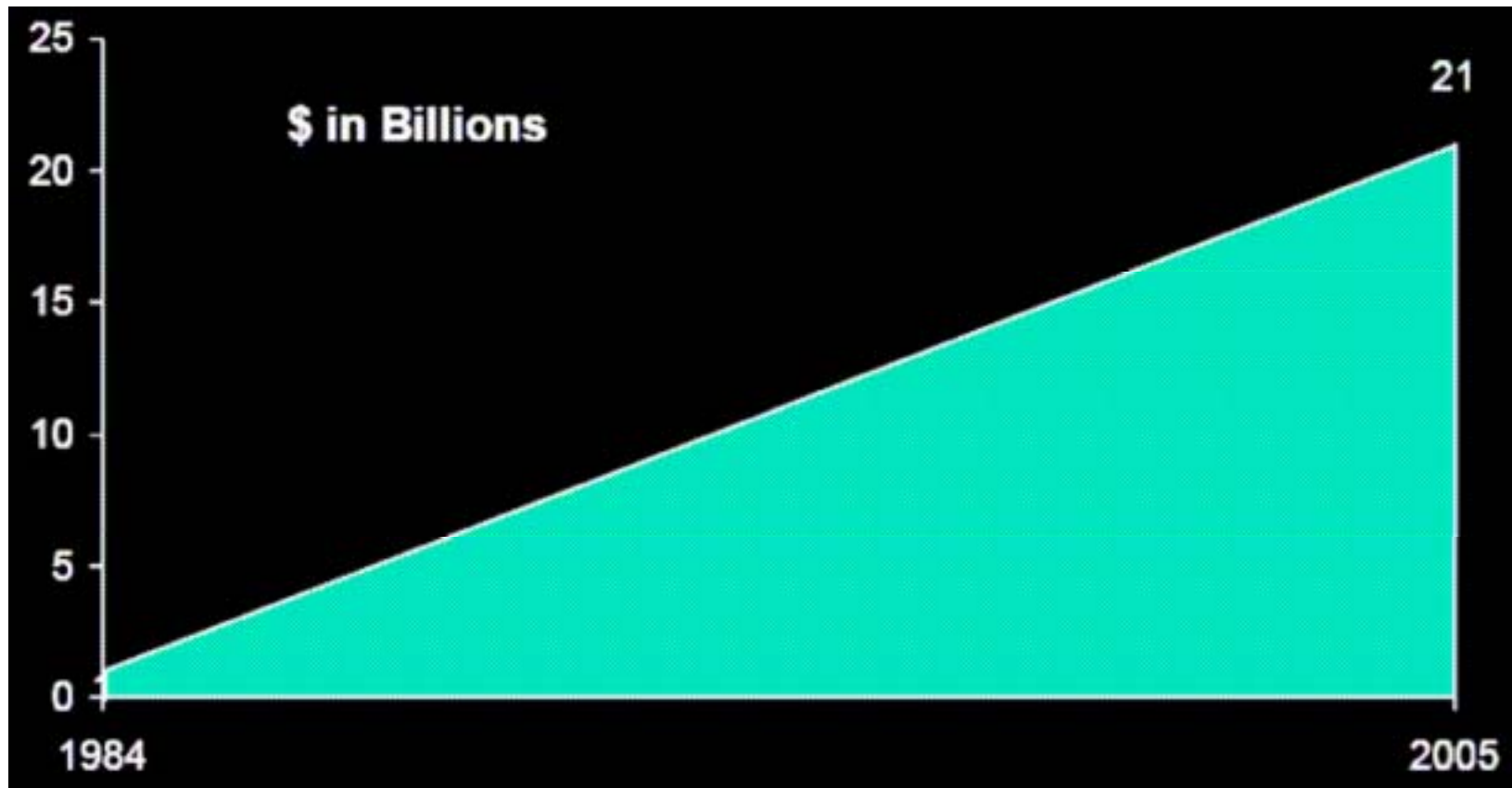
BRINGING COST DOWN THROUGH SUBSTITUTION

- ❑ Before 1984, pharmaceutical approval processes burdened generic companies with costly developmental expenses, and extensive testing requirements.
- ❑ The Hatch-Waxman Act of 1984 struck a delicate balance between protecting patents and expediting the approval of generic drugs.
- ❑ As a result, consumers save an average of 70 to 80% per prescription.
- ❑ Hatch-Waxman Act today saves consumers \$8-10 billion every year.

