Women's Health Across the Lifespan

A PHARMACOTHERAPEUTIC APPROACH

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Disclaimer: *Dr. Calis contributed to this textbook in his personal capacity. The views expressed are his own and do not necessarily represent the views or policies of the Food and Drug Administration, the National Institutes of Health, or the United States Government.*

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Dedication

I dedicate this book to my three wonderful boys—Thor, Leif, and Lars—who remind me to cherish every moment and create lasting memories; and to my amazing mom Ellen, who has been an inspiring role model in becoming an independent, loving, and confident woman.

—Laura Marie Borgelt

I would like to thank my Mom and Aunt Dolores; the nurses in my upbringing who paved the way for a healthcare profession; my Dad; my Grandma Guelig; my brother and his family; my sister and her family; and all my great relatives, friends, teachers, and colleagues who consistently provide support, encouragement, happiness, and especially love along the way of my professional endeavors.

—Mary Beth O'Connell

I dedicate this book to my wonderful son, Lance, whose arrival has been a blessing and source of endless happiness in my life and to my husband, Heath, for all his love and endless support....steady as we go.

—Judith Ann Smith

This book is dedicated to my loving wife and our precious little girls; to my devoted mom, sisters, and brother; and to my beloved dad who left us too soon—with special thanks to our Blessed Mother for her guidance and inspiration.

—Karim Anton Calis

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Foreword

Women's bodies are different from those of men! This seems such an obvious statement—even children recognize the differences at an early age. Yet, it has been only recently that the scientific and healthcare communities have begun to give due attention to the fact that these differences exist beyond just body shape and reproductive systems and organs, and that they are very important in the full understanding of the health and well-being of women and men, and how we can best prevent, diagnose, or treat all conditions and diseases. Important causes of mortality and morbidity such as osteoporosis, cardiovascular disease, chronic pain, addiction, and mental health, among many others, may differ in various aspects between women and men. Almost all organ systems have shown sex and gender variations from differences in anatomy, physiology, and pathophysiology to the response to medications. Even more attention is needed in consideration of pharmacotherapeutic approaches to women, with the appreciation of sex differences that can and do influence their effectiveness or effects. This new text, *Women's Health Across the Lifespan: A Pharmacotherapeutic Approach,* goes beyond the reproductive healthcare issues that are unique to women and examines the issues of chronic illness that have a higher prevalence in women and warrant sex/gender differences in treatment regimens. Its publication is not only timely but provides a needed comprehensive source of valuable information.

Healthcare providers must integrate the biopsychosocial aspects of sex/gender specific care in confronting treatment adherence problems and disparities in health status and health outcomes. Women's health research is a model for expanding the study of the many important factors that affect the health of girls and women. This holistic approach, reaching beyond biomedical and biobehavioral contributors, includes poverty; culture and ethnicity; geographic location and environmental influences; access to healthcare; education; gender differences in provider-patient interaction; communications; sexual orientation; occupational stresses; and the unique demands of disabilities as potential contributing factors to the health of women. Furthermore, women can be considered as the portal to family and community health—often as motivators or caregivers for their families and those around them and as givers of life through whom their own preconception and pregnancy bodily health can affect future generations. So, considerations of how healthcare is delivered to women have far reaching implications. The editors have applied the holistic approach in the development of this text to assist healthcare professionals and others to identify and effectively consider all of these issues when treating their female patients.

Since the establishment of the NIH Office of Research on Women's Health, the concept of women's health has expanded to embrace the entire lifespan, from in utero to infancy and childhood, adolescence, reproductive years, menopause, and the elderly years. Additionally, this concept has extended further to include the totality of physical, mental, behavioral, and sociocultural factors that contribute to the total body health of women. This text helps respond to many of these concerns through its chapters that detail not only the historical, biological, and behavioral facets of women's health across the lifespan as we understand it today, but also by informing through narrative and case studies the challenges for principles of pharmacotherapeutics in the care of women. This book provides an interdisciplinary and multidisciplinary resource for the future care of girls and women through its incredible wealth of information, especially as one of the first to place emphasis on sex and gender differences in regards to medication protocols.

