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Book Reviews

Pharmacokinetic Optimization in Drug Research: Biologic, Physicochemical and Computational Strategies. Bernard Testa, Han van de Waterbeemd, Gerd Folkers, Richard Guy, Eds. Verlag Helvetica Chimica Acta, Postfach, CH-8042 Zürich, Switzerland, 2001, xiv, 655 pp., illustrations, CD-ROM, $140.00.

This is a timely publication that is based on an excellent meeting that took place in March 2000. The book is not based entirely on the meeting but has been supplemented by contributions from a number of experts in the field, as outlined by Bernard Testa in the preface. Lead optimization is taking on an increasingly important role in the pharmaceutical industry, with so many new possible leads being identified at the present time. Pharmacokinetic optimization is a rapidly developing subject, and one of the many impressive features of this volume is that 13 of its chapters are produced by industrial contributors who are actively involved in this type of work, including GSK, Pfizer, Novartis, Merck, Hoffmann-La Roche, and Abbott.

The book takes the form of a brief introduction to pharmacokinetic optimization followed by four specific sections: the molecular and biologic background; biologic strategies; physicochemic strategies, and computational strategies. Each section has its own specific merits.

The section "Molecular and Biologic Backgrouns" contains four well-balanced introductory chapters, including a brief update on the current views of membrane structure—which has moved on over the last decade. This chapter, written by Ole Mouritsen and his colleagues, is an important summary and reference is made to another publication "In Search of a New Biomembrane Model," which is not widely circulated but is published by the Royal Danish Academy of Sciences. Gastrointestinal and brain penetration is described by Han van de Waterbeemd and Denis Smith, a brief chapter that is reasonably well referenced. In view of the overall aims of the book, it is a pity that more space was not devoted to the interpretation of the Lipinsky "rule of five," which is only briefly mentioned in this chapter. The prediction of metabolism was covered by Bernard Testa and Gabriele Cruciani and is presented in a rather futuristic manner. There is clearly a long way to go before reliable methods are likely to emerge. An overview of prodrug design also provides a well-referenced introduction to what can be achieved with specifically tailored molecules.

The section "Biological Strategies" consists of nine chapters describing various techniques used to obtain permeability, metabolism, and toxicology parameters—the acquisition of which is essential for reliable structural activity studies, which in turn will lead to useful *in silico* predictive methods. Methods are also described and reviewed for monitoring the permeability of the gastrointestinal tract, blood–brain barrier, skin, and the lung. Problems associated with plasma protein binding are addressed, and ideas relating to high throughput ADE screening are presented. Each of the chapters is very well written and well referenced, presenting the reader with a unique accumulation of "up-to-date" data.

Consisting of 10 chapters, "Physicochemical Strategies" is the largest section of the publication. Again, each one is written by an expert currently working in the field. For me, this was the strongest part of the publication, and the chapters by Faller, Comer, Avdeet, and Reymond were each outstanding, describing as they do, rapid methods for estimating solubility, ionisation, and permeability. Modern methods based on drug partitioning into stationary phases and liposomes are described in three additional chapters. This section contains a unique collection of review articles and consequently is invaluable to both industrial and academic pharmaceutical scientists.

Several new methodologies are described in the section "Computational Strategies," including a comparison of logP calculation programs, prediction of oral absorption, analysis of the influence of hydrogen-bonding on membrane permeability, and homology models for cytochrome P450. Inevitably, it is early days with many of these models, but the programs are improving, and this book provides an excellent insight into the current state of play of *in silico* analysis, an approach of increasing importance.

In summary, this is an outstanding publication. It has been extremely well-produced and contains remarkably few typographical errors. It also contains a CD of the entire proceedings of the meeting entitled "Lipophilicity in Drug Disposition," which was held in Lausanne in March 2000. There are some excellent posters included on this CD. Overall, the book is extremely well-referenced; in fact, it is a goldmine of information. At the time of writing this review, the first edition has already sold out, but a reprinted edition is on the way. This book is a key reference book for any scientist interested in drug design.

