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Date

December 3, 1971

INVESTIGATION INTO PARKINSON'S DISEASE
AND THE ADVENT OF L-DOPA

by

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ABSTRACT

The research problem was defined in relation to the lack of individualized reporting in research literature by patients with Parkinson's disease using the newly discovered drug, l-Dopa. Therefore, the investigator felt that the literature about the Parkinsonism patient was incomplete. Two problem areas were chosen by the investigator for exploratory study: 1) What social, psychological and physiological experiences do individual Parkinson's patients taking l-Dopa have, both in relation to their disease and their medication? Can any commonalities of such experiences be identified in a group of patients with Parkinsonism? And, 2) where do patients with Parkinson's disease obtain their information about this disorder and about l-Dopa? What effect, if any, does the possession of this information have upon their outcome and/or progress?

Seventeen patients in varied environmental locations were interviewed by the investigator, utilizing a 12-item interview schedule. Included in the interview schedule was a test for degree of patient knowledge about l-Dopa and Roche Charts for Evaluation of Patient Progress. Data obtained from the interviews was presented through a modified case study format. Certain case study variables, lending themselves to numerical presentation, were also presented. Analysis was undertaken by comparing the collected data with literature-based material and identifying certain commonalities between patients.

The findings of the study, because of the small sample size, shall have to be considered specific to this particular investigation. Subjects investigated were comparative to literature-based populations as to age-range, reports of side effects, and improvement ratio. They were not comparative as to age of onset of Parkinsonism. The group studied proved to be better educated and to enjoy a higher status of previous occupation than the average American over 65 years of age. A majority of the subjects reported approaching their physician initially to request l-Dopa treatment; likewise, over half of the patients reported gaining no satisfactory amounts of information from the physicians, indicating their rather high degree of evaluated drug knowledge came predominantly from the mass media. The impact of Parkinsonism was noticeably negative in both the physical and the social realm for most of the patients. The study findings provoked recommendations for further study involving both Parkinson's patients and health professionals.

Chapter 1

INTRODUCTION

Parkinson's disease, a condition relatively prevalent in the geriatric age group, has recently become the focus of a number of medical, nursing and popular mass media articles. A new drug discovery made this previously untreatable disease suddenly manageable. Patients with the condition were given new hope, not for complete recovery, but for improved functioning ability. What are the events surrounding the discovery of the new medication, l-Dopa? The following is a summarized account of gathered information concerning Parkinson's disease and the advent of l-Dopa.

Historically, Parkinson's disease has been recognized since ancient times, specifically when Greece's esteemed physician, Galen, first described the malady.¹ However, it was not until 1817 that a man named Dr. James Parkinson, for whom the disease is named, accurately described the disorder. Naming it "paralysis agitans", Dr. Parkinson² wrote of a disease whose symptoms included:

¹Esta, Carine and Guy Owens, Neurological and Neurosurgical Nursing (St. Louis: C. V. Mosby Company, 1970), p. 189.

²Martha E. Haber, "Parkinson's Disease: Challenge to Health Professions," The Nursing Clinics of North America, 4:263, June, 1969.

Involuntary tremulous motion with lessened muscular power in parts not in action and even when supported, with a propensity to bend the trunk forward, and to pass from a walking to a running pace, the senses and intellect being uninjured.

He had quite accurately defined this disease whose principal symptoms consist of muscular rigidity, impaired articulation, contractural deformities involving flexors, propulsive and accelerated gait, loss of automatic movement, poor body balance, fixed expression on the face, episodes of "freezing" into place, difficulty in turning, body restlessness, a tremor which starts during rest and subsides with voluntary movement (but is absent during sleep and frequent during a stressful situation), excess salivation and spastic closure of the eyes.³

Occurring in persons aged 45-80 years, the average Parkinson's patient is approximately 55 years of age.⁴ The disease is a progressive one, beginning with unilateral involvement, then bilateral involvement, followed by a gradually worsening marked disability which often forces the patient to confinement in bed or a wheelchair.

Usually, there is little difficulty in diagnosing Parkinsonism when the disease is advanced. But characteristically, the onset is insidious and often only one of the cardinal symptoms may be present. Most frequently, the disease begins with tremor in one, or occasionally,

³Haber, *op. cit.*, pp. 264-265.

⁴*Ibid.*, p. 265.

both hands. There is a typical movement of the thumb and fingers called "pill rolling". Limb stiffness often follows with overall slowing of movements. With progression of the disease, the face becomes expressionless and eye blinking decreases. The patient finds it difficult to maintain erect posture and becomes stooped. There is a shuffling gait without arm swing and speech is slowed and monotonous in tone. Drooling and seborrheic dermatitis are common.⁵

The incidence of Parkinsonism in the United States has been estimated to be approximately 1.2 million patients⁶, increasing by 150,000 to 800,000 new cases discovered each year.⁷ Thus, Parkinson's disease comprises about 8% of the chronic disabling diseases as well as one of the most frequent of the extrapyramidal disorders and one of the most crippling.⁸ Researchers Papavasiliou and Gellene anticipate that, considering the increasing population of the elderly, the prevalence of Parkinson's disease may continue to rise.⁹ Causes of

⁵George C. Cotzias, Larodopa (New Jersey: Roche Laboratories, 1970), p. 9.

⁶Haber, *op. cit.*, pp. 263-264.

⁷John C. Krantz and Jelleff Carr, The Pharmacologic Principles of Medical Practice (Baltimore: Williams and Wilkins Company, 1969), p. 212.

⁸Krantz and Carr, *op. cit.*, p. 213.

⁹Paul S. Papavasiliou and Rosemary Gellene, "Modification of Parkinsonism--Chronic Treatment with l-Dopa," New England Journal of Medicine, 280:337, February, 1969.

mortality in this patient seem to be the same as for the general population, except for a high incidence of respiratory, urinary, and intestinal infections--including obstruction.¹⁰

The symptoms of this disorder are thought to stem from a malfunction of the brain's extrapyramidal motor system. Ordinarily, nerve cells of this complex system exert an automatic regulating influence on the voluntary movements that have their origin in the cerebral cortex. In Parkinsonism, however, these normal controls are lost. Contributing factors to this condition have been delineated--arteriosclerosis and encephalitis. More recently, influenza has been thought to be a contributory factor even though the patient may not have experienced acute symptoms.¹¹ Most often, however, the cause of the disease remains unknown.¹²

There exists no known cure for this disease, but some of the crippling symptoms have been alleviated by drugs, surgery, and therapy. [Intensive physical therapy] has been found to improve the conditions of some patients from a level of 50% of normal to 75%. Surgical destruction of the globus pallidus of the brain is suitable for only

¹⁰Haber, *op. cit.*, p. 267.

¹¹*Ibid.*

¹²Mary W. Falconer and Mabel Norman, The Drug, The Nurse, The Patient (Philadelphia: W. B. Saunders Company, 1968), p. 341.

10-12% of patients and seldom of use in those over 65 years of age.¹³ A great number of drugs--including Artane, Disipal, Pagitane, and various other cerebral stimulants, tranquilizers, and muscle relaxants have been used with varying effectiveness--rigidity and tremor being the most responsive symptoms in those who show improvement. Anti-cholinergics have been by far the most widely used.¹⁴

As Duvoisin has remarked, "It is probably safe to say that every medicinal alkaloidal preparation known to man has been employed in the treatment of Parkinsonism at some time in the past century."¹⁵ Yahr¹⁶ summarizes the use of drug treatment with this observation: "... under the most optimal circumstances, the best that can be expected from.. (these drugs) is a 20% reduction in the severity of symptoms with a modest improvement of functional capacity." Thus, as late as 1966, a Public Health Service bulletin prepared by several of the nation's leading neurologists reported that "no promising new forms of medical treatment exist for Parkinsonism syndrome."¹⁷

¹³Falconer, *op. cit.*, p. 341.

¹⁴Cotzias, *op. cit.*, p. 10.

¹⁵R. C. Duvoisin, Bulletin of the New York Academy of Medicine, 41:898, July, 1965.

¹⁶Melvin Yahr and others, "Treatment of Parkinsonism With Levodopa," Archives of Neurology, 21:353, October, 1969.

¹⁷U. S. Department of Health, Education, and Welfare, Parkinson's Disease, Special Report, U. S. Public Health Service Publication No. 652 (Bethesda, Maryland: National Institute of Neurological Diseases and Stroke, 1969), p. 10.

Hope for the Parkinson's patient was not dispelled at this point for much interesting biochemical research was being performed with increasingly significant results. Arvid Carlsson¹⁸ of Sweden recognized, in 1958, that Reserpine, an antihypertensive agent, depletes the corpus striatum of its principal amine, dopamine, and may produce extrapyramidal symptoms similar to those of Parkinsonism. Carlsson subsequently reversed this effect of Reserpine on the corpus striatum by administering dopamine.

Dopamine is found chiefly in certain of the brain's extrapyramidal regions--particularly the substantia nigra, (corpus) striatum and (globus) pallidum. In Parkinsonism, Carlsson postulated that the substantia nigra is damaged or the connecting fibers cut, depriving the brain of its normal supply of dopamine.

Hornykiewicz¹⁹ and his colleagues examined brains obtained at autopsy from patients with idiopathic and postencephalitic Parkinsonism and noted gross depletion of striatal dopamine; the concentration of homovanillic acid, the major metabolite of dopamine, is similarly reduced in the brain and cerebrospinal fluid of Parkinsonian patients. These research findings, in addition to others performed by

¹⁸Andre Barbeau, "l-Dopa Therapy in Parkinson's Disease: A Critical Review of Nine Years' Experience," Canadian Medical Association Journal, 101:60, December, 1969.

¹⁹Barbeau, *op. cit.*, p. 61.

such individuals as Blaschko and Barveau,²⁰ support the conclusion that dopamine is a synaptic transmitter, that it regulates much of the functioning of the brain's extrapyramidal centers, and that its depletion functions in the etiology of Parkinsonism.

The exact mode of action of dopamine has not been elucidated. It has been suggested that this catecholamine-type chemical may act as a neurohumoral transmitter of the predominantly inhibitory nigral impulses which may control the function of both the corpus striatum and the globus pallidum. Loss of nigral inhibitory influences (mediated by dopamine) on the function of the globus pallidum may be the cause of rigidity. The corpus striatum may normally act to inhibit spontaneous movement by influencing cortical activity. The function of the substantia nigra might be to depress striatal inhibition of motor activity, thus leading to motor activation.²¹

Dr. George C. Cotzias, senior scientist and head of the physiology division of Brookhaven National Laboratory at Upton, Long Island, New York is largely credited for the development of l-Dopa, a direct metabolic precursor of dopamine. (Dopamine itself is not useful in the treatment of the human Parkinsonism victim as it does not penetrate the blood-brain barrier while l-Dopa does pass this

²⁰*Ibid.*, p. 62.

²¹O. Hornykiewicz, "Dopamine and Brain Function," Pharmacological Review, 38:1236, July, 1966.

barrier, entering sympathetic neurons and becoming decarboxylated to dopamine and other metabolites.)²² Cotzias and his colleagues achieved large oral dose regimens for periods of up to a year by gradually increasing the intake of l-Dopa, titrating this against adverse effects in each patient individually. The initial success of the drug was quite dramatic. Of the first 28 persons treated at Brookhaven, improvement was "marked" or "dramatic" in 20 and "moderate" in four others.²³ Furthermore, there seemed to be a remarkable consistency in the results obtained at different centers, utilizing Cotzias' technique of slowly increasing dosage. Dr. Melvin D. Yahr²⁴ of Columbia University and the Neurological Institute in New York, wrote in a recently published paper: "Comparative evaluations of l-Dopa with existing Parkinson agents indicates it is at least 3.5 times more effective."

Like some other experimental medicines, l-Dopa can provoke undesirable drug reactions, the chief reason that it was only recently licensed by the Federal Food and Drug Administration. The most frequently reported²⁵ drug reactions seem to be the following: a

²²Barbeau, *op. cit.*, p. 60.

²³George C. Cotzias, "l-Dopa in Parkinson's Disease," Hospital Practice, 10:37, September, 1969.

²⁴Yahr and others, *op. cit.*, p. 354.

²⁵Cotzias, Larodopa, p. 19.

tendency toward mental and motor excitement (symptoms anywhere from fleeting muscle twitches or facial tics, to involuntary movements of the legs or dyskinesia), mild insomnia, nausea, anorexia, vomiting, hypotensive episodes, cardiac arrhythmias, confusion, elevation of mood, constipation, mental depression, sedation, flushing, elevations of BUN, SGOT, SGPT, LDH, bilirubin, alkaline phosphatase and protein-bound iodine, occasional reductions in white blood count, hemoglobin and hematocrit, elevations of uric acid, occasional positive Coombs test and darkened urine. The earliest and most common initial side effects are nausea, vomiting, and anorexia. In some patients, however, Cotzias²⁶ reports that these appear only when dosages of almost 3 Gm/day are reached or when single doses of 1.5 Gm are first given.

Neurological side effects, most common of which are involuntary choreiform movements, may develop in many patients, especially as maintenance dosages are reached or continued for some time. These can be eliminated by reduction of dosage, with some sacrifice of the anti-parkinson effect.²⁷ Psychiatric side effects may be the most disturbing of the on-ward drug reactions attributed to L-Dopa. These consist of agitation, depression with suicidal tendencies, bizarre psychosexual

²⁶Cotzias, "L-Dopa in Parkinson's Disease," p. 38.

²⁷Yahr and others, *op. cit.*, p. 352.

behavior, and other manifestations.²⁸ It seems quite obvious to this investigator that the use of l-Dopa therapy demands the weighing of possibly serious side effects in a patient with Parkinson's disease and syndrome against the potential of a restored patient.

It is not known why some patients fail to benefit even from a relatively large dosage of l-Dopa. It may be that, Peaston²⁹ suggests, absorption from the alimentary tract, normally rapid, differs in these subjects, and the effect of dietary factors merits further investigation.

Even with the new discoveries in drugs, medical and nursing journals continue to encourage other types of rehabilitation of Parkinson's patients. Stern and his associates³⁰ utilized varying therapeutic exercises and rehabilitation techniques in conjunction with l-Dopa treatment and felt that their efforts were instrumental in restoring several patients to gainful employment. Physical therapists, DeJong and Thibaut³¹, have also developed helpful management

²⁸Cotzias, Larodopa, p. 20.

²⁹M. J. Peaston and J. R. Bianchine, British Medical Journal, 1:400, 1970.

³⁰Peter Hans Stern and others, "Levodopa and Physical Therapy in Treatment of Patients With Parkinson's Disease," Archives of Physical Medicine and Rehabilitation, 10:273-277, May, 1970.

³¹Jean Thibaut and David DeJong, Rehabilitation of the Parkinson Patient (Miami: National Parkinson Foundation, 1968), pp. 1-9.

measures for the Parkinsonism patient.

The aforementioned has been but a brief summary of the types of information that have been reported in the literature regarding the patient with Parkinson's disease to date. Much of this type of information has a distinct medical-physiological aura about it. That is, most of what knowledge has been gained about the Parkinsonism patient has related to the disease entity itself rather than the individual who is the victim of the disease. With the exception of but one source that the investigator consulted, no mention was made of any types of case studies having been conducted regarding the experiences and reactions of individuals with Parkinson's disease using l-Dopa. More typically, the collected data surveyed by the investigator seemed to emphasize numerical representations of mass experimental testing of the drug or the physiological aspects, rather than emotional or psychological reactions of Parkinsonism patients.

Georgia Travis³² is the single author consulted who gave any indication of the profound social or emotional significance that Parkinsonism symptoms may have for its victims, but even she makes rather generalized, group-oriented statements. This author observes that:

Shaking can be embarrassing, fatigue causes social isolation and depression, and the tendency to drool adds much suffering to

³²Georgia Travis, Chronic Disease and Disability (Berkeley: University of California Press, 1966), pp. 108-109.

the lives of the Parkinson's patient. The rather blank look on the face of this person lends an impression of stupidity, although intelligence is most definitely not affected by the disease.

Simarily, many of the nursing texts consulted, symbolized by Shafer's³³ text entitled Medical-Surgical Nursing, advised the nurse caring for the patient with Parkinson's disease to accomplish the following goals:

Support the patient if he appears depressed over his condition, help him reduce his regular work gradually, instruct close relatives on the manifestations of the disease, prevent accidents, turn frequently and make certain the side rails are utilized.

The investigator does not argue the fact that all of the above types of information can be helpful knowledge aids in the nursing care of the Parkinson's patient. In illustration, the statistical data has provided scientific proof of desirable or undesirable courses of direction for professionals to take in dealing with these patients. Likewise, social difficulties likely to be experienced by the patient with Parkinson's disease can stimulate health professionals to devise effective means of emotional counseling for these individuals. And, methods of nursing care are naturally essential to the relative health and well-being of the Parkinsonism patient.

³³Kathleen Newton Shafer and others, Medical-Surgical Nursing (Saint Louis: C. V. Mosby Company, 1967), pp. 867-868.

Yet, it is the considered opinion of the investigator that these types of literature-based information do not entirely complete the picture of the patient with Parkinson's disease, and especially the one who is taking the new medication, l-Dopa. Indeed, an important factor seems to be missing. That factor is the individual patient. It is he who suffers the disease, experiences its gradual deterioration, and hopes for a future cure. Without this individual's presence, the literature reports become incomplete.

How may the individual patient be represented in a research effort? Faye Abdellah and Eugene Levine³⁴ indicate that the use of the case study or "a detailed, intensive, factual description of individuals.... may be one of the most effective means of researching in uncontrolled natural settings."

In the investigator's opinion, the case study, or the reporting of the individual experiences of patients, may also be one of the most important means of attaining the necessary information basic to achieving a major health goal; personalizing and individualizing patient care. Comparisons between these individualized experiences if they can be made, may develop an even broader picture of the Parkinsonism patient.

³⁴Faye Abdellah and Eugene Levine, Better Patient Care Through Nursing Research (London: The Macmillan Company, 1965), p. 53.

What types of information might be beneficial for study with regard to the patient with Parkinson's disease taking l-Dopa? The investigator believes that not only the usually obtained information dealing with background of each patient (as age, occupation, marital status, onset of disease and experiences with the disease and l-Dopa) might be meaningful, but other, not as directly obtainable data could be dealt with. In example, the Parkinson's patient currently has available to him, via the mass media and the medical profession, quite complete information regarding l-Dopa. Knowledge of the drug's positive and negative effects have been widely publicized in both popular and professional magazines and journals. The impact, the availability, the effects of this knowledge (i.e. placebo effect, power of suggestion, and psychosomatic reactions) are subjects which also lack directed research action with regard to the patient with Parkinson's disease.

It will, therefore, be the intention of this paper to shed an exploratory light upon the aforementioned areas with the implicit hope of creating a more complete picture of the patient with Parkinson's disease and illuminating areas of his medical and/or nursing care which may be possibly improved upon.

Statement of the Problem

The research problem was defined in relation to the lack of individualized reporting by patients with Parkinson's disease using l-Dopa in the research literature. As a result of the lack of this type of experiential-based information, the investigator has concluded that the literature about the Parkinsonism patient is incomplete.

Two problem areas were chosen by the investigator for exploratory study: 1) What social, psychological, and physiological experiences do individual Parkinson's patients taking the newly discovered drug, l-Dopa, have, both in relation to their disease and their medication? And, similarly, can any commonalities of such experiences be identified in a personally interviewed group of patients with Parkinson's disease? And, 2) where do patients with Parkinson's disease obtain their information about this disorder and about l-Dopa? What effect, if any, does the possession of this information have upon their outcome and/or progress?