I hope that *Women's Health Across the Lifespan* will stimulate change in some practice paradigms, especially shifting from lack of consideration of sex/gender differences to algorithms and practices specific to a more individualized treatment of disease and promotion of healthy lifestyle behaviors including known sex/gender differences. Medications are important to the care of girls and women, but adherence to these therapies may not always be optimal due to many reasons in the lives of women. By understanding the concept of the totality of girls and women, providers can help improve individual female wellness and disease prevention and control. With a sex/gender approach, we are learning more about the health of women, their families, and their communities.

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This book will be a valuable resource for new and established healthcare practitioners. The reader will be able to incorporate a better understanding of sex/gender influences into the delivery of care and his or her own standards of approach to patient issues. The reader should also be able to individualize medication therapy and maximize the resultant health outcomes from preconception to the end of life for girls and women. The cases and bioethical challenges help the reader identify sex and gender differences and then individualize care based on sex/gender principles. And, hopefully, readers will gain an appreciation of the importance of new scientific advances related to evolving technologies, therapies, and practices that can unravel the continuing and emerging gaps in knowledge about women's health, spurring them to become advocates for women's health and the study of sex/gender factors.

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Preface

That men and women are different seems obvious. The sexes are different physically, physiologically, emotionally, and socially. They are also potentially different in their pharmacokinetics, pharmacodynamics, and response to drug therapy. But historically, the same approach has been applied to the medical care of both sexes. In fact, until now, no one comprehensive resource existed that addressed the complex pharmacotherapeutic and health needs of women. As a result, there has been a significant gap in knowledge that we believe has limited the ability of medical professionals to provide optimal healthcare for girls and women. Healthcare providers need to have an appreciation for the potential influences of sex and gender on medication disposition, response, and quality of life as these can profoundly affect wellness and disease.

To illustrate this point, imagine your next clinical encounter with a girl, woman, mother-to-be, or grandmother. Providing your patient with the best care will mean individualizing her medication therapy to fit her unique medical needs while balancing the complex psychosocial influences of her everyday life. Physiologic and hormonal stresses, social pressures, psychologic issues, emotional challenges, and economic strains are among the factors that must be considered along with sex-related clinical differences.

We developed *Women's Health Across the Lifespan: A Pharmacotherapeutic Approach* to be a comprehensive primary reference for healthcare professionals and students who work or interact with female patients. Several goals guided us as we planned the book. First, we wanted to ensure that in discussing pharmacotherapy issues, we addressed not only sex- and gender-specific medication response, but also the social, economic, physiologic, spiritual, emotional, and ethical issues that directly or indirectly affect medication use. In order to present a well-balanced approach for each topic, we enlisted the assistance of a diverse group of healthcare professionals and content experts from around the world to serve as contributors and reviewers. We also strongly believed that the information presented in this book should further enhance and augment the information already available in primary care resources. Finally, we made every effort to ensure that the content is comprehensive, authoritative, objective, up-to-date, and evidenced based. All of these principles informed our goal of making this book a necessary resource that complements other references by providing a greater depth of coverage on sex and gender issues, which are vitally important to health.

We chose not to present the book in a chronological order so we could more comprehensively address broader social and ethical issues that affect girls and women at various stages in their lifespan. To achieve this goal, the book is organized into eight sections:

1. The historical and social context of women's health
2. The biology, physiology, and wellness of girls and women
3. Menstrual health
4. Contraceptive methods
5. Preconception, pregnancy, and postpartum care
6. Selected conditions that affect women differently or disproportionately compared to men
7. Cancers that affect women
8. Ethical issues in women's healthcare

In order to provide a logical, orderly presentation for readers, we created a standard template for our clinical chapters. The clinical presentation and pathophysiology sections will be helpful for readers to fully understand the rationale for medication therapy. Guidelines and preventive therapy are discussed where applicable. The treatment sections include the overall treatment goals along with a discussion of nonpharmacologic and pharmacologic therapies, monitoring, and patient education. Information regarding complementary and alternative therapies is provided where appropriate based on available evidence.

