

<インタビューを通じて OTC 薬による副作用被害に対する私信>

OTC 薬の使用は、消費者が容易に手に入れことができること（利便性）と低コストが消費者のメリットになっている。一方で、これには OTC 薬による副作用被害のリスクが伴うという矛盾が生じる。特にスイッチ OTC 薬の使用に関しては、薬剤師が介入することにより、副作用被害を軽減できると思われるが、薬剤師による消費者への教育・指導については薬剤師によるボランティアとしてではなく、法的な規制・措置が必要であると思われる。

写真1



写真2

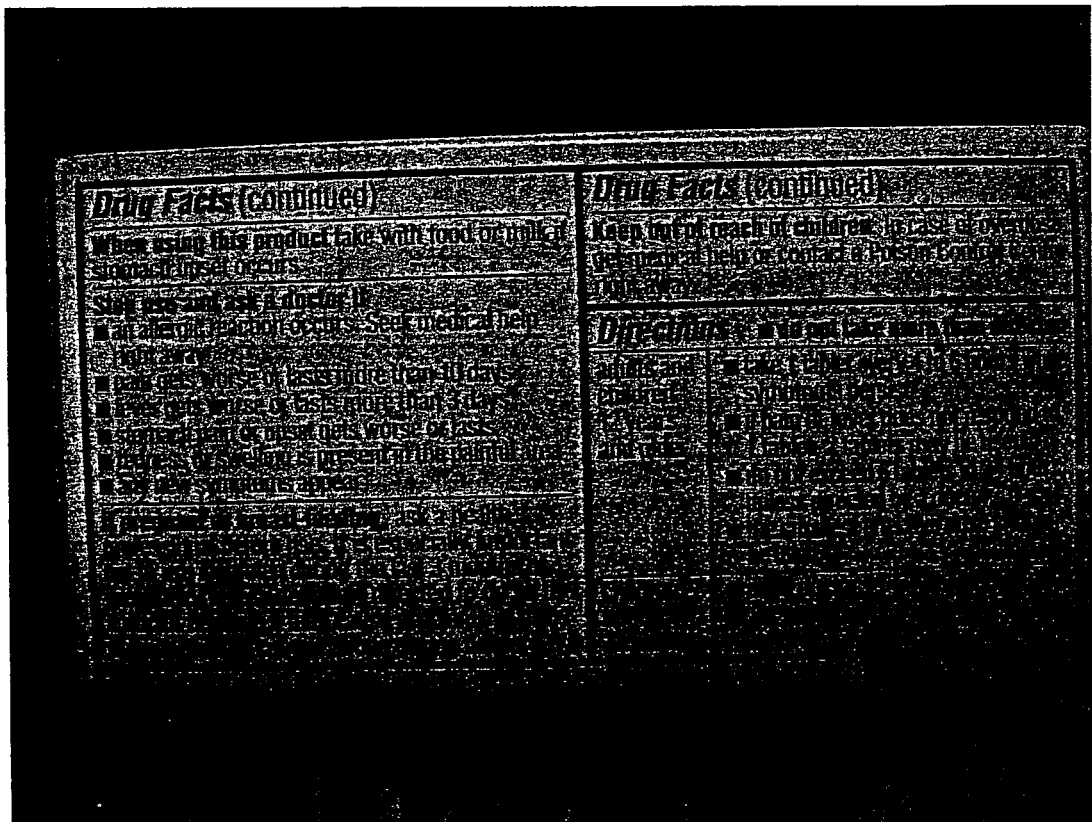


写真 3

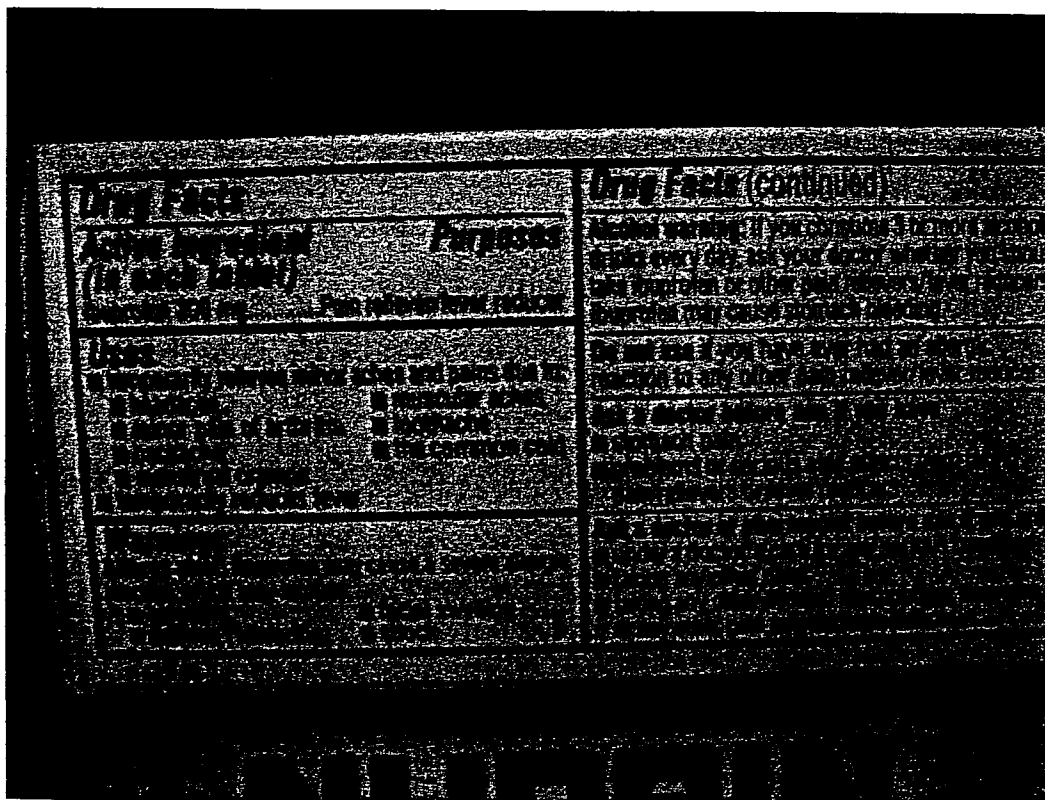


写真 4

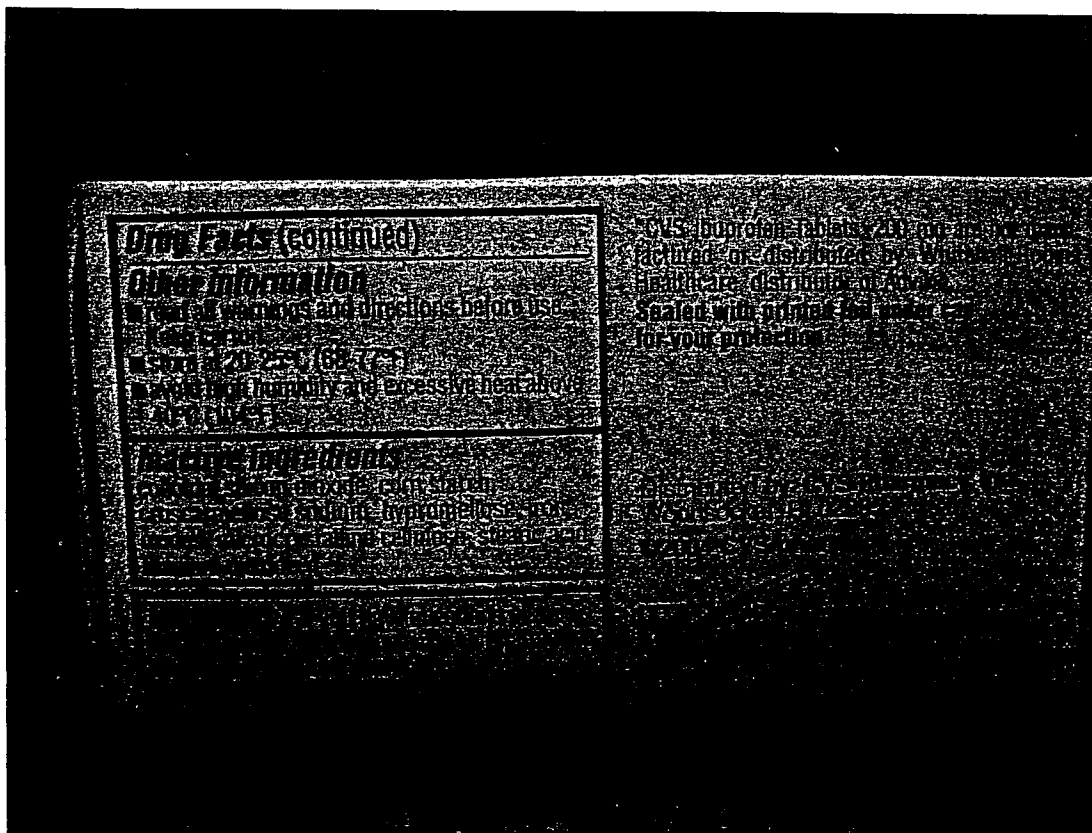


写真 5

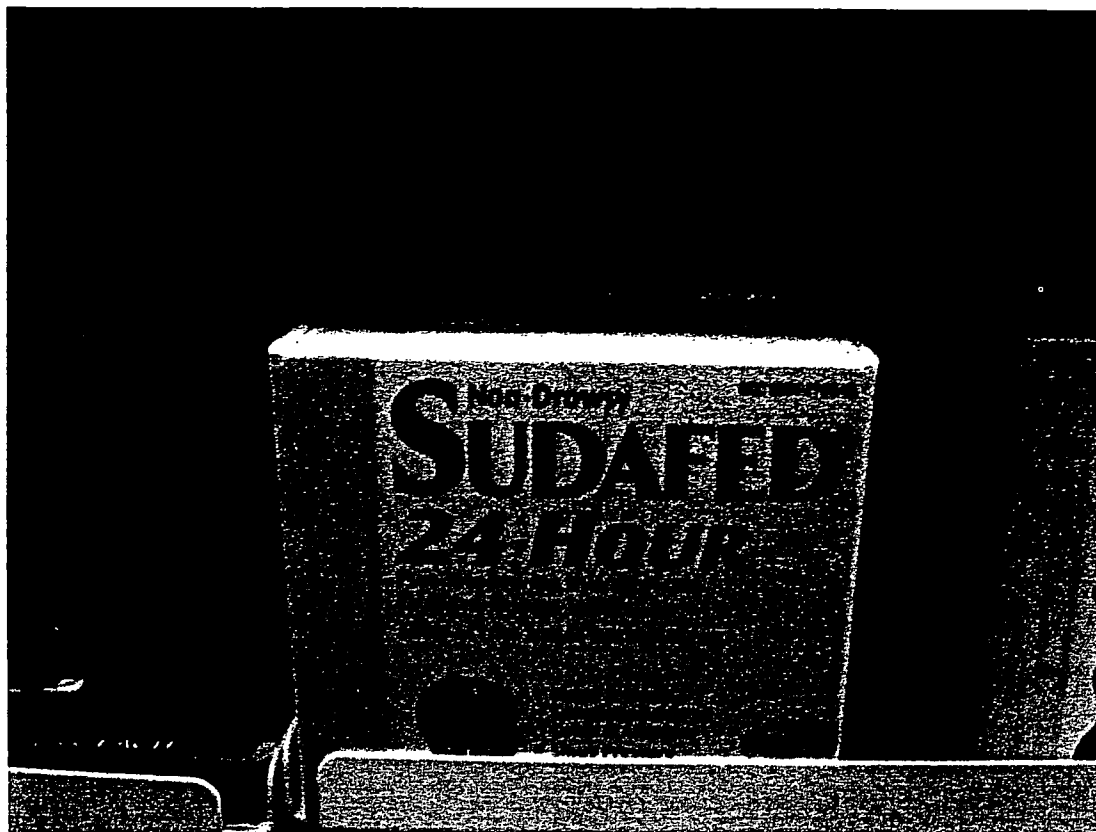