Purpose of the Study

The primary purpose of this study was to describe the personal experiences of the Parkinsonism patient using the newly discovered drug, l-Dopa, making comparisons where applicable. Utilizing the case study approach for the investigation, the gathered data might serve to complete the picture of the patient with Parkinson's disease, supplying

the type of information noticeably lacking in the research literature. This type of information could provide the basis for creating nursing care plans for the Parkinson's patient taking l-Dopa and instigating guidelines for those health professionals involved in supplying anticipatory guidance to these patients.

Methodology

The method of research utilized in this study consisted of an exploratory, descriptive attempt designed to elicit Parkinsonism patients' personal experiences and interpretations of the disease and l-Dopa. An interview collaborator, or an individual familiar with the patients, was also present during the interview. (See definition on page 20.) A pilot project of limited scope was conducted initially during which the investigator-designed tool was tested and revised slightly. On the basis of that experience, the personal interview tool used in the main study was constructed. This tool consisted of both check-list type and open-ended, free-response questions. Within the framework of the interview tool, Roche Laboratories' Patient Evaluation of Progress Charts and an investigator-designed evaluation form for degree of patient knowledge of l-Dopa was also utilized to elicit specific information. Both the patient and the interview collaborator sample each totaled seventeen. The data obtained from the interviews was treated in two ways: 1) the individual interviews

were prepared in modified case history-anecdotal form for general discussion and evaluation, and 2) commonalities related to specific problem variables were identified through factor analysis of these interviews and presented in numerical form. The median range and percentage evaluations were used where applicable.

Assumptions

Patients can be induced by the interview technique to verbalize their knowledge, attitudes, and feeling regarding a subject.

The investigator can interpret the reported data as being expressions of underlying beliefs that determine perception.

The way an individual reacts to his diseased state, or his health behavior, is mediated by a complex interaction of physiological, psychological, emotional, and social factors which are difficult to separate.

It is possible for an organic reaction to be psychogenic in origin.

It is possible to determine the degree of specific drug knowledge from a patient by eliciting facts about its name, mode of action, side effects, and medical information possessed by him on the specific drug.

Family members or those individuals maintaining a close relationship with the Parkinsonism patient may be a source of additional information about the patient not necessarily perceived by the

patient himself.

Additional assumptions were cited in Appendix E where predictive rationale underlying the use of the questionnaire items was explained.

Limitations

There were many individual patient variations and no control was made for drug dosage, length of time using the drug, age, physical condition, complications, severity of disease, and other drugs in use. These factors severely limited the investigator's ability to draw conclusions regarding commonalities between patients.

The small population investigated in the study consisted of insufficient numbers of which to perform statistical analysis. Similarly, the number of patients selected for the study most certainly do not adequately represent the total number of Parkinsonism patients using l-Dopa residing in the state of Montana.

As a somewhat questionable number of positive attitudes toward l-Dopa were elicited in the interviews, the possibility that the presence of the investigator could have influenced the production of these responses should be considered. This tendency to be influenced by an individual's personality (in this case, the investigator's) has been named the "Hawthorne" or "Halo" effect,--often unavoidable in the personal interview situation.

Age-influenced memory loss or forgetfulness of the patient sample even though the family member or interview collaborator was present for support, may limit the reliability of the data to a certain extent.

A definite bias existed in the study for those Parkinsonism patients who could effectively communicate with the investigator. Those who were deemed too severely affected by the disease or who appeared to have tendencies toward senility were dropped from the study. Therefore, the study is limited in that it does not begin to represent all types of patients who have Parkinson's disease.

The lack of previous interviewing experience by the author was probably the core limitation in the study. A rather high level of skill would seem to be required to elicit feelings and attitudes in a one-time-only interview session with an individual who is basically a stranger to the interviewer. This was, of course, a critical factor in determining the worth and reliability of the collected data.

Definition of Terms

A concerted effort was made to assure that all technical and non-technical terminology employed in this paper were well within the range of connotation typical of the expectations and the use made of them by practicing members of the nursing profession.

The following definitions of terms shall be used consistently throughout the study:

Anticipatory Guidance. A method by which (an advisor) provides preparatory information to (an advisee) regarding a forthcoming event within the range of predictive reality.

Parkinsonism Patient (also, patient with Parkinson's disease, Parkinson's patient). Any individual with a medically diagnosed case of "paralysis agitans" or Parkinson's disease--in this study, those patients who also take the medication, l-Dopa.

l-Dopa (also, Levodopa, L-Dopa, or various biochemical designations). A newly discovered medication designed to treat the patient with Parkinson's disease, administered in individually titrated dosages. (Further information about the drug may be obtained in the introductory phases of this paper.)

Interview Collaborator. Any individual, usually but not necessarily a blood relative, closely associated with the support and care of the subject patient with Parkinson's disease, who participates in the study interviews with the patient.

Drug. Any chemical or biological substance, other than food, intended for use in the treatment, prevention, or diagnosis of disease.

Untoward Drug Reaction or Side Effect. An additional drug effect not primarily sought and usually not evaluated as therapeutic; or, any undesirable effect caused by the administration of a drug,

but not directly attributable to the pharmacological action of that drug.

"High Degree of Drug Knowledge". Terms describing the Parkinsonism patient, with or without the aid of the interview collaborator, who was able to relate the following information to the interviewer: 1) the name of the drug l-Dopa--or some other trade and/or official designation of the same drug; 2) the current dosage he was taking; 3) a brief, but accurate sketch of the drug's currently accepted mode of action; and 4) a list of at least five of the drug's probable side effects.

"Moderate Degree of Drug Knowledge". Terms describing the Parkinsonism patient, with or without the aid of the interview collaborator, who was able to relate the following information to the interviewer: 1) the name of the drug l-Dopa--or some other trade and/or official designation of the same drug; and 2) the current dosage he was taking, but was unable to recall the currently accepted mode of action, nor more than five of the drug's probable side effects.

"Little or No Drug Knowledge". Terms describing the Parkinsonism patient who, with or without the aid of the interview collaborator, was unable to recall little, if any, information about l-Dopa.

Placebo Effect or Action. Any psychological, physiological, or psycho-physiological effect of any medication which is given with therapeutic intent, which is independent of, or minimally related to the pharmacological properties of the medication, and which operates

through a psychological mechanism.

Placebo. A medicine given, not for its pharmacological effects, but for its psychological effects.

Organization of the Remainder of the Study

The remainder of this study is organized into five sections. Chapter 2 concerns a review of pertinent literature which tended to relate to certain areas of emphasis in this exploratory study. Chapter 3 provides a more complete description of the methodology employed in this study. Chapter 4 involves the presentation of data collected in this study. The analysis of this data is undertaken in Chapter 5. And, finally, Chapter 6 presents the summary, findings, conclusions, and recommendations for further study.

Chapter 2

REVIEW OF THE LITERATURE

The initial portions of the introduction to this study were utilized to examine currently reported knowledge regarding the patient with Parkinson's disease in a somewhat abbreviated, but comprehensive manner. Historical information, most frequently occurring symptoms, average age range of the patients, incidence, physiology, etiology, traditional treatments, in addition to data concerning the discovery and the development and use of l-Dopa, were included in the aforementioned section of this paper. Little other information concerning the Parkinsonism patient seemed available, or in some cases, pertinent to the study. As an example of the latter observation, the highly complex biochemical studies being undertaken in the further development of l-Dopa were interesting to the investigator, but not particularly applicable to this paper.

Thus, operating on the assumption that the introductory phases of this study presented what information is known about the patient with Parkinson's disease, it was the investigator's decision to utilize the literature review section of the study to determine the availability of information that might shed some light on factors which might be relevant to, but not necessarily descriptive of, the patient with Parkinson's disease. It was the considered opinion of

this investigator that this approach might serve to give support for the interview tool questions, provide a more creative and broadened basis for analysis of the gathered data, and provoke a broader foundation from which to draw conclusions and implications at the end of the study.

Review of the Literature

To the untrained individual, the human being appears to be composed of rather simply constructed components, designed to perform certain specialized tasks. Simply explained, the legs are to be used for locomotion, the brain for cognition, etc. To the members of the health profession, specifically medicine and nursing, human beings are by far more complex; the intricate interrelationships of the various systems of the body has become crucial knowledge to those responsible for the delivery of health care. To "specialize" in a particular field of medicine or nursing can no longer mean the mere dealing with a small physical area of the body. Author Ritter³⁵ Expresses this idea as follows: "The organism in its totality is as essential to the explanation of its elements as its elements are to an explanation of the organism." Thus, speaking of the patient with Parkinson's disease, one cannot consider only the symptomatology of

³⁵Ritter, W. E., The Unity of the Organism or the Organismal Concept of Life (Boston: Badger Publishing Company, 1929), p. 18.

the malady, but what effects, for example, that these symptoms have upon the individual's total life functions in his environment. This theory which emphasizes an equilibrium within the organism and of the organism in its environment is becoming increasingly useful in facilitating the relating to each other of the medical specialties and the application of facts discovered in them. In addition, it has given rise to the term, "psychosomatic medicine" in accordance with which psychic and somatic represent two angles of observation from which the organismal unit should be studied. Dunbar³⁶ comments that the two views should be "superimposed or viewed stereoscopically". The effect of this point of view on our definitions of health and disease is indicated in the following statement by a noted clinician:³⁷

There is no such thing as purely psychic illness or purely physical ones, but only a living event taking place in a living organism which is itself alive only by virtue of the fact that in it psychic and somatic are locked in unity.

The following statements from a psychiatrist³⁸ on the one hand, and an internist³⁹ on the other hand, further seem to indicate a new emphasis upon the wholistic concept of man:

The question, "Physical or psychic?", therefore is in most cases wrongly put and should be replaced by the question: "To what extent physical and to what extent psychic?"

We can no longer separate either nervous or organic, or

³⁶Flanders Dunbar, Psychosomatic Diagnosis (New York: Harper and Row Company, 1968), p. 6.

³⁷*Ibid.*, p. 6. ³⁸*Ibid.* ³⁹*Ibid.*

functional or organic. If we think in terms of disturbed function, the only adequate concept is that changes take place which are reversible and irreversible in a series terminating in the gross anatomical. We know now that bodily changes may be brought about by mental stimuli, by emotion, just as effectively as by bacteria and toxins, and that physiological changes accompanying emotion may disturb the function of any organ in the body.

By what mechanisms may such "anatomical changes" which Dunbar discusses be brought about? One mechanism documented in the literature, is via the "power of suggestion". There does exist definitive proof to support the ability of one or more individuals to have influence upon another's behavior via the element of verbal suggestion. In a much larger sense, it has been implied that the element of suggestion is operational throughout the whole fabric of medical therapeutics. Ulett and Peterson⁴⁰ write an explanation of the effects of this process:

On the sensory side, belief perception; on the side of mentation, it affects memory, ideation, and prejudice, upon all of which are based insight, judgment, and decision. And, finally, on the motor side, belief affects overt physical and physiological behavior. The desire and capacity to believe that which the intellect knows to be without rational proof is characteristic of the human species.

Considering Ulett and Peterson's remarks in relation to the individual with Parkinson's disease taking the newly discovered drug, l-Dopa, the factor of suggestion might possibly be operational in the information

⁴⁰George A. Ulett and Donald B. Peterson, Applied Hypnosis and Positive Suggestion (St. Louis: The C. V. Mosby Company, 1965), pp. 1-2.

he received from his physician or the local newspaper, for example.

Continuing with this subject area, the plethora of reports concerning the placebo effect of drugs should be investigated as additional support for the notion of suggestibility as a factor in health explanations. An experiment performed in Budapest compared two groups of patients with bleeding ulcers. The placebo group was given an injection of sterile water by the physician, who advised them this was a "new and very potent therapeutic drug"; the control group received the same injection from the nurse, who stated "it was an experimental drug whose effects were uncertain." The placebo group had 70% excellent remissions, lasting over a year, while the control group had a remission rate of 25%.⁴¹

Most of the studies which have been done on the placebo effect of drugs have been primarily concerned with the techniques' positive effects. However, documentation exists to suggest that negative effects can also occur. Pure placebos of lactose have produced "epigastric pain, diarrhea, urticaria, and angioneurotic edema of the lips."⁴²

⁴¹J. D. Frank, "The Dynamics of a Psychotherapeutic Relationship," Psychiatry, 22:17-39. Cited by David Mechanic, Medical Sociology (New York: The Free Press, 1968), p. 187.

⁴²L. Meyer and H. M. Peck, Drug Induced Diseases (Assen, The Netherlands: Royal Vangorcan Publishers, 1962), p. 1.

In demonstrating further how external cues may influence behavior and feeling states under an altered psychology, Schacter and Wheeler⁴³ have shown how subjects, given epinephrine injections, will experience either anger or euphoria, dependent upon whether they had an appropriate explanation and directive external cues about the medication:

When an individual had appropriate explanation for his feelings, he felt little need for evaluating himself in terms of his environmental stimuli and was not affected by them; if no explanation was given for his altered feelings, external cues tended to determine his emotional state.⁴⁴

Pratt, Seligmanin and Reader⁴⁵ tend to support this statement as they found that those patients who were given thorough explanations of symptoms, etiology, and treatment participated more effectively with their physician than those who felt the communication to be inadequate.

In summary to this point, the investigator has used empirical evidence to support the existence and potency that the presence of suggestion can have in the influence of manifest physiological disease in patients. It may be presumed that the patient with Parkinson's disease is no more immune to this process than any other patient with

⁴³S. Schacter and L. Wheeler, "Cognitive, Social, and Physiological Determinants of the Emotional State," Pschiatry Review, 10:379-399, Cited in Mechanic, *op. cit.*, p. 351.

⁴⁴Schacter and Wheeler, *op. cit.*, p. 352.

any other disease. There does exist evidence of this point in the history of treatment of individuals with Parkinson's disease. Aring⁴⁶ comments that "a somewhat fantastic feature of the historical therapy of Parkinson's syndrome is that some 70% of patients respond for a time to any of the dozens of drugs available." Yahr and his associates⁴⁷ have also noted that "the extensive literature on the drug therapy of Parkinsonism is replete with contradictory reports of the agents of pharmacologically identical agents." Furthermore, Yahr and company⁴⁸ feel that "even widely accepted standard drugs for Parkinsonism produce little more than placebo effects."

Whether or not l-Dopa can produce these "placebo-type effects" is still under study. Several investigators have reported variable reactions by patients to the drug, however. Among these are McDowell⁴⁹ and his associates who state:

Variations in severity are common in Parkinson's syndrome, often depending primarily on other physical and emotional problems.

⁴⁵L. Pratt and others, "Physicians View of the Level of Medical Information Among Patients," American Journal of Public Health, 11:47, 1957.

⁴⁶C. D. Aring, "The Riddle of the Parkinson Syndrome," Archives of Neurology, 6:1-5, January, 1962.

⁴⁷Yahr and others, *op. cit.*, p. 351.

⁴⁸*Ibid.*, p. 352.

⁴⁹Fletcher McDowell and others, "Treatment of Parkinson's Syndrome with l-Dihydroxyphenylalanine (Levodopa)," Annals of Internal Medicine, 72:35, January, 1970.

Many patients experience a period of exhilaration when they begin to improve with levodopa and later become disappointed and begin to complain again when they find that some of their disability remains or that side effects are troublesome. We have not observed a continued progression of significant symptoms or disability in patients who experienced definite improvement and who have continued levodopa at a steady dose.

Another investigator, Barbeau,⁵⁰ also found that those patients suffering depression and less than marked improvement often "lacked motivation and had been expecting a miracle because of the excessive publicity given this new form of treatment by the press."

In the investigator's opinion largely gained from personal experience as a nurse, physicians and/or nurses are not always aware of the cumulative effect that health information, improperly transmitted, may have upon their patients. Yet, health professionals are legally, morally, and ethically required to provide accurate and adequate information to their patients. In example of the professional literature exhortations with regard to this subject area, certain authors, exemplified by men like Gerald Caplan and Irving Janis, have recognized the importance of the need for health professionals to be concerned with patient's psychological preparation for physical care to follow. Caplan⁵¹ contends that this preparation, or "anticipatory guidance", should be "a valuable method for mobilizing patient's

⁵⁰Barbeau, *op. cit.*, p. 64.

⁵¹Gerald Caplan, An Approach to Community Mental Health (New York: Grune and Stratton, Inc., 1961), p. 170.

strength beforehand so that he is able to meet a crisis situation more constructively." In explaining this technique, Janis⁵² forwards the idea that:

The arousal of anticipatory fear prior to exposure to a stressful life situation is one of the necessary conditions for the development of effective inner defenses that enable a person to cope psychologically with the stress stimuli. The evidence strongly suggests that if certain....types of inner attitudes are formed before danger materializes, the chances of developing traumatic or disorganizing symptoms are greatly reduced.

These "certain types of inner attitudes" can be promoted in the giving of health information by "stressing the real detail of what they will perceive", Caplan⁵³ categorically urges, but the realities should be provided with "a way of handling them, a picture of support, reassurance, and the hope of a successful outcome."

In the area of "anticipatory guidance" in the use of new or experimental drugs for patients, the legal and ethical control on physicians becomes even more definitive. Among medical ethics, there exists a strong edict that "the voluntary and informed consent of a person is necessary before an experiment can be performed."⁵⁴ The

⁵²Irving L. Janis, "Emotional Inoculation: Theory and Research in Effects of Preparatory Communication," Psychoanalysis and the Social Sciences (New York: International Universities Press, 1965), p. 141-142.

⁵³Caplan, *op. cit.*, p. 57.

⁵⁴Eric W. Martin, Techniques of Medication (Philadelphia: J. B. Lippincott Company, 1969), p. 221.

Food and Drug Administration further legally requires that the "physician must give to the patient all the necessary warnings, contraindications, and other important precautionary information regarding experimental drugs."⁵⁵ This law receives support from the Declaration of Helsinki and the Nuremberg Code, both of which clearly state that the patient should know "the nature, duration, purpose, methods, means, inconveniences, hazards, and effects that the drug might have upon him."⁵⁶ In the case of the nurse, she is legally required to provide to the patient only that information permitted her by the physician.⁵⁷

Considering all of the aforementioned literature, it would appear to this investigator that the health professional might be placed in a troublesome quandry with regard to the provision of information regarding the experimental drug. To illustrate, the physician, presumably attuned to the potent affect of suggestion, is legally required to give complete information on an experimental drug, as l-Dopa. Yet, he at the same time, must consider the possible effect of this information upon his patient, both negative and positive in nature. If, in example, he warns the patient with Parkinson's disease

⁵⁵Martin, *op. cit.*, pp. 221-224.

⁵⁶Martin, *op. cit.*, p. 223.

⁵⁷Julien D. Payne, "Law and the Nurse," The Nursing Clinics of North America (Philadelphia: W. B. Saunders Company, 1967), p. 71.

about one of the drug's most frequently reported side effects, nausea, will the patient be more or less likely to experience this symptom?

In addition, many currently acceptable trend reports, as in example, those reported by Matheney and colleagues,⁵⁸ indicate that the American public is a more informed public via the proliferation of mass media-transmitted information on health matters. For the patient with Parkinson's disease who most recently has become a subject of many popular magazine, newspaper, and television outputs, the investigator also questions the suggestibility effect, if any exists, of the availability of these types of information to this patient. Not only the factor of suggestibility is in question here but whether or not the patient with Parkinson's disease is actually collecting mass media information about his disease and if so, from what source, how much of the data does he seem to comprehend, and of what use is he making the material? To the investigator, these seem to be some of the crucial issues to the exploratory study about to be presented.

This brief discussion of relevant literature has established certain background correlates to this explorative attempt to describe the sampled patients with Parkinson's disease. The investigator wishes to reemphasize that these correlates were chosen in the hope that they might be useful in understanding and interpreting the data sample.

⁵⁸Ruth V. Matheney and others, Fundamentals of Patient-Centered Nursing (St. Louis: C. V. Mosby Company, 1964), pp. 15-24.