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Antisense Drug Technology. Principles, Strategies, and Applications. Stanley T. Crooke, Ed., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016, http://www.dekker.com, 2001, xiii, 929 pp., illustrations, $225.00.

One of the most comprehensive books in the field of antisense technology, this multi-authored book is a timely publication in this rapidly growing field of intensive research. The book covers the basic principles of antisense action, its chemistry, drug design, and therapeutic applications. The use of antisense agents as research tools to elucidate the

functions of specific gene products and as therapeutic agents has been the subject of intense research interest. Initially, their mode of action was poorly understood, and the biologic effects of antisense agents were often misinterpreted. However, research into these gene-based inhibitors of cellular action recently has succeeded in realizing their exciting potential, particularly as novel therapeutic agents. This book is an excellent reference for scientists and advanced students who are interested in the design and applications of antisense agents. The editor has done an excellent job of persuading experts in the field to contribute to a wide range of topics.

The book is organized into three sections: The first section, consisting of five chapters, provides an excellent overview of the technology. Chapter 1 introduces the reader to the history, principles of antisense drug development, and mechanisms of action. Particularly, the recommendations on the different controls to be included in experimental design are very useful. Chapters 2 and 3 are devoted to the medicinal chemistry of antisense agents and the current analytical methods. Chapter 4 and 5 describe potential applications of antisense agents. Chapter 5 is particularly useful for individuals interested in learning how to design the most appropriate oligonucleotide sequences for efficient antisense action. The second section focuses on the pharmacokinetic, pharmacologic, and toxicologic properties of antisense oligonucleotides. This section, along with the abundant references, is an excellent, up-to-date overview of data/studies in animals as well as humans. The last section is broader in scope and covers useful discussion on various novel classes of oligonucleotides such as peptide nucleic acids, locked nucleic acids, and oligonucleotide conjugates. Also included in this section are a number of chapters on the application of antisense agents in various disease conditions such as viral and inflammatory diseases. Of particular interest in this section is the chapter on novel delivery routes and formulations of oligonucleotides. Clearly, the intracellular delivery and uptake of oligonucleotides remains a key problem for antisense therapeutics. Although the authors have touched upon this problem, it would have been highly beneficial to have additional chapters focused on intracellular trafficking of oligonucleotides and the various delivery approaches that have been used to overcome this problem. In the last three chapters, the authors describe other related strategies such as ribozymes, triplex forming oligonucleotides, and DNA-binding molecules.

There is an extensive bibliography of references at the end of each chapter, and the chapters along with their references are a tremendous resource. Overall, this book provides a comprehensive review of the various aspects of antisense technology and is highly recommended as a reference book for pharmaceutical scientists and, in particular, for those who work in the field.

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Gene Therapy Protocols, 2nd Edn. Jeffrey R. Morgan, Ed., Humana Press Inc., 999 Riverview Drive, Suite 208, Totowa, NJ 07512, www.humanapress.com, 2002, xv, 520 pp., illustrations, $125.00.

The book covers both viral and non-viral gene therapy. The more frequently used non-viral and viral gene delivery systems are represented, such as: naked DNA administered by electroporation or a gene gun; targeted polylysine/DNA complexes; cationic lipid/DNA complexes; retroviral gene transfer; lentiviral gene transfer; adenoviral gene transfer; adeno-associated viral gene transfer; and Herpes virus gene transfer. There are at least two chapters devoted to each of the above technologies describing modifications to improve performance, manufacture or decrease toxicity.

Protocols for new gene delivery systems and control of gene expression include genetically modified skin substitutes; viral liposomes for DNA delivery; solvoplex synthetic vectors for intrapulmonary delivery; Simian Foamy Virus vectors; characterization of chimeric RNA-DNA oligonucleotides; and regulated expression of plasmid based gene therapies using the gene switch.

Overall, the format for each chapter is a brief introduction, a description of the technology, key results regarding performance of the technology and, finally, detailed protocols describing how the technology was assembled and tested. There are notes in selected chapters describing key points to pay attention to. All the chapters are well written, and the protocols are easy to understand. This book is applicable to those directly involved in the field of gene therapy. Those researchers not directly in the field of gene therapy will require basic molecular biology skills, including isolation of plasmid from bacteria cultures. For viral gene delivery, it is assumed that the researcher has the plasmids needed to transfect the packaging cell line to make the virus.