We felt strongly that some special features within each chapter would make the information more relevant to users, particularly students. As a result, specific pedagogy was incorporated to enhance learning in the classroom. Each chapter in this book includes measurable learning objectives that can be used to assess learning. All chapters include a patient case, typically presented in a "book

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end" fashion, where subjective and objective information appears at the beginning of the chapter and the assessment and plan close the chapter. This allows the case to complement the chapter content and highlight critical concepts in therapeutics and clinical practice. Chapters also include a feature called "therapeutic challenges." The therapeutic challenges present difficult or unresolved issues in women's health pharmacotherapy that can be debated and further studied. They are intended to spur critical thinking and further exploration of a topic, and may be particularly suitable for in-class and group discussions. Tables and figures highlight the most relevant content. For many chapters, additional textbook content—including more patient cases, tables, and figures—can be found online at www.ashp.org/womenshealth. The added content is noted in the book with the following text and computer screen icon:

Additional content available at
www.ashp.org/womenshealth

An important and innovative feature of the book is that full reference lists for each chapter can be found online. Where possible, these references are hyperlinked to their corresponding PubMed citations or other relevant sources of additional information.

Our goal was to create a book that would help healthcare professionals, educators, and students to

- discover the unique facets of girls' and women's healthcare;
- address healthcare needs across the female lifespan;
- describe rational, evidence-based pharmacotherapeutic interventions based on sex and gender differences;
- foster lively discussions about controversies and challenges in the care of girls and women; and
- stimulate research that leads to advances in women's healthcare.

We are confident that this comprehensive resource will help to advance educational endeavors in girls' and women's health, and ultimately improve the care provided to these patients. We are sincerely grateful for the contributions of the chapter authors and reviewers who generously shared their knowledge, experience, and time to enhance the scope, depth, and accuracy of this resource. We greatly appreciate the support, guidance, and assistance of the staff at the American Society of Health-System Pharmacists. The expertise, insight, and positive encouragement of Dana Battaglia and Rebecca Olson were especially valuable. Our greatest hope is that you, the reader, will find that this resource helps you in caring for and treating your patients in a way that considers all the unique, complex, and dynamic aspects of girls and women during their lifetime.

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Abbreviations

17P	17-alpha hydroxyprogesterone caproate
Ab	antibody
ACCP	American College of Chest Physicians
ACEI	angiotensin-converting enzyme inhibitors
ACG	American College of Gastroenterology
ACOG	American College of Obstetricians and Gynecologists
ACS	American Cancer Society
ACSs	acute coronary syndromes
AEDs	antiepileptic drugs
AGA	American Gastroenterological Association
AGC	atypical glandular cells of uncertain significance
AIs	aromatase inhibitors
AIS	adenocarcinoma in situ
ALLHAT	Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial
ALND	axillary lymph node dissection
ANA	antinuclear antibodies
ANC	acid-neutralizing capacity
Anti-CCP	anticyclic citrullinated peptide
APs	antipsychotics
aPTT	activated partial thrombin time
ARBs	angiotensin receptor blockers
ART	assisted reproductive technology
ASC	atypical squamous cells
ASC-US	atypical squamous cells–unspecified
ASRM	American Society for Reproductive Medicine
AUC	area under the curve
BAP	British Association for Psychopharmacology
BBT	basal body temperature
BCT	breast-conserving therapy
BDD	body dysmorphic disorder
BED	binge-eating disorder
BIA	bioelectrical impedance analysis
BI-RADS	Breast Imaging Reporting and Data System
BMD	bone mineral density
BMI	body mass index
BMR	basal metabolic rate
BNP	B-type natriuretic peptide
BSE	breast self-evaluation
BSO	bilateral salpingo-oophorectomy
cAMP	cyclic adenosine monophosphate
CBE	clinical breast evaluation
CBT	cognitive behavioral therapy
CCBs	calcium channel blockers
CCRs	chemokine coreceptor antagonists
CD	Crohn's disease
CHCs	combined hormonal contraceptives
CHD	coronary heart disease
CI	confidence interval
CIN	cervical intraepithelial neoplasia
CLAS	culturally and linguistically appropriate services
CMF	cyclophosphamide, methotrexate, and fluorouracil
CMV	cytomegalovirus
CNS	central nervous system
COC	combined oral contraceptive
COX	cyclo-oxygenase
CR	complete response
CRP	C-reactive protein
CT	computed tomography
CXR	chest x-ray
D&C	dilatation and curettage
DASH	Dietary Approaches to Stop Hypertension
DCIS	ductal carcinoma in situ
DFS	disease-free survival
DHEA	dehydroepiandrosterone
DHHS	Department of Health and Human Services
DHT	dihydrotestosterone
DIG	Digitalis Investigation Group
DMARDs	disease-modifying antirheumatic drugs
DMPA	depot medroxyprogesterone acetate
DMSO	dimethyl sulfoxide
DNA	deoxyribonucleic acid
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
DUB	dysfunctional uterine bleeding
DVT	deep vein thrombosis
EASI	extra-amniotic saline infusions
EBAF	endometrial bleeding associated factor
EBRT	external beam radiotherapy

