Disorders of Human Learning, Behavior, and Communication

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Psychopharmacology of the Developmental Disabilities

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Preface

Purpose and Scope

The purpose of this book is to make the considerable developments in psychopharmacology of the developmental disabilities readily available in one source. We have defined developmental disability as a significant shortfall in intellectual ability, academic achievement, or adaptative behavior relative to age expectations (Matson & LaGrow, 1983). The book sets out to provide coverage of the major classes of medication currently in use, newer drugs being explored, and major areas of concern as they relate to drug treatment. In doing this, we have been extremely fortunate in being able to involve distinguished international experts in the field so that the book should contain a truly authoritative summary of the current state of psychopharmacology in this field.

This book is for all workers in developmental disabilities, not just those with medical or nursing responsibilities or a particular interest in pharmacotherapy. A knowledge of medication effects is of importance because psychoactive drugs may influence (either for better or worse) the effectiveness of other nonmedical forms of therapy such as behavior modification, special education, and so forth. As shown in Chapter 1, drug therapy is an extremely prevalent form, perhaps the single most common mode, of therapy in the developmental disabilities. Given that drugs can have far-reaching effects, both in terms of their therapeutic actions and in terms of adverse effects, some familiarity with the state of psychopharmacology is of obvious relevance to all in this field.

This is a timely point for such a book, because the level of research activity and general interest in psychoactive drugs has been high in recent years, due to several vigorous programs of drug research over the last decade. In addition, at the National Strategy Conference on Mental Retardation and Mental Health in Washington, D.C. (1985), major sections of the program were reserved for discussions of pharmacological and other therapies. Another reflection of this interest can be seen in *Psychopharmacology Bulletin*, which devoted a section to research on mentally

retarded/developmentally disabled individuals (Reatig, 1985). In 1986, a special workshop was sponsored by the U.S. National Institute of Mental Health (NIMH) to consider the methodological problems in arriving at accurate and valid psychiatric/psychological diagnoses when conducting treatment research with mentally retarded populations (Special Workshop, 1986). In 1987, the NIMH and the National Institute of Child Health and Human Development put out a joint Request for Proposals (MH 87-11) which specified psychopharmacology of mentally retarded people as a high priority area for funding. Finally, there has also been greatly increasing legal activity of late in the United States with regard to drug treatment (see Chapter 2), and this may have major implications for the utilization of such therapy.

This book is largely concerned with the psychopharmacology of mentally retarded people. Research with autistic children is also reviewed and, to a lesser extent, various authors have discussed research with seizure disorders (insofar as they are often associated with lower functional levels), Tourette syndrome, hyperactivity (Attention Deficit Disorder), and childhood psychosis. However, the emphasis has consistently been placed on drug research carried out with people having subaverage intellectual functioning.

In selecting material we were guided by the following considerations. First, we wished to cover all of the major psychotropic drug groups used with this population. This resulted in separate chapters on neuroleptic drugs, antiepileptic drugs, other traditional psychotropic drugs (e.g., cerebral stimulants, antidepressants), and novel psychotropic agents (e.g., fenfluramine, clonidine). There is also a chapter on vitamin and dietary treatments for behavioral control. Second, there is a need for material on drug effects in their natural context and how to study their effects there, leading to a chapter on drug prevalence, patterns of drug use, methodological considerations, measures of drug change, and likely future directions. Third, the use of medication with this socially disadvantaged group raises a number of ethical and legal issues, resulting in a chapter summarizing the latest litigation relating to pharmacotherapy in the developmental disabilities. Fourth, there has been much concern about the neurological syndrome of tardive dyskinesia as a sequel to therapy with neuroleptics, and a separate contribution reviews this topic in detail. Fifth, advances in measuring drug concentrations in blood and related theoretical and technical problems quantifying and interpreting these concentrations are discussed in a separate chapter. Sixth, we felt that there has been a general failure in the past to relate the substantial body of animal drug research to this field. A chapter on behavioral pharmacology attempts to establish the relevance of this information to the treatment of the developmental disabilities and to show how its methods and findings might be extended to the field. Finally, this material is brought together and discussed in a

separate chapter in terms of how psychopharmacological drug research with developmentally disabled persons relates to the broader area of psychopharmacology in general.