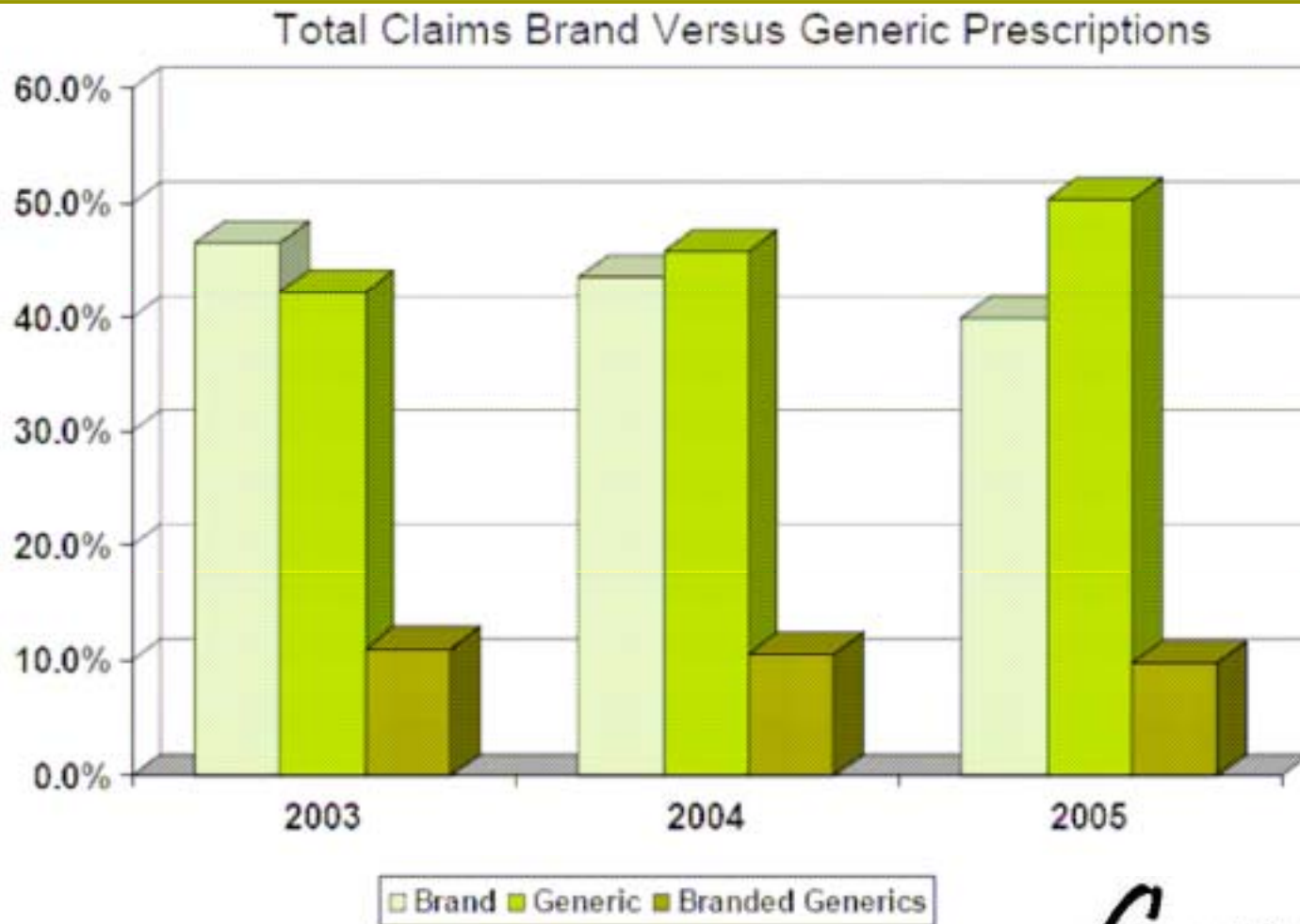
HISTORICAL GROWTH IN SUBSTITUTION



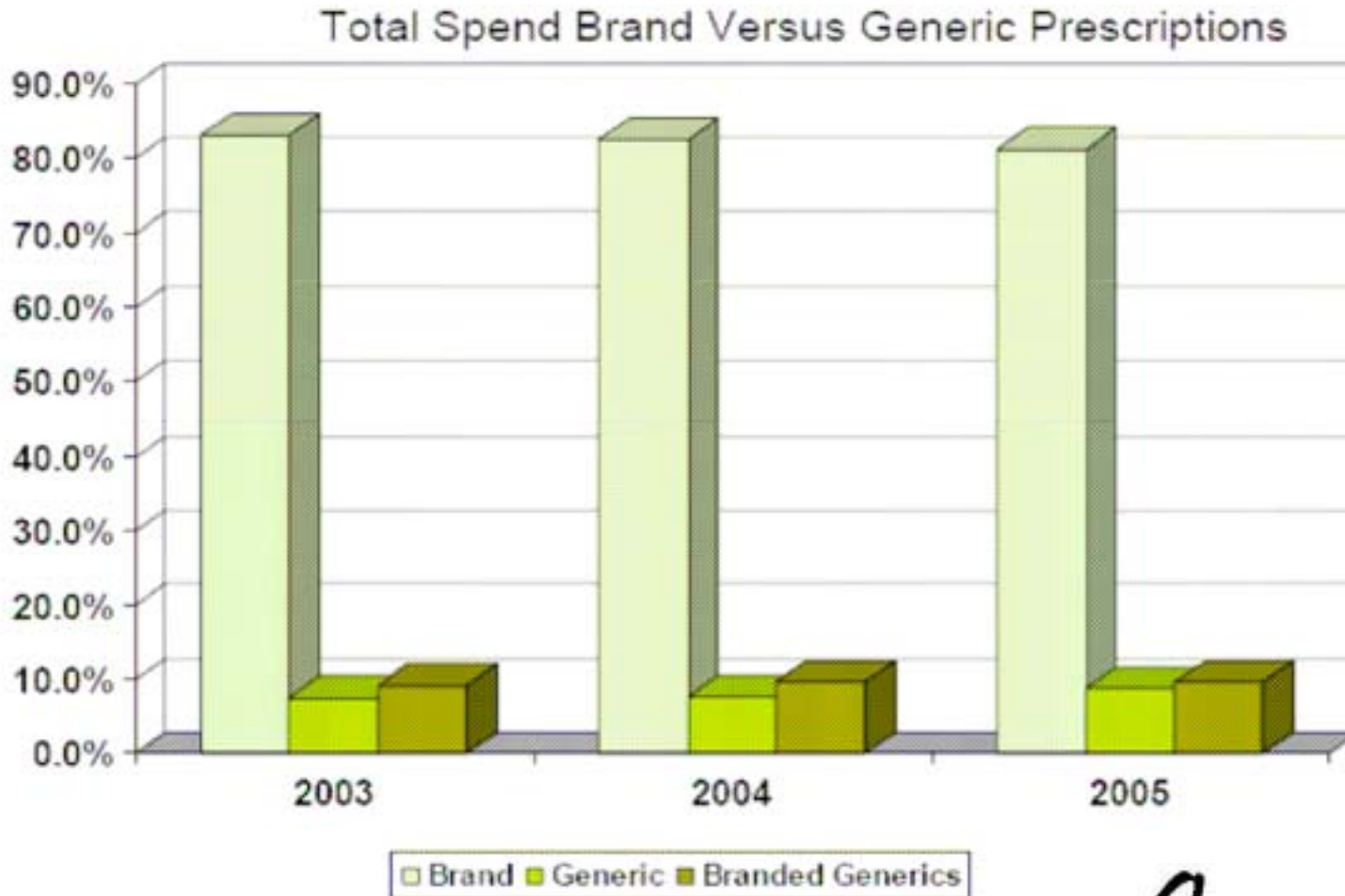
HISTORICAL GROWTH IN REVENUES



INDUSTRY OVERVIEW



INDUSTRY OVERVIEW



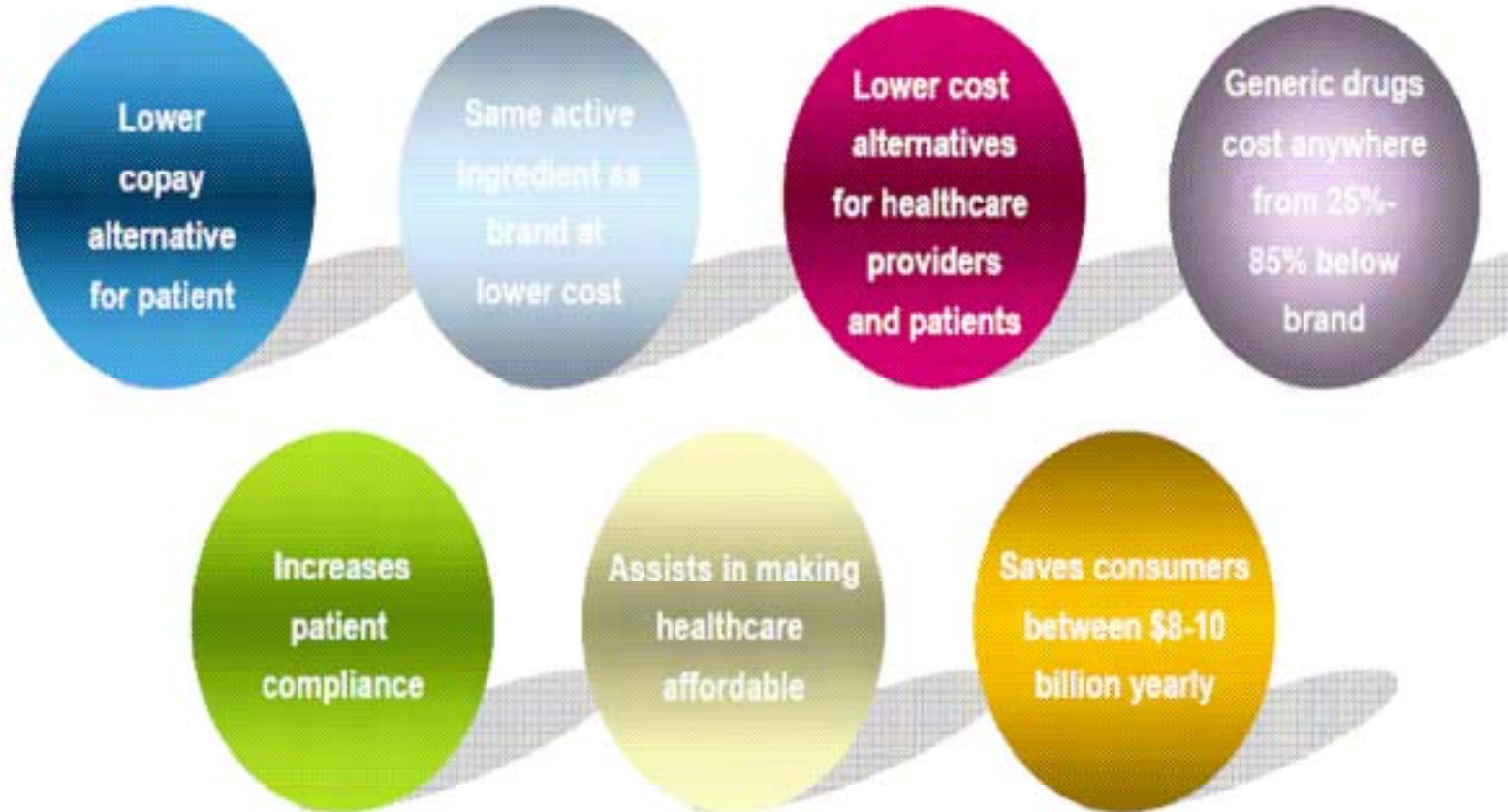
THE GENERIC MARKET

- ❑ Sales in the U.S. totaled \$21 billion in 2005; an increase of 14% over the previous year.
- ❑ A total of 3.6 billion prescriptions were filled in the U.S. between October 2004 and September 2005.
- ❑ In July 2005, the ratio of generic/brand share of market by volume (weighted average) was 54/46. In 2006, it is estimated to be 58/42.
- ❑ 7,602 of the 10,375 drugs listed in the FDA's Orange Book have generic counterparts

WHY GENERIC DRUGS MAY BE A GOOD CHOICE

- ❑ Eight out of ten adults, regardless of income, would choose a generic if the saving was \$10 or greater.
- ❑ Every 1% increase in generic utilization results in 1-2% total cost savings.
