DRUG-INDUCED DISEASES
Prevention, Detection, and Management

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When it comes to the future, there are three kinds of people: those who let it happen, those who make it happen, and those who wonder what happened.

—John M. Richardson, Jr.

This book is dedicated to our students, past, present, and future, who we know are well equipped to make it happen.
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Much has changed in pharmacotherapy since the publication of the second edition of this text. New drugs have been introduced, and postmarking experience with those previously available has given us a better understanding of associated risks. In addition, patterns of medication use and drug exposure have continued to be affected by the way drugs are promoted, by reclassification of drugs from prescription to nonprescription status, by changes in drug prices, and by product shortages, which, unfortunately, have become commonplace.

As a result of an aging population and other factors, more people are using more drugs today than ever before. Nearly half of Americans report having used a prescription medication in the last 30 days, and nearly a quarter used three or more. Perhaps the only things that have stayed about the same are the systems we use for prescribing, dispensing, administering, and monitoring drug therapy, which have not changed appreciably since the mid-1900s. As a consequence, drug-related morbidity and mortality is rampant. Nearly 20 years ago, Ernst and Grizzle estimated that drug-related problems cost Americans more than $177 billion and were responsible for more than 200,000 deaths annually. It is unlikely that those horrifying statistics have improved in the years since.

There are numerous ways we can improve medication use. These include the reassessment of the risks and benefits of direct-to-consumer advertising; possible expansion of the authority of the U.S. Food and Drug Administration to include “nutraceuticals” and dietary supplements; a slower, more controlled launch of newly approved drugs to allow an evaluation of safety and efficacy in population subsets not thoroughly evaluated during clinical trials; more structured, broad-based programs for postmarketing surveillance; and the development of fully integrated and properly aligned systems of prescribing, dispensing, administering, and monitoring drug therapy and for educating consumers about safe and effective medication use.

Change won’t be easy (or quick); however, and, until improvements are made, individual practitioners will continue to be their patients’ best defense against drug-related morbidity or mortality—a responsibility that requires exceptional vigilance. The third edition of Drug-Induced Diseases: Prevention, Detection, and Management will help with that. Editors Tisdale and Miller have assembled a remarkable team of experts to serve as chapter authors and reviewers, and together they have created an essential resource for healthcare practitioners. The text uses a unique disease-oriented approach and organizes critical information in an easily retrievable format. It has been carefully updated using a standardized search strategy to include drugs introduced since the previous edition as well as new information about drugs previously marketed. Tables and figures also have been updated, where appropriate, to enhance readability and the text includes new chapters.

Drug-related morbidity and mortality is rampant. Drug-Induced Diseases: Prevention, Detection, and Management is an extraordinary work that continues to be the standard for understanding and preventing drug-induced diseases. It can be a practitioner’s most useful tool.

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We are very pleased to present this third edition of *Drug-Induced Diseases: Prevention, Detection, and Management*. The second edition is used throughout the United States and in 20 other countries around the world, and it is gratifying to know that the text is helping fill a previously unmet need for this type of reference.

In the preface to the first edition, readers were reminded of healthcare providers’ prime directive, “First, do no harm.” Although drug therapy can prolong and improve a patient’s quality of life, it is important to remember that drugs are also capable of causing harm by triggering new ailments or exacerbating those that already exist. The potential benefits of drug therapy, therefore, must always be weighed carefully against the potential harm.

Unfortunately, we don’t always know all the risks associated with a given drug in advance. Premarketing trials fail to identify serious adverse events in at least 20% of drugs approved by the U.S. Food and Drug Administration (see Chapters 1–5). Despite best efforts to ensure that all drugs are safe and effective, millions of patients each year develop drug-induced diseases—some previously known and some previously unknown. In the second edition’s preface, readers were reminded of Heraclitus’ admonition, “If you do not expect the unexpected, you will not find it.” Whenever drug therapy is employed, healthcare providers must train themselves to be on the lookout for unexpected consequences.

Pharmacists, physicians, nurses, and other healthcare professionals on the front lines of patient care and pharmacotherapy must be knowledgeable about the risk of drug-induced diseases and methods of prevention, detection, and management. Students in the health professions must learn that pharmacotherapy has both benefits and risks. Every time a patient presents with a new disease or an exacerbation of an existing condition, someone needs to ask, “Could this problem be drug-induced?”

