DRUG COMMERCIALIZATION

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INTRODUCTION…..

THIS COURSE WILL PROVIDE AN OVERVIEW OF ENTIRE PROCESS FROM TARGET IDENTIFICATION AND COMMERCIALIZATION.

THIS COURSE COVERS TOPIC RANGING:

- PHARMACOECONOMICS
- INTELLECTUAL PROPERTY AND FREEDOM TO OPERATE
- MANAGED MARKET
- MARKETING STRATEGY
- PORTFOLIO MANAGEMENT & BUSINESS MODEL

OBJECTIVE…..

- HOW TO LAUNCH A PRODUCT IN MARKET AND SELL THE PRODUCT AS WELL AS MANY OTHER FACTS IN THE COMMERCIAL ASPECT OF MAKING A DRUG SUCCESSFULLY.

PHARMACOECONOMICS…

PHARMACOECONOMICS IS A FIELD THAT IS USED BY HEALTH CARE PAYERS TO COMPARE THE **COST VS. BENEFIT** OF ALTERNATIVE DRUG FOR POPULATION OF PATIENT.

- ❑ BALANCING COST AND OUTCOMES OF PHARMACEUTICAL THERAPIES AND SERVICES.
- ❑ **OBJECTIVE**

➢ DEFINE BASIC TYPE OF PHARMACOECONOMIC ANALYSIS.

➢ DESCRIBE VALUE PROPOSITION FOR PHARMACEUTICAL USING DIRECT COST, INDIRECT COST AND QUALITY OF LIFE DATA.

TYPES OF PHARMACOECONOMIC ANALYSIS….

- COST OF ILLNESS (COI)
- COST MINIMIZATION (CMA)
- COST EFFECTIVENESS (CEA)
- COST BENEFIT (CBA)
- COST UTILITY (CUA)

VALUE OF PHARMACEUTICAL 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

INTELLECTUAL PROPERTY STRATEGY AND BIOSIMILARS…

- **INTELLECTUAL PROPERTY AND PATENT** PROVIDE LEGAL PROTECTION FOR INVENTORS IN ORDER TO PREVENT THE OTHER PEOPLE FROM MAKING USE OF THEIR IDEAS. IT'S BASICALLY AN EXCLUSIVE RIGHT FOR THAT INVENTION. IT'S GRANTED PRIMARILY BY STATES AND GOVERNMENT TO THE INVENTOR. THE INVENTOR CAN BE EITHER A COMPANY OR AN INDIVIDUAL. AND THE HOLDER AS THE SOLE RIGHT OVER THE INVENTION.
- **<u>ACTS WHICH ARE MAJOR CHANGES IN PATENT LAW:</u>**

- AMERICA INVENTS ACT (A.I.A.)
- BAYH-DOLE ACT
- HATCH-WAXMAN ACT

CONT…..

- BIOSIMILAR IS A BIOLOGICAL PRODUCT THAT IS HIGHLY SIMILAR TO A US-LICENSED REFERENCE BIOLOGICAL PRODUCT NOT WITHSTANDING MINOR DIFFERENCES IN CLINICALLY INACTIVE COMPONENTS. AND FOR WHICH THERE ARE NO CLINICALLY MEANINGFUL DIFFERENCES BETWEEN THE BIOLOGICAL PRODUCT AND THE REFERENCE PRODUCT IN TERMS OF THE SAFETY, PURITY, AND POTENCY OF THE PRODUCT .
- **THE BIOSIMILAR USER FEE ACT:**

- IT IS VERY IMPORTANT BECAUSE IT'S BASICALLY AMENDING. IT AUTHORIZED THE FDA TO ASSESS AND COLLECT FEE. TO EXPEDITE THE REVIEW PROCESS OF BIOSIMILAR BIOLOGICAL PRODUCTS. SO THAT'S VERY INTERESTING BECAUSE SUPPOSEDLY IF YOU ARE A BIOSIMILAR MANUFACTURER, WELL YOU WANT YOUR DRUG TO BE APPROVED QUICKLY. YOU DON'T WANT IT TO SIT ON THE SHELF IF YOU ARE DOING WHAT IS REQUIRED. AND, YOU KNOW THE REASON FOR THAT, THAT THIS WENT THROUGH IS BECAUSE THERE IS A VERY IMPORTANT PUBLIC HEALTH BENEFIT. A LOT OF THESE DRUGS, ESPECIALLY IN ONCOLOGY, HAVE IMPROVED SURVIVAL RATES. IN RA, THEY HAVE IMPROVED QUALITY OF LIVE SUBSTANTIALLY IN TERMS OF RHEUMATOID ARTHRITIS.