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Polymers from the Inside Out. An Introduction to Macromolecules. Alan E. Tonelli and Mohan Srinivasarao, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012, http://www.wiley.com, 2001, xxv, 249 pp., illustrations, $78.50.

This book covers most of the topics that can be found in typical polymer books, such as polymer synthesis, polymer structure, and polymer properties. The book is a relatively short one as compared to other polymer textbooks, and it is not surprising to notice that some topics were not covered. For example, only emulsion polymerization method was discussed without related methods, such as suspension, bulk, and solution polymerization.

Chapters on microstructure and conformation of polymers presented useful examples, such as the NMR spectroscopic method for determining polymer microstructure, and theoretical and experimental analysis of polymer conformations as well as polymer dimension. The book contains two chapters covering solution and bulk properties of polymers. Solution properties include intrinsic viscosity, solubility, and liquid crystalline state, whereas bulk polymer states dealt with polymer liquid, polymer glass, polymer elastomer, crystalline polymers, and polymer fibers. Both thermal transition properties and mechanical properties (e.g., impact strength and moduli of bulk polymers) were defined, and their characteristic behavior was explained. In dealing with the polymer solubility in Chapter 6, it could have been better if the solubility parameter and polymer–solvent interaction parameter, two of the most important solution properties, were presented with introduction of the Flory–Huggins theory.

One of the distinguishable features of this book is inclusion of a chapter on biopolymers, which are not usually handled in the traditional polymer textbooks. A series of naturally occurring biopolymers were very informative for understanding the scientific nature and applications of biopolymers. Each section of the biopolymer chapter was well differentiated by the type of polymer materials, and the structure and properties of each polymer were well summarized. However, the resolution of the figures was extremely low and the poor quality of the figures was very distracting.

The questions at the end of each chapter were so well organized that solving those questions provides a good opportunity to review the materials covered in each chapter. Although the structure of the book generally was well designed, descriptions on many topics were too simple and compact, as the author tried to include many subjects in a small volume. The qualitative analysis of experimental and phenomenological behavior of polymeric materials in the text is not so difficult to understand, but the quantitative analysis seems relatively more difficult because of its spatial and logical compactness, especially for the readers confronting the polymer chemistry for the first time. For this reason, this book is not to be used as an introductory book on polymers.

Overall, this book was successful in summarizing a variety of fundamental features of polymeric materials in a small volume. This book may be used as a polymer textbook for the senior-level undergraduate students or junior-level graduate students.

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Enzyme Technologies for Pharmaceutical and Biotechnological Applications. Herbert A. Kirst, Wu-Kuang Yeh, and Milton J. Zmijewski, Jr., Eds., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016-0602, http://www.dekker.com, 2001, xv, 611 pp., illustrations, $195.00.

Recent advance in enzymology is combined with genomic science. We can design a molecular structure of a specific enzyme and obtain it very easily by gene control of microorganisms. With this book, readers can gain important insights into enzyme technologies in both pharmaceutical and biotechnological industries. The 24 topics of this book highlight how, what, and where enzymes have become critically important or are rapidly emerging in these two overlapping and interdependent industries.