- ❑ Brand and generic cost differential averages between \$60-80 per Rx.
- ❑ Generic Pharmaceutical Association web page states average price (2004):
 - Brand prescription \$96.01
 - Generic prescription \$28.74

WHY GENERIC DRUGS MAY BE A GOOD CHOICE



SESSION II

RESEARCH & DEVELOPMENT

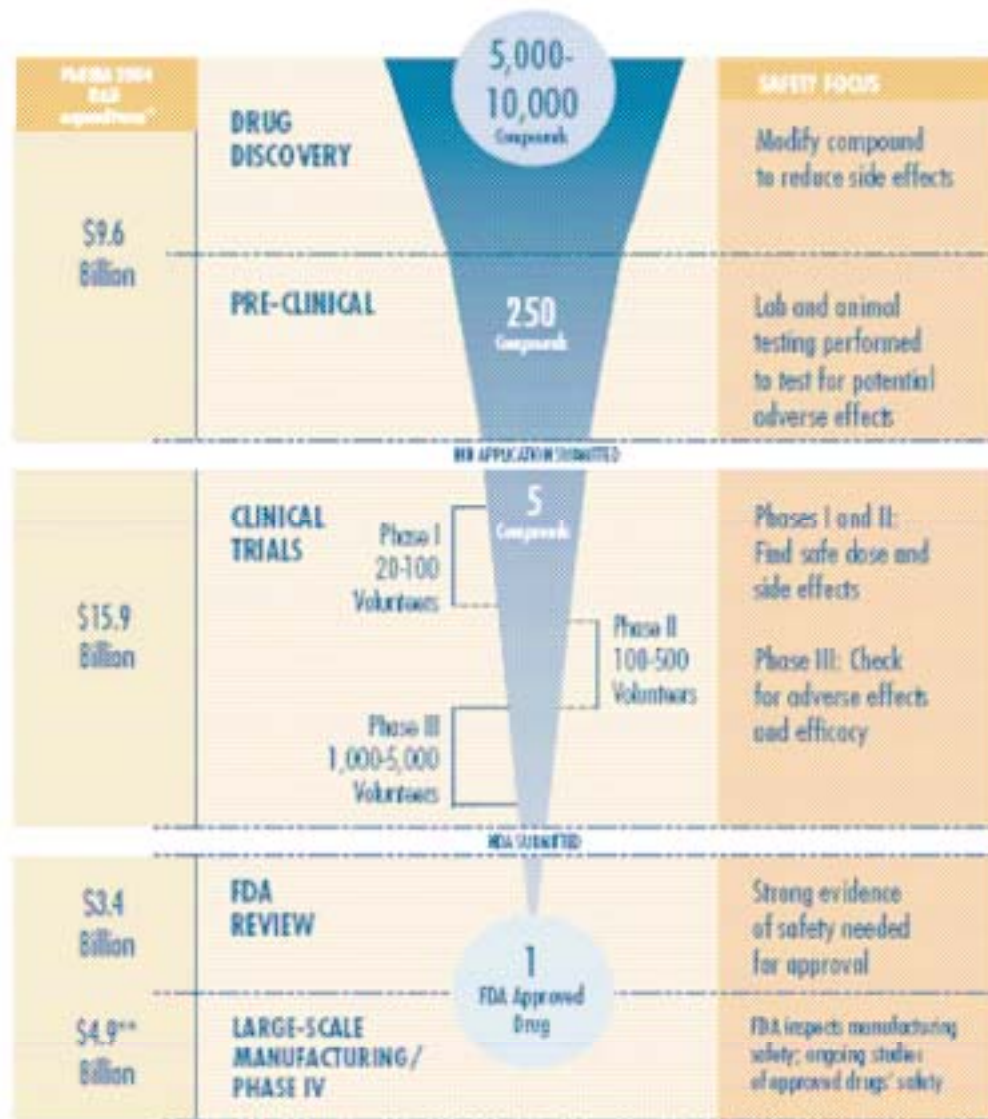
INDUSTRY AND FDA STANDARDS ARE RIGOROUS

- ❑ The pharmaceutical industry is more research intensive than even the electronics, communications, and aerospace industries. On average, a PhRMA company spends more on research each year than such companies as Microsoft, Boeing, and IBM.
- ❑ In 2005, the entire biopharmaceutical industry spent an estimated \$51.3 billion on R&D.
- ❑ 6.1 times the investment in 1990.
- ❑ PhRMA (Pharmaceutical Research and Manufacturing Association) companies alone invested an estimated of \$39.4 billion in R&D.