PHARMACEUTICAL MARKETING & BIOTECH DRUGS…

- **OBJECTIVE:**

- PHARMACEUTICAL TRADITIONAL MARKETING: THE 4PS
- FDA: REGULATORY RULES
- PHARMA NEW BUSINESS MODEL
- NOVEL APPROACH: THE 4CS
- **PHARMACEUTICAL MARKETING**
- WHAT MAKES A DRUG SUCCESS?
- MARKETING’S ROLE IS TO INCREASE SALES
- THE 4PS (PRODUCT, PLACE OR MARKET, PRICE, PROMOTION)
- ELEMENT OF THE “IDEAL DRUG PROFILE”
- DESIGN MARKETING PLAN
- MARKET SHIFT: PHARMA CHANGE STRATEGY

➢ MOVE FROM GENERAL PRACTITIONER AND FAMILY PRACTICE MARKET TO SPECIALTY MARKET.

➢ PORTFOLIO MOVING FROM SMALL MOLECULE TO BIOLOGICS AND MACROMOLECULE.

BUSINESS MODEL AND PORTFOLIO MANAGEMENT IN THE PHARMACEUTICAL INDUSTRY..

- **OBJECTIVE:**
- TOP 3 BUSINESS MODELS IN THE PHARMACEUTICAL INDUSTRY
- 3 KEY STRATEGIES TO REFUEL THE PIPELINE
- **THE PHARMA BUSINESS MODELS:**
- INVENTOR BUSINESS MODEL
- GENERIC BUSINESS MODEL
- OTC BUSINESS MODEL
- **HOW TO REFUEL THE PIPELINE:**
- FIRST, THE PIPELINE NEEDS TO BE BALANCED BETWEEN SHORT TERM AND LONG-TERM PROJECTS.
- IN-HOUSE R & D.
- IN-LICENSING.
- COMPANY ACQUISITION.

CONCLUSION…

- A SUCCESSFUL PRODUCT LAUNCH DEPENDS ON THE STRATEGIC IMPLEMENTATION OF FULLY INTEGRATED PROJECT, PROGRAM, AND PORTFOLIO MANAGEMENT INTO THE PRODUCT COMMERCIALIZATION LIFE CYCLE. HOWEVER, WHILE MOST PHARMACEUTICAL COMPANIES HAVE TALENTED FUNCTIONAL RESOURCES, ORGANIZATIONS OFTEN LACK THE DEDICATED EXPERTISE AND DISCIPLINE NEEDED TO LEAD THE MATRIX STRUCTURE AND INTERDEPENDENCIES ESSENTIAL TO THE SUCCESS OF A COMMERCIALIZATION PROGRAM.
- THE VALUE OF PROJECT AND PORTFOLIO LEADERSHIP FOR A DRUG COMMERCIAL LAUNCH PROGRAM HAS BECOME INCREASINGLY EVIDENT AS MORE PHARMACEUTICAL ORGANIZATIONS LEVERAGE THIS EXPERTISE TO MAXIMIZE ORGANIZATIONAL CAPABILITIES AND CAPACITY TO LAUNCH NEW DRUGS WITH SPEED, EFFICIENCY, AND EFFECTIVENESS. IMPLEMENTING SUCH EXPERTISE ENABLES THE PHARMACEUTICAL COMPANY TO TRANSFORM ITS VISION INTO AN ACTIONABLE ROAD MAP, COMPRESS TIME TO MARKET, AND STREAMLINE OPERATIONS TO ACCELERATE BENEFITS FOR THE PATIENT AND VALUE FOR THE COMPANY.

Thank you