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EBV	Epstein-Barr virus
ED	emergency department
EDNOS	eating disorders not otherwise specified
EE	esterified estrogens
EE	ethinyl estradiol
EEG	electroencephalogram
EGFR	epidermal growth factor receptor
EIC	endometrial intraepithelial carcinoma
EMB	endometrial biopsy
EPDS	Edinburgh Postnatal Depression Score
EPL	early pregnancy loss
EPS	extrapyramidal symptoms
ER	estrogen receptor
ESBC	early-stage breast cancer
ESR	erythrocyte sedimentation rate
ET	estrogen therapy
FAMs	fertility awareness methods
FDA	U.S. Food and Drug Administration
FEV1	forced expiratory volume in 1 second
FIGO	International Federation of Gynecology and Obstetrics
FOD	female orgasmic disorder
FSAD	female sexual arousal disorder
FSH	follicle stimulating hormone
GABA	gamma-aminobutyric acid
GAD	general anxiety disorder
GD	gestational diabetes
GERD	gastroesophageal reflux disease
GFR	glomerular filtration rate
GI	gastrointestinal
GIFT	gamete intrafallopian transfer
GMT	geometric mean titer
GnRH	gonadotropin releasing hormone
GOG	Gynecologic Oncology Group
H_2RA	histamine-2 receptor antagonists
HAART	highly active antiretroviral therapy
HBOC	hereditary breast/ovarian cancer
HCG	human chorionic hormone
HDL-C	high-density lipoprotein cholesterol
HER2	human epidermal growth factor 2
HELLP	hemolysis, elevated liver enzymes, low platelet count
HERS	Heart and Estrogen/progestin Replacement Study
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
hMG	human menopausal gonadotropin
HNPCC	hereditary nonpolyposis colorectal cancer
HPA	hypothalamic-pituitary-adrenal
HPO	hypothalamic-pituitary-ovarian
hPTH	human parathyroid hormone
HPV	human papillomavirus
HSDD	hypoactive sexual desire disorder
HSG	hysterosalpingogram
HSV	herpes simplex virus
HT	hormone therapy
IBC	inflammatory breast cancer
IBD	inflammatory bowel disease
IBS	irritable bowel syndrome
IBS-C	irritable bowel syndrome with constipation
IBS-D	irritable bowel syndrome with diarrhea
IBS-M	mixed IBS
IBS-U	unsubtyped IBS
ICD	International Classification of Diseases
ICSI	intracytoplasmic sperm injection
ICSs	inhaled corticosteroids
IGT	impaired glucose tolerance
IL	interleukin
IMS	International Menopause Society
IND	investigational new drug
INR	international normalized ratio
IP	intraperitoneal
ISMP	Institute of Safe Medication Practices
IUC	intrauterine contraceptive
IUI	intrauterine insemination
IVF	in vitro fertilization
IVF-ET	in vitro fertilization–embryo transfer
IVF-ICSI	in vitro fertilization–intracytoplasmic sperm injection
JNC	Joint National Committee
LABA	long-acting beta-2 agonist
LABC	locally advanced breast cancer
LCD	low-calorie diet
LCIS	lobular carcinoma in situ
LDL-C	low-density lipoprotein cholesterol
LEEP	loop electrosurgical excision procedure
LES	lower esophageal sphincter
LGSIL	low-grade squamous intraepithelial lesion
LH	luteinizing hormone
LHRH	luteinizing hormone–releasing hormone
LMP	last menstrual period
LMWH	low molecular weight heparin
LND	lymph node dissection
LNG	levonorgestrel
LNG-IUD	levonorgestrel intrauterine device
LNG-IUS	levonorgestrel-releasing intrauterine system
LPS	lipopolysaccharides
LUNA	laparoscopic uterosacral nerve ablation
LVEF	left ventricular ejection fraction