On enzyme technologies, the book covers four basic principles and applications in (I) biosynthesis of antibiotics, (II) biocatalysis, (III) modern screening/optimization, and (IV) emerging new enzymatic technologies. In Part I on biosynthesis, the emphasis is placed on improvements in antibiotic yield and ways to increase antibiotic structural diversity by modifications of the biosynthetic pathways from diverse microorganisms. Here, the emphasis is on using genes to deliver enzymes and to thereby perform metabolic engineering including precursor-directed biosynthesis or mutasynthesis. The use of recombinant techniques to generate protein products that are unnatural to the microbial world is also discussed, using specific examples of challenging problems in this area. Part II in biocatalysis covers the direct application of enzymes as chemical tools in manipulating small- to medium-sized synthetic organic compounds. Manipulation of the enzyme tools by genetic engineering is described. Part III is concerned on screening and optimization of enzyme inhibitors. The goal of integrated approaches in therapeutic research using enzyme is to treat human and animal diseases. For screening, the activity assays for the enzyme targets adopt both conventional (colorimetry, spectrometry, and radioactivity) and contemporary methodologies (fluorescence). A selective enzymatic assay maximizes validated hits from large diversified libraries of samples derived from natural products and synthetic compounds, including those arising from combinatorial chemistry. These topics on screening concentrate on development of effective enzymatic assays, each of which represents specific, kinetic, and molecular interactions between the enzyme and its substrate as well as inhibitors and thus reflects the pharmacological and chemical interplay at the targeted enzyme. Part IV in emerging technologies examines some non-traditional methods by which enzymes may play important new roles in the drug discovery processes of the future. The present ability to completely locate and sequence the gene clusters responsible for the multistep biosyntheses of complex natural products has spawned new technologies. Such technologies can precisely and/or deliberately modify certain parts of gene clusters within organisms or, alternatively, can interchange portions of gene clusters between organisms. Unnatural natural products may be formed by fermentation of the new genetically modified microorganisms. The exchange of genetic material can be logically extended into a combinatorial paradigm called combinatorial biosynthesis or combinatorial enzymology, thereby leading to even larger numbers of new natural products. The last topic of Part IV summarizes essential and overlapping enzyme technologies. With the completion of most of the human genome sequence, assigning a precise function to genes and redesigning the function of enzymes can play increasingly significant roles in drug discovery. Also, the utility of functional genomics in identifying disease-relevant enzyme targets depends closely on the molecular understanding of these targets under physiological and pathologic conditions

The contents of this book are informative, practical, timely, and applicable worldwide to the pharmaceutical and biotechnological industries. The reader will acquire a better understanding on applied sciences in the field. Areas that have been extensively covered in reviews and the general literature have been minimized here. The book is intended primarily for industrial and research scientists with interests in adopting and maximizing enzyme technologies for pharmaceutical discovery, development, and manufacturing.

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Nano-Surface Chemistry. Morton Rosoff, Ed., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016-0602, http://www.dekker.com, 2001, xi, 678 pp., illustrations, $195.00.

Nanoscale technology of industrial surfaces and colloids, including nanoscale measurements and molecular architecture, has received a great deal of attention in recent years. Because the conventional rules or principles in macroscopic scales may not be applicable to the nanoscale surfaces, interfaces, or confinement, the surface phenomena become more important in the nanoscale processes. Availability of a wide spectrum of new building blocks and the ability of nanoscale positioning have broadened opportunities for nanofabrication to form supramolecular devices. In these contexts, the book raised many important issues on the concepts and principles of nanoworld while describing a number of progresses made to date.

Precise control of positioning and imaging in nanoscale has enabled *in situ* processing of single molecular architectures, while Langmuir-blodgett films and self-assemblies or supramolecules have made it possible to engineer new molecular architectures and functions, all of which can be potentially applied to molecular electronic devices. Recurrent topics in the nanocolloid science have bridged the gap between naoscale occurrences and macroscopic phenomena. The solid nanomeric deformation was used to explain the kinetics of wetting, dewetting, and capillary flow, since the surface effect prevails in those phenomena. The simultaneous mapping of surface topography and surface potential allowed determination of the interaction between molecules at environmental conditions. The bio- or bio-inspired systems provide another platform for nanotechnology. Examples are biomolecular systems of glycoproteins that spontaneously aggregate to form crystalline arrays, and DNA nanoensembles condensed by polyelectrolytes of opposite charges for gene transfer through the cell membranes. The area of the self-assembled nanomachines is still in its infant stage, too early for demonstration of any devices. The book describes nanostructures that are important in various applications, such as hollow nanocapsules containing colloidal particles and nanohost of drugs using reversed micelles. The book also describes electrophoretic transport of electrolytes confined in nanostructures that is important in a number of biochemical applications.