写真 6

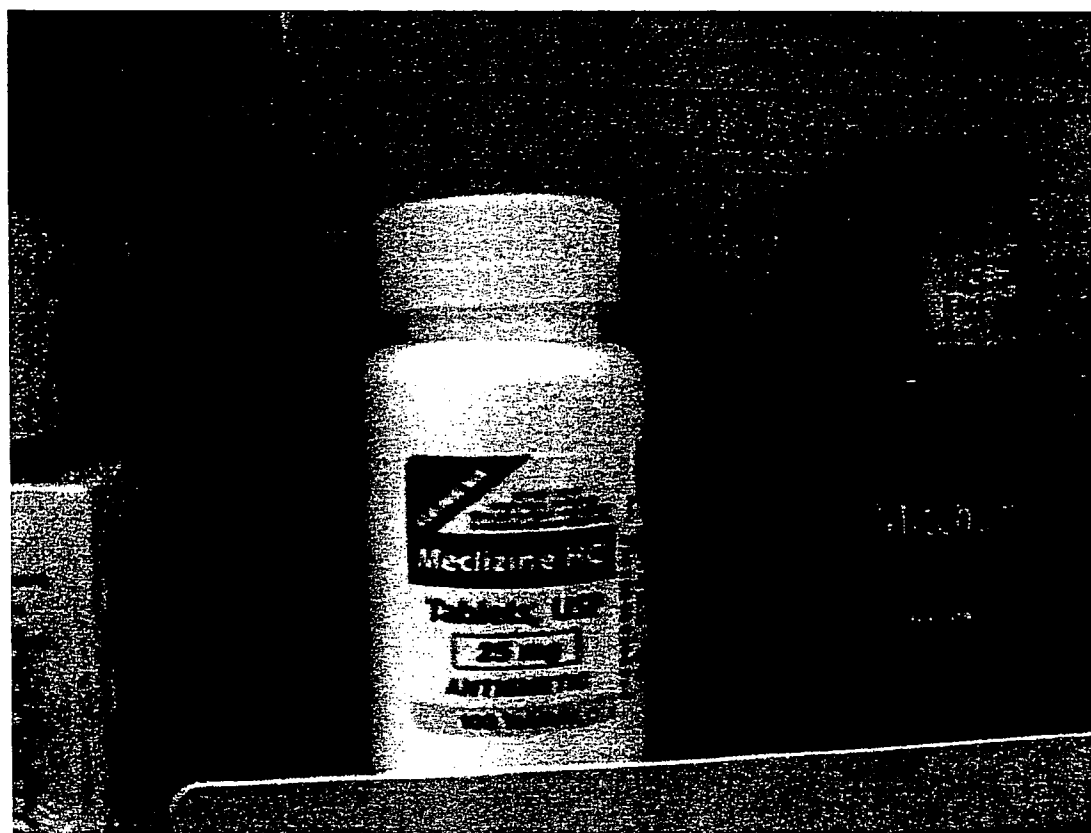


写真7



写真8



写真9



写真10



写真 1 1



写真 1 2



写真 1 3



写真 1 4

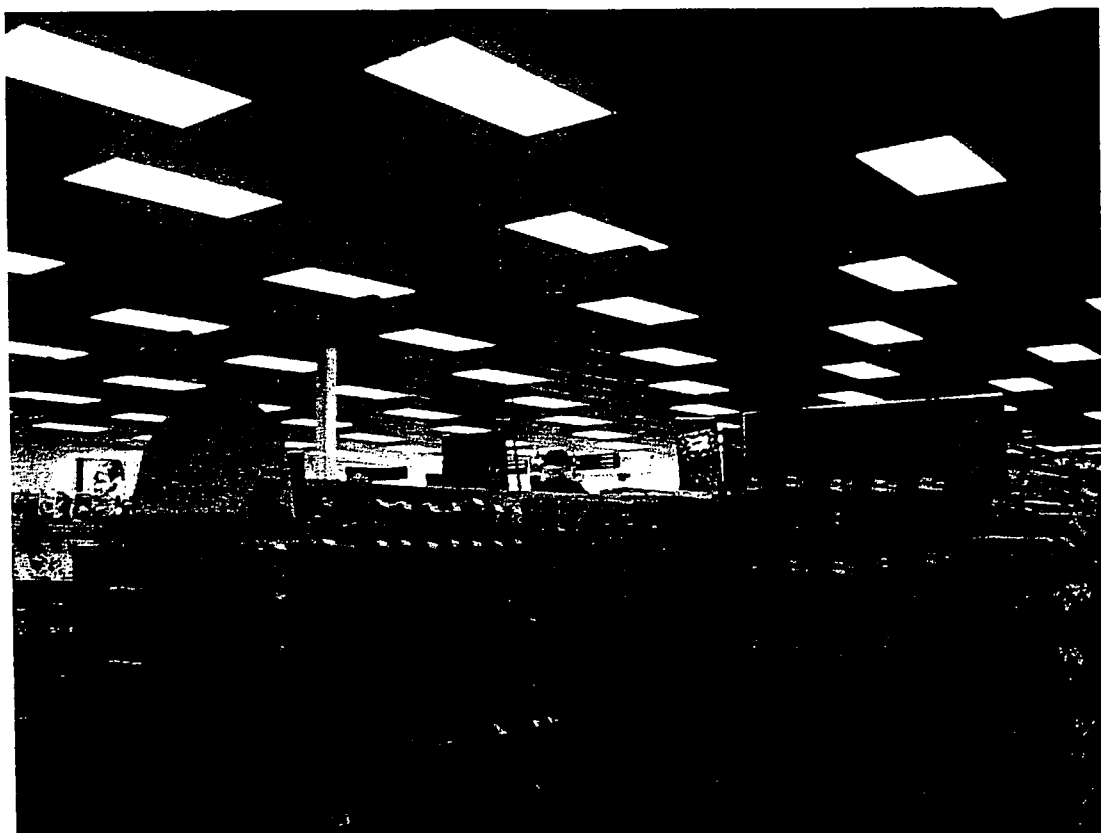


写真 15



写真 16 薬局の中からの写真

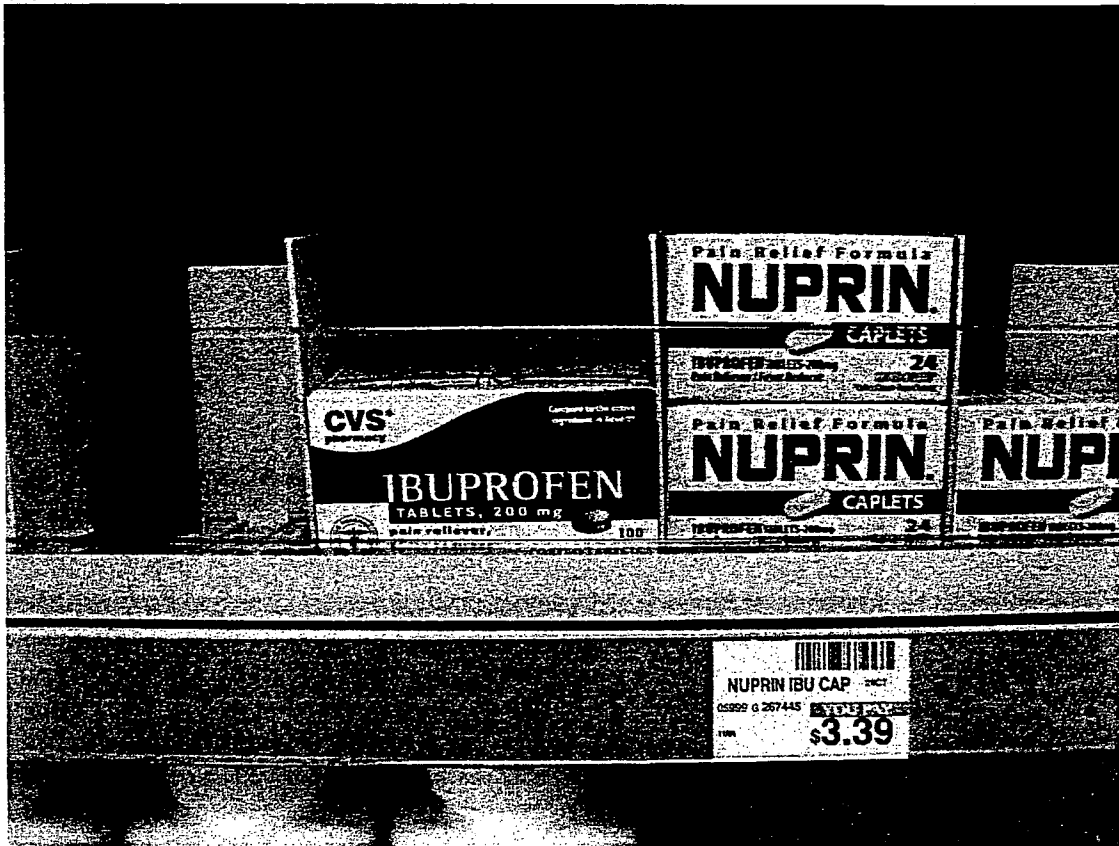


写真17



写真18





資料 1

HANDBOOK OF
NONPRESCRIPTION
DRUGS



An Interactive Approach to Self-Care
fourteenth edition

Contents

<i>Foreword</i>	<i>ix</i>
<i>Preface</i>	<i>xi</i>
<i>Contributors</i>	<i>xiii</i>