Chapter 3

METHODOLOGY

As was outlined in Chapter 1 briefly, the research approach to this study consisted of an exploratory, descriptive attempt to create a more broadened picture of the patient with Parkinson's disease. The study was begun with a limited pilot investigation in which the author employed a rather loosely structured, open-ended interview technique with a limited sample. Out of this experience was devised the interview tool for this investigation. Revisions of the original tool were comparatively few; only certain questions regarding certain biographical material were added, plus a more structured criteria and questions were devised to test for degree of patient knowledge of l-Dopa.

Data Gathering

The initial and possibly the most difficult aspect of the study consisted of actually locating patients with Parkinson's disease taking the relatively newly marketed drug, l-Dopa, and their interview collaborators. This search, in addition to the subsequent contact phase through mail and telephone, led the investigator to many varied locations--convalescent homes, private homes, hospitals, clinics, physicians' offices, and, in one instance, the local golf course. Some of these locations were visited to locate names and

addresses of the patient sample, some to gain permission from their attending physicians to interview the sample patients, and some to interview the patients in their residential environments. The only specification for selection for the study was that the individual had to have a medically diagnosed case of Parkinson's disease and be currently taking the medication, l-Dopa. A family member or an individual closely associated with the patient's care (or interview collaborator) had to be present during the interview or be contactable by the investigator. The use of the interview collaborator by the investigator was designed to test and/or verify the data obtained in the interview. No attempts were made to control for age, length of disease, length of drug usage, drug dosage, or any other variables with the exception of the single one aforementioned.

Once the location of a prospective patient with Parkinson's disease was obtained, a letter (presented in Appendix A), was dispatched to the individual regarding the purpose of the interview and an attempt was made to elicit a possible time for the interview which, ideally, would also be convenient for the interview collaborator. The investigator followed the letter to the patient with a pre-arranged telephone call. The interview date and time was usually decided upon at this point. If permission was granted by the patient for interview, the investigator also requested the name of the patient's physician for his permission to conduct the study. This physician

contact was in all cases obtained, with permission granted, prior to the investigator-patient interview.

Seventeen patients and interview collaborators meeting the criteria of the study were selected for interview during a five month period, extending from January through May, 1970. Eight other patients interviewed during this period were found not to be suitable for the study, due to several reasons: 1) The lack of the necessary communication skills for interview--as a probable result of the disease's symptomatology; 2) the absence of sufficient information from patient or family member to construct a factual case history; and 3) verified or indicated conditions of senility of patients. These three problems served to severely limit the sample size. Thus, the criteria for selection of patient sample became not one of random selection as the investigator had originally planned, but one of primarily the availability of the patient for interview, and secondarily, the suitability of the patient for interview. As was noted under the limiting factors of this study, both the relatively small sample number and the obvious bias for patients able to communicate effectively were problems not overcome in this investigation. The problems undoubtedly grew out of this selection process, in the investigator's considered opinion.

All of the interviewed individuals resided in Montana in communities ranging in population from approximately 200 to over 50,000 persons. As was previously noted, the sampled patients were

characterized by varied living arrangements, including convalescent homes, hospitals, and privately owned homes.

The purpose of the interview was presented to the patient and his family member as a research project connected with the investigator's university study program that was oriented toward discovering how patients with Parkinson's disease in Montana were faring after taking the newly discovered drug, l-Dopa. The interview tool had two portions: 1) questions designed to elicit biographical information and factual knowledge from the patient and his interview collaborator; and 2) questions designed to elicit feelings and attitudes by the patient and his interview collaborator. The interview tool's questions were designed to gradually promote increasingly unstructured dialogue from the patient and/or his interview collaborator. Examples of information which the sampled population was called upon to recall were: (the patient's) background medical history, including the events, experiences, and emotional reactions surrounding the onset of the Parkinson's disease, several other biographical and socio-economic variables, perceived areas of improvement and/or areas of difficulty after taking l-Dopa, and initial source of knowledge about both the disease and the drug. The investigator criteria for determination of the degree of patient knowledge is described under the definition of terms in Chapter 1 of this study, utilizing the terms, "little or no", "moderate", and "high" degree of knowledge, describing the success of the patient in answering

specific questions about l-Dopa. As for the Roche Laboratory Charts,⁵⁹ these were originally designed for physician use in the analytical evaluation of a patient taking l-Dopa from visit to visit. In this study, the investigator chose the charts for a slightly different purpose. That is, they were utilized for each individual patient's evaluation of his own progress since taking l-Dopa. In initiating this particular portion of the interview, the patient was told to attempt to picture himself both in the past and in the present. In considering the past, or the "before" aspect, the patient was encouraged to evaluate himself at the time when he considered his symptoms to be the most marked (or his "worst" time). In considering the present, the patient was encouraged to evaluate himself as he felt at the time of the interview.

There are three categories in the Roche Charts: 1) the "Symptoms" category, 2) the "Activity" category, and 3) the "Side Effects" category. In the "Symptoms" category, the first column marked "Evaluation (0-4)"--is for assessing the extent to which the patient's symptoms are present. This column is used to rate the

⁵⁹Patient Response Charts for Evaluation of Patient Progress Prepared in collaboration with the Department of Neurology, The New York Hospital, Cornell Medical Center (courtesy of Fletcher McDowell, M.D.; John E. Lee, M.D.; Thomas Swift, M.D.; Richard D. Sweet, M.D.; James S. Obsbury, M.D.; and Jeffrey T. Kewslar, M.D.--adapted from the authors' published article in Annals of Internal Medicine, 72:29, 1970) Distributed by Roche Laboratories, Division of Hoffman LaRoche, Inc., Nutley, New Jersey 07110.

severity degree of symptomatology as follows: 0=absent, 1=mild, 2=moderate, 3=marked, and 4=impossible to do or test. The terminology was explained in simpler terms than on the original chart. In the second column, "Weighted Value" appears at the head, which signifies that each symptom has already been assigned a numerical value based on the individual symptom's relative importance as an incapacitating factor. To achieve the patient's score, for each symptom, the "Evaluation" figure is multiplied by the established "Weighted Value" number. This total is then entered in the "Patient Score" or the third column. Under the "Activity" heading, the same procedure as with the "Symptoms" category is followed. The "Weighted Value" in this case is used to indicate the degree of impairment of everyday functions. The patient in this study is asked to use the "Symptom" and "Activity" categories twice, describing the degree of impairment both before and after taking l-Dopa. A percentage of improvement (or improvement ratio) is then calculated from combining the "before" and "after" scores of each category.

The third category, or the "Side Effects" portion, is provided to list the degree of known untoward drug reactions occurring to each patient as well as additional idiosyncrasies specific to each patient. The patient is requested to evaluate each side effect only as "absent", "present", or "marked". (An example of the Roche Chart, utilizing data collected for case #1, is provided in Appendix F.)

During the interview, the investigator sought to speak directly to the patient in most cases, attempting to elicit his comments to the questions initially. The interview collaborator's role was identified to him or her as "an aid to the memory of the patient" and this individual was encouraged to interrupt or add to the patient's comments as the interview progressed. At the conclusion of the interview, the patients and interview collaborators were also encouraged to supply any additional information not dealt with previously and/or ask any questions which would seem relevant to the study.

The investigator, with the permission of the patient, utilized brief notations during the interviews to record significant data. It was the investigator's considered opinion that the use of the tape recorder during the interview might have served to stifle the spontaneity of the subjects' comments to a certain extent. Thus, the investigator felt it necessary to utilize the slightly less reliable recording method of note-taking. Directly following the interview, the investigator rewrote the interview events, from memory, into a process recording form in an effort to reproduce the events occurring as accurately as possible. In addition, the investigator recorded her own personal impressions elicited from the interview of the patient, plus any other relevant observations which might prove beneficial to later data analysis.

Chapter 4

PRESENTATION OF DATA

The data collected for this study shall be presented in two forms: 1) modified case studies consisting of summarized data derived from the patient-interview-collaborator interviews, accompanied by descriptive impressions by the investigator of other pertinent data, and, 2) comparative characteristics of the total investigated sample, presented in either verbal or numerical form, depending upon applicability.

Seventeen individuals, each accompanied by an interview collaborator, were interviewed by this investigator. Each patient had a medically diagnosed case of Parkinson's disease and was taking the newly-developed medication, l-Dopa, at the time of the interview.

Modified Case Studies

CASE #1

This 75 year old Caucasian male was interviewed in his home with his wife present. He had retired from the vice-presidency of a large farm implement company after having been employed with them for forty years. This patient had attended one year of a business school, while his wife had continued her education no further than high school. The couple resided alone, reporting thirty years at their present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 69, while he and his wife were traveling in Minnesota on vacation. His right hand "became difficult to control and grasping objects became virtually impossible." The couple traveled immediately to a physician in Minneapolis who subsequently referred the patient to the

Mayo Clinic in Rochester. There, the patient was diagnosed as having a questionable case of "Wilson's Disease." Two months later during which the patient reports some relief of symptoms, the couple traveled via automobile to Arizona and sought another physician's advice. This physician made the initial diagnosis of Parkinson's disease. During their stay in Arizona, the patient reports undergoing a prostatectomy. His physician, the patient relates, "told him next to nothing" about Parkinson's disease, but the patient's wife "went directly to the public library to inform both herself and her husband" about his condition. Both the patient and his wife report (the patient's) gradually lessening abilities to function outside their home. "About all I do now is visit with my grandchildren and do a bit of gardening," the patient reported.

The patient's wife first read of l-Dopa in a popular magazine. The couple remarked how "excited" they were about the drug's discovery. They traveled to their home-town physician and inquired about the possibility of the patient taking the drug. He consented. The patient reported the physician explaining only that l-Dopa was experimental, that there might be certain side-effects, and not to get his "hopes up regarding recovery from his condition." The rest of what the patient and his wife know of the drug came from magazines, newspapers, and "more trips to the library", they stated. They also regularly associated with another Parkinsonism patient and "swapped information", the wife reported. On the drug eight months at the time of interview, the patient was able to name the drug ("l-Dopa"), give his current dosage ("1500 mg/day"), provide the drug's presumed mode of action ("it replaces a chemical lacking in the brain"), and name six side effects ("vomiting, nausea, loss of appetite, blood pressure problems, shaking, and mental problems"). In addition, the wife produced over ten articles from popular magazines and newspapers as well as literature from the Parkinson Institute in Florida. The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 56% improvement ratio since taking the drug. He reports experiencing anorexia, dyskinesia, some depression, difficulty in reading, diarrhea, and discolored urine--all symptoms of which were attributed to the drug. Despite these difficulties, both the patient and his wife repeatedly expressed their gratitude to the drug for the patient's "many improvements." The wife asked the investigator how she could "overcome her husband's depressions, as "I have to push him every day to go to the physical therapy department for his exercises." They expressed jointly the most concern over the patient's current problems with diarrhea.

Investigator Impressions

This couple seemed quite openly enthusiastic regarding the drug. Both kept interrupting each other in an effort to provide the investigator with the requested information. The patient appeared quite severely involved, with some difficulty in speech, marked walking disability, mask facies, and postural problems.

Despite the obvious availability of mass media material at hand regarding the drug, plus the tested high degree of drug knowledge, this couple frequently asked the investigator for her opinion or for information regarding certain aspects of the drug. Most of these questions appeared to the investigator to be requests for reassurance rather than for actual information. (In example, the wife asked, "Do you think my husband will be able to continue to take the drug with the kinds of problems he is having with it? I hope so.") The investigator attempted to provide answers to these types of questions within the range of her knowledge of the drug and disease, as well as according to the range of her legal functions as a Registered Nurse. This policy applies to this case and to all of the rest of the interviewed cases. This patient was able to refer another Parkinsonism patient to the investigator.

CASE #2

This 70 year old Caucasian male was interviewed in his rented apartment with his wife present. His previous occupations had included being a grocery owner for twenty years, followed by a car dealership managerial position for six years. Both he and his wife completed their educations with high school. The couple resided alone, reporting two years at their present location of a community numbering over 20,000 persons.

The patient recalled the first indication of Parkinsonism at age 64 while he and his wife were traveling in Arizona on vacations. His right leg "began to tremble and made driving impossible." Thus, the couple returned to their home and consulted their family physician. This physician, apparently unable to diagnose the patient's condition, referred him to a consulting neurologist who, in turn, made the diagnosis of Parkinsonism. The patient was placed on Artane and "a tranquilizer" at that time. His physician, the patient relates, told him "nothing" about his condition, but the patient "read about the disease in a medical book and found out that it had to do with the deterioration of muscles." The patient reported that his condition forced him to retire from his car dealership position "when I had a few good years left in me." The couple's son, living in a nearby community and apparently concerned about his father's welfare, urged his parents to move to a location by him. The patient and his wife complied, moving to their apartment near their son's home. "I was very bad then, so I guess it was a good idea", the patient stated, but both he and his wife expressed great regret over their move at the present time. "We were part of a small community there; here, all we know are a few people," the wife stated.

The couple initially heard of l-Dopa through a friend in their original community who provided the patient with an article from a popular magazine regarding the drug. At this point, the drug was not available for public use, but the couple approached their physician in the hope that he might obtain it for them. This physician was unable to meet their request until six months later. "He only said the drug was something new and gave me some literature to read about it," the patient stated. "We've been trying to collect as much information as we can about l-Dopa," the wife contributed, and mentioned another patient (Case #13) in the same community who "provides us with answers to our questions." On l-Dopa a total of 19 months at the time of interview, the patient was able to name the drug ("l-Dopa"), give his current dosage ("2250 mg/day"), and name one side effect ("makes you sick to your stomach"), but was unable to give an explanation for the drug's mode of action. The couple produced three articles from popular

magazines regarding the drug. The patient was evaluated by the investigator as demonstrating a moderate degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating an 87% improvement ratio since taking the drug. He reports experiencing nausea and some dyskinesia upon questioning by the investigator. Both the patient and his wife noted the "surprising improvements" that the patient has made--pointing to his ability to "walk without a cane, turn his head without rigidity, hunt and play golf, whereas he could do none of these before l-Dopa." The wife praised her husband, saying he seemed to have a new "lease on life." This couple was able to refer the investigator to another Parkinsonism patient in the same community (Case #13).

Investigator Impressions

This patient seemed almost totally void of obvious Parkinsonism symptoms, except for a slight mask facies and mild limp. Although the couple seemed extremely pleased about his progress, they were obviously unhappy about their living conditions. The investigator suspects that they will make determined steps to move back to their home community if the move can possibly be made over the son's certain objections. During the interview, most of the couple's questions seemed stimulated by the interview schedule itself. That is, when the investigator was questioning the patient with the list of the most frequent side effects of l-Dopa, he would often give the appropriate answer, then question why, for instance, the drug would cause that problem. The couple seemed to utilize the investigator as an information source, requesting interpretation of material they had read in many instances.

CASE #3

This 63 year old Caucasian female was interviewed in her mobile home, accompanied by her student nurse granddaughter. She was a retired sales clerk, while her deceased husband had been a wheat farmer and apartment house manager. The patient had completed her high school education, while the granddaughter was completing her fourth year of college. This woman resided alone, reporting 27 years at her present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 58 directly following "the time when I fell and fractured my wrist." She reported a rather sudden onset of dysphagia, difficulty in speaking, mild tremor in both hands, and edema of the right leg. Although the physician she contacted reduced the fracture, he did not apparently diagnose the Parkinsonism. One month later, the patient reports she "changed physicians" to one who did make the initial diagnosis of Parkinson's disease. She remembers the doctor telling her that Parkinson's disease "was not curable, but that he would provide medications which would ease the symptoms; also, the disease was not fatal." The patient states that she asked her granddaughter for more information on the condition. As to how Parkinsonism affected her life, the patient replied that "it only added to my problems." She had apparently undergone a gastrojejunostomy for multiple ulcers a year ago and was still suffering from the "dumping syndrome" of nausea and vomiting quite severely. The patient stated, "I can hardly get around now--it's really cut down on my trips outdoors. I mostly just sit now. I don't get many visitors except my family."

The patient first heard of l-Dopa through a letter from a California-resident sister who strongly urged the patient to seek her physician's consent to take the medication. The patient did travel to her physician, who voiced some reluctance to grant her request "because of my stomach problems", but finally agreed to give l-Dopa on a trial basis to her. The patient stated that her doctor did not explain "anything" to her about the drug. Again, she relied upon her granddaughter to collect the necessary information. On l-Dopa a total of 8 months at the time of interview, the patient was able to give the name of the drug ("Levo-dopar is what I'm taking"), give her current dosage ("500 mg 3x/day"), give the drug's presumed mode of action ("we lack a substance in the brain that it replaces"), and name five side effects ("nausea, vomiting, shakiness, heart troubles, and vomiting"). The patient's granddaughter did not aid the patient in this testing area, incidentally. In addition, the patient had in

her possession over 20 articles from magazines, newspapers, professional literature and material from the Parkinson Institute in Florida on her condition. The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 33% improvement ratio since taking the drug. She reports experiencing marked nausea and anorexia, depression, dysuria, and vertigo since taking l-Dopa. This patient is considering asking her doctor if she may cease taking the drug "until she feels better."

Investigator Impressions

Although this patient's granddaughter participated very little in the actual interview, she did seek the investigator for conversation at a later date. She expressed much worry over her grandmother's depressed state and poor motivation, much of which she attributed to her recent widowhood and resultant loneliness. The investigator had noted early in the interview that the patient seemed quite depressed, often close to tears, and very pessimistic regarding her future. Considering this mental state, the investigator made a second visit to the patient principally for supportive reasons. The patient seemed to respond to this approach somewhat, thanking the investigator for listening to her problems. With the patient's permission as well as her physician's, the investigator referred her to the local public health department for further supportive visits on a regular basis by a Registered Nurse.

CASE #4

This 77 year old Caucasian female was interviewed in her son's home, with her daughter-in-law present. She gave her occupation as a "retired housewife" with eight living children. The patient was residing with her son and his family, having recently moved from an East Coast state where she had spent most of her life. The community in which the patient now lives numbers over 55,000 persons in population and she has resided there for a total of three months.

The patient recalled the first indication of Parkinsonism at age 68 following a car accident in which she suffered a "severe whip-lash" injury. Her head "began to shake uncontrollably" even though it was "in a brace." No diagnosis of her illness was made for "five years", during which time the patient reports "hardly ever leaving the house because I couldn't walk, talk, or anything."

Upon moving to Montana, the patient's son, a career officer in the service, "recognized the symptoms of Parkinson's disease and sent the patient to his private physician for verification." The physician apparently did verify the son's suspicions at that time, explaining "this was a disease, a shakiness that a lot of old people get." The daughter-in-law commented that her husband went to the local library for information on the disease and there, located also, material on the discovery and use of l-Dopa in a popular magazine.

The son telephoned the patient's physician and requested the patient be allowed to try l-Dopa; he consented. The physician reportedly told the patient that she "might have nausea by taking the drug, that he would gradually increase the drug dosage", and that she "should eat with the drug." The patient stated that she had read one magazine article about the drug, but that her son had "researched a lot of information about l-Dopa." On the drug for three months at the time of interview, the patient was able to name the drug ("l-Dopa"), and give her current dosage by reading the prescription label ("250 mg 4x/day"), but could not provide the drug's presumed mode of action nor any other side effects except "nausea--because my doctor told me to expect that." The daughter-in-law produced over 15 articles from popular magazines and newspapers as well as professional literature that her husband had collected but that the patient "hadn't read them yet." The patient was evaluated by the investigator as demonstrating a little degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 38%

improvement ratio since taking the drug. She reports experiencing some depression, dyskinesia, and a dry mouth since taking the drug, but "I think it's helped me somewhat" the patient stated, "and I hope I'll continue to get better."