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MAOIs	monoamine oxidase inhibitors
MBC	metastatic breast cancer
MDD	major depressive disorder
MHC	major histocompatibility complex
MI	myocardial infarctions
MMPs	matrix metalloproteinases
MMSE	mini-mental state exam
MOMPs	major outer-membrane proteins
MPA	medroxyprogesterone acetate
MRM	modified radical mastectomy
MS	multiple sclerosis
mT	methyltestosterone therapy
MTCT	mother-to-child transmission
N-9	nonoxynol-9
NAAT	nucleic acid amplification tests
NAMS	The North American Menopause Society
NAS	neonatal abstinence syndrome
NCCN	National Comprehensive Cancer Network
NCEP	National Cholesterol Education Program
NFP	natural family planning
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
NK	neurokinin
NNRTIs	non-nucleoside reverse transcriptase inhibitors
NO	nitric oxide
nPEP	nonoccupational exposure prophylaxis
NRT	nicotine replacement therapy
NRTIs	nucleoside reverse transcriptase inhibitors
NSAIDs	nonsteroidal anti-inflammatory drugs
NSTEMI	non-ST-elevation myocardial infarction
NTDs	neural tube defects
NVP	nausea and/or vomiting during pregnancy
OB/GYN	obstetrics and gynecology
OCs	oral contraceptives
OCD	obsessive-compulsive disorder
OCPs	oral contraceptive pills
OGTT	oral glucose tolerance test
OHSS	ovarian hyperstimulation syndrome
OMH	Office of Minority Health
OR	odds ratio
ORT	oral replacement therapy
OS	overall survival
PCOS	polycystic ovary syndrome
PCR	polymerase chain reaction
PE	pulmonary embolism
PEG	polyethylene glycol
PEFR	peak expiratory flow rate
PET	positron-emission tomography
PFMT	pelvic floor muscle training
PFS	progression-free survival
PGE_2	prostaglandin E_2
$PGF_{2\alpha}$	prostaglandin $F_{2\alpha}$
PIs	protease inhibitors
PID	pelvic inflammatory disease
PMDD	premenstrual dysphoric disorder
PMS	premenstrual syndrome
POI	primary ovarian insufficiency
POP	progestogen-only pill
PPA	phenylpropanolamine
PPIs	proton-pump inhibitors
PPPH	persistent primary pulmonary hypertension
PR	progesterone receptor
PSN	presacral neurectomy
PT	prothrombin time
PTSD	post-traumatic stress disorder
PTU	propylthiouracil
RA	rheumatoid arthritis
RCTs	randomized controlled trials
REM	rapid eye movement
RF	rheumatoid factor
RID	relative infant dose
ROC	risk of ovarian cancer
RPR	rapid plasma reagin
RR	response rate
RR	relative risk
RT	radiation therapy
SAD	seasonal affective disorder
SEER	Surveillance and Epidemiology and End Results
SERMs	selective estrogen receptor modulators
SGO	Society of Gynecologic Oncologists
SGOT	serum glutamic oxaloacetic transaminase
SGPT	serum glutamatic pyruvate transaminase
SHBG	sex-hormone binding globulin
SIL	squamous intraepithelial lesions
SIR	standardized incidence ratio
SLE	systemic lupus erythematosus
SNB	sentinel node biopsy
SNRIs	serotonin-norepinephrine reuptake inhibitors
sono-HSG	sonohysterography
SR	sustained release
SREs	skeletal related events
SS	Sjögren's syndrome
SSRIs	selective serotonin reuptake inhibitors
STDs	sexually transmitted diseases