INDUSTRY AND FDA STANDARDS ARE RIGOROUS

- ❑ Biopharmaceutical companies conduct on average 10–15 years of research on a new medication.
- ❑ For every 5,000–10,000 compounds tested, only one receives FDA approval and becomes a new treatment.
- ❑ Domestic PhRMA companies spend an estimated 19.2 percent of domestic sales on R&D - the highest percentage of any major U.S. industry.
- ❑ The FDA approved 28 new drugs in 2005.

THE R&D PROCESS



* \$3.2 billion uncategorized

** This figure includes Phase IV testing only

DEVELOPMENT COSTS

Average Cost to Develop One Drug:

Year	Cost (in millions)
2000	\$800
1987	\$318
1975	\$138

As regulatory requirements become more stringent and the amount of information needed grows, the cost to develop a drug continues to go up.

BRANDS THAT GOT HERE



GENERIC CONVERSION OPPORTUNITIES

Chemical equivalence

Two drugs with active ingredients that are identical at the molecular level



Prozac

fluoxetine

Occurs 95%+ of the time with little intervention

Therapeutic equivalence

Two drugs with active ingredients that are identical at the clinical level



Zoloft

fluoxetine

Occurs infrequently without intervention

The Biggest Opportunity Is *Therapeutic* Equivalence

WHAT IS A GENERIC DRUG?

A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. All approved products, both innovator and generic, are listed in FDA's *Approved Drug Products with Therapeutic Equivalence* (*Orange Book*).

WHAT IS AN ANDA?

An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA's Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD), provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

WHY TERMED “ABBREVIATED”?

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent.

INNOVATORS CAN FIGHT

ANDAs can be submitted for products that are identical to an approved product in terms of:

- Active ingredients
- Dosage form
- Strength
- Route of administration
- Conditions of use.

If any of these characteristics differ, manufacturers have the right to request a change from a listed drug, otherwise known as a suitability petition, and the FDA must accept the petition.

SESSION III

MARKET STUDIES

SEA OF INFORMATION

Studies and Surveys are constantly conducted by:

- Government Agencies
- Private Research Organizations
- Private Financial Organizations
- Private Information Organizations
- Universities
- Pharmaceutical Companies

USEFUL INFORMATION

Using and paying for useful information is an investment:

- Conduct your own
- Private libraries
- Consultants
- Alliance

USEFUL STUDIES

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END RESULT:

CONSUMERS TRUST GENERICS

- A survey conducted by ChangeWave Research, an investment research firm, demonstrated the increasing acceptance of generic pharmaceuticals:
 - 59% said they currently ask their doctor if a generic drug is available at the time they get a prescription.
 - 67% said their insurance companies either advise or require them to accept generics.
 - 76% of healthcare professionals said physicians are more willing to prescribe generics now than they were a year ago.
 - 90% of healthcare professionals said insurance companies and other payers are increasing pressure to prescribe generics.

END RESULT:

CONSUMERS TRUST GENERICS

- A study by AARP found:
 - An overwhelming majority of Americans (84%) say generic drugs are an important part of controlling rapidly increasing drug costs.
 - Two-thirds usually choose generics over brand names when available.
 - 90% are willing to accept generic drugs as a way to reduce their drug costs.
 - 24% respondents said they have not been able to afford a prescription medication when there was no generic available.

SESSION IV

REGULATION OF THE GENERIC MARKET

THE “HATCH-WAXMAN” ACT

THE LEGAL LANDSCAPE

- ❑ Principal goal: balance incentives to innovate and competition in the pharmaceutical marketplace.
- ❑ Incentives to innovate are assured through patent term extensions and other intellectual property protections for brand companies.
- ❑ Competition in the pharmaceutical marketplace is assured through the creation of an expedited approval path for generic drugs.

GENERIC DRUG APPROVAL PATHWAY

- ❑ goal: to provide for generic drug approvals as soon as patents, other intellectual property protections expire.
- ❑ goal is achieved by providing for expedited method of resolving patent disputes.
- ❑ brand company NDA must identify patents that “claim” the brand drug.
- ❑ generic ANDA must account for each listed patent with a “certification”.

GENERIC DRUG APPROVAL PATHWAY

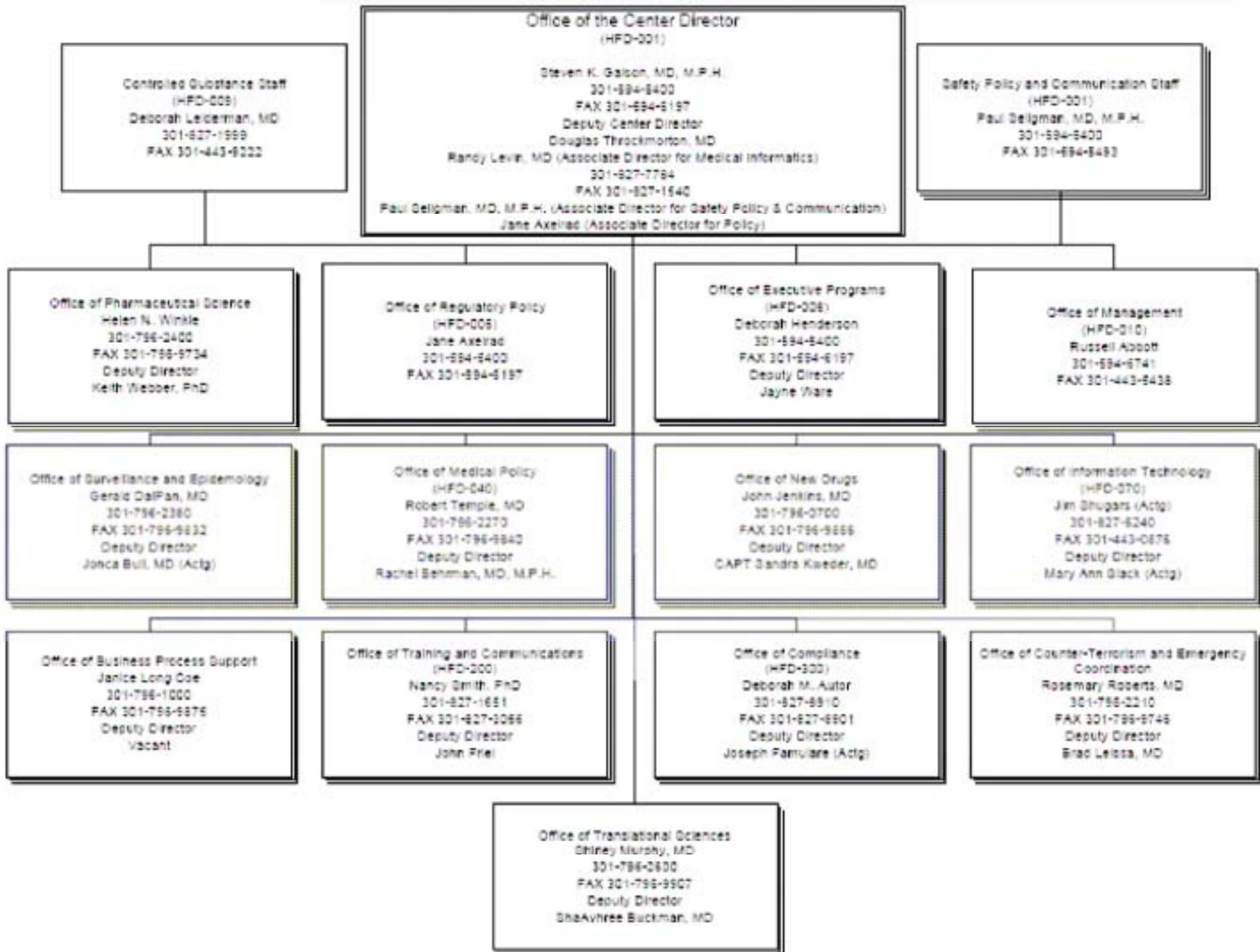
- ❑ Paragraph I certification: no patent information filed on the original product.
- ❑ Paragraph II certification: patent has expired on the original product.
- ❑ Paragraph III certification: the patent will expire in the future on the original product.
- ❑ Paragraph IV certification: patent is invalid on the original product.