Investigator Impressions

The daughter-in-law, in this instance, provided most of the substance of this interview. She stated that the patient had been a "virtual recluse" for many years before coming to live with them. Now, she had been persuaded to "go to church and tolerate much more activity" since taking the drug. The investigator sensed during the interview that the patient was perhaps a great deal less impressed with her progress than was the rest of the family. In example, during the Roche Progress Chart evaluation, the daughter-in-law persistently interrupted the patient to give her higher ratings than the patient gave herself on improvement gains. The daughter-in-law also indicated that the patient "had been reluctant to advance her activities outside the house, but we persuaded her to do so because we think it's good for her."

This interview session was also unique because of the fact that after initial telephone contact was established, the daughter-in-law initially refused the investigator permission to interview the patient. Once the goal of the interview was more fully explained, the daughter-in-law and the patient granted the necessary permission and both were extremely hospitable when interviewed.

CASE #5

This 74 year old Caucasian female was interviewed in a retirement home with her husband present. She was a retired elementary teacher with two years of college completed, while her husband was a retired insurance agent and accountant with four years of college completed. The patient had been a resident of the retirement home for two years, while her husband maintained separate residence at the couples' home in the same community, numbering over 13,000 persons. They reported living in the community over 50 years.

The patient recalled the first indication of Parkinsonism at age 63 while the couple was on a vacation tour of South America. The patient reports a "gradually increasing tremor of both hands" as her initial symptom. The couple did not seek a physician until four months later when a gradual development of symptoms "began to interfere in the patient's ability to do housework." The patient's husband flew her to the Mayo Clinic in Rochester, Minnesota where the tentative diagnosis of Parkinson's disease was made. "They told us nothing about it", the patient stated. After this, the husband recalled that he "spent a lot of time in the library looking things up about Parkinson's disease. The patient stated that all of her "outside activities had been curtailed" as her condition worsened.

The couple were first informed about l-Dopa through a letter from a friend who enclosed a popular magazine article dealing with the drug. At this point, the drug was not available for public use. However, the patient's husband reports that he wrote to one of the state's influential Senators in Washington, encouraging him to "urge the Federal Drug Administration to release the drug from its experimental trappings." Because of his efforts, the husband contends that "several of the state's physicians were able to obtain l-Dopa a lot earlier than most." When the drug became available, the patient's husband reported that he contacted their physician to urge him to obtain the drug, "which he did do." The patient reported that the physician "explained everything that he knew about the drug, including side effects, how it worked, and the dosages he would be starting me on." She went on further to say that her physician had "played down her hopes, telling her not to become too optimistic." Since this time, the couple managed to collect "a huge amount of information on the disease and drug from our friends and from reading about it." On the drug 21 months at the time of interview, the patient was able to name, with some assistance from her husband, the drug ("l-Dopa"), give her current dosage ("5000 mg/day"), provide the drug's presumed mode of action ("we seem to lack a chemical controlling the muscles at the base of the brain--called dopamine--and

l-Dopa replaces dopamine"), and name six side effects ("nausea, vomiting, blurring of vision, depression, blood problems, lack of appetite"). The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 75% improvement ratio, since taking the drug. She reports experiencing nausea, anorexia, flushing, dyskinesia, depression, a "rash" and blurring of vision, all symptoms of which are attributed to the drug. The patient's husband told the investigator that the patient "may get to go home pretty soon" and "it's almost impossible to tell you how much she has improved these past few months."

Investigator Impressions

This particular patient is especially unique in that the investigator had participated in her nursing care prior to the time of her beginning l-Dopa. In fact, the patient sparked the investigator's initial interest in this study. In the investigator's opinion, this patient was, indeed, severely involved with her Parkinsonism and, in fact, an invalid--unable to care for even her basic needs. To observe her ambulating and speaking clearly again was a pleasant surprise for the investigator and a type of verification of her and her husband's testimony of improvements made.

Also, the investigator had an opportunity to discuss this patient with a Registered Nurse in charge of her care. She tended to reiterate on the patient's progress since taking the drug. However, interestingly enough, the nurse told of a period of time when the patient developed a severe, "near psychotic" episode of withdrawal serious enough to require a series of "electric shock treatments." This occurred approximately one year after drug treatment was initiated, according to the nurse, and "symptoms ceased after the shock treatments." The nurse hypothesized that the "patient probably has no memory of the incident and the husband perhaps didn't want to remind her of it." No mention of any such hospitalization had been made to the investigator. On all other points, the nurse verified the information provided by the couple.

CASE #6

This 77 year old Caucasian male was interviewed in a retirement home with his wife present. He was a retired owner of an insurance firm with four years of college completed, while his wife had completed four years of a "liberal arts" college curriculum. The couple had been residents of the retirement home for one year, having resided in the community of over 13,000 persons for over 50 years.

The patient recalled the first indication of Parkinsonism at age 71, "when I was thinking about retiring anyway", during a luncheon speaking engagement in California. The patient reports that his "knees buckled" and that upon falling, he was unable to rise again. Prior to this occurrence, he had been "feeling generally tired with many headaches." The couple traveled immediately to a physician who made the initial diagnosis of Parkinson's disease. The patient reports the physician explaining little about the condition except that "it might not get any worse than it is right now." The wife explained, "after that diagnosis, my husband just continued to get worse, until he was practically an invalid. That was why we decided to move to this retirement home so that he could get the care he needed." The wife explained that she had gone to the library to "obtain information" on her husband's condition at his request.

The patient reports receiving the initial news of l-Dopa's discovery through his local physician who mailed him some professional literature on the subject. From that point on, the couple wrote to the Parkinson's Institute in Florida for further information, but were told that the "drug wasn't available for general use yet." The wife told of "waiting patiently until the FDA released the drug", then requesting their physician to obtain l-Dopa for the patient. The patient indicated that he had quite a close relationship with his physician and that the physician "was anxious to try the drug out on him." The patient reported that the physician explained "quite completely information about the drug in language we could understand." On the drug 19 months at the time of interview, the patient, with the aid of his wife, was able to name the drug ("l-Dopa"), give his current dosage ("3500 mg all together"). In addition, the wife produced an entire file cabinet full of literature about Parkinson's disease and l-Dopa "collected from anyone or any magazine we can get out hands on." The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge. Incidentally, Cases #5, 6, and 7 all resided in the same retirement home and "have frequent conversations together", according to this patient's wife.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 29% improvement ratio since taking the drug. He reports experiencing nausea, anorexia, flushing, some depression and other "changes of mood", heart problems and some hypotension. Despite these problems, the wife felt that the patient should continue with the drug. The patient appeared to feel somewhat differently, stating "I don't know if it's all worth it."

Investigator Impressions

This patient appeared quite severely involved, deferring to his wife to answer many questions for him when "he couldn't find the right words." The interview lasted over two hours, with the wife often directly contradicting her husband's rather disparaging words for his progress. The patient appeared quite depressed, stating at one point to his wife, "I'll never get out of this wheelchair, so we might as well forget all of this" and the wife responding, "but you've come such a long way already." The investigator suspected some organic brain damage (?senility) on the patient's part, as he many times during the interview tended to become vague or change subjects "midstream" in a conversation. However, the wife seemed to be functioning at a normal level, so much of the interview was documented through her.

The investigator had the opportunity to discuss this patient with the Registered Nurse in charge of the patient's case. She tended to verify most of the patient's history, indicating that his physician suspected some senile reactions unrelated to the administration of l-Dopa. She also stated that the patient's motivation seemed to be sporadic and that his improvement since taking the drug had been comparatively mild.

CASE #7

This 72 year old Caucasian male was interviewed in a retirement home with a Registered Nurse in charge of his present care. He was a retired lawyer with six years of college completed. The patient was a widower with no contactable relatives; thus, the interview consultant in this case, the Registered Nurse, had completed three additional years of education past high school. This patient had been a resident of the retirement home for one year, previously carrying on a law practice in California for the past thirty years. The retirement home in which the patient currently resides is located in a community numbering over 13,000 persons.

The patient recalled the first indication of Parkinsonism at age 67 when he began to have "pain in his left leg when bending over." He consulted a doctor "immediately" and was placed in a hospital for observation. There, a diagnosis of Parkinson's disease was made. The patient reports the physician explaining little about the condition. Thus, when the patient was released from the hospital, he relates that he went to the public library for information on his condition. After reading the necessary material, the patient concluded that his affliction was "mild, but likely to get worse." "I was just about to retire anyway", the patient stated, "so the fact that I had Parkinson's disease just forced the issue."

The patient reports receiving the initial news of l-Dopa through articles sent to him by friends in California. Interested, he sought out a group of physicians in Salt Lake City "who were authorized to prescribe it" and requested that he be allowed to return to Montana on a relatively "small dosage" of the drug. The patient reported that, again, the physician explained "very little" about l-Dopa, only that he had a "good chance to respond favorably to it as his disease was not as severe as some." On the drug 5 months at the time of interview, the patient, without aid of the nurse, was able to name the drug ("l-Dopa" or "LevoDopar"), give his current dosage ("1000 mg/day"), provide the drug's presumed mode of action ("it supposedly replaces an enzyme in the brain called Dopamine"), and could name eight known side effects ("nausea, vomiting, hypotension, blood dyscrasias, mental changes, lack of appetite, heart trouble, and shakiness"). The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 49% improvement ratio since taking the drug. He reports experiencing no

side effects from the drug, whereas the nurse present stated she had noted that the patient seemed "flushed" on occasion. The patient reported having "withdrawal" problems from being on Artane "for so long", naming depression as his main problem. The patient at this point voiced his optimism that l-Dopa would "block" the progress of his disease since "they caught it so early."

Investigator Impressions

This patient appeared quite mildly involved to observation. The investigator noted only a slight tremor of the hands as a possible indication of Parkinsonism. The nurse verified this observation, also stating that this patient spent a great deal of his time "reading about his condition and often seemed more knowledgeable about current advances in Parkinsonism than even they, "the health professionals." The investigator had noted this patient's rather sophisticated Parkinsonism vocabulary. At the time of interview, the nurse commented, this patient was having a difficult time with "Artane withdrawal symptoms", some of which she suspected were more "psychological than physiological." She felt that this problem was probably interfering somewhat in the patient's progress, as far as mental attitude was concerned.

CASE #8

This 79 year old Caucasian female was interviewed in a convalescent hospital setting with her daughter-in-law present. She was a retired elementary teacher with two years of college, while her deceased husband was a former high school teacher. The daughter-in-law had completed high school. The patient has resided in the hospital for 3 months, having lived in a retirement home previous to that time for the past five years. The community in which she lives numbers 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 68 when her son, a physician, noted her marked hand tremor during a visit one day. Since then, the patient reported a "gradual increase of tremor in both extremities, difficulty in walking, and problems with speech", all of which forced her to move from the self-sufficient living circumstance to the present convalescent setting. Her son referred her immediately to a fellow physician who confirmed her son's suspicions of Parkinsonism. The patient recalled that "her son had told her all about the disease," but all she could remember of what he said was that "it was a condition old people get."

The patient recalled first hearing of l-Dopa when her son suggested to her physician that he prescribe the drug for the patient, which he did after some extensive "tests." The patient stated that her doctor had told her "that he was going to try out a new drug on her" and that her son "had told her about it, too." On l-Dopa three months at the time of interview, the patient was unable to give any of the requested information about the drug, stating she "couldn't remember all of what everyone had told her." Her daughter-in-law stated that "she didn't know much about the drug either, but had the information available at home from her husband." The patient was evaluated by the investigator as having no knowledge of the drug. From a Registered Nurse in charge of the patient's care, the investigator learned that the patient was taking 4500 mg/day of l-Dopa.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself and her daughter-in-law as demonstrating a 56% improvement ratio since taking the drug. She reports experiencing some nausea, depression, and edema of the right leg. The patient spoke at length during the interview of "trying to get well enough to move back to her former residence", but "didn't notice as much improvement in herself as everyone else seemed to."

Investigator Impressions

This patient expressed much dissatisfaction with her present hospital stay, apparently rejecting the patient role to a great extent. She stated, often during the interview, that "they put me here. I didn't want to come, but they said I had to." Her daughter-in-law sat quietly throughout most of the interview, but told the investigator privately that her mother-in-law "was very bitter about having Parkinson's disease and her loss of independence as a result of the condition." She "blamed us, (the daughter-in-law and son) for placing her at the convalescent hospital", the daughter-in-law stated, "but she wasn't able to care for herself any longer at her retirement apartment."

The Registered Nurse in charge of the patient's care tended to verify the daughter-in-law's conclusions. The Registered Nurse stated "that there were times when the patient spoke to no one for days at a time" and "actively resented anyone attempting to help her with her needs." The Registered Nurse indicated that the hospital's physical therapist was formulating plans to help the patient increase her physical capacities and that she and her staff were attempting to "find some way to get through to the patient."

CASE #9

This 78 year old Caucasian female was interviewed in her apartment with her daughter present. The patient with her now deceased husband, was a co-manager of a wholesale store. Both the patient and her daughter completed their high school educations. The patient resided alone, reporting having lived in the community of over 55,000 persons for 49 years.

The patient recalled the first indication of Parkinsonism at age 76 when she began to experience "gradual lameness over her whole body, with marked tremor in her right arm." As her condition worsened, the patient sought the advice of her physician after being urged to do so by her son-in-law and daughter. The physician whom she initially saw told her "it was just something a lot of old people get and not to worry about it." Dissatisfied with this statement and "suffering from worse symptoms", the patient consulted a second physician who made the diagnosis of Parkinsonism. The patient reports that the physician told her "absolutely nothing" about Parkinson's disease, but that her son-in-law "looked some things up about it" for her. Placed on Pheno-barbital by her physician, the patient commented, "I just tried to put everything out of my mind and forget that I ever had Parkinson's disease." "I really cut down on my outside activities, however", the patient stated.

The patient first heard of l-Dopa through her physician who "suggested I try out this new drug for Parkinson's disease." The physician told her "nothing" about the drug except that it was "experimental and the effects varied with each patient." The patient stated that her daughter-in-law, plus another friend who also had Parkinsonism and was taking l-Dopa, "provided her with a lot of information." On the drug 6 months at the time of interview, the patient was able to name the drug ("l-Dopa"), give her current dosage ("2000 mg daily), and two side effects ("nausea, and it gives you a low tolerance for coffee"). Her friend with the Parkinson's disease reportedly told her the latter side effect. The patient was unable to give the mode of action of the drug. The patient was evaluated by the investigator as having a moderate degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 75% improvement ratio since taking the drug. She reports experiencing nausea, a lack of appetite, and a low tolerance for coffee since taking the drug. She commented that she "thinks l-Dopa is awfully strong and unpredictable", but that she "is willing to take the risk since she

feels she is "definitely getting a lot better."

Investigator Observations

The patient talked the majority of the time in this particular interview, but her daughter did state that there had been "much improvement" in her mother since taking l-Dopa. The patient expressed much pride during the interview of "being independent", indicating that if she were to suffer furthering disability she'd "rather die." It was difficult for the investigator to detect that this patient even had Parkinson's disease. Except for a slight limp and moderate tremor in her right hand, she manifested no obvious symptoms.

She was able to refer the investigator to two of her "friends" in the community who also had Parkinson's disease and were taking l-Dopa.

CASE #10

This 84 year old Caucasian female was interviewed in a general hospital where she was a patient with her husband present. She was a retired nursery school teacher, while her husband still engaged in a "small ranching operation." Both of the couple report a high school education. They reside alone in a small country community of approximately 200 persons.

The patient recalled the first indication of Parkinsonism at age 81 following a fall in which she fractured her wrist. She states that she was "unable to do as much around the house because of a constant hand tremor and a slight limp." The patient was currently in the hospital after fracturing her distal right femur and hip. She was completing her eighth month in the hospital at the time of interview. It was during this hospital stay that a definitive diagnosis of Parkinsonism was made. "Before that, I just didn't have anything done about my shakiness because I didn't think it was that serious." the patient stated. The patient reports that her physician told her that her disease could keep her a "cripple" if she "didn't keep active." No further information on Parkinsonism was evidently sought by the patient. The patient had been taking a total dosage of 3000 mg daily at the time of interview, according to the Registered Nurse in charge of her care. The patient was acquainted with l-Dopa through her hospital physician who said he was going to try out "a new drug to stop her shakiness." "That was all he told me", the patient said, "but I do know that it makes me nauseated and belch all of the time." Neither the husband or the patient were able to give the investigator any information about l-Dopa. The investigator was told to "ask the nurse about those things" by the patient. The patient had been taking the drug 5 months at the time of the interview. She was evaluated by the investigator as demonstrating no drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 34% improvement ratio since taking the drug. She reports experiencing nausea, lack of appetite, and some depression since taking the drug.

Investigator Observations

This patient proved quite difficult to interview. She cried through most of the questioning, obviously very discouraged over her long hospital stay. Commenting that the Parkinsonism "only added to her problems", the patient seemed more anxious to talk of her hip and

leg disabilities than the Parkinson's disease. Her husband participated very little in the interview, but appeared quite uncomfortable with his wife's crying. He later apologetically told the investigator that "she just sometimes gets this way." The investigator attempted some supportive verbal nursing care, including comfort measures, while she spoke with the patient. This approach seemed to meet some of the patient's needs, as she thanked the investigator for "taking her time to listen to an old lady."

Following the interview, the investigator sought out the Registered Nurse on the nursing unit for further information on the patient. The nurse commented that the patient is "usually quite motivated, but lately has begun to think she will never be discharged." The staff had noted a "fair improvement of her tremor", the most obvious sign of Parkinsonism that the investigator noted, since taking the drug. The investigator requested permission of both the patient and the nurse to visit the patient again. With permission granted, the investigator visited the patient two more times. Most of these sessions were spent in helping the patient verbalize her fears of disability, death, and generalized depression about her current state of affairs. The investigator noted a definite change of mood at the conclusion of the second visit. The patient seemed to have developed a somewhat more positive attitude about her condition. She was scheduled for ambulation for the first time the next day. The investigator was informed that the patient tolerated the activity quite well.

CASE #11

This 67 year old Caucasian female was interviewed in her trailer home with her husband present. She was a retired restaurant cashier while her husband was a retired car mechanic. Both report completing their high school educations. The couple reside alone, reporting 40 years at their present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 65 when she was hospitalized for an apparent gastrointestinal "upset." The diagnosis of Parkinsonism was made "by accident" during her recovery period at the hospital. Before this, the patient had noted that her "hands shook a lot" and that it was "becoming difficult to do housework." The patient reports that her physician told her that "Parkinson's disease was disabling and hard to get rid of." The patient commented that she had not "heard of this disease" and after consulting a friend "who knew something about it", she concluded that "a nerve in her head wasn't working right." The patient stated that she "didn't know where to look for more information" on Parkinsonism.

The patient was first informed of the advent of l-Dopa through her doctor who suggested she try taking the drug. The patient reports that her physician did not tell her anything about the drug, but "gave her some pamphlets" about it to read. She stated that she "had not gotten around to reading the pamphlets, but if (the investigator) wanted to know anything, she would try to find them." On the drug three months at the time of interview, the patient was able to give the drug's name ("l-Dopa"), but was unable to give further information about the medication except that "it helps the nerve in the head get well and increases one's sexual desire." The patient was evaluated by the investigator as demonstrating little drug knowledge. The patient's prescription label on her l-Dopa capsule bottle read 250 mg 4x/day, or 1000 mg daily.

