

Preface to the Sixth Edition

We are happy to complete this 6th edition of our book, which continues to be widely used in the US and abroad. This edition contains a total of 363 formulations for use primarily in pediatric patients, although some adults, especially the elderly, may also benefit from their use if they have difficulty swallowing tablets or capsules.

We have added 83 formulations to this edition. As in previous editions, multiple formulations with different vehicles have been included for certain drugs because of varying availability of vehicles in different practice settings in the US and other countries. Some ready-to-use vehicles, like Ora-Plus, Ora-Sweet, Ora-Blend, and SyrSpend, are readily available in the US, but not in many other countries. In that situation, an extemporaneously prepared methylcellulose 1% suspension may be used with syrup in place of the ready-to-use vehicles. Ready-to-use Hypromellose or SnoTears are available in certain countries, but not in the US.

Many drugs used in the pediatric patient have not been approved by the US Food and Drug Administration (FDA) for use in infants and children. When a drug is not approved for use in infants, it is unlikely to be commercially available in a suitable formulation for this population. In a survey of 57 large and small hospitals, we found the need for over 100 stable extemporaneous liquid formulations.¹ Another survey of 20 pediatric hospitals noted that compounded liquid formulations were used for 28% of the inpatients.²

The Best Pharmaceuticals for Children Act offers a 6-month marketing exclusivity incentive to the manufacturers of the marketed products that conduct pediatric studies in response to a written request from the FDA. However, this applies to drugs under patents and may be an attractive incentive mainly for commonly used products.

The Pediatric Research Equity Act gives the FDA authority to require pediatric studies if meaningful therapeutic benefit exists. These regulations are positive developments for labeling of medications for use in pediatric patients; however, their impact on the availability of suitable formulations of most generic drugs used in this population has been extremely limited.

Some drugs, such as spironolactone, are available in a liquid formulation abroad but not in the US; the reverse is true for other drugs. If a suitable formulation is available in one country, such should be the case in all countries.

Access to suitable formulations is essential for the proper use of medications in infants and children. Thus, every effort should be made to market the needed formulations. If it is not possible, at least the procedure to prepare a stable dosage form should be included in the package information as has been done for a few drugs, including lisinopril and rifampin.

We are grateful to all the practitioners, educators, and researchers for their contributions to patient care. We also appreciate your continued interest in this book and your suggestions to improve it. We look forward to receiving your comments on the Feedback Forms provided at the back of this book.

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Reference

1. Pai V, Nahata MC. Need for extemporaneous formulations in pediatric patients. *J Pediatr Pharmacol Ther* 2001;6:107-19.
2. Lugo R, Cash J, Trimby R, Ward R, Spielberg S. A survey of children's hospitals on the use of extemporaneous liquid formulations in the inpatient setting (abstract). *J Pediatr Pharmacol Ther* 2009;14:156.