<i>How to Use the New Case Problem-solving Model</i>	<i>xxi</i>

SECTION I

The Pharmacist's Role in Self-Care

Editor: *Nicholas G. Popovich*

1 Self-Care and Nonprescription Pharmacotherapy	3
<i>Somnath Pal</i>	
2 Patient Assessment and Consultation	17
<i>Brian J. Isetts and Lawrence M. Brown</i>	
3 Multicultural Aspects of Self-Care	37
<i>Magaly Rodriguez de Bittner and Gloria J. Nichols-English</i>	
4 Legal and Regulatory Issues in Self-Care Pharmacy Practice	57
<i>Ilisa B.G. Bernstein and Edward D. Rickert</i>	

SECTION II

Pain and Fever Disorders

Editor: *Karen J. Tietze*

5 Headache and Muscle and Joint Pain	73
<i>Tami L. Remington</i>	
6 Fever	111
<i>Liza Takiya</i>	
7 Musculoskeletal Injuries and Disorders	131
<i>Eric Wright</i>	

SECTION III

Reproductive and Genital Disorders

Editor: *Leslie A. Shimp*

8 Vaginal and Vulvovaginal Disorders	159
<i>Leslie A. Shimp</i>	
9 Disorders Related to Menstruation	181
<i>Leslie A. Shimp</i>	
10 Prevention of Unintended Pregnancy	205
<i>Louise Parent-Stevens and Jennifer L. Hardman</i>	
11 Prevention of Sexually Transmitted Infections	225
<i>Charles D. Ponte</i>	

SECTION IV**Respiratory Disorders**Editor: *Karen J. Tietze*

- 12 Disorders Related to Cold and Allergy 239
Karen J. Tietze
- 13 Cough 271
Karen J. Tietze
- 14 Asthma 287
Dennis M. Williams and Timothy H. Self