Investigator Observations

This patient's husband had very little information to contribute, but suggested that the Parkinsonism his wife had "wasn't her only problem." With that suggestion, the patient launched into a wide variety of ailments and conditions she had suffered in the past. To the investigator, the patient seemed somewhat depressed and hypochondriacal. She spoke of having "called the public health nurse to come over one time when she was feeling low", but that she "had to tell

her that it was something very serious in order to get the nurse to come over." In addition, the patient offered many rather unsophisticated explanations for her "heart troubles"--("I have a short circuit in a vein"), as well as the information she provided for her Parkinsonism regarding the "nerve" trouble. The patient appeared to need someone to listen to her as she made it extremely difficult for the investigator to leave her home at the conclusion of the interview. The patient requested "please stay, I have a lot of things to tell you about myself" and "may I have your phone number in case I have anything go wrong with my heart or that nerve in my head?" The investigator felt that this patient's problems might need long-term and perhaps, mental health aid principally because of the sometimes bizarre content of the woman's many complaints. The investigator did contact the public health department and was told by the nurse in charge that this particular patient "had had many contacts with a local psychiatrist for hypochondriasis" as well as was a frequent caller on their department. The nurse suggested that further follow-up by their department might be instituted to determine the patient's need for continuing mental treatment. To protect the investigator from "knotty entanglements" with this patient ("she's likely to call you long distance with reversed charges"), the nurse strongly suggested that the investigator "close this case." The investigator followed her suggestion.

CASE #12

This 68 year old Caucasian female was interviewed in her home with her husband present. She was a retired accountant while her husband was presently engaged as a creamery operator. The patient attended two years of business college, while her husband completed his high school education. The couple resided alone, reporting fifty-five years at their present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 65 when she "began to suffer a severe limp", having to quit her job as accountant for her husband's business. She contacted her physician "immediately" and he referred her to the Minnesota Mayo Clinic for further evaluation. By this time, the patient reports, "her legs were becoming more and more swollen and she could hardly walk." At the Mayo Clinic, they were "unable to find out what was wrong" with the patient. Finally, the patient reports, a diagnosis of Parkinson's disease was made in a nearby medical center. The patient reports that her physician told her "nothing" about her Parkinson's disease, but that she and her husband "looked up" the disease in her medical books at home. The patient gave the investigator the exact sequence of the disease's progression at this point--("first, most people have a hand tremor,").

The couple were first informed about l-Dopa through their daughter-in-law in another state who sent them some popular magazine information on the drug. From then on, the patient reports, "we picked up anything we could find on the subject." They report suggesting to their physician that the patient be allowed to take the drug. With his consent, the patient stated that "he only told us that the drug was experimental and that we'd just have to wait and see if it did any good." On the drug fourteen months at the time of interview, the patient was able to name the drug ("Levo-Dopar or l-Dopa"), give her current dosage ("4000 mg daily"), provide the drug's presumed mode of action ("it replaces dopamine in the brain"), and name five side effects ("loss of appetite, nausea, heart troubles, lowers the blood pressure, and shaking"). In addition, the husband produced a manila folder with numerous professional and popular media articles concerning the drug. The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 67% improvement ratio since taking the drug. She reports experiencing

some loss of appetite, excess belching and further edema of the legs since taking the drug. The husband referred the investigator to two other Parkinsonism patients "who we talk to once in awhile when either of us has problems with the Parkinson's disease."

Investigator Observations

This couple seemed quite satisfied with the patient's recovery since taking l-Dopa, with many hopes for the future that she would "get even better." The patient reports that she has been doing "bookkeeping in her home for the first time since she became ill" and "feels almost normal" now. To the investigator, this patient seemed quite independent and somewhat resentful about "almost becoming an invalid" so that she was thinking about "going to one of those awful rest homes." At this point in time, however, she seemed to be becoming "more optimistic about a full recovery." She did report a hospitalization two months ago with what she feared was a "reaction from the l-Dopa", but turned out to be "just the flu." The patient indicated that she felt some fear of the "side effects" of l-Dopa because of her "high dosage" and "it was such a powerful drug."

CASE #13

This 56 year old Caucasian male was interviewed in his private home with his wife present. He is currently the owner and operator of a sign company and several apartment houses, besides being politically involved in his community as well. Both he and his wife are high school graduates. The couple reside alone, reporting fifteen years at their present location of a community numbering over 20,000 persons.

The patient recalled the first indication of Parkinsonism at age 51 while he was at an out-of-state football game with his cousin, an orthopedic surgeon. This doctor noted that the patient's "left arm was trembling", suggesting that the patient either had "Parkinson's disease or a brain tumor." The patient stated that he just "put his symptoms off to the excitement of the game at that time." When the tremor became worse, the patient reports that he consulted with a neurosurgeon in Chicago who "wanted to operate on my brain." The patient states that during this time "he looked in the library for everything he could find on Parkinson's disease." Returning to Chicago for a second time with a "bad tremor now in both hands", the patient was given a definitive diagnosis of Parkinsonism. From this point, the patient was referred to Dr. George Cotzias, the prominent developer of l-Dopa in New York, for an interview. This physician gave him a "detailed description of where they were at with the experiments with l-Dopa." The patient was then sent to Washington, D. C. and received the then first experimental dosages of l-Dopa for a month. The patient reports that his condition has not effected his work abilities "at all" except that he feels more "nervous and takes tranquilizers."

On the drug 18 months at the time of interview, the patient was able to name the drug ("l-Dopa"), give his current dosage ("5000 mg daily"), provide the drug's presumed mode of action ("the drug is supposedly a replacement for dopamine, a muscle enzyme, in the brain, but they're not certain about that"), and name seven side effects ("nausea, vomiting, blood changes, blood pressure changes, loss of appetite, movements in the arms, and some people flush"). In addition, the patient was able to produce an entire file box of information on the drug, including some of Dr. Cotzias' more recent professional articles. The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 59% improvement ratio since taking the drug. He reports experiencing only one side effect, that of "becoming violently ill if he drinks even a

small amount of alcohol" since taking the drug. The patient did not see this problem as presenting any difficulty in his life.

Investigator Impressions

This patient appeared highly tense throughout the interview. His wife, who participated very little in the conversation, indicated that if she could get her husband to "calm down", she would be "very happy." She stated that "he's always been nervous, but not this bad until he found out he had Parkinson's disease." The patient appeared to the investigator to be highly fearful of losing his abilities to carry on a rather "large amount of business responsibilities" because of the Parkinsonism. "I know what this stuff (Parkinsonism) can do to a person", the patient stated, pointing to the possibility of his becoming disabled. The patient commented that he has "always had a high tolerance for any kind of drug", when the investigator pointed out that his dosage of l-Dopa was quite high. The patient stated that he takes "Librium 25-50 mg 4x/day and sometimes oftener" with little effect.

As a small point of interest, at the conclusion of this interview, the patient was called from his company regarding an injured employee. The patient asked the investigator to accompany him to his company office, where we found a man who had "fainted" on the job. The patient took the man to the hospital at the advice of the investigator.

CASE #14

This 70 year old Caucasian male was interviewed at the local club house at a golf course with his wife present. He was a retired farmer and active in a local farmers' organization, while his wife listed her occupation as "retired housewife." The patient reports completing the 11th grade, while his wife finished high school. The couple resided alone, reporting fifty-five years at their present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 61 following "a bad case of the flu." His left hand "had poor coordination and severe tremor," while he "found it hard to walk or balance himself." The patient was taken immediately to the hospital where the physician diagnosed his "non-flu symptoms" as Parkinson's disease. The patient reports that his physician told him "nothing" about his condition except that there was "no cure." The patient's wife stated that she wrote several letters to the Parkinson's Foundation to obtain information on the disease. From this source, the couple learned that surgery "sometimes cured Parkinson's disease" and located a physician in New York who did do "brain surgery" on the patient. The patient rather disappointedly stated that he'd had little remission of symptoms since the operation and was quite dissatisfied with the care received in New York, indicating that they "didn't follow-up my case, just sent me home." The patient told the investigator that "nothing was the same when I got Parkinson's disease", indicating that he was a very active man until his condition made him "quit everything."

The patient reports first hearing of l-Dopa through a friend's letter which contained a popular magazine article on the subject. "We were very interested," the patient's wife stated, and looked every place for further information on the drug." The patient stated that "it took a lot of talking to persuade my rather conservative doctor to prescribe the drug for me." His physician, the patient reports, "explained nothing" about the drug, except that he "was reluctant to prescribe it because it was so experimental." On the drug nine months at the time of interview, the patient was able to name the drug ("l-Dopa"), give his current dosage ("1000 mg daily"), provide the drug's presumed mode of action ("it replaces a substance in the brain"), and name five side effects ("nausea, vomiting, low blood pressure, mental illness, and loss of appetite"). In addition, the patient's wife produced a folder of drug articles "which we refer to if any trouble arises." The patient was evaluated by the investigator as demonstrating a high degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 52% improvement ratio since taking the drug. He reports suffering from "insomnia, nausea, some strange movements in his hands and feet, and a recent bowel obstruction treated operatively", all of which he attributed to the drug. The patient was rather "fearful" of continuing with the drug because of his recent surgery and the fact "that the obstruction might happen again." Yet, he felt that perhaps the risk was worth it" as he "felt so much better" since taking l-Dopa.

Investigator Impressions

This patient and his wife were just finishing nine holes of golf when interviewed by the investigator. The only obvious symptomatology of Parkinsonism noted by the investigator of this patient was a rather marked mask facies, slow ambulation, and slight hand tremor. The patient indicated that he had increased his activities "quite a bit" since treatment with l-Dopa and that things "were pretty bad" before this. The patient indicated that he hoped that his physician would not "raise his dosage", as he was "sure something worse" would happen to him. The patient's wife related her pleasure at her husband's improvements and "felt grateful that he was where he was at." The couple commented that they considered at one time further "brain surgery", but that their previous experience had proved very "discouraging" and that they had decided against it. They referred two "friends" with Parkinson's disease to the investigator for possible interview.

CASE #15

This 68 year old Caucasian male was interviewed in the hospital where he was a patient with his son present. He was a retired rancher. Both the patient and his son had completed their high school educations. The patient resided alone in an apartment, reporting 25 years at his present location of a community numbering over 13,000 persons.

The patient recalled the first indication of Parkinsonism at age 67 when his son "noticed how shaky my hands were." The son apparently was familiar with the symptoms of Parkinson's disease and "persuaded" his father to consult a doctor. The patient was reportedly reluctant to see a physician for this problem because he "had seen a lot of old people shake like that." His physician verified the son's diagnosis and told the patient that "it's a condition old people get from a lack of a substance in their brain." "Lots of research is going on now to find a cure", the physician reportedly told the patient.

The patient was first notified of l-Dopa's discovery on the aforementioned visit to his physician. The physician reportedly explained to the patient that he was going to "try out a new drug on him to see if it would stop the shaking and "that it replaces this substance in the brain that is lacking." The patient and son stated neither had had opportunity to read about the drug in any of the mass media. On the drug 5 months at the time of interview, the patient was able to name the drug ("l-Dopa"), give his current dosage (with the aid of the son--"1000 mg daily"), provide the drug's presumed mode of action ("it replaces something in the brain that is lacking"), but could not name any side effects of the drug. The patient was evaluated by the investigator as demonstrating a moderate degree of drug knowledge.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 39% improvement ratio since taking the drug. He could not name any side effects he might have encountered except a "lack of appetite" lately.

Investigator Impressions

This patient was currently in the hospital with urinary retention difficulties. He had a marked mask facies with a moderate hand tremor and ambulatory difficulty. The investigator spoke with a Registered Nurse in charge of his care who commented that the "patient did not seem as concerned about his condition as his son was." Likewise, the

investigator noted that the son provided most of the interview data while the patient frequently stated in contradiction, "oh, I was never that bad off." Whether the patient was denying his condition or actually felt that his condition did not warrant that much concern was never brought to light.

This patient seemed to wish "everything to be left to" his physician, imploring the investigator several times to "ask my doctor" or "my doctor can tell you about that better than I can." As to the use of the l-Dopa, the investigator was not successful in penetrating this patient's attitudes to the extent that any verified negative or positive impression could be obtained.

CASE #16

This 81 year old Caucasian female was interviewed at the hospital where she was a patient with her daughter present. She was a retired elementary school teacher while her husband (now deceased) was a rancher. Both the patient and her daughter had completed their high school educations. The patient resided with her daughter and family, reporting 60 years at her present location of a community numbering over 55,000 persons.

The patient recalled the first indication of Parkinsonism at age 75 while she was a hospital patient. Her physician noted that her "hands were shaking" and told her then that she had Parkinson's disease. The patient told the investigator that her daughter "looked up" the disease in a book at home so as to be prepared to ask her physician questions about it. "I never could remember to ask him those things," the patient stated, "so my daughter did that duty." The daughter reports that the physician "more or less" said "everything that was in the book" that she read about Parkinsonism. The daughter commented that she had to "remind her mother about her condition occasionally." "I went sort of down-hill from then on", the patient stated, "so my daughter decided I couldn't manage myself so I moved in with them."

The patient was currently in the hospital for initiation of l-Dopa treatment and physical therapy for assistance to ambulate. The daughter stated that she had "read about this new drug for Parkinson's disease" and went to the patient's physician to "see if Mother could take it." The physician reportedly consented, "but said in view of her age, that he wouldn't be giving her a very high dosage at first." The patient stated that she "did not know what they were giving her, except it's something experimental," while her daughter was able to give only the drug's name ("l-Dopa"). The daughter stated that she "planned to look around for more information" so that she could ask "half-way intelligent questions" of her physician. The patient was evaluated by the investigator as demonstrating no drug knowledge. A hospital Registered Nurse informed the investigator that the patient was taking 500 mg daily and had been taking the drug for 14 days.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by herself as demonstrating a 10% improvement ratio since taking the drug. She reports experiencing some nausea since taking the drug. The daughter expressed much hope that her mother "might stick with the program of therapy planned for her."

Investigator Impressions

The daughter of this patient told the investigator after the interview privately that her mother "had lost all hope of ever getting out of the hospital" and "was not participating in the therapy very well." She implied that what her mother "really wished for was to die." The Registered Nurse in charge of this patient's care verified the daughter's observation, stating the patient told her that she "didn't see why everyone was going to all of this trouble for an old woman." The investigator noted that this patient, though alert for her age, did not seem particularly impressed with the attempts being made to improve her condition, stating "I don't know why you want to talk with me; I haven't done anything too newsworthy here."

CASE #17

This 78 year old Caucasian male was interviewed in a rest home with the Registered Nurse in charge of his care present. He was a retired grocery store owner with an 8th grade education. The patient was a widower. The Registered Nurse interview collaborator had completed four years of college. The patient reported residence in the rest home for five years, in the same community of over 8,000 people continuously for the past 50 years.

The patient recalled, with the aid of the nurse, the first indication of Parkinsonism at age 76 when one of the rest home staff noted his "generally deteriorating ability to walk and his trembling hands." The nurse reported this symptomatology to his physician via the telephone. The physician examined the patient at the rest home and admitted him to the local general hospital for a "check-up." There, the nurse reports, the diagnosis of Parkinson's disease was made and the patient was placed on l-Dopa. The nurse reports that the physician told the patient "very little" about Parkinson's disease and l-Dopa, but that she had spent some time "educating" him about the disease because "he was interested in knowing what was wrong with him and what was being done about it." On the drug 5 months at the time of the interview, the patient, with some coaching from the nurse, was able to give the name of the drug ("l-Dopa"), his current dosage ("2000 mg daily"), but neither the nurse nor the patient could provide the presumed mode of action nor more than two side effects ("nausea and loss of appetite"). The nurse stated that she had not "had the opportunity to read up on all of l-Dopa's literature", but "would do so after the interview was over." The patient was evaluated by the investigator as having little drug knowledge, primarily because of his obvious need to seek information almost totally from his nurse.

Utilizing Roche Laboratories' Patient Evaluation of Progress Charts, the patient was evaluated by himself as demonstrating a 43% improvement ratio since taking the drug. He reports experiencing some nausea and loss of appetite since taking the drug.

Investigator Observations

This patient was difficult to evaluate in especial reference to knowledge spheres because his nurse constantly "coached" him in his answers and dominated much of the conversation. The gentleman appeared quite severely involved, but generally optimistic about his condition. "I think I'll be ready to help plant flowers by next spring", he said.

He appeared alert, well oriented, and quite satisfied with his life, but thought he should "let the expert, my nurse, answer most of the questions."

Characteristics of the Sampled Individuals

Seventeen individuals who were diagnosed as having Parkinson's disease and who are currently taking the medication, l-Dopa, were interviewed by the investigator. The data obtained through interview was presented earlier in this chapter in a modified case study format. The investigator shall at this point select fifteen variables from these case studies which lent themselves to numerical presentation and formulate a summary of specific characteristics of the studied sample. The variables to be presented are as follows: 1) Age, 2) Sex, 3) Marital Status, 4) Present or Previous Occupation, 5) Education, 6) Length of Time at Present Location and Type of Residence, 7) Residential Community Population, 8) Length of Time with Parkinsonism and Age of Onset of Parkinsonism, 9) Length of Time of Usage of l-Dopa, 10) Current Dosage of l-Dopa, 11) Improvement Ratio, 12) Drug Knowledge Evaluation, 13) Reports of Side Effects, 14) Identification of Interview Collaborator, and 15) Education of Interview Collaborator.

Age. The subjects interviewed in this study ranged in age from 56 to 84 years. The respondents fell into the following age classifications:

Under 60 years of age	1
Over 60 but less than 65	1
Over 65 but less than 70	3
Over 70 but less than 75	4
Over 75 but less than 80	6
Over 80 but less than 85	2
Total in Sample	<u>17</u>

The median age of the sampled individuals was 72.7 years.

Sex. Distribution of the sample by sex shows a very slight predominance of women, numbering nine, compared with eight men.