This book provides excellent reviews on various topics in the nanoworld, such as nanoscale surface chemistry, self-assembly, bio-inspired systems, and industrial nanostrutures. The book could have been even better if it included other important topics. Discussion on the transformation of nanoscale manipulators to bulk properties as well as biomedical and pharmaceutical applications, for example, would have been useful additions to the book.

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Goodman & Gilman's The Pharmacological Basis of Therapeutics. Joel G. Hardman, Lee E. Limbird, and Alfred G., Eds., McGraw-Hill Medical Publishing Division, Two Penn Plaza, 12th Floor, New York, NY 10121-2298, http://www.mghmedical.com, 2001, xviii, 2148 pp., illustrations, $125.00.

"Three objectives have guided the writing of this book—the correlation of pharmacology with related medical sciences, the reinterpretation of the actions and uses of drugs from the viewpoint of important advances in medicine, and the placing of emphasis on the applications of pharmacodynamics to therapeutics," and so the preface to the first edition of *Goodman & Gilman's The Pharmacological Basis of Therapeutics* sets forth the standard for what has become "The Bible" to all serious students of pharmacology. Now sixty years later, Hardman and Limbird have completed the 10th edition of *Goodman & Gilman's* continuing the fine tradition started by Louis Goodman and Alfred Gilman and holding true to the objectives set for by the original editors. The previous edition (the 9th) was the first edition not to have major editorial input from a member of the Goodman or Gilman family and represented the initial offering by the new editorial team of Hardman and Limbird. In many ways, the 10th edition represents only subtle revisions and updates to its immediate predecessor. However, the rapidly changing face of medicine and the latest advances in pharmacotherapeutics had many readers clamoring for a revised version of this authoritative text.

Features that were retained in the present edition include the helpful two-color graphics that were first introduced in the 9th edition. These illustrations convey clear messages and can become the basis for teaching many general principles associated with drug action. The organization of each chapter provides a helpful synopsis and sections covering historical perspectives, basic discoveries, clinical applications of drug use, as well as the very latest information on investigational drugs. New chapters are devoted to the topics of ethanol (chapter 18), prokinetic agents (chapter 38), and antiretroviral agents (chapter 51). Existing chapters have been revised to include the latest advances in drug development including antimigraine agents (chapter 11), anesthesia (chapters 13–16), and COX-2 inhibitors (chapter 27). Whereas many longtime contributing authors to *Goodman & Gilman's*

are absent from this edition, their replacements plus the returning authors still comprise probably the most impressive list of authors of any biomedical textbook. The editors point out the significant tension that is brought about in compiling a text that seeks to balance the completeness of "our intellectual heritage" with "applicability" into a resource that is useful to the variety of potential readers who will turn to this book for information. While the level of detail in this book may be overwhelming to many and may preclude its use as a primary textbook in many pharmacology classes, *Goodman & Gilman's* 10th edition will be a useful reference for the serious student looking for additional information on the various drug classes.

In the preface to this 10th edition, the editors note the death of Louis Gilman in November 2000, and therefore have dedicated this edition to both Louis Goodman and Alfred Gilman for their pioneering spirit that in many ways defined the field of pharmacology. On the occasion of the 10th edition, one ponders how *Goodman & Gilman's* will change over the next 50 to 100 years. Regardless of the format and content, it is clear that this gold standard of pharmacology will be included in the library of all serious students of biomedical research and practice including physicians, pharmacists, and pharmaceutical scientists.

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Drug Delivery to the Lung. Lung Biology in Health and Disease Series, Volume 162. Hans Bisgaard, Chris O'Callaghan, and Gerald C. Smaldone, Eds., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016-0602, http://www.dekker.com, 2002, xvi, 511 pp., illustrations, $175.00.

Successful drug therapy using aerosolized medications relies upon the delivery of sufficient drug to the target sites in the lung, according to the age and disease state of the patient. Despite improved understanding and recent technological advances in aerosol delivery devices, one of the major obstacles faced by clinicians remains the selection of an appropriate delivery system for each individual patient. This book provides a comprehensive review of inhalation drug delivery, including the underlying structure and function of the respiratory system, together with critical patient-inhaler interactions.