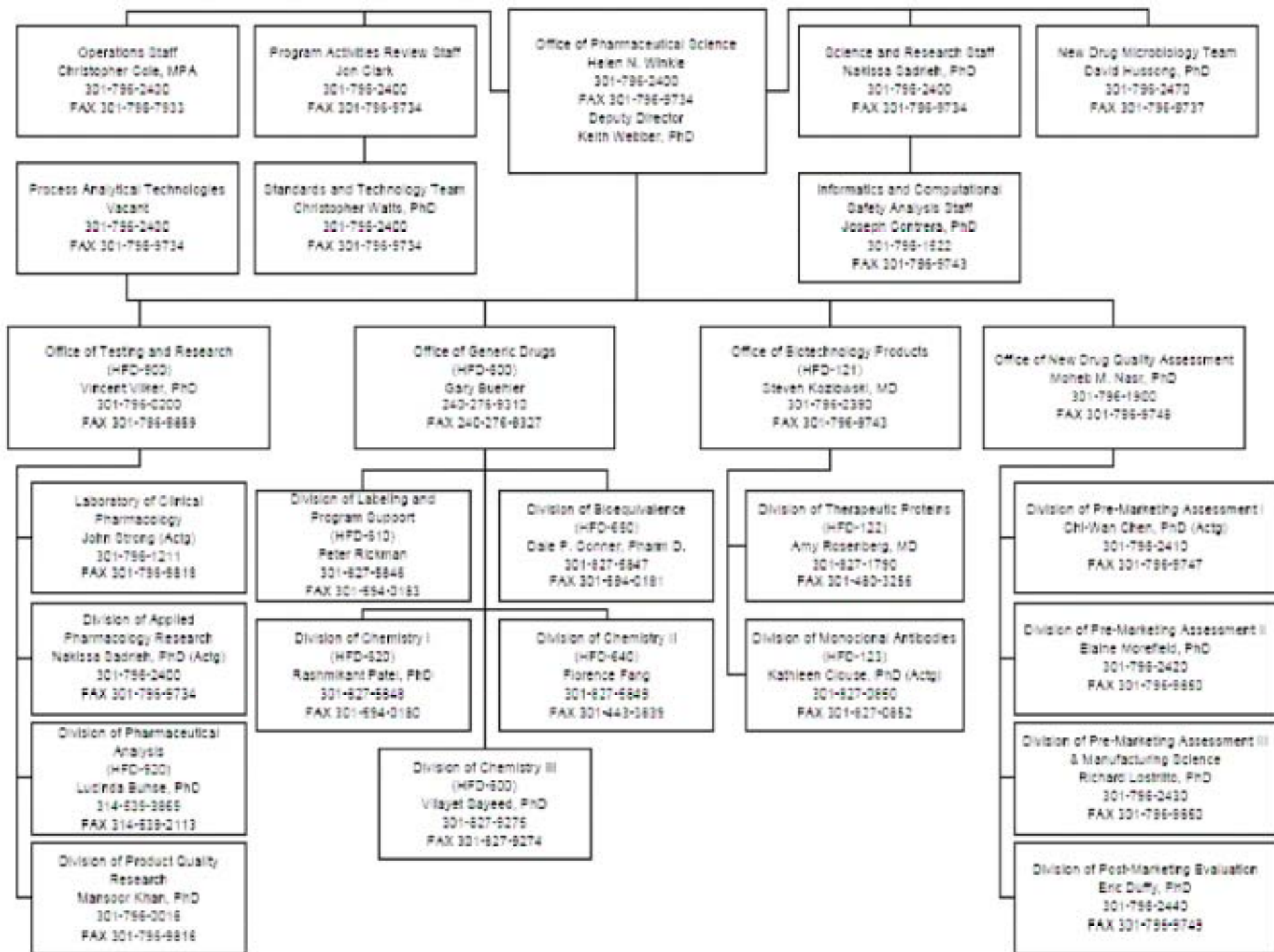
GENERIC DRUG APPROVAL PATHWAY

- ❑ Paragraph IV certification is act of artificial infringement that triggers patent dispute that may be litigated.
- ❑ Litigation provides for patent dispute resolution without actual infringement.
- ❑ Incentive to challenge patent: successful defense against a patent may guarantee generic ANDA applicant to 180 days on the market without generic competition.

ORGANIZATION CHART

OFFICE OF GENERIC DRUGS IN THE CENTER FOR DRUG EVALUATION AND RESEARCH





CONTENT OF AN ANDA

An ANDA has two primary parts:

- ❖ Chemistry, Manufacturing and Control (CMC) part
- ❖ Bio-equivalence part

SAFETY + BENEFIT = HOPE FOR PATIENTS

When the U.S. Food and Drug Administration (FDA) considers whether or not to approve a new application, two issues are paramount:

- Do the results of well-controlled studies provide substantial evidence of effectiveness?
- Do the results show the product is safe; do the drug's benefits appear to outweigh its risks?

WHAT IS THE FOCUS DURING THE REVIEW OF ANDA?

The Generic drug application reviewers at the OGD focus on:

- bioequivalence data
- chemistry and microbiology data
- request for plant inspection, and
- request for drug labeling information

(Now present the slides of the CMC and BE)

ANDA APPROVAL

Once the FDA has completed its review of the ANDA, the applicant is sent one of the following:

- ✓ An approval letter: indicates that the FDA is satisfied with the application and the drug can be marketed.
- ✓ An approvable letter: indicates that the FDA is satisfied with the application, providing certain issues are resolved.