Marital status. Classification of the subjects by marital status reveals a majority of married individuals; nine, or over half of the sample, fell into this category. By contrast, five widows and three widowers took part in the study. As divided by marital status, the sample may be numerically represented as follows:

	Married	Widowed	Single	
Male	5	3	0	
Female	4	5	0	
Total in Sample	<u>9</u>	<u>8</u>	<u>0</u>	<u>17</u>

Present or previous occupation. Of the sampled individuals, sixteen subjects viewed themselves as retired, or not participating in any occupation, while only one subject, the youngest, remained actively engaged in a business occupation. The sampled subjects, including both sexes, listed themselves as being predominantly engaged at one time in the business and professional fields. Fourteen individuals fell into this category, while the remaining three subjects were either engaged in housekeeping activities or ranching-agricultural related occupations. The sample distribution for occupation was as follows:

Business and Professional Occupations

	Managerial Positions	General Business	Education	Law
Male (6)	5			1
Female (8)	1	3	4	
Total	<u>6</u>	<u>3</u>	<u>4</u>	<u>1</u> <u>14</u>

Housekeeping Occupation

Male (0)	0
Female	1 (also resided on ranch)
Total	<u>1</u>

Ranching-Agricultural Occupations

	Ranching	Farming
Male (2)	1	1
Female (0)	0	0
Total	<u>1</u>	<u>1</u> <u>2</u>

Education. Fifteen of the interviewed subjects had completed their high school educations, while six of these had furthered their education beyond high school. Two individuals reported not having completed their high school educations. As divided by sex, the sample group may be represented in the following categories as to educational achievement:

	Elementary Completion	High School Completion	College Attendance
Male	8	3	3
Female	9	6	3
Total	<u>17</u>	<u>9</u>	<u>6</u>

Length of time at present location and type of residence. The length of time at the present location of the sampled subjects ranged from 3 months to 55 years, with those in the private homes claiming residence the longest time and one individual in a convalescent home claiming residence for the shortest time. As to type of residence, the sample was distributed along fairly equalitarian lines. Five individuals resided in private homes, three in a rather elaborate retirement home, two in rented apartments, two in mobile homes, three in general hospitals, one in a convalescent hospital, and one in a rest home. As divided by sex, the sample group fell into the following residential categories, including length of time at current residence:

	Private Home	Retirement Home	Rented Apt.	Mobile Home	General Hospital	Convalescent Hospital	Rest Home
Male	3	2	1	0	1	0	1
Female	2	1	1	2	2	1	0
Total	<u>5</u>	<u>3</u>	<u>2</u>	<u>2</u>	<u>3</u>	<u>1</u>	<u>1</u>

Time Range of Residence

Private Home: 6 months, 15 years, 30 years, 55 years, and 55 years = 5 subjects

Retirement Home: 1 year, 1 year, and 2 years = 3 subjects

Rented Apartment: 2 years, 49 years = 2 subjects

Mobile Home: 27 years, 40 years = 2 subjects

General Hospital: 2 weeks, 6 months, 8 months = 3 subjects

Convalescent Hospital: 3 months - 1 subject

Rest Home: 5 years = 1 subject

Residential community population. The majority of the sampled subjects tended to reside in Montana's more urban-like areas. Only one patient resided in a community of less than 1000 population. The sample distributed itself into the following categories as to residential community population:

	0-6000	7000-13,000	14,000-20,000	21,000 and above
Male	0	4	2	2
Female	1	1	0	7
Total	<u>1</u>	<u>5</u>	<u>2</u>	<u>9</u>

Length of time with Parkinsonism. The subjects in the study were called upon to reveal the time at which they first noted symptoms of Parkinson's disease. Whether or not this time was actually the initial onset was not of issue here, but the time to which the patient himself first perceived symptoms was considered of importance in providing a fairly accurate picture for the investigator of the effect that the condition had on the patient's life. The subjects reported a range of disease duration of one to eleven years. Median age of disease duration was 5.4 years for the seventeen subjects, while the average age of onset was 67.9 years. The patients were categorized as to sex in the following areas:

Length of Time with Parkinsonism

	1-2 yrs.	3-4 yrs.	5-6 yrs.	7-8 yrs.	9-10 yrs.	11-12 yrs.	
Male	2	0	3	3	0	0	(8)
Female	2	2	2	1	1	1	(9)
Total	<u>4</u>	<u>2</u>	<u>5</u>	<u>4</u>	<u>1</u>	<u>1</u>	<u>17</u>

Age of Onset

Under 60 years of age	2
Over 60 but less than 65	2
Over 65 but less than 70	7
Over 70 but less than 75	2
Over 75 but less than 80	3
Over 80 but less than 85	1
Total	<u>17</u>

Length of time of l-Dopa usage. The members of the sample were requested to provide the investigator with the length of time that they had been taking the drug, l-Dopa. Responses to this question varied from a length of time of 14 days to 21 months, the median treatment period being 10.4 months. The patients were catagorized as to sex with relationship to the treatment duration variable as follows:

	1-5 mos.	6-11 mos.	12-16 mos.	17-21 mos.	
Male	3	1	1	3	(8)
Female	4	3	1	1	(9)
Totals	<u>7</u>	<u>4</u>	<u>2</u>	<u>4</u>	<u>17</u>

Current dosage of l-Dopa. The individuals interviewed for the study were taking quite varied amounts of the drug, l-Dopa. Dosages varied from 500 mg daily to 5000 mg daily, with a median dosage of 2308.8 mg daily. The patients were categorized as to sex with relationship to their current dosage of l-Dopa and represented as follows:

	500-1500 mg	1500-2500 mg	2500-3500 mg	3500-4500 mg	4500-5500 mg	
Male	4	2	1	0	1	(8)
Female	4	2	1	2	0	(9)
Totals	<u>8</u>	<u>4</u>	<u>2</u>	<u>2</u>	<u>1</u>	<u>17</u>

Improvement ratio, if any, since taking l-Dopa. All of the patients interviewed registered some improvement on the Roche Laboratories' Patient Evaluation of Progress Charts ranging from a low of 10% to a high of 83% perceived improvement ratios, with a median ratio established at 48.4%. The improvement ratios of each patient, categorized by sex are as follows:

	10-20 %	20-30 %	30-40 %	40-50 %	50-60 %	60-70 %	70-80 %	80-90 %	
Male	0	1	1	2	3	0	0	1	(8)
Female	1	1	3	0	1	1	2	0	(9)
Totals	<u>1</u>	<u>2</u>	<u>4</u>	<u>2</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>1</u>	<u>17</u>

Drug knowledge evaluation. Eight patients, or slightly less than half of the interviewed sample were evaluated by the investigator as demonstrating a high degree of drug knowledge of l-Dopa, while three were evaluated as having moderate knowledge of the drug, and two as possessing little or no knowledge of l-Dopa. The sample, divided by sex, was catagorized as follows with relation to drug knowledge:

	High Degree	Moderate Degree	Little or No Knowledge	
Male	5	2	1	(8)
Female	3	1	5	(9)
Totals	<u>8</u>	<u>3</u>	<u>6</u>	<u>17</u>

Reports of side effects. The reports by patient of possible side effects of l-Dopa were both numerous and variable. Nausea, anorexia, and mental changes in the form of depression seemed to comprise the most frequent complaints of all of the patients. A categorization of the various reported side effects are as follows:

Symptom	No. of Patients Reporting Symptom
1. Nausea	10
2. Anorexia (loss of appetite)	9
3. Mental Changes (all depressions)	7
4. Dyskinesia (unusual movements of extremities)	5
5. Flushing	3

Other symptoms reported by only one patient individually included difficulty in reading, blurred vision, diarrhea, discolored urine, difficulty in urination, vertigo or dizziness, heart problems, hypotension, edema of the legs, low tolerance for coffee, frequent eructation or belching, insomnia, bowel obstruction, and a low tolerance for alcohol.

Identification of interview collaborator participating in interview. A predominance of spouses attended the interview sessions with participant patients, numbering nine husband and wife pairs. Two daughter-in-laws, two daughters, and one son comprised the remainder of the direct family member-patient interview collaborators. Two Registered Nurses in charge of the particular patient's care were included in two interviews for lack of available family members.

Education of interview collaborator. The interview collaborators were all relatively well educated. All had completed their high school educations, while six had continued their education into college.

This chapter has concerned itself with the presentation of the data collected from seventeen patient interviews. Chapter 5 shall consist of an analysis of the collected data. The analysis of the data will be confined to only the most obvious, interesting, pertinent, or outstanding points of the study, with a directed effort by the investigator to disregard those aspects of the interview which seem irrelevant or superfluous.

Chapter 5

ANALYSIS OF DATA

Two types of data collected for this exploratory study were presented in Chapter 4: 1) Patient responses to open-ended questions in the interview which tended to contain descriptions of individual reactions and experiences, and 2) patient responses to single-answer questions in the interview which tended to contain comparative and/or numerical types of data. The former type of data tended to be rather unstructured and thus did not yield to any sort of systematic analysis. Therefore the investigator shall utilize this material for discussion pertinent to broad trends noted in the data, referring to the identified problem areas for this study in the latter portions of the analysis.

The second type of data, that which lent itself to numerical representation, shall be compared with literature-based data to detect similarities and/or differences. If no material is found available in the literature for comparison, as in the instance of the investigator-based test for drug knowledge, the collected data shall be internally compared; that is, compared with other variables collected specifically for the study. In example, drug knowledge shall be compared with a variable known to correlate with general knowledge, that of education.

The investigator chose fifteen variables which commonly characterized the sampled interview participants and numerically presented them in the previous chapter. A discussion and analysis of the collected data shall at this point be undertaken by the investigator.

Analysis of Numerical Data

Age. The age range of the sampled individuals (54-80 years) in the study compared to the literature reports of the accepted age range of Parkinson's patients (45-80 years) does not differ to the degree that any discussion seems necessary. However, the literature's assertion that the "average age of the patient with Parkinson's disease is 55 years"⁶⁰, while the average age of the patient reported in this study was 72.7 years, may be fruitful for analysis. Obviously, the patients reported in this study are much older than the "average" patient with Parkinsonism. Investigating further into this particular subject, the subject patients also reported an older age of onset of their condition than that which is indicated in the literature. A greater number of the sampled patients fell into the 65-70 year old range when they reportedly contracted the disease, with the average age of onset reported at 67.9 years, considerably older than the 45-55 year old patient which the literature describes. The possible reasons

⁶⁰Haber, *op. cit.*, p. 265.

for this difference could be many and varied. However, the investigator speculates that the disease's symptomatology may be a factor in at least the older reported age of onset. It may be entirely possible, in view of the very gradual onset of the disease, that the patients in the study simply failed to notice the Parkinsonism symptomatology until it interfered in their activities. Thus, an older age of onset might have been reported. A study by Mechanic tends to support this supposition. Under conditions of manageable difficulties, Mechanic⁶¹ reports that "persons have a tendency to normalize or ignore symptoms that do not become too severe." This author found that when illness is of a kind that is common and familiar, and the course of the illness is predictable, the presentation of the illness for medical scrutiny "is substantially related to an index of inclination to use medical services. The patient in Case #15 who stated that he had noticed that "a lot of old people shake" may be a good example of the individual who would not seek medical attention for his problem. Mechanic⁶² then indicates that as symptoms become more atypical, less familiar, and less predictable in their course, the role of social and situational factors in bringing a person for medical attention becomes less

⁶¹David Mechanic, *Medical Sociology* (New York: The Free Press, 1968), p. 122.

⁶²*Ibid.*

important. Likewise, the individual in Case #1 whose vacation was strongly interfered with may be an example of one who would seek medical attention.

Another possible reason for this finding may be found in the limitation of the selection process of this study. Since the patients chosen for the study were neither matched for any particular characteristic, nor chosen via a random selection method, nor located in any large, statistically significant numbers, the possibility exists that the investigator happened to chose an older segment of the Parkinson's population, while a younger, perhaps even less accessible population probably exists. A broader discussion of this variable shall be undertaken in the latter portion of this chapter for the purpose of including some case-study material pertinent to the subject.

Sex. The literature defines no particular predominance of either sex in the prevalence of Parkinsonism.⁶³ Accordingly, the subjects in this study did not demonstrate any outstanding dominance of either sex reporting the condition of Parkinson's disease.

Marital status. A slight predominance of married individuals was indicated in the study. Also, widows slightly outnumbered widowers among the sampled subjects. While in view of national statistics, the

⁶³Barbeau, *op. cit.*, p. 60.

sample may contain a fairly large number of married couples, the ratio of widowers to widows might have been predicted, considering the average age of these individuals. Population reports reveal 53.9% of women over 65 are widowed compared with 20.4% of men.⁶⁴ The variable of marital status shall be considered in the latter portion of this chapter as a contributory factor to the subject's reactions to their disease.

Present or previous occupation. The investigator speculates that the reason for the high number of business and professional occupations reported by the subjects in the study may be related to the subject's accessibility. Author Ross⁶⁵ reports that there is a "confirmed and direct relationship between social class and receipt of medical care. As income, education, and occupation rise, the corresponding amount of medical care received also rises." And, those Parkinson's patients interviewed in the study had all sought medical treatment for their disorder. Many of the patients in this study happened to be located through physicians. The social class of the majority of those patients, considering their occupations appears to be predominantly middle, and possibly upper class (in a few instances).

⁶⁴Howard I. Wells, Jr. (ed.), Proceedings, Second National Conference of the Joint Council to Improve the Health Care of the Aged (Chicago: 1961), p. 35, citing Bureau of the Census, Current Population Reports, Series, p. 20, No. 96.

⁶⁵Ross, J. A., "Social Class and Medical Care," Journal of Health and Human Behavior, 8:35-40, 1962.

Thus, analyzing these characteristics in total, the investigator arrives at her speculation that the sampled patients may have been more accessible to interview via their seeking medical care, than other patients in lower strata who may have not sought medical aid for their condition so readily. Sociologist Koos⁶⁶ adds further support for this supposition, in his observation that upper-class persons are more likely than lower-class persons "to view themselves as ill when they had particular symptoms and to seek a doctor's advice."

It may also be relevant to investigate the economics of taking the medication, l-Dopa. As a relatively new drug, l-Dopa is quite expensive at this point in time.⁶⁷ Therefore, the investigator might further speculate that those patients who had higher incomes might be more inclined to utilize the drug than those patients with lower incomes. Also, although the investigator did not question subjects on their incomes, the subjects' generally higher-ranked occupations may be sufficient indication of income to make this supposition.

Education. Most sociologists would agree that the education an individual has can be predictive of his occupational achievement. Accordingly, individuals in the study seemed considerably better

⁶⁶E. Koos, The Health of Regionville: What the People Thought and Did About It (New York: Columbia University Press, 1954), p. 94.

⁶⁷Haber, *op. cit.*, p. 263.

educated than the average American over 65, since over 50% of the respondents have had formal education through and beyond high school.⁶⁸ Likewise, this upward trend in education was noted in occupational achievement, which was also rather high. The factor of education shall be discussed in the latter portions of this chapter as a possible variable in the subjects' drug knowledge.

Length of time at present location and type of residence. This variable was revealing of a wide range of answers. As Jaco points out, a patient's "environment can be highly predictive of his reaction to his disease."⁶⁹ In the latter portion of the chapter, the investigator shall compare the progress and experiences of patients residing in the hospital-type environment as opposed to those residing in their own private homes. Likewise, the variable of Resident Community Population, which tended to range in Montana's more urban areas, may be a factor in patient response and shall also be discussed later.

Length of time with Parkinson's disease. A greater percentage of patients fell into the category of having the disease for 5-6 years.

⁶⁸U. S. Department of Health, Education and Welfare, Public Secondary Schools, Statistics of Education in the United States, 1958-59 Series, Number 1. (Washington, D. C.: U. S. Government Printing Office, 1961). In 1920, 23.9% of the youth between 14 and 17 years of age were enrolled in high school. This group would comprise our present population over 68 years of age. Prior to 1920, the percentage was lower.

⁶⁹E. Gartley Jaco, Patients, Physicians, and Illness (Glenco, Texas: The Free Press, 1958), pp. 4-5.

Comparing these figures to the average in the Cotzias⁷⁰ studies, the subjects in this investigation had had the disease a comparatively similar time. Cotzias reports over 50% of his patients demonstrating the syndrome for 10 years or less. Apparently length of time with Parkinson's disease is not necessarily predictive of the disease's severity, as some of the Cotzias⁷¹ patients reported having Parkinson's disease for over 15 years and yet were not considered as severely involved as some of those patients reporting the disease for a shorter time.

Length of l-Dopa Usage. Most of the patients in laboratory studies⁷² involving l-Dopa usage have been under observation for over three years, while the patients in this study have been using the drug for only a median treatment period of 10.4 months. Thus, changes in the severity rating and/or improvement ratio might be somewhat misleading. That is, if the laboratory studies by Cotzias,⁷³ McDowell,⁷⁴ *et al.* can be taken as representative of most patient groups, it may be reasonably assumed that these particular patient ratings would tend to

⁷⁰Cotzias, Larodopa, p. 20.

⁷¹Cotzias, Larodopa, p. 18.

⁷²*Ibid.*, pp. 14-21.

⁷³*Ibid.*, p. 14.

⁷⁴McDowell, *op. cit.*, p. 29.

be higher for improvement and lessening for severity as l-Dopa usage continues for a period of time. Even so, comparison for this variable is difficult in that the drug was only made available for general public usage less than two years ago. Thus, the patients in the study did not have the opportunity for use of l-Dopa as soon as those experimental groups did in the first days of its usage.

Current dosage of l-Dopa. Most of the consulted investigating experimental scientists report utilizing an average of 3000 mg to 8000 mg of l-Dopa daily in obtaining positive results. The median dosage of 2308.8 mg established in this study seems to indicate somewhat of a conservative approach on the part of the physicians caring for the patient subjects. However, since these physicians were not interviewed as a part of this investigation, this observation shall have to remain a supposition. Another possible reason for the comparatively low dosage range may have been the relatively short period of time each patient had been taking the drug as compared with the rather lengthy period of official laboratory investigation. Physicians of the subject patients may be intending to gradually increase the drug dosage into more researched levels at a later date. The investigator had no opportunity to observe this phenomena.

Drug knowledge. The eight patients who were evaluated as having a high degree of drug knowledge also had a relatively high educational attainment, with the exception of Cases #11 and #17, who had completed

their educations through the 11th and 8th grades, respectively. Interestingly enough, these patients' interview collaborators also tended to be relatively well educated, having all finished high school, with five of these individuals completing some or all of college. Since knowledge and the quest for knowledge is commonly correlated with education and social class, previously discussed, perhaps the rather surprising number of patients demonstrating a high degree of drug knowledge could be at least partially attributed to these factors. Other aspects of this variable shall be discussed under the case study material in the latter portions of this chapter.

Source of drug knowledge. Perhaps the most striking finding of this study was the relatively large number of patients (ten) attributing their knowledge of drug and disease, not to their physicians, but to popular mass media. If the patient did not actually obtain the information himself, often a family member did so for him, mostly from the mass media. Comparing the source of drug knowledge to the degree of drug knowledge is also food for thought. Five patients demonstrating a high degree of drug knowledge attributed their achievement to the mass media, while three patients named their physicians as initial developers of their high degree of knowledge. Of the seven patients who attributed their knowledge to their physicians, four demonstrated moderate to no drug knowledge, while three demonstrated a high drug knowledge. The findings for the comparisons of degree of knowledge of

Parkinsonism and source of that knowledge are quite similar, with 12 patients attributing their knowledge of Parkinsonism to mass media, as compared to five patients to physician. It was also interesting to note that those patients residing in hospital or custodial care-type institutions, of which there were five individuals, all demonstrated a lower degree of knowledge than the majority of individuals residing in more independent settings. (The investigator includes the three individuals residing in the aforementioned elaborate retirement home in the latter category because of their relative independence and availability of library resources.) The investigator speculates that the hospital or hospital-like environment more than likely was a contributory factor in the limited accessibility of information to the patient. Nurses are legally required to give information only under the direction of physicians.⁷⁵ However, the physicians, in the cases under consideration, did not provide any great amount of information to the patients themselves. Thus, it is possible to consider the environmental factor as one condition possibly affecting drug knowledge of the subject patients.

Improvement ratio. The investigator did not interview the subject patients' physicians and thus had no verifiable professionalized data with which to compare the patient estimates of improvement.

⁷⁵Payne, *op. cit.*, p. 71.

However, in the majority of cases, the interview collaborator or the individual more often quite involved in the patient's care, tended to verify patient estimates of his improvement. The investigator, at the initiation of the study, questioned the possibility of the patients tending to actually over-rate themselves in an effort to present their case in a more favorable light than it actually existed. Possibly, the investigator reasoned, the "Hawthorne Effect" might be an interfering factor here. In only two cases (#6 and #11), however, did this occurrence seem a distinct possibility to the investigator.

Somewhat surprisingly perhaps, the improvement ratios tended to compare favorably with those reported in the literature. The average improvement ratio reported in Roche Laboratories' patient responses was actually higher than those improvement ratios reported in this study. 60.2% improvement in overall symptomatology is reported in Roche's 974 patients,⁷⁶ while this study's subjects report a considerably lower ratio of 48.4%. As has been previously pointed out, this study's subjects have been undergoing l-Dopa therapy a comparatively shorter time than those patients of the literature-based investigations. This factor might account for the lower improvement ratio. Also, the numbers of patients involved in these two investigations are hardly viable for comparison. However, the figures do fall into similar ranges.

⁷⁶Cotzias, Laradopa, p. 21.