SECTION V**Gastrointestinal Disorders**Editor: *Rosemary R. Berardi*

- 15 Heartburn and Dyspepsia 317
Robert P. Henderson and Valerie T. Prince
- 16 Intestinal Gas 349
Patrick D. Meek
- 17 Constipation 367
Clarence E. Curry Jr. and Demetris M. Butler
- 18 Diarrhea 405
Paul C. Walker
- 19 Anorectal Disorders 433
Juliana Chan and Rosemary R. Berardi
- 20 Pinworm Infection 457
Jeffrey A. Goad and Lawrence Neinstein
- 21 Nausea and Vomiting 469
Laura Shane-McWhorter and Jolie Fermo
- 22 Poisoning 493
Wendy Klein-Schwartz and Barbara Insley Crouch
- 23 Ostomy Care and Supplies 509
Joan Lerner Selekof and Sharon Wilson

SECTION VI**Nutrition and Nutritional Supplementation**Editor: *Carol J. Rollins*

- 24 Essential and Conditionally Essential Nutrients 539
Yvonne Huckleberry and Carol J. Rollins
- 25 Meal Replacement and Performance-enhancing Foods 577
Mark Neumham
- 26 Infant Nutrition and Special Nutritional Needs 597
Katherine H. Chessman
- 27 Overweight and Obesity 631
Sarah J. Miller and Cathy L. Bartels

SECTION VII

Ophthalmic, Otic, and Oral Disorders

Editor: *Michael A. Oszko*

28	Ophthalmic Disorders	659
	<i>Richard G. Fiscella and Michael Kirk Jensen</i>	
29	Prevention of Contact Lens-related Disorders	691
	<i>Janet P. Engle</i>	
30	Otic Disorders	723
	<i>Linda Krypel</i>	
31	Prevention of Hygiene-related Oral Disorders	739
	<i>Robert G. Smith</i>	
32	Oral Pain and Discomfort	769
	<i>Pamela J. Sims and Kevin M. Sims</i>	

SECTION VIII

Dermatologic Disorders

Editor: *Gail D. Newton*

33	Atopic Dermatitis and Dry Skin	811
	<i>Steven A. Scott and Robert W. Martin III</i>	
34	Scaly Dermatoses	831
	<i>Steven A. Scott and Robert W. Martin III</i>	
35	Contact Dermatitis	849
	<i>Kenneth R. Keefner</i>	
36	Diaper Dermatitis and Prickly Heat	873
	<i>Victor A. Padron</i>	
37	Insect Bites and Stings and Pediculosis	889
	<i>Wayne Buff</i>	
38	Acne	913
	<i>Joye Ann Billow</i>	
39	Prevention of Sun-induced Skin Disorders	929
	<i>Edward M. DeSimone II</i>	
40	Skin Hyperpigmentation and Photoaging	955
	<i>John S. Esterly, Lee E. West, and Dennis P. West</i>	
41	Minor Burns and Sunburn	969
	<i>John D. Bowman and Robert H. Moore III</i>	
42	Minor Wounds and Secondary Bacterial Skin Infections	987
	<i>Daphne B. Bernard</i>	
43	Fungal Skin Infections	1009
	<i>Gail D. Newton and Nicholas G. Popovich</i>	
44	Warts	1027
	<i>Gail D. Newton and Nicholas G. Popovich</i>	
45	Minor Foot Disorders	1037
	<i>Gail D. Newton and Nicholas G. Popovich</i>	
46	Hair Loss	1061
	<i>John S. Esterly, Lee E. West, and Dennis P. West</i>	

SECTION IX**Other Medical Disorders**Editor: *Nicholas G. Popovich*

- 47 Diabetes Mellitus 1075
Robert W. Bennett and Cynthia P. Koh-Knox
- 48 Insomnia..... 1117
M. Lynn Crismon and Patricia Ludi Canales
- 49 Drowsiness and Fatigue..... 1133
Robert J. Anderson and Diane Nykamp
- 50 Tobacco Use and Dependence 1149
Robin L. Corelli, Karen Suchanek Hudmon, and Lisa A. Kroon

SECTION X**Home Medical Equipment**Editor: *Leslie A. Shimp*

- 51 Home Testing and Monitoring Devices..... 1179
Wendy Munroe Rosenthal and Geneva Clark Briggs
- 52 Adult Urinary Incontinence Supplies 1213
Christine K. O'Neil

SECTION XI**Complementary and Alternative Medicine**Editor: *June McDermott*

- 53 Botanical Medicines 1231
Anne Lamont Hume and Kathryn Michele Strong
- 54 Nonbotanical Natural Medicines 1275
Cydney E. McQueen
- 55 Homeopathic Medicines..... 1305
June E. Riedlinger and Begabati Lennihan

Appendix IPregnancy and Lactation Risk Categories for Selected Nonprescription Medications
and Nutritional Supplements.....