Non-approvable letter indicates that the FDA has found deficiencies in the application and provides the applicant with 10 days to respond.

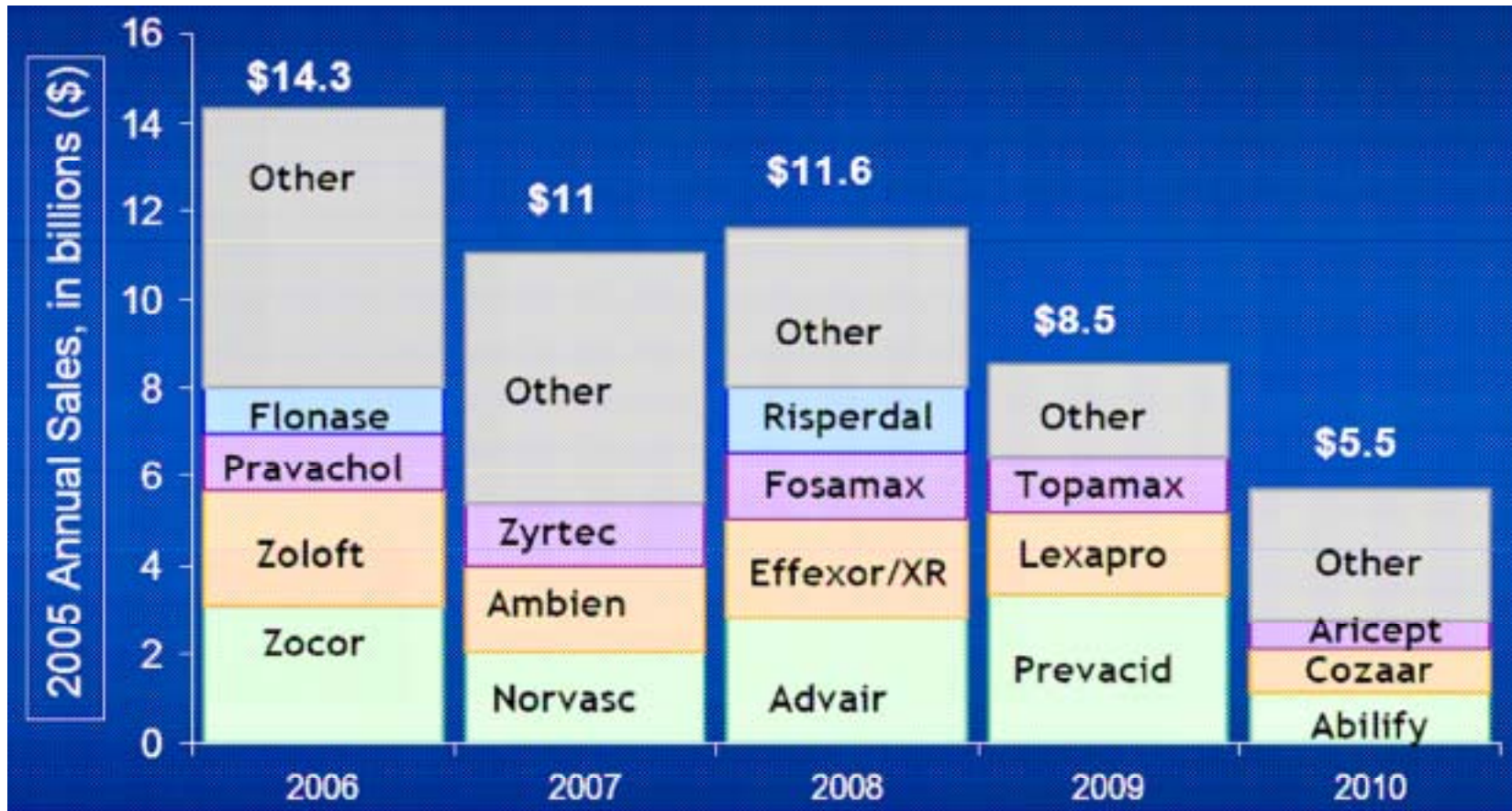
SESSION V

OPPORTUNITIES, APPROACH, AND ACCESS STRATEGY

INDUSTRY EXPECTATIONS FOR THE GENERIC MARKET

- ❖ Brand name pharmaceuticals worth more than \$43 billion in sales are expected to expire through 2009:
 - Approximately \$12B in 2006,
 - \$11B in 2007,
 - \$10B in 2008, and
 - even more in 2009.
- ❖ Today's generic market is worth \$21B.
- ❖ The projected five-year annual sales growth rate for global generic drugs is 22%, while that of the global branded drugs is 10%.

A CRUCIAL POINT IN TIME BRAND DRUGS GOING GENERIC



MAJOR PATENT EXPIRATIONS

2003

Prilosec
Atrovent
Sonata
Accutane
Ortho Novum
777
Ortho
TriCyclen
Remeron
Wellbutrin SR

2004

Paxil
Cipro
Lotensin
Synthroid
Celexa
Serzone
Alphagan
Oxycontin
Neurontin

2005

Allegra
Amaryl
Arava
Biaxin
Duragesic
Metaglip
Oxycontin
10/20/40
Zithromax

2006

Allegra-D
Concerta
Flonase
Lamisil
Pravachol
Proscar
Provigil
Skelaxin
Tricor
Zocor
Zoloft

2007

Actonel
Actiq
Ambien
Clarinox
Norvasc
Topamax
Zyrtec
Zyrtec D



GENERIC HIGHLIGHTS FROM 2005

Generic approval	Brand name	Generic name	Use	Market sales in 2004 (\$M) ¹
1Q 2005	Duragesic®	fentanyl transdermal system	Chronic pain	\$1,395
2Q 2005	TriCor®	fenofibrate	Hyperlipidemia	\$712
	Lamictal®	lamotrigine	Epilepsy	\$847
	OxyContin®	oxycodone (10 mg, 20 mg, 40 mg)	Chronic pain	\$1,888
3Q 2005	Allegra®	fexofenadine	Seasonal allergic rhinitis	\$1,296
4Q 2005	Zithromax®	azithromycin	Bacterial infections	\$1,409
			% of total drug spend in 2004	3.86%

EXPECTED GENERIC CLASS OF 2006*

Brand name (generic name), manufacturer	Use	2005 US Retail Sales (\$M)
<i>Colestid</i> ® (colestipol), Pharmacia	Hyperlipidemia	\$15
<i>Pravachol</i> ® (pravastatin), Bristol-Myers Squibb	Hyperlipidemia	\$1,395
<i>Zantac</i> ® (ranitidine) injection, GlaxoSmithKline	Hypersecretory	\$123
<i>Flonase</i> ® (fluticasone), GlaxoSmithKline	Rhinitis	\$1,098
<i>Xanax XR</i> ® (alprazolam), Pfizer	Panic disorder	\$94
<i>DynaCirc</i> ® (isradipine), Reliant	Hypertension	\$17
<i>Zocor</i> ® (simvastatin), Merck	Hyperlipidemia	\$3,393
<i>Zoloft</i> ® (sertraline), Pfizer	Depression	\$2,664
<i>Proscar</i> ® (finasteride), Merck	BPH	\$248
<i>Toprol XL</i> ® (metoprolol succinate), AstraZeneca	Hypertension	\$1,266
<i>Mobic</i> ® (meloxicam), Boehringer Ingelheim	OA/RA	\$992
<i>Zofran</i> ® (ondansetron), GlaxoSmithKline	CINV	\$818
% of total drug spend in 2005		5.75%

*Availability dates for first-time generics are subject to significant change as a result of multiple patent protections, patent litigation, pediatric or other exclusivities, and at-risk launches.