Reports of side effects. Again, the various side effects noted in this study's small number of patients compared favorably with those noted in much larger sample investigations. In the McDowell⁷⁷, Cotzias⁷⁸, and Roche Laboratory⁷⁹ studies, nausea and anorexia were the most frequently reported untoward drug reactions noted, as was noted in this investigation. And, similarly, psychiatric and cardiovascular (flushing) symptoms rated high in occurrence in the larger investigations as they did in this study. Those symptoms not reported in the literature, but reported in this study included specifically, a "low tolerance for coffee" and a "low tolerance for alcohol." Interestingly enough, both of these symptoms reportedly manifested themselves in the two patients after they had been told "by their friends" that they might experience these problems. No literature-based knowledge of these side effects existed for either patient. The investigator feels that the element of suggestion might be primarily evident in these two particular cases.

The initial portion of this chapter has been concerned with the analysis of data obtained in interview which lent itself to numerical representation. The data has been compared both internally with other variables cited in the study and externally with data

⁷⁷McDowell, *op. cit.*, p. 29.

⁷⁸Cotzias, *op. cit.*, p. 14.

⁷⁹*Ibid.*, pp. 21-22.

presented in the literature concerning Parkinsonism and the advent of l-Dopa. The investigator felt that several of the variables presented deserved further analysis with relation to the forthcoming discussion of the modified case studies.

Analysis of Modified Case Study Material

Concerning the age of onset of Parkinsonism, the investigator has previously pointed out the subjects' relatively older age as opposed to literature reports and three possible reasons for this finding: 1) gradual onset of symptoms and failure to notice condition, 2) selection process limitation, and 3) incidental location of more accessible population. In relation to the first aforementioned reason, only in Cases #7, 9, and 12 were reports of the literature-validated "gradual onset" of Parkinsonism. Similarly, five individuals in Cases #8, 11, 15, 16, and 17 named other individuals, as physicians and family members as the person responsible for pointing out symptoms to the patient indicative of their condition.

In contrast, the remaining nine cases were productive of a very interesting commonality between patients. That is, each one of these individuals reported that he or she was engaged in a relatively "unusual" situation at the time of the initial onset of Parkinsonism. Vacations, a speaking engagement, fractured bones, a football game, a car accident, and a case of influenza comprised the reported events prominent in subjects' minds at the onset of symptoms of Parkinson's

disease. All of these individuals tended to remember no symptoms of their condition prior to these specific events. One obvious possible reason for this finding is again reflected in the description of the disease, that of a slow, gradual onset. The patients may merely not have noticed the previously evolving symptoms until a comparatively stressful situation forced them to their attention. This point was previously supported through author Mechanic.⁸⁰ A prime example might have been the male patient portrayed in Case #2 who suddenly found it terribly difficult to drive a long distance from his home residence. It is possible to speculate that he merely had not driven such a long distance prior to his vacation and fatigue tended to aggravate an already present condition. Or, those patients who found it necessary to travel to a hospital for emergency treatment may have had professional health individuals note their symptoms incidentally. All of these reasons fall in the range of possibility and should be considered as contributory factors to the relatively older age of onset of Parkinson's disease as reported by patients.

However, the investigator has one further speculation for consideration to undertake. It, too, could be listed under possibilities for this reported variable, although much more difficult to prove. Hans Selye, M.D., is a highly respected physician who has formulated a theory of disease which might be applicable here. According to

⁸⁰Mechanic, *op. cit.*, p. 122.

Selye⁸¹, stress is "the rate of all wear and tear on the body caused by life," or for more complicated definition, "the state manifested by a specific syndrome which consists of all the nonspecifically induced changes within a biologic system." The "nonspecific changes" are encompassed in the general adaptation syndrome (or G.A.S.) consisting of three stages: the alarm reaction, the stage of resistance, and the stage of exhaustion. Each of these stages, according to Selye⁸², are characterized by certain physiological events in the body. The "stressor", or that which causes stress consisting of anything from change of temperature to the threat of death, acts to produce generalized stress reactions in the whole body.

The main regulators of the stress syndrome, the brain, nerves, pituitary, thyroid, adrenals, liver, kidney, blood vessels, connective tissue cells, and white blood cells are, in turn, coordinated by two main body systems, the endocrine and the nervous. Through the base of the brain, the alarm signal reaches the pituitary gland, headquarters of all hormonal responses. Acting through the nervous system, stressors produce adrenalin and acetylcholine, which can influence the G.A.S. mechanism selectively at any point. Selye⁸³ concludes his theory by

⁸¹Hans Selye, M.D., The Stress of Life (New York: McGraw-Hill Book Company, 1956), p. 54.

⁸²*Ibid.*, pp. 55-56.

⁸³Selye, *op. cit.*, p. 64.

stating that some stressors produce adaptive-defensive reactions which successfully cope with the aggression on the body, during the stage of resistance. However, this successful coping reaction may actually be in the form of a disease. Selye uses many examples, as the formation of an abscess to prevent further spread of a disease throughout the body. In contrast, this author⁸⁴ also states that "at times, body reactions tend to be excessive and quite out of proportion to the fundamentally innocuous irritation to which it was first exposed." Then, he states, the diseases of adaption become more serious, as in duodenal ulcers and diabetes.

Utilizing Selye's viewpoint in relation to the supposed physiology of Parkinsonism, the investigator evolved a theory which may be included in an explanation of the onset of Parkinsonism in the nine patients who reported being involved in unusual situations at the time. Dopamine, the catecholamine thought to be lacking in patients with Parkinsonism, is known to be a precursor of the hormone norepinephrine.⁸⁵ The substance is also more recently thought to be active in an independent sense, with cells in the brain specifically designed as dopamine receptors.⁸⁶ Given these facts and understanding that a stressor, such

⁸⁴*Ibid.*, pp. 149-170.

⁸⁵Barbeau, *op. cit.*, p. 59.

⁸⁶D. B. Calne and M. Sandler, "1-Dopa and Parkinsonism," Nature, 226:22, April, 1970.

as the unusual situations that the nine subjects were experiencing, can provoke the nervous system to secrete increasing amounts of the hormones of adrenalin (or norepinephrine) into the nervous system⁸⁷, the investigator would wish to pose the following question: Could unusually potent stressors, such as accidental injury or mental strain as the patients reportedly experienced, be factors in depleting an individual's dopamine supply, affecting his defense-mechanism hormonal production of adrenalin, and eventually exhausting his resources to the point of giving rise to Parkinsonism symptoms? Or, similarly, if by some mechanism, the dopamine production had previously been lessened, could the potent stressor be the event that finally precipitated the Parkinsonism symptoms? These questions, though unanswerable and quite superficial, due to the investigator's basic lack of competence in the field of physiology, are still food for thought and did develop through the results of this study.

Cases #1, 2, 5, 7, 9, 12, 14, 15, and 17 or over half of the interviewed subjects were generally evaluated by the investigator as having made a "good" adjustment to their illness. Possibly Cases #4 and 13 may also be included in that category, with some reservations. It was interesting to note the relative consistency between the patients' verbal reports of their progress and the scores obtained on

⁸⁷Selye, *op. cit.*, p. 65.

the Roche charts. Those indicating a relatively good adjustment to their illness, or a total of eleven patients, established a median of 58.2% progress after taking l-Dopa, while those indicating a less than satisfactory adjustment to their illness attained a median progress of 30.6%. The difficulty of establishing a "cause-effect" relationship is obvious here, but perhaps the investigator could speculate safely that the charts' reports were comparatively valid with the patient reports on their progress.

The companionship of marriage and opportunity for mutual moral support as opposed to the oftentimes lonely atmosphere of the custodial or hospital institution stimulated the investigator to consider the mental attitudes of those individuals residing in each environment. Also, the experience of widowhood as compared to marriage was seen as a variable which might be compared in searching for possible reasons for the way each patient viewed his disease and progress with l-Dopa in the study.

Those married individuals in Cases #1, 2, 5, 12, and 14, who resided in their own homes, indeed seemed more adjusted to their illness. The investigator noted, especially, in these particular cases that the couples seemed to derive much support from each other; that the uninvolved individual often was quite involved in the involved spouse's care.

However, the widowed patients were more varied in their responses and probably not as productive of data trend. Out of the seven patients who were without marriage partners, the investigator evaluated Cases #3, 4, 6, and 8 as making a poor adjustment to both their illness and their medication, because of frequent reports of depression or lack of motivation on the part of each patient. One of these patients (#8) also happened to reside in an institution. Of those married individuals who were evaluated by the investigator as being poorly adjusted to their illness (Case #10, 11, and 16), only one (#10) resided in a convalescent setting. Other variables, such as closeness of the patient to a family and/or staff member, were quite different in nature and not productive of noticeable data trends. The prevalence of patients in the urban-like setting, contrary to investigator expectations, did not seem an influential factor in their response to the disease. Some patients, as aforementioned, were still able to maintain social contact with each other, despite the sometimes isolating impact of the urban environment. There seems a good possibility, in the investigator's opinion, that the characteristic Montana urban area is not actually large enough in population to be a negative influence in these patients' lives.

The investigator noted in virtually all of those patients who reported that their physicians told them little about Parkinsonism and/or l-Dopa, a certain tinge of hostility toward these physicians.

Each of these patients informed the investigator in their individual way that they felt "neglected" or "unintelligent" in the face of being provided with no information about their condition. Similarly, these individuals seemed to choose other channels of information, as the mass media or a friend, only after they obtained no satisfaction from their physician. Of those persons who relied almost solely on the physician for information, they seemed to enjoy a closer relationship with the physician.

If this finding (the negatively-oriented doctor-patient relationship) is a reflection of a trend in health care today, health professionals may find themselves more suit-prone, according to Richard M. Markus⁸⁷ of Cleveland, Ohio, President of the American Trial Lawyers Association. Speaking before a panel on professional liability at a meeting of the American Association of Neurological Surgeons, Markus said his clients who file malpractice suits complain most frequently about how they were treated as human beings and not how they were treated as patients:

A typical claimant who comes to my office gives a long tale about the doctor's receptionist who was rude, the secretary who was cold and the doctor who won't answer questions. Then they just incidentally tell me about their medical complaints. Doctors should listen to their staff and how they talk to patients. They should listen to themselves.

⁸⁷Paul Recer, "Doctors Told Warmth Could Cool Law Suits," The Billings Gazette, April 25, 1971, p. 10, col. 1.

Even tape-record a conversation between a patient and a physician and play it back later if it will help them.

In the same meeting, Crawford Morris⁸⁸, another Cleveland attorney, stated that "medical machines, a heavy work load and a scarcity of medical workers all tend to make the physician's contact with his patients less personal." Senator William B. Saxbe⁸⁹, R-Ohio, told the surgeons, "You doctors have lost a lot of your magic. There are times when people would no more think of suing their doctor than they would of suing a near and dear friend."

The finding supporting a basic lack of information given by physicians to the subject patients regarding l-Dopa raises another disturbing question. Recalling the varied, but explicit legal, moral and ethical mandates on physicians to provide adequate information on experimental drugs, which l-Dopa basically is at this point, this question must be asked: Why were the subject patients, except for those predominantly residing in hospital or custodial-type institutions, not given adequate information on l-Dopa? Rather than indict those particular physicians at this point, the investigator feels that this point deserves further study of factors obviously not precisely identified in this effort.

⁸⁸Recer, *op. cit.*, p. 10.

⁸⁹*Ibid.*

Perhaps the nurse should also take heed to the lack of information provided many of the patients in the study for she could be caring for the Parkinson's patient in any setting. Considering her legal limitations on the passage of information, she perhaps should consider obtaining permission from the oftentimes busy physician to undertake some of the necessary teaching of information for the Parkinsonism patient. In fact, the investigator feels that there existed no patient in the entire study who could not have benefited from supportive, educational, and regular visits of a health professional. In Case #1, for instance, this male patient appeared to need the type of reassurance his wife could not provide him, nor could possibly the mass media information he had at hand. He was asking the investigator, a health professional, for the kind of support which would take him, an individual with special problems, into account in relation to his condition. In those cases where depression was acute, as in Case #3, the investigator took further steps beyond the interview session to insure continuing support. These were only seventeen patients, chronically ill with Parkinsonism, out of many who suffer the same condition. The investigator speculates that it is not unreasonable to assume that others, like the individuals interviewed, are not having their needs met while they continue an experimental-type existence, on a newly discovered medication, with no guaranteed results.

In further consideration of patients' attempts to gain information from their physicians, it was quite interesting to note the rather large number of patients who reported being the individuals who requested their physicians to obtain l-Dopa for their treatment. Twelve out of the seventeen patients reported approaching their physicians for the drug. This finding may seem surprising in view of the accepted role of the physician, a highly educated individual who normally is the one initiating treatment of a patient's disease condition. The investigator speculates that the most probable reason for this behavior lies in the actual impact that the discovery of the drug appeared to have in this patient's world. Many of the subject individuals reported their "excitement" and optimism at the prospect of being treated with this "miracle" drug. It would seem quite reasonable then, that these patients might be more forward than usual in attempting to obtain this highly desirable form of therapy for their once-considered untreatable condition.

Another interesting finding of the study involved the fact that five of the patients were able to refer other patients with Parkinson's disease taking l-Dopa to the investigator. There was some indication in the interviews that these individuals consulted each other for information on their condition, comparing experiences and observations, as well as maintaining the usual type social relationship. This arrangement gives rise to some interesting sociological questions, not dealt

with in the interview schedule of this study and thus not conducive to full analysis. With regard to the factor of suggestion and exchange of information between patients, it would seem facilitative to devise a sociological study of the relationships and roles of the patients participating in these types of groups. Recalling the two individuals who developed "side effects" of aversion to coffee and alcohol after other patients had informed them of their similar experiences, the factor of suggestion may be viable in any number of situations involving essentially close relationships. Also, the role of the isolate, or the patient with no acquaintances with other individuals with Parkinsonism, (as in Case #4) and his reactions to his Parkinsonism and l-Dopa might be a fruitful area for investigation.

It was noted in the majority of the interviews that patients tended to rate the initial severity of their Parkinsonism in terms of what they were not able to do physically. The Roche Evaluation of Patient Progress Charts, in the "activity category", are actually a formalized method of using this common literature-based reaction. Schulman and Smith⁹⁰ report that in older people the "healthy state is equated with qualities that directly or inferentially portray the adequate performance of one's routine or usual tasks." Several

⁹⁰Sam Schulman and Anne M. Smith, "The Concept of Health Among Spanish Speaking Villagers of New Mexico and Colorado," Journal of Health and Human Behavior, 4:226-234, Winter, 1963.

patients confined this reaction to a gradual "slowing down", as the patient in Case #10 who complained of not being able to housekeep as effectively as before her illness, while others, more bitterly blamed the onset of their disease as effecting a drastic change in their lives (as the couple in Case #2 who had to virtually leave their home community to be closer to their son and larger medical facilities). The social, as well as the physical impact of Parkinson's disease is quite evident in most of the case studies. A majority of the patients reported having to confine most of their activities to their home settings, others having to move to custodial institutions because they could no longer remain independent. Although many of these patients only implied that these problems cost them their outside social relationships with other people, the implication was still present. The female patient in Case #3 who stated, "I only visit with my family now", is a prime example of the somewhat negative social significance that the onset of Parkinsonism carried with it for many of the patients in the study. However, there were also more optimistic indications in this direction from the reports of ten patients. Each reported or gave some indication that they were able to function more normally in both the physical and social spheres after 1-Dopa treatment.

The last variable to be discussed concerns a subject which has been threaded throughout the entire study--that of the power of suggestion. The investigator, in a final search through the data for

some indication of this variable, discovered a rather questionable relationship between degree of drug knowledge and number of manifested side effects. The patients in the study demonstrating a high degree of knowledge of l-Dopa established a median average of 4.3 side effects each, while those demonstrating moderate, little or no knowledge compiled a median average of 2.2 side effects each. The most obvious reasoning for this finding lies in the fact that those individuals manifesting a high degree of drug knowledge might also be able to identify a greater number of untoward drug reactions in themselves than those possessing a lesser degree of l-Dopa knowledge. Still, the investigator could question the possibility that those individuals who knew of certain side effects might be more prone to develop them than those patients who did not have that knowledge. While this is an interesting possibility, it shall have to remain in the realm of speculation without more investigated evidence.

The investigator will conclude, at this point, the analysis of the case study material. It is undoubtedly obvious, with even a cursory glance at the mere bulk of the interview-obtained data, that further discussion is possible. However, one of the limitations of my non-experimental, exploratory research such as this one is the great difficulty, if not the impossibility, of deriving cause and effect relationships. The effects of the many extraneous variables, according

to authors Abdellah and Levine,⁹¹ "can be confounded to such an extent as to lead to the drawing of spurious relationships" when this design is utilized. On the other hand, the advantage of this research lies in the...."possibility of extending the research to larger study populations."⁹²

In order to avoid the confusion inherent in any attempt to compare highly variable individuals and to apply the trend-type findings to the suggestions for further study, the investigator chooses to move on to Chapter 6. This section shall contain the summary, conclusions, and recommendations for further study based on the analysis conducted in this chapter.

⁹¹Abdellah and Levine, *op. cit.*, pp. 211-212.

⁹²Abdellah and Levine, *op. cit.*, p. 212.

Chapter 6

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Summary

It was the purpose of this study to exploratively describe the reactions and experiences of the patient with Parkinson's disease using the newly discovered drug, l-Dopa, making comparisons between patients where applicable.

The investigator had noted the rather disturbing lack of case study material on the patient with Parkinson's disease using the new medication. Believing that individualized reporting by patients can serve as a valuable basis from which to plan professional health care, the investigator sought to identify the social, psychological, and physiological experiences that individual Parkinson's patients taking the drug l-Dopa had underwent, making comparisons between patients as possible. In addition, the investigator wished to determine the source of information about the disease and drug for Parkinson's patients, identifying any effects that the possession of this information has upon the patient.

Personal interview was selected as the method of investigation. An investigator-designed interview schedule which consisted of both open and close-ended questions was utilized to obtain data. No scientific or statistical method was attempted for selection of sample, due

to the initial difficulty of locating subjects suitable for study.

The data presented in a modified case-study format, consisting of interview conversational answers arranged in a summarizing fashion. Variables identified in the case material which lent themselves to numerical representation were also presented.

The analysis of the study data was designed to elicit major trends noted in the data. These trends were derived from the identification of commonalities between patients and comparison of the study-obtained data with literature-based materials.

Conclusions

Because of the small sample size utilized in the study, the investigator is severely limited in her ability to generalize the study findings to other situations. Therefore, the presented findings shall have to be considered specific only to this particular investigation.

The study and analysis of the ideas, opinions, and information provided by patients with Parkinson's disease using l-Dopa and their interview collaborators suggested the following findings:

- 1) 17.7 years difference existed between the reported average age of onset of patients with Parkinsonism in the literature compared with the study subjects. Possible reasons for this difference were discussed, including the characteristically gradual onset of the disease and failure to notice symptoms on the part of the patient, the incidental location of a comparatively older Parkinson's patient as a

result of the study's selection limitations, and an investigator-instigated theory utilizing Selye's stress concept. Other possible reasons for this finding may exist.

2) The group studied proved to be better educated and to enjoy a higher status of previous occupation than the average American over 65 years of age. Likewise, the group studied demonstrated a surprisingly high degree of knowledge of l-Dopa. The investigator suggested that the variable of educational attainment may have had an influence on the patient's interest in locating information about l-Dopa.

3) A possibly conservative group of physicians treating the subject patients or consideration of the relatively short interval time the patients had been taking l-Dopa may be explanations for the finding that this study's subjects were taking lesser amounts of the drug than is reported in the experimental literature.

4) A majority of the patients reported obtaining information about their disease and drug from the mass media, rather than physicians. In most of these cases, the patient reported first attempting to obtain information from his physician and then, when no satisfaction was obtained, turning to the mass media sources. Inherent in this finding were cases of five patients who obtained some information, usually interpretation of mass media information, through fellow Parkinsonism patients. Environmental residence was a variable implicated in this finding. For example, those individuals residing in

hospitals tended to obtain their disease and drug information, usually little, through their physicians.