Drug Use Often a Matter of Controversy

The use of drugs to treat maladaptive behavior in developmentally disabled persons can be an emotive topic, especially to those who advocate the use of alternative methods (see Aman, 1985; Aman & Singh, 1986), and it can be seen as one way of arbitrarily defining the field as "medical." Hersen (1979) has discussed a problem which occurs when workers are so committed to a particular form of therapy that they reject all other approaches, such as pharmacotherapy. Elsewhere (Aman & Singh, 1986), we have suggested that there has been a prevalent "anti-drug" sentiment in the field in recent years. Workers cannot afford to make up their minds before the data are available, nor is it appropriate to design drug studies in such a way that a therapeutic outcome is unlikely. Although drugs appear to have been overused in the past (often as the *only* form of treatment), we believe that pharmacotherapy still has a legitimate and potentially valuable place in the treatment of developmentally disabled people. It is hoped that the discussions which appear in this book will help to give an objective summary of the potential and limitations of pharmacotherapy with this population.

Caveat—The Breuning Studies

In the early 1980s, a young researcher named Stephen E. Breuning published a large number of reports and reviews relating to drug effects in mentally retarded individuals. Many of the studies reported the use of large groups of subjects, extensive sampling of maladaptive and adaptive behavior, and often elegant and complex methological designs. Most of these investigations showed marked and clear-cut detrimental effects due to neuroleptic drugs in this population, and they were widely cited in the mental retardation literature (Aman & Singh, 1986). This work had a marked effect on the field, to the extent that at least one state modified its guidelines regarding the use of psychotropic drugs to be consistent with Breuning's findings (Holden, 1987).

In 1983, Robert L. Sprague, Ph.D. (a senior colleague of Dr. Breuning) noted irregularities in Breuning's reported results. In a detailed and lengthy letter, Sprague reported his concern about Breuning's research to the National Institute of Mental Health (NIMH). As a result of Sprague's action, the NIMH convened a panel of senior scientists to investigate possible scientific misconduct on the research grants with which Dr. Breuning

was associated. On April 20, 1987, the investigative panel released its findings (Panel to Investigate Allegations of Scientific Misconduct, 1987). Among the panel's more important findings were the following:

> . . . that Stephen E. Breuning knowingly, willfully, and repeatedly engaged in misleading and deceptive practices in reporting results of research . . . that he did not carry out the described research; that only a few of the experimental subjects described in publications and progress reports were ever studied; and that the complex designs and rigorous methodologies reported were not employed. Dr. Breuning also misrepresented, implicitly or explicitly, the locations at which research was supposedly conducted (pg. 30).
>
> The Panel unanimously concludes, on the basis of all the facts, that Dr. Stephen E. Breuning has engaged in serious scientific misconduct (pg. 37).

Others have also commented on the scandal and the events surrounding it. Interested readers are referred to articles and/or letters by Aman (1987), Ferguson, Cullari, and Gadow (1987), Gualtieri (1987), Holden (1986, 1987), Hostetler (1987a, 1987b), Mulick (1987), and Sprague (1987). It is clear that great caution must be exercised in interpreting these studies—indeed, the NIMH panel concluded that most of Breuning's drug studies in this field were never actually carried out. Obviously, replication of these studies by independent and responsible workers should be a high priority for the field.

We, the editors, and most of the contributors were aware of the Breuning controversy when preparing chapters for this book. Therefore, we avoided citing the questionable material so as not to promulgate further what may be fabricated results. On one or two occasions, reference is made in the book to Breuning's research to place in context the impact his reports had on the field. However, it is important that workers new to the field (or not already aware of the alleged fraud) be cognizant of the episode so that they do not inadvertently adopt Breuning's numerous reports as the basis for further research or to guide clinical practice. This is clearly a danger which we must try to avoid.

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