The purpose of this book is to provide a comprehensive source of information regarding the prevention, detection, and management of drug-induced diseases for current and future healthcare practitioners. Our hope is that it will also encourage practitioners to weigh the risks and benefits before initiating pharmacotherapy and to always expect the unexpected.

As in the previous editions, we consider drug-induced diseases to be a specific subset of adverse effects caused by drugs—a subset characterized by the severity of symptoms and outcomes. For the purposes of this book, we have defined a drug-induced disease as an unintended effect of a drug that results in mortality or morbidity with symptoms sufficient to prompt a patient to seek medical attention and/or require hospitalization.

The text has been structured to facilitate readers’ ability to find specific information related to drug-induced diseases. Section I describes the changing regulatory, legal, and practice landscape as they relate to drug-induced diseases; provides a general overview of the epidemiology and public health impact of these conditions; discusses factors that may contribute to the development of drug-induced diseases; describes the structure and strategy of postmarketing surveillance for their detection and characterization; and provides a general approach to patient evaluation. Sections II through XII are organized around specific diseases in which drugs have been implicated as causative agents or, in some cases, the organ system that is involved.

The disease-related chapters follow a consistent structure: causative agents, epidemiology, mechanisms, clinical presentation and differential diagnosis, risk factors, morbidity and mortality, methods of prevention, management, and information for patients. Each chapter underwent blinded external review by one or more additional content experts.
Numerous changes and, we believe, significant improvements have been incorporated into this edition. Three chapters have been added: Bleeding Disorders, Teratogenicity, and Oral Manifestations of Systemically Administered Drugs. Chapters have been expanded, and information throughout has been carefully updated by the contributors. Chapter authors used a structured and more consistent literature search strategy to ensure relevant information was not inadvertently overlooked.

As in previous editions, each chapter includes a series of standard tables, which are in a consistent format throughout. All of the “Agents Implicated” tables include an indication of the strength of the evidence (Level of Evidence) that links a listed drug to a specific drug-induced disease:

- **Level of evidence A** has been assigned when there is evidence of causality from one or more randomized, controlled clinical trials.
- **Level of evidence B** indicates that there is evidence of causality from nonrandomized clinical trials, prospective observational studies, cohort studies, retrospective studies, case-control studies, meta-analyses, and/or postmarketing surveillance studies.
- **Level of evidence C** has been assigned when evidence of causality is from one or more published case reports or case series.

Undertaking a book such as this is not an easy task, and we gratefully acknowledge the work of the chapter authors and expert external content reviewers. Without their significant contributions, this book could not have been completed. We also want to express our appreciation for the assistance of the ASHP staff. We sincerely hope that this text helps practitioners as they work to continually improve patient outcomes related to drug therapy.

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October 2018
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FIGURE 8-3  Drug-Induced Phototoxicity and Photoallergy
The photo on the left depicts a case of drug-induced phototoxicity secondary to demethylchlortetra-
cycline use for treatment of acne. The woman was wearing a hat that protected her face and neck
from sunlight exposure, but her hands were exposed to sunlight while holding a railing at a sporting
event. The photo on the right depicts a case of drug-induced photoallergy secondary to trimethoprim–
sulfamethoxazole use for *Pneumocystis jiroveci* pneumonia prophylaxis. Eczema and hyperpigmenta-
tion of the sun-exposed areas are noted. Photos reprinted with permission from Wolff K, Johnson RA,
Suurmond D. *Fitzpatrick’s Color Atlas and Synopsis of Clinical Dermatology: Common and Serious

FIGURE 29-2  Transthoracic Echocardiogram
with Color Doppler Map from the Parasternal
Window in the Long Axis of the Same Patient as
in Figure 29-1
Demonstrating a jet of moderate mitral regurgitation
(arrow) directed slightly posteriorly, due to mild restriction
of the posterior leaflet, as is characteristic of anorexiant-
induced valvulopathy. LV = left ventricle, RV = right
ventricle.

FIGURE 29-3  Apical 4-Chamber View from a
Transthoracic Echocardiogram from the Same
Patient as in Figures 29-1 and 29-2
Demonstrating a jet of moderate mitral regurgitation
(arrow) directed slightly posteriorly and laterally, due to
mild restriction of the posterior leaflet, characteristic of
anorexiant-induced valvulopathy. LA = left atrium,
LV = left ventricle, RA = right atrium, RV = right ventricle.