5) Twelve of the seventeen patients interviewed reported approaching their physicians initially to request treatment with l-Dopa. The investigator felt that this finding indicated the tremendous impact that the discovery of the drug had on these patients' world and the resultant desirability of obtaining this form of treatment, as seen by these patients.

6) The improvement ratios obtained from patient evaluation of their progress on Roche Laboratory charts was equivalent to literature-based data obtained through physician evaluations of patient progress, demonstrating the reliability of this tool.

7) Reports of side effects, with two rather notable exceptions, also compared favorably with literature-based experimental data. There was some indication that the two non-reported untoward reactions may have been manifested in the individuals via the power of suggestion from other patients. This study also suggested that the relationships developed between the patients in the study may be fruitful areas for investigation of suggestion in the group setting.

8) The patients who relied exclusively upon their physicians for disease and/or drug information seemed to have a more positive attitude toward their physician than those who had been unsuccessful in seeking information from their physician. The investigator suggested

that this identified problem may be a factor in the increase of suits involving patients and physicians.

9) The patients typically tended to rate the severity of their disease in terms of things they physically could not do. This finding also included activities that they socially could not perform. The impact of Parkinsonism on both spheres of the patients' lives, the physical and the social, was noticeable and generally destructive. However, the use of l-Dopa and resultant improvements made, served to increase the physical and social capacities of the majority of patients. Still, the investigator suggested that this finding may be important in planning the health care of these patients.

10) Very few of the interview collaborators actively contradicted or interfered in the interview process. Most, on the other hand, served as validation for the content of the interview provided by the patient, as well as noting material that the patient had not remembered or recognized about himself. This finding suggested that the use of an interview collaborator as part of a methodology may be a beneficial aid for an investigator.

11) The patients with an evaluated high degree of drug knowledge were found to have a greater number of untoward drug reactions than those possessing moderate, little, or no drug knowledge. The possibilities that the more sophisticated patients manifested more side effects, because they could identify more in themselves, or that

they might be more prone to develop them than patients who did not have that knowledge, via the power of suggestion, were suggested as factors in the finding.

12) The virtual bulk of data collected from such a small sample of patients with Parkinsonism taking l-Dopa and only briefly summarized above, suggests to the investigator the reliability, if not the practicality, of her research design. First, although some of the data corresponded with the typically numerical literature-based material, much of it did not. The age range of the subject Parkinson's patients, in example, did not compare favorably. In the investigator's opinion, the finding may or may not be valid. Many more subjects would have to be interviewed to establish statistical significance. However, the point remains that case-study material of this sort tends to raise interesting questions. If, for instance, the age onset of these patients does not fit, why does it not fit, or is it possible that the literature-based figures need changing? Further investigation can only find the answers. Secondly, the feelings and attitudes portrayed in the case study material give a human quality to the subject individuals, a factor that, in the investigator's opinion, is lacking in statistical studies of patients. The nursing and medical professions need this type of information upon which to base plans for individualized health care. After all, who could provide "Tender Loving Care" to a number on a page? Thus, the investigator's basic conclusion from this study

remains that, despite the effort involved in creating patient case studies on a much larger scale than this study, more of their kind needs to be done. This conclusion should not only involve the patient with Parkinsonism taking 1-Dopa, but any other patient with any other disease as well.

Recommendations

The findings in this study provide a basis for recommendations of two types: 1) Those suggestions for further study that actually arose from the data collected on the patient with Parkinson's disease taking 1-Dopa, and 2) those recommendations for the health professions, indicated through the experiences and reactions of the subject patients.

First, the small sample of patients investigated in this study and the relatively difficult task of locating them perhaps make the following recommendations for further study more practicle for the urban Parkinsonism research center having a large available research population:

- 1) A revised interview schedule similar to the investigator tool needs to be administered to a statistically workable population. Questions needed to be added to determine whether or not any unusual event tended to precipitate symptoms or if they evolved gradually. Further investigation or any relationship developed between patients on a social level to determine the effect, if any, on their disease and drug knowledge as a result of

associating with persons having similar problems needs to be established.

- 2) Physicians and/or nurses responsible for the patient's care need to be interviewed separately from the patient for the purpose of comparing the patient's impressions of his health care vs. the health professionals'. It is entirely possible, even in this study, that the physicians gave certain information to patients about their condition and drug, but that the communication was not successful. Certainly, this vital issue identified in the study must be investigated further, for it has drastic implications for health care of the future.
- 3) A means of studying the placebo effect of l-Dopa in the experimental laboratory should be studied further. Some "double blind" efforts have been undertaken previously, but this study points to the factor, for example, of other patients influencing the reactions of the subject patients. Thus, a more encompassing effort to measure this effect should be undertaken.
- 4) The effects of marriage, place of residence, and drug knowledge need to be studied in further detail as factors relevant to Parkinsonism patients' reactions to their disease and l-Dopa. In addition, the effects on patient reaction of social isolation, as a result of disease-caused deterioration, need to be investigated.

Secondly, the recommendations for health professionals which grew out of this study are few in number, but tremendously important in relevancy.

- 1) If physicians are to continue to provide health information to the public, some effort shall have to be made to change a possibly souring professional image. Physicians may have to be made to realize, via statistical material, if necessary, that the American public appears to be becoming a more knowledgeable public on the subject of health matters. If no effort is made toward this end, the investigator foresees that health professionals may find themselves replaced by machines designed to provide the diagnosis, treatment, and answer any questions asked by the patient. If time is becoming a lessening asset in the physician's life, then he'd perhaps do well to utilize other professionals, specifically the nurse, to perform his teaching functions for him. The nurse, if this event should occur, shall have to become a better informed individual herself in order to give the up-graded type of information the public, as revealed by this study, seems to be seeking.
- 2) The public health nurse shall need to become attuned to the growing number of patients with Parkinsonism, residing in private homes, rather than institutions, as a result of a

drug-induced higher level of functioning. These persons, as pointed out by this study, still need the type of service a professional nurse can provide, that of continued emotional support. The hospital-oriented nurse might also do well to heed this suggestion, recognizing that the Parkinsonism patient's problems are likely more intense in the institutional setting. The investigator further recommends that educational classes could be created for the purpose of information-giving and sharing of experiences between patients and conducted by the nurse in a community. Using this means, the patients' manifested needs could predictably be met on both a private and social level.

- 3) Both hospital and public health-oriented nursing care plans need to be devised to meet the revealed needs of the patients in the study. Similarly, the medical and nursing profession must be made to realize the necessity of individualizing the type of anticipatory guidance each Parkinson's patient taking l-Dopa should receive.

APPENDICES

APPENDIX A

SAMPLE PATIENT LETTER

January 10, 1971

Dear (Patient):

I am a Registered Nurse-graduate student currently fulfilling the requirements for a Master's degree in Nursing at Montana State University. At present, I am interested in interviewing patients with Parkinson's disease who are currently undergoing drug therapy with the new medication, L-Dopa. It is my understanding per (another patient, clinic, or physician) that you might be an interesting person to contact regarding this subject. Please feel free to contact (another patient, clinic, or physician) as a reference in this matter.

In the interview, I am primarily interested in securing information regarding the following topics: 1) your past medical history with reference to the onset of your Parkinsonism, 2) the effects, good and poor, that you've experienced after taking L-Dopa, 3) the source(s) from which you first heard of the drug, and 4) anything else of interest about yourself that you think might be helpful to me. Of course, your identity and information you provide me would be confidentially treated. Also, I would like to have (your wife, a member of your family, or close friend) present in the interview. Ofttimes another individual who knows you well might be able to give additional information about your case that you might not have noted.

I will be in (resident community) on (date). For the purposes of obtaining your permission for interview, and if obtained, selecting a convenient time and place for us to meet, I shall telephone you at (time and date). Please feel free to contact me at the below-listed telephone number should you have any questions regarding my study prior to (date).

Thank you very much for your cooperation in this matter.

Sincerely,

Kay R. Ewan, R.N.
(Address)
(Telephone Number)

APPENDIX B

ANSWER TO REQUEST FOR INFORMATION (Copy)

ROCHE LABORATORIES

Division of Hoffman-LaRoche, Inc.-Nutley, New Jersey,-
Professional Services Department
Original Research in Medicine -
Chemistry and Bioelectronics

March 3, 1971

Dear Mrs. Ewan:

We are in receipt of your request for information concerning the use of Larodopa (Levodopa) Roche in the treatment of Parkinson's disease and syndrome.

We are pleased to enclose a complete folder with assorted reprints, "Guide to Therapy", "Guidelines for Patient", patient response chart, and our latest monograph on the product Larodopa. Please feel free to utilize this information in your thesis research.

Unfortunately, at the moment we can't make any statistical analysis since we have not accumulated information on the number of patients taking the drug, and the dose for each patient. We can say, however, that virtually 100% of the patients experienced one or more side effects while being gradually titrated to their optimal dosage.

More recently received data is being reworked and we hope to have some of the statistical information you desire in the future.

I certainly hope that the above information and the enclosed data are adequate for your purpose.

Thank you very much for your inquiry, and I hope that your project is a resounding success.

Cordially,

(Name)
Product Services Coordinator
Professional Services

APPENDIX C

ANSWER TO REQUEST FOR INFORMATION (Copy)

BROOKHAVEN NATIONAL LABORATORY
Associated Universities, Inc.
Upton, Long Island

Medical Department

June 9, 1971

Dear Mrs. Ewan:

Your letter of May 7th arrived just as I was preparing for a lecture tour abroad. Therefore, I am afraid that your thoughtful inquiry could not get the time and attention it deserves. I was quite interested in some of your findings in the study you are undertaking. We scientists often become so engrossed in our biochemical world that we forget the sociological aspect exists for patients as well. You have sparked some questions in my mind that I shall have to ponder for a time.

In my absence, our diminished staff shall be somewhat overworked and I hate to impose any more burden on them at this time. I have, therefore, enclosed some of the more recent reprints of our studies in the treatment of Parkinsonism in the hopes that they will answer some of your questions.

Should you have any questions after reading the enclosed materials, please try us again. Perhaps at that time one of our doctors or myself will have an opportunity to answer your specific questions.

Sincerely yours,

Dr. George Cotzias
Brookhaven National Laboratory
Medical Department
Upton, Long Island

APPENDIX D

INTERVIEW SCHEDULE

1. Case Number _____
2. Age _____
3. Sex _____
4. Marital Status _____
5. Educational Background _____
 - a. Patient _____
 - b. Interview Collaborator _____
6. Previous or Present Occupation _____
7. How many years have you lived in this residence and in this community? _____
 - a. (Interviewer: Note type of residence, community name, community population) _____
8. Onset of Parkinsonism:
 - a. At what age did you first notice the symptoms of Parkinson's disease? _____
 - b. What kinds of symptoms did you have? _____

 - c. At what point did you go to the doctor for treatment? _____

 - d. What did the doctor tell you about your condition at that time? _____
 - e. Can you tell me how your condition has affected your life? (i.e. your job, your family, outside activities, etc.) _____

9. 1-Dopa--Patient's Perspective on Usage of Drug:

- a. Where did you first hear about 1-Dopa (i.e. friends, physician, magazines, etc.) _____
- b. Did you or your doctor suggest that you try out the drug? _____
- c. What did your doctor tell you about 1-Dopa? _____

10. Test of Drug Knowledge:

- a. Can you tell me the name of the drug you are taking for your Parkinsonism? _____
- b. Do you know the dosage of the drug you are taking? _____
- c. Can you tell me how the drug works in your body? _____
- d. Since this drug is known to have certain side effects, can you name at least five of them? _____

11. Patient Response Charts for Evaluation of Patient Progress:

(Investigator's Explanation, showing patient the chart):

I am now going to try to determine how much you have improved since you have taken 1-Dopa. First, I will name the major symptoms of Parkinson's disease and you will try to tell me how severe you think those symptoms are in you both before and after taking the drug. The choices are five in number: absent, mild, moderate, marked, very severe. I will keep the choices in front of you so that you won't have problems remembering what they are. Secondly, I will name certain common activities we all do every day and you will again try to tell me if you have problems with these things, again rating them by the choices before and after taking the drug. The last thing I will ask you to do is tell me the kinds of side effects of 1-Dopa you think you have had plus answer whether or not you've had the ones I will name. Do you understand these instructions? Let us begin.

CHART COPY
(as shown to patient)

Key: 0 = absent 3 = marked
 1 = mild 4 = impossible to
 2 = moderate do or test

SYMPTOMS	Before	After
Rigidity (Stiffness) _____		
Tremor (Shakiness) _____		
Akinesia (Loss of muscle movement) _____		
Dementia (Forgetfulness, depression, changes of mood) _____		
Postural abnormality _____		
Depression _____		
Seborrhea (Oily skin) _____		
Sialorrhea (Excess saliva flow) _____		
Blepharospasm (Spasm of the eyelid) _____		
Mask Facies (Lack of facial expression) _____		
SUBTOTAL	SUBTOTAL	

CHART COPY
(Continued)

ACTIVITY	Before	After
Dressing _____		
Walking _____		
Getting out of bed _____		
Turning in bed _____		
Getting out of a chair _____		
Climbing stairs _____		
Use of toilet _____		
Bathing _____		
Speech _____		
Handwriting _____		
SUBTOTAL _____		SUBTOTAL _____

SIDE EFFECTS A = Absent P = Present M = Marked		
	Before	After
Nausea _____		
Anorexia (Loss of appetite) _____		
Flushing _____		
Dyskinesia (Unusual muscle movement) _____		
Mental changes _____		
Cardiac Disturbance (Heart trouble) _____		
Hypotension (Drop in blood pressure) _____		
Other _____		
SUBTOTAL _____		SUBTOTAL _____

12. How do you feel about taking l-Dopa? _____

13. Interview Collaborator:

a. Can you add to anything that the patient has said about
himself? _____

APPENDIX E

EXPLANATION OF QUESTIONNAIRE ITEMS

Each of the items incorporated into the questionnaire was selected to provide some kind of data relevant to the research design. Each item was believed to either assess the degree to which certain factors contribute to patients' perception of their illness or to be an expression of that perception. In each instance, a number of assumptions and expectations guided the author's selection of items. These are set forth below as explicitly as possible in the limited space.

ITEM 2: Age. This factor was believed to be influential in determining patient perception of his illness, since the advancement of age is usually associated with an increasing number of medical episodes and leads to polarization of attitudes toward the illness process.

ITEM 3: Sex. It was anticipated that the perception of the illness process would vary according to sex, since the sexes are differently conditioned by society in relation to approved modes of emotional and behavioral responses to illness. The roles are so differentiated, in fact, that perceptions held by each sex must be taken into account when evaluating the nature and meaning of the perception to the individual.

ITEM 4: Marital status. This factor is relevant to the extent that it reflects the patient's life complexity and social context. The process of illness might, therefore, be influenced by this factor.

ITEM 5: Educational background. The educational background of an individual is accepted as at least one influential factor in molding his attitudes and perceptions. It is predicted that this factor might also be relevant to a patient's later quest for knowledge, and in this study, his sophistication about medical matters. Likewise, the interview collaborator was thought to be an influence on the patient's perceptions, by virtue of his or her close association with the patient. Thus, the interview collaborator's educational background was also taken into consideration.

ITEM 6: Previous or present occupation. In many previous studies, an individual's social class had been cited as one factor influencing his illness behavior. Since the older population's housing or present income may be questionable variables in determining their social class, their present or previous occupations were chosen as the variable most likely to be indicative of their position in the social hierarchy.

ITEM 7: How many years have you lived in this residence and in this community? It is predicted that the patient's environment, including his type of residence, the length of time he has lived in the community, and the population of that community shall be influential factors in his illness behavior.

ITEM 8: a) At what age did you first notice the symptoms of Parkinson's disease? This question was asked for two reasons:

1) the time at which the disease symptomatology initially became perceived by the patient was thought to be an influence on his reactions to his illness; and 2) comparison of this data with literature-based material might be interesting and informative.

b) What kinds of symptoms did you have? Again, this question was asked to illicit answers which would allow the investigator to determine the potency of the disease condition's effect on the patient's life and to allow comparison of the obtained data with literature-based material.

c) At what point did you go to the doctor for treatment? It was predicted that the severity and impact of symptoms on the patient's life would be a potent factor in the determination of when he sought a physician's aid.

e) Can you tell me how your condition has affected your life? The answer to this open-ended question was presumed to be productive of the total patient attitude toward his experiences with his illness in both a physical and social sense.

ITEM 9: a) Where did you first hear about l-Dopa? This factor relates to the primary source of information about l-Dopa for the patient.

b) Did you or your doctor suggest that you try out this drug? The fact that a patient suggests to his physician a form of treatment may be indicative of the total impact that this "miracle" drug has had on the patient's life and/or a changing relationship between doctor and patient.

c) What did your doctor tell you about l-Dopa? Determining whether or not physicians are providing anticipatory guidance about a basically experimental drug is related to legal, moral, and ethical questions.

ITEM 10: Test of drug knowledge. The test of drug knowledge was designed to elicit fairly specific answers about l-Dopa which would indicate whether or not the knowledge obtained about this form of therapy had been successfully comprehended or not.

ITEM 11: Roche Charts for Evaluation of Patient Progress.

Comparison of the patient's verbal descriptions of his progress and a numerical estimate of the severity of his symptoms and ability to perform certain activities was undertaken with these charts. The comparisons were thought to be an indication of the validity of the patient's statements about his progress; they were also valuable for comparison with literature-based material.

ITEM 12: How do you feel about taking l-Dopa? This open-ended question was felt to be predictive of the patient's impressions and attitudes toward the entire drug therapy experience.

ITEM 13: Interview Collaborator: Can you add to anything that the patient has said about himself? The interview collaborator was basically urged to interrupt or add to the conversation between investigator and patient at any point. It was predicted that this individual, familiar with the patient, might be both a validator of the patient's testimony and an asset in bringing forth observations about the patient (not noted by the patient).

APPENDIX F

AN EXAMPLE OF THE ROCHE CHART

The seventeen patients in the study rated their progress with l-Dopa therapy by evaluating the severity of their symptoms and ability to perform certain activities both before and after taking the drug. Recordings were made on the Roche Laboratories' Patient Response Charts. An example of this chart, utilizing the data collected for Case #1, is provided. The explanation of the chart can be located in the main body of the paper. The portion of the chart containing the listing of side effects has been previously reproduced in Appendix D, page 131.

ROCHE PATIENT RESPONSE CHART

CASE #1

0 = absent 3 = marked
1 = mild 4 = impossible to
2 = moderate do or test

	Evaluation (0-4)		Weighted Score	Patient Score	
	Before	After		Before	After
<u>SYMPTOMS</u>					
Rigidity	3	1	X 7	21	7
Tremor	1	0	X 5	5	0
Akinesia	3	2	X 9	27	18
Dementia	0	0	X 8	0	0
Postural abnormality	3	2	X 3	9	6
Depression	2	2	X 5	10	10
Seborrhea	0	0	X 2	0	0
Blepharospasm	2	1	X 2	4	2
Sialorrhea	2	1	X 2	4	2
Mask Facies	3	3	X 1	3	3
			Subtotal	84	48
<u>ACTIVITY</u>					
Dressing	3	1	X 5	15	5
Eating	3	0	X 7	21	0
Walking	3	2	X 10	30	20
Getting out of bed	3	1	X 6	18	6
Turning in bed	2	0	X 4	8	0
Getting out of chair	3	0	X 5	15	0
Climbing stairs	3	2	X 2	8	4
Use of toilet	3	1	X 6	18	6
Bathing	4	2	X 6	24	18
Handwriting	3	1	X 5	15	5
			Subtotal	202	78

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