SIGNIFICANT GENERIC POSSIBILITIES IN 2007*

Brand name (generic name), manufacturer	Use	2005 U.S. retail sales (\$M)
Norvasc [®] (amlodipine), Pfizer	Hypertension	\$2,000
Ambien [®] (zolpidem), Sanofi-Aventis	Insomnia	\$1,800
Zyrtec [®] (cetirizine), Zyrtec-D 12 Hour [®] (cetirizine/pseudoephedrine), Pfizer	Allergies	\$1,200
Imitrex [®] (sumatriptan), GlaxoSmithKline	Migraine headache	\$1,100
Lotrel [®] (amlodipine/benazepril), Novartis	Hypertension	\$1,000
Paxil [®] CR (paroxetine extended-release), GlaxoSmithKline	Depression	\$855
% of total drug spend in 2005		3.77%

*Availability dates for first-time generics are subject to significant change as a result of multiple patent protections, patent litigation, pediatric or other exclusivities, and at-risk launches.

SIGNIFICANT GENERIC POSSIBILITIES IN 2008*

Brand name (generic name), manufacturer	Use	2005 U.S. retail sales (\$M)
<i>Risperdal</i> [®] (risperidone), Janssen	Schizophrenia	\$1,687
<i>Fosamax</i> [®] (alendronate), Merck	Osteoporosis	\$1,537
<i>Depakote</i> [®] (divalproex), Abbott	Seizure disorder, bipolar disorder	\$659
<i>Kytril</i> [®] (granisetron) Roche	CINV	\$60
% of total drug spend in 2005		1.9%

*Availability dates for first-time generics are subject to significant change as a result of multiple patent protections, patent litigation, pediatric or other exclusivities, and at-risk launches.

SIGNIFICANT GENERIC POSSIBILITIES IN 2009*

Brand name (generic name), manufacturer	Use	2005 U.S. retail sales (\$M)
Prevacid [®] (lansoprazole) TAP	GERD	\$3,322
Lexapro [®] (escitalopram) Forest	Depression	\$1,901
Avandia [®] (rosiglitazone) GlaxoSmithKline	Diabetes	\$1,489
Aciphex [®] (rabeprazole) Eisai	GERD	\$1,163
Lamictal [®] Tablets (lamotrigine) GlaxoSmithKline	Seizure disorder	\$1,153
Altace [®] (ramipril) Monarch	Hypertension	\$745
Clarinex [®] (desloratadine), Clarinex-D [®] (desloratadine/pseudoephedrine) Schering	Allergies	\$379
Avandamet [®] (rosiglitazone/metformin) GlaxoSmithKline	Diabetes	\$315
Sonata [®] (zaleplon) King	Insomnia	\$121
Zerit [®] (stavudine) Bristol-Myers Squibb	HIV	\$93
% of total drug spend in 2005		5%

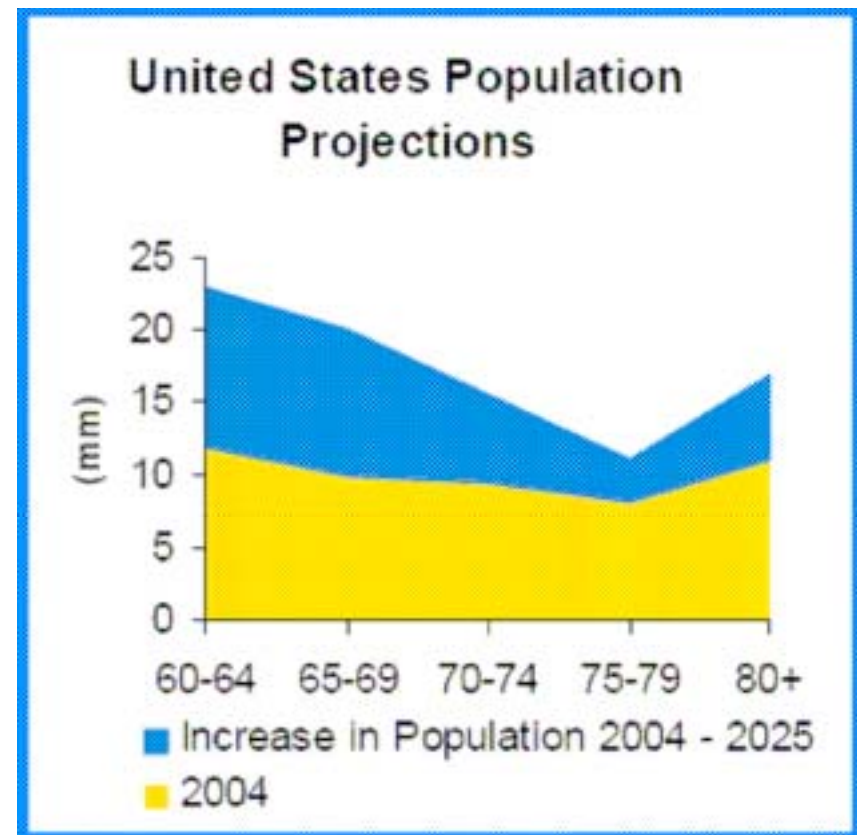
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SIGNIFICANT GENERICS BY THERAPEUTIC CATEGORY

	2006	2007	2008	2009
CV	Pravachol [®] , Zocor [®] , Colestid [®] , DynaCirc [®] , Toprol XL [®]	Norvasc [®] , Coreg [®]	-	Altace [®]
CNS / Neurology	Zoloft [®] , Xanax XR [®] , Effexor [®]	Ambien [®] , Imitrex [®] , Paxil CR [®] ,	Risperdal [®] , Depakote [®]	Lexapro [®] , Topamax [®] , Lamictal [®] Tabs, Sonata [®]
GI / GU	Zantac [®] Inj, Proscar [®] , Zofran [®] , Salagen [®]	-	Kytril [®]	Aciphex [®] , Prevacid [®]
Respiratory	Flonase [®]	Zyrtec [®]	Pulmicort [®] , Serevent [®]	Clarinet [®]
Other	Novantrone [®] , Retrovir [®] , AndroGel [®] , Glucotrol XL [®] , Mobic [®]	-	Fosamax [®]	Zerit [®] , Avandia [®] , Avandamet [®]

LARGE MARKET AIDED BY PIPELINE & DEMOGRAPHICS

- ❑ 45 million people uninsured today (16% of the population)
- ❑ Over the next 20 years, the number of people over 60 years old will increase by over 35 million
- ❑ Elderly tend to have high acuity diseases that drive 70% of healthcare costs
- ❑ Healthcare industry stakeholders continue to seek access and cost efficiencies.



