path model. This model places older adults in four categories: Robust (life expectancy of greater than five years and functionally independent); Frail (life expectancy of less than five years and significant functional impairment); Moderately Demented (life expectancy from two to ten years with or without functional impairment); and End of Life (life expectancy less than two years). Preventive interventions are graded in four levels, from strongly recommended to not recommended, based on evidence in the literature. The clinical glidepath is illustrated nicely in tabular form (Table 1, p 203). However, there is a misprint: the heading of the last column should be “End of Life” rather than “Robust Elderly.”

This part of the book also includes a chapter on rehabilitation and individual chapters on cardiac, pulmonary, and stroke rehabilitation. These chapters thoroughly review principles and strategies of rehabilitation. The section on dementia and cognitive disorders covers a wide array of topics, including communication disorders, delirium, cellular changes and clinical aspects of Alzheimer disease, mild cognitive impairment, vascular dementia, treatment of behavioral disorders, depression in late life, older patients with Down syndrome, and drug misuse in older persons. Also included are well-written chapters on management of chronic pain, back pain, multidimensional geriatric assessment, restraints, frailty, women’s health, and centenarians.

Part 4, “Health Care Systems,” has expanded chapters on geriatric medical education and practice in different parts of the world, including nursing home care, improving quality of care, resident assessment instruments and data sets, and geriatric day hospitals. Individual chapters describe the health care systems and practice of geriatric medicine in the United States, United Kingdom, European Union, Australia, Israel, China, India, Japan, and Latin America. This section of the book gives an excellent perspective on how geriatric medicine is being practiced in different parts of the world.

In a book of this size and scope, the key points provided at the end of each chapter are a useful service to the reader. Most chapters have relevant figures and tables. Typical of large, multi-author texts, there is some redundancy, but it is not a significant weakness. Chapter bibliographies, which begin with key references, are extensive and up-to-date.

Principles and Practice of Geriatric Medicine is an excellent reference for learners at all clinical and preclinical levels and a useful contribution to the geriatric medicine literature.

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Disclosure: From July 1998 through June 1999 Dr Nanda was a fellow in geriatrics at Saint Louis University, where Dr Morley was (and is) director of the Division of Geriatrics.

Financial Disclosure: Dr Nanda has reported that he is on a speaker panel with Forest Pharmaceuticals.

Drugs, Developing World


INVESTIGATIVE JOURNALIST SONIA SHAH has written a lucid, well-researched work on professional and governmental corruption and mismanagement associated with clinical trials conducted by the pharmaceutical industry in the developing world. It deserves the attention of leaders of the medical profession and policy analysts concerned about the human consequences of US health care costs rapidly approaching the point of unsustainability (25% of total gross domestic product).

The Body Hunters opens dramatically, with a group of physicians and scientists meeting in 2003 at a pharmaceutical industry–sponsored symposium, on a dull October day in a windowless, basement conference room in Washington, DC. The attendees’ published presentations explore the commercial possibilities of conducting clinical trials among the world’s impoverished ill. One common theme is that the destitute ill should welcome this access to expensive innovative medicines. Another theme asserts that phase 3 clinical trials for safety, quality, and efficacy have become a “vast canyon” draining drug company profits. Shah valuably highlights the adverse consequences when such an ideology drives changes in the governance of globally important drug safety organizations, such as the US Food and Drug Administration (FDA).

Shah takes the reader through the problems associated with placebo-controlled trials, essentially conceived as “why risk trying to show you’re better than something, when all you need to show is that you’re better than nothing?” She emphasizes that the FDA’s continued acceptance of placebo-controlled trials for safety, quality, and efficacy purposes in lieu of comparisons with extant drugs is dangerous for patients. It also inhibits the development of clinical trials that facilitate objective proof of innovation in pharmaceuticals through “fourth hurdle” evidence-based cost-effectiveness assessments of their community value. In chapter 3, “Growing the Pharma Monolith,” Shah examines the problem of the financial influence of the pharmaceutical industry on academic medicine through advertising, lobbying, gifts, honoraria, and program sponsorships. She additionally scrutinizes the FDA’s acceptance of biomarkers rather than actual health outcomes, eg, quality-adjusted life-years, as proof of efficacy.

Much of this general material is excellently covered in other books, especially Marcia Angell’s The Truth About the Drug Companies and Ray Moynihan and Alan Cassels’ Selling Sickness. Shah’s work, with its unique emphasis on clinical trials in the developing world, is a valuable addition.

In chapter 4, “Uncaging the Guinea Pig,” Shah describes how, after World War II, principles such as those enunciated in the Belmont Report—respect for persons, beneficence, and justice—were built, brick-by-brick, into an efficient domestic regulatory system. However, as she discusses in chapter 5, “HIV and the Second Rate Solution,” these pro-
tive case concerns the subsequent legal action against researchers alleged to have overridden safety concerns and failed to inform patients about the experimental use of oral Trovan (a new broad-spectrum antibiotic) to treat an outbreak of meningitis in malnourished children in Nigeria.

Shah concludes with a plea for more large-scale clinical trials using the best-utilized therapeutic comparators in a non-market-driven medicines research program. Many regulatory agencies involved in health technology assessment (outside the United States) are already requiring clinical trials to involve such head-to-head comparisons. To alleviate the problems that Shah recounts, I have described a multilateral treaty on reward of pharmaceutical innovation through internationally harmonized assessment of safety, quality, efficacy, and cost-effectiveness, funded independently by a tax on global financial transactions. This treaty would establish the principles underpinning such assessments, for example, safety, quality, efficacy, equity of access, and a sustainable and responsible industry. It would also describe principles for trial design as well as parallel and shared evaluations premarketing and postmarketing, conditional approvals based on binding outcome agreements, consistent and transparent assessment of linked usage and outcome data, best use of surrogate outcomes or modeling, increased disclosure of marginal cost of production, and better governance of industry commercial-in-confidence claims over clinical trials data (transparent, protected of public safety, and not made unilaterally). The treaty and its funding would also confer liability protection and indemnity for assessors.

Financial Disclosures: None reported.

BOOK AND MEDIA REVIEWS

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