The book, edited by renowned experts in the field of aerosol medicine, encompasses the general principles of inhalation drug delivery, together with the latest innovations in this rapidly expanding field, while emphasizing clinical relevance. This comprehensive volume is a welcome and timely addition to the *Lung Biology in Health and Disease* series, and is an excellent reference source for physicians and other healthcare providers involved in aerosol medicine. In addition, this volume will be of general interest to the pharmaceutical scientist, as it provides a 'real world' perspective on the factors, which really influence clinical outcomes in inhalation therapy.

Drug Delivery to the Lung begins with a historical perspective of inhaled drug therapy, followed by a review of the basic principles of particle behavior in the human respiratory tract. In accordance with the book's purpose to bridge basic aerosol science and clinical practice, the practical differences between the behavior of "ideal" and "real" particles are addressed. Effective drug therapy is related to the dose and deposition pattern of drug delivered to the airways, which in turn is dependent upon both patient and delivery device/formulation characteristics. Airway geometry is strictly a patient characteristic and this text includes an excellent review of the current understanding relating to the structure and function of the respiratory system, and how these change with age and disease. Such developmental aspects in the respiratory system influence the effective delivery and deposition of aerosolized medications, and their relevance to aerosol therapy is discussed. Subsequent chapters discuss the latest advances in *in-vitro* and *in-vivo* aerosol characterization methods, together with the latest strategies employed to improve total and regional lung delivery to adults and children in health and disease. Drug Delivery to the Lung also presents a unique and interesting perspective addressing the important factors which influence the clinical outcome of aerosol therapy. Notably, it would appear that patient preference and compliance are perhaps the most significant factors associated with the efficacy of inhalation therapy. While this text cannot provide a universal solution to these issues, it highlights the significant issues that clinicians must understand, and follow, if they are to make intelligent device choices for their patients.

A description of the major aerosol delivery systems is necessary in any book focusing upon inhaled drug delivery, and this volume is no exception. Nebulizers, metered dose inhalers, spacers and dry powder inhalers are discussed, together with the latest developments in novel delivery systems. A timely review of the transition from chlorofluorocarbon to hydrofluoroalkane propellants is included and addresses the current status of the transition and what can be expected in the future. Finally, the book concludes with a chapter solely devoted to compliance issues associated with asthma medicine, signifying the practical importance of compliance in effective aerosol therapy.

Drug Delivery to the Lung is a well-written text providing an alternative and important perspective in inhalation therapy. The editors should be commended for their insightful creation of this pioneering publication, which provides a foundation in basic aerosol science, but more importantly relates these basic principles to good clinical practice. While the majority of readers will be 'clinicians, nurses and respiratory therapists interested in the role of aerosol delivery for optimal management of lung disease', this text is a valuable resource for all of those involved in aerosol drug delivery.

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Pharmaceutics

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Handbook of Clinical Drug Data, 10th Ed., Philip O. Anderson, James E. Knoben, and William G. Troutman, Eds., McGraw-Hill Medical Publishing Division, Two Penn Plaza, 12th Fl., New York, NY 10121-2298, http://www.pbg.mcgraw-hill.com, xvii, 1,148 pp, $44.95.

Materials and Surface Science

Polymers in Medicine. Macromolecular Symposia 172, Jaroslav Kahovec, Ed., Wiley-VCH Verlag GmbH, P.O. Box 101161, D-69451 Weinheim, Germany, http://www.wiley-vch.de/home/macrosymp, 2001, x, 165 pp., illustrations, 71 Euro.

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Conjugated Polymer and Molecular Interface. Science and Technology for Photonic and Optoelectronic Applications, William R. Salaneck, Kazuhiko Seki, Antoine Kahn, Jean-Jacques Pireaux, Eds., Marcel Dekker, Inc., 270 Madison Avenue, New York, NY 10016, http://www.dekker.com, 2002, xvi, 866 pp., illustrations, $225.00.

The Physics and Chemistry of Materials, Joel I. Gersten and Frederick W. Smith, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012, http://www.wiley.com, 2001, xxix, 826 pp., illustrations, $110.00.

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