1337

Appendix II

Botanical Medicines to Avoid in Pregnancy and Lactation

1343

Index..... 1347*Color Plates*..... *Follow page 778*

Foreword

Self-care is defined by the World Health Organization (WHO) as “those activities that individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health.” These activities can be initiated by individuals on their own behalf or recommended by health care professionals. (The pharmacist’s role in self-care is discussed at <http://www.who.int/medicines/library/dap/who-dap-98-13/who-dap-98-13.pdf>. Accessed December 15, 2003.) Self-care should be viewed as a continuum of self-initiated behaviors that enhance the health and independent functioning of individuals, rather than as a failure of the individual to use professional medical services. Self-care behaviors can be classified as (1) healthful lifestyle behaviors intended to promote health and prevent disease, (2) medical self-care behaviors that relate to symptoms and treatment, and (3) behaviors that relate to improving quality of life and daily living in individuals with disabling limitations associated with physical or cognitive function, or chronic disease. The use of nonprescription medications, complementary and alternative therapies, nondrug measures, diagnostic tests, and medical devices are integral parts of self-care.

Today, many individuals take an active role in their own health care. Numerous factors have contributed to the growing self-care movement in the United States, including an increase in direct-to-consumer advertising of prescription and nonprescription medications. Information obtained from television commercials, newspaper and magazine advertisements, the Internet, and health-related articles serves to empower the consumer to make decisions about their own health care. However, individuals embracing self-care may not have adequate information to determine if their medical condition is amenable to self-treatment and if the self-selected treatments are appropriate for the condition.

Individuals who wish to self-treat minor health disorders are faced with a staggering number of single-entity and combination nonprescription products. The Consumer Healthcare Products Association indicates that “retail sales of nonprescription medications in the United States in 2002 exceeded \$17.2 billion, reflecting an increase from \$2.9 billion in 1971. (See http://www.chpa-info.org/statistics/OTC_Retail_Sales.asp for further information. Accessed December 15, 2003.) Other similar surveys confirm the increased use of nonprescription medications. Sales may be boosted further by the Internal Revenue Service Revenue Ruling 2003-102, which went into effect October 1, 2003. This ruling allows employers to reimburse properly substantiated nonprescription

medication expenses, but not dietary supplements, from flexible health care spending accounts. (See <http://www.irs.gov/pub/irs-drop/r-03-102.pdf> for the full text of the ruling. Accessed December 15, 2003.)

The anticipated increase in the number of prescription medications that will be reclassified as nonprescription will further confound the patient’s dilemma in selecting appropriate self-treatment. All health care practitioners should be able to assist individuals in the management of their own self-care. However, pharmacists, because of their accessibility and expertise with respect to nonprescription and prescription medications, are in a unique position to fulfill the self-care needs of most individuals with minor health ailments.

Complementary medicines (e.g., botanical and non-botanical natural medicines) and alternative therapies (e.g., homeopathic remedies) are also experiencing exponential growth in the United States and reflect societal changes in attitude toward natural and preventive medicine. Patients use these therapies as (1) adjuncts to conventional prescription medications, (2) treatment for minor health conditions, and (3) preventive measures to foster good health. In the past, complementary and alternative medicines have been primarily distributed through health food stores and by mail order. However, these therapies are sold in mainstream mass-market outlets today, including grocery stores and pharmacies. Unlike nonprescription medications, however, no federal regulatory agency evaluates the safety and effectiveness of complementary and alternative therapies.

Homeopathic therapies, another alternative to traditional medicine, have been used for years in this country. In the past, most homeopathic products were distributed through health food stores and by mail order. Today, homeopathic therapies are regulated by the federal government, homeopathic manufacturers are subject to inspection—as are the conventional pharmaceutical companies—and there is an official homeopathic national formulary.

The increased use of complementary and alternative medicines—as well as the paucity of clinical evidence as to their safety and effectiveness, and the potential for serious adverse events when these products are combined with each other or with nonprescription and prescription medications—demand that health care practitioners be knowledgeable about alternatives to traditional medications and be able to provide therapeutic information and guidance to the consumer.

John A. Gans
Executive Vice President & CEO
American Pharmacists Association



Nonprescription Product Therapeutics

W . S T E V E N P R A Y

Factors That Shape the Nonprescription Product Market

OUTLINE

Regulation of Nonprescription Drugs and Devices *The Rx Legend*

The Durham-Humphrey Amendment of 1951
The Kefauver-Harris Amendments of 1962
Medical Device Regulation

The Nonprescription Product Review

Phases of the Review
Criticism of the Review
Products Not Reviewed
Benefits of the Review

Current FDA Nonprescription Product Overview

The Nonprescription Drug Advisory Committee (NDAC)
The FDA OTC Review Process

The Prescription-to-Nonprescription (Rx-To-OTC) Switch

Methods by Which Prescription Medications Gain OTC Status

Types of Rx-to-OTC Switches
Factors Considered in Rx-to-OTC Switch Decisions

Benefits to the Rx-to-OTC Switch Movement
Problems with the Rx-to-OTC Switch Movement