APPROACH AND STRATEGY

- Leverage
 - intensive experience
 - cost advantages in research, development and manufacturing
 - Free Trade Agreement with the U.S
- Invest
 - in infrastructure to better control processes
 - in higher standards per regulatory requirements
- Early Identification of Viable Patents Pays Off
- Be the 1st, 2nd, or 3rd to enter

APPROACH AND STRATEGY

- ❑ Develop image of a specialty supplier of pharmaceutical products with a focus on unique therapeutic categories, quality and service.
- ❑ Expand Product Line into numerous therapeutic categories
- ❑ Develop Strategic Relationships
 - Capitalize on strengths of potential partners
- ❑ Maintain an entrepreneurial attitude
 - Stay flexible and able to move quickly
- ❑ Learn from Indian Generic Model

CHALLENGES FACING MOROCCAN COMPANIES

- ❑ Communications- language
- ❑ Tougher Environmental and Regulatory Standards
- ❑ Business Execution
 - Current Focus on short term profits rather than long term
 - Supply Chain optimization
- ❑ Guarantee of continuous supply of IPAs
- ❑ Willingness to invest in skilled people

SESSION VI

NETWORK OF THE GENERIC MARKET

HOST OF SOURCES

- Pharmaceutical corporations
- Industry correspondents (press releases)
 - Science research
 - Financial interest
 - Information data
- Professional Associations
- Government Agencies

SESSION VII

DISTRIBUTION AND MARKETING TOOLS

DISTRIBUTION

Channels of Distribution for Prescription Drugs:

- Wholesalers
- Chain pharmacies (mass merchandisers)
- Retail pharmacies
- Managed care providers
- Governmental agencies

MARKETING

- Trade Shows
- Press Releases
- Joint Ventures with pharmas
- Contract with a Sales/Marketing firm

CREATE “IN-HOUSES” SALES/MARKETING TEAM



Advantage

- ❖ Full control and autonomy
- ❖ Common goals and objectives
- ❖ Direct contact with generic market

Disadvantage

- ❖ Cost of operation
- ❖ Learning curve challenge
- ❖ Time involved to build team
- ❖ Risk of bureaucracy
- ❖ Significant corporate commitment

LICENSE/DISTRIBUTE THROUGH GENERIC MARKETER



Advantage

- ❖ Turn-key transaction
- ❖ Benefits of full product line
- ❖ "Arms Length" generic involvement

Disadvantage

- ❖ Cost of doing business very high
- ❖ Lack of full control -- no identity
- ❖ Conflict of business objectives
- ❖ "Arms Length" generic involvement/partner sold
- ❖ Full distribution objectives hindered
- ❖ Impossible to transfer market share – when they get own ANDA
- ❖ No differentiation – blend into "line"
- ❖ Transfer of power as business grows

CONTRACT WITH SALES/MARKETING PARTNERS



Advantage

- ❖ Cost savings = profit opportunity
- ❖ Generic market knowledge
- ❖ PhRMA -- Generic experience
- ❖ Full distribution opportunities
- ❖ Client has full decision making control
- ❖ Turn-key sales & marketing department
- ❖ Gain generic knowledge "Arms Length"
- ❖ Turn-key, home-grown reporting systems
- ❖ Exceptional established generic trade, business and personal relationships
- ❖ Corporate commitment minimized

Disadvantage

- ❖ Reception of Outside Representation
- ❖ Order/invoice/distribution system may be required
- ❖ Lack of full corporate commitment

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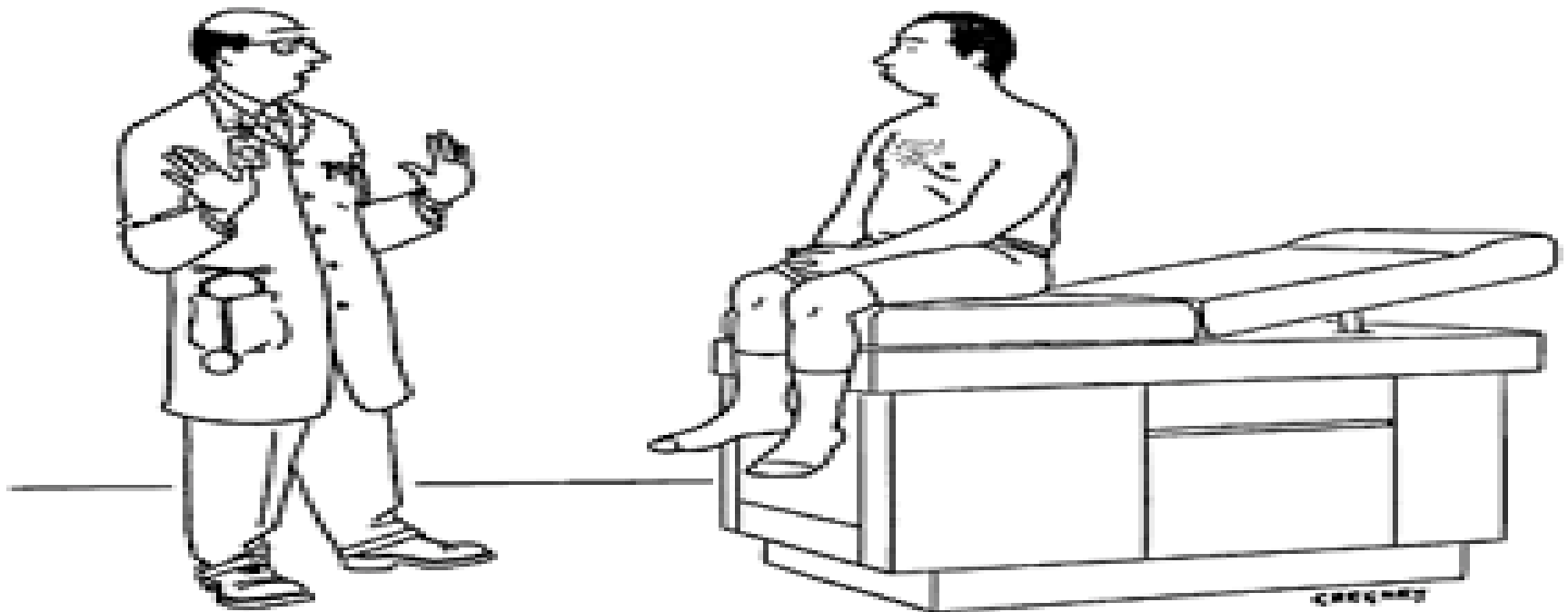
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HAVING COVERED ALOT OF GROUND...

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"Whoa—way too much information!"

HOW TO REACH US

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