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STEMI	ST-elevation myocardial infarction
STIs	sexually transmitted infections
SWOG	Southwest Oncology Group
TAH/BSO	total abdominal hysterectomy with bilateral salpingo-oophorectomy
TCAs	tricyclic antidepressants
Tdap	tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis
TENS	transcutaneous electrical nerve stimulation
TNF	tumor necrosis factor
TNF-α	tumor necrosis factor alpha
TNM	tumor-node-metastasis
TPMT	thiopurine-methyl transferase
TRAb	TSH receptor antibodies
TSH	thyroid-stimulating hormone
TSI	thyroid-stimulating immunoglobulin
TSS	toxic shock syndrome
TTTS	twin-to-twin transfusion syndrome
TVUS	transvaginal ultrasound
TWEL	transepidermal water loss
TZDs	thiazolidinediones
UC	ulcerative colitis
UFH	unfractionated heparin
UI	urinary incontinence
UKCTOCS	United Kingdom Collaborative Trial of Ovarian Cancer Screening
U.S.	United States
USPSTF	U.S. Preventive Services Task Force
UV	ultraviolet
VDRL	venereal disease research laboratory
VEGF	vascular endothelial growth factor
VLPs	virus-like particles
VTE	venous thromboembolism
WBC	white blood cell
WHI	Women's Health Initiative
WHO	World Health Organization
WISDOM	Women's International Study of Long Duration after Menopause
WISE	Women's Ischemia Syndrome Evaluation
XRT	external radiation therapy
ZIFT	zygote intrafallopian transfer

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List of Web Resources

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Table—Advances in Women's Healthcare and Research
Timeline—Historical Timeline of Selected Events, Policies, and Key Decisions Related to Women, Women's Health, and the Role of Pharmacy in Women's Health
Table—Leading Causes of Death in the U.S.
Sidebar—Key Women in the Advancement of Women's Health Research at the National Institutes of Health

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Table—Culturally and Linguistically Appropriate Service Standards (CLAS)
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Figure—Median Income Estimates by Occupation (based on estimates from 2005–2007)

Chapter 5: Issues in Lesbian, Bisexual, and Transgender Healthcare
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Chapter 7: Sex and Gender Differences
Table—Examples of Adverse Drug Reactions Reported to Occur at a Higher Rate in Women

Chapter 8: Health and Wellness
Table—Examples of Wellness Resources

Chapter 9: Medication Use and Complementary and Alternative Therapy
Text—Major Types of Complementary and Alternative Therapies
Text—10 Things to Know About Evaluating Medical Resources on the Web
Table—Resources About Complementary and Alternative Methods of Healing for Consumers and Healthcare Providers

Chapter 13: Premenstrual Syndrome and Premenstrual Dysphoric Disorder
Table—American Psychiatric Association *DSM-IV* Criteria for Premenstrual Dysphoric Disorder

Chapter 18: Family Planning and Nonhormonal Contraception
Table—Helpful Websites for Patient Information
Text—Elective Female and Male Sterilization

Chapter 31: Nutrition and Eating Disorders
Case—Anorexia Nervosa
Table—Cognitive Behavioral Therapy
Case—Binge Eating Disorder

Chapter 33: Gastrointestinal Disorders
Case—Gastroesophageal Reflux Disease
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Chapter 34: Mental Health
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Chapter 36: Substance-Use Disorders
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Chapter 37: Immunity and Autoimmune Diseases
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Case—Graves' Disease
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Chapter 38: Sexually Transmitted and Infectious Diseases
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