A Third Class of Drugs

The Pharmacist's Responsibilities with a Third Class of Drugs
The Various Proposals for a Third Class of Drugs
Supporters of a Third Class of Drugs
Opponents of a Third Class of Drugs

Summary References

The nonprescription product market is dynamic and ever-changing, with many older nonprescription drugs discontinued and many new OTC products introduced each year. Some of the new nonprescription products hold special challenges for pharmacists, because they were formerly limited to prescription status. To better understand the forces that shape this volatile market, this chapter examines the regulation of nonprescription drugs, the FDA's OTC review, the Rx-to-OTC switch phenomenon, and the national call for a third class of drugs.

REGULATION OF NONPRESCRIPTION DRUGS AND DEVICES

The Rx Legend

Prior to passage of the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938, the line between prescription and nonprescription products was nonexistent (although the Harrison Narcotic Act of 1914 had made narcotics prescription-only).¹ This legislation required that manufacturers submit a new drug application providing proof of safety prior to marketing medications.^{2,3} It also required that adequate directions and warnings be provided on all drug labels, unless the label specifically carried a new prescription legend, "CAUTION: Federal Law Prohibits Dispensing Without Prescription."

There was no actual requirement that any medication carry the legend. As a result manufacturers opted to attempt to provide directions and warnings to allow self-use and were slow to adopt the legend. Thus many dangerous medications were labeled as though safe for self-use, and the distinctions between prescription and nonprescription products remained unclear during the ensuing 2 decades.

The Durham-Humphrey Amendment of 1951

In 1951 the Durham-Humphrey Amendment to the FD&C Act of 1938 attempted to further define nonprescription and prescription medications and to clarify the requirement for the Rx legend.^{1,3} Products without the prescription-drug legend became known as "nonlegend" or nonprescription medications, a new class of medications now popularly known as "over-the-counter drugs" or OTCs.

The Kefauver-Harris Amendments of 1962

In 1962 the Kefauver-Harris Amendments to the FD&C Act mandated proof of effectiveness for prescription medications marketed after 1938.² (Medications marketed prior to 1938 are known as "grandfathered" drugs because, at that time, they were assigned GRASE [generally recognized as safe and effective] status.)

Medical Device Regulation

In 1976 the Medical Device Amendments to the FD&C Act clarified the marketing requirements of medical devices. Ac-

ording to this amendment manufacturers must notify the FDA at least 90 days before marketing a medical device for the first time.² If the application is simple, it is usually approved within the 90 days, although more complicated applications may require more time, causing the manufacturer to wait a longer period before marketing the device.⁴

THE NONPRESCRIPTION PRODUCT REVIEW

The Kefauver-Harris Amendments gave the FDA authority to review nonprescription drugs marketed after 1938 for proof of safety and efficacy. The FDA carefully considered the most appropriate method to use in this review. In 1972 the Food and Drug Administration began the review.^{5,6} Because there were an estimated 300,000 nonprescription products to review, the agency quickly realized that the product-by-product method used for prescription products would not be feasible with OTCs. The FDA decided to facilitate the review by placing OTCs into therapeutic classes (e.g., antidiarrheals, antacids, otic products).⁷ The subsequent OTC drug review, certainly one of the most comprehensive programs undertaken by FDA, proceeded in three phases⁸:

- Phase 1—Review panels evaluate products. "Advance Notice of Proposed Rulemaking" published for each therapeutic class.
- Phase 2—Deliberations for Category II and III ingredients. "Proposed Rule" or "Tentative Final Monograph" published for each therapeutic class.
- Phase 3—Deliberations continue for Category II and III ingredients. "Final Rule" or "Final Monograph" published for each therapeutic class.

Phases of the Review

PHASE 1

In Phase 1 of the review the FDA appointed an advisory review panel for each therapeutic class.^{9,10} The advisory review panels were asked to amass data regarding the safety and efficacy of the ingredients included in products sold for that condition. Panels were made up of representatives from medical and scientific fields as voting members such as physicians, pharmacologists, toxicologists, and pharmacists and other professionals appropriate for that group of products (e.g., dentists or podiatrists).¹¹ Consumer and industry representatives could be included on panels but only as nonvoting members.³ FDA employees too could be included on the panels but also not as voting members.

The review panels asked manufacturers to submit products for which review was desired. The advisory panel listed the various ingredients in products sold for that condition and then exhaustively searched for evidence of safety and efficacy. During the reviews the advisory panels examined 20,000 volumes of data concerning 1454 uses of 722 individual ingredients and held 508 meetings.^{7,11}

The reviews concluded with the publication of a report, a

Handwritten notes:
 Phase 1
 Phase 2
 Phase 3
 Monographs