Statement of

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Before the

Subcommittee on Health and Environment
oithe
Committee on Commerce
United States House of Representatives

on

Medical Devices: Innovation and Provider/Patient Perspectives

April 30, 1997

Summary

Parkinson's Disease (PD) is an age-related disorder that affects approximately 1,000,000 patients in North America and it is projected that the incidence will increase 4 fold by the year 2040. In addition to the personal suffering that PD causes patients and their families. it is estimated that PD results in a loss of revenue to the United States Government of $7 billion annually. Current therapy largely consists of brain dopamine replacement with the drug levodopa. While levodopa provides substantial benefit in the early stages of the disease, after 5 to 10 years most PD patients develop disability that can not be satisfactorily controlled with existing medications. Recently, interest has focused on the capacity of several surgical procedures to provide benefit for patients with advanced PD. Among these, one of the most promising is deep brain stimulation (DBS). DBS has the advantage that it does not necessitate making a destructive lesion in the brain and can Therefore be empioyed with relative safety Preliminary clinical trials indicate that DBS can provide remarkable benefits for patients with advanced PD who can not be adequately controlled with levodopa. DBS thus has the potential to substantially improve the quality of life and independence of these patients. However. in the United States. the development and review time for new therapies such as DBS is exceedingly long and the time to approval continues to grow. AS a result patients are denied access to critical and potentially life saving therapies such as DBS. Further, companies are discouraged from investing in new and promising technologies that might offer hope to other patients. Obviously, the FDA must determine that the benefit of a new product outweighs its risks and that the risks have been adequately defined. However, it is imperative that Congress encourage the FDA to avoid unnecessary delays that hold up development and approval so that our patients will not have to be deprived of important new therapies for one day longer than is essential than is essential to meet FDA standards.

Introduction

Thank you very much for allowing me to appear before you today. My name is Warren Olanow and I am Professor and Chairman of the Department of Neurology at the Mount Sinai School of Medicine in New York City. Prior to assuming my position at Mount Sinai, I was director of the Movement Disorder Centers at Duke University and the University of South Florida. During my career. I have treated more than 5,000 patients with Parkinson's Disease and have specialized in the development of new medical and surgical therapies designed to improve the quality of life of these patients.

Parkinson's disease (PD) is an age-related disorder that presently affects approximately 1 ,000,000 Americans. The average age of onset is 60 years and an individual's lifetime risk of developing PD is approximately 2%. Based on L'S census bureau population figures, it can be projected that by the year 2040 the incidence of PD will have increased by 4 fold as a consequence of the aging of the population. Current medical therapies provide substantial benefit for patients in the early stages of the disease_ but the vast majority of patients eventually develop disability that can not be satisfactorily controlled despite the best of available therapies. Patients with advanced disease may thus be forced to live 10 years or longer with an unacceptable level of disability. This is not only a hardship for patients and their families. but is estimated to cost the United States Government approximately $7 billion annually in health care expenditures and lost revenues.

Parkinson's disease is characterized by a group of cardinal signs and symptoms that include:

- Tremor – shaking of the hands that can impair a patient's ability to drink a glass of water, eat food. or write a letter.
- Rigidity or stiffness – this limits a patient's capacity to perform a movement.
- Bradykinesia or slowness in performing voluntary movements
- Gait disturbance – trouble walking, turning, and getting started such that in advanced stages patients may nor be able to walk independently and are confined to a wheel chair or to bed.
- Falling episodes – patients lose their balance and fall putting them at risk for fractures

Collectively, these problems can restrict a patients activities of living so that they can not bathe alone. can not feed or dress themselves. can not turn in bed. can not walk to the bathroom. and basically can nor live an independent life.

PD is associated with a loss of nerve cells in a region in the central part of their brain known as the substantia nigra pars compacta. These cells normally manufacture the chemical neurotransmitter, dopamine. In PD, nerve cell loss results in a profound reduction in brain dopamme levels.

Current therapy for PD is based on an attempt to restore dopamine levels in the brain using a drug called levodopa (usually sold in the United States as Sinemet®). Initially, virtually every PD patient responds to levodopa. However, after approximately 5-10 years of levodopa treatment the majority of PD patients develop a series of serious side effects which include:

- Dyskinesia – involuntary flailing movements that can be more disabling than the PD itself.

- Motor fluctuations – patients cycle between "on" periods in which they respond to levodopa but may have dyskinesia and "off" periods in which they may be frozen and completely unable to move
- Neuropsychiatric problems – confusion and hallucinations

Further, with the passage of time patients begin to develop problems that do not respond to levodopa such as freezing, postural instability, autonomic insufficiency, and dementia. **Thus. despite the initial benefits associated with levodopa therapy, after 5 to 10 years of treatment. more than 75% of PD patients experience unacceptable levels of disability that can not be satisfactorily controlled with levodopa or other available medications.** Accordingly, there has been an intensive search to find new and innovative therapies that might slow disease progression and restore function to patients with existing disability. There are several new medical therapies that are currently being investigated but substantive advances in the medical treatment of PD appear to be many years away. New surgical procedures are more promising in the near term.

Surgical Therapies for **Parkinson's Disease**

Surgical approaches Save recently attracted considerable attention in the scientific and lay communities as possible restorative treatments for patients with advanced PD. Surgical procedures that involve making a destructive lesion in the brain such as thalamotomy and pallidoromy have been employed in the treatment of PD for almost a century. Historically, these treatments provided improvement in uemor but did not affect the other more disabling features of PD. With the introduction of levodopa, these procedures fell out of favor and less than 100 per

year were performed during **the** 1970's and 1980's. Since the 1990's, there has been a resurgence of interest in destructive surgical procedures, particularly pallidotomy. This is due to:

- improvements in surgical and anesthetic techniques.
- the use of MRI and neurophysiologic techniques to more accurately define the target site and to minimize the risk of experiencing side effects.
- scientific advances have provided a rationale for making a destructive lesion in the globus pallidus, a nucleus of cells located deep within the brain. In PD, there is excess nerve cell firing in the globus pallidus leadiug io the development of the signs and symptoms of PD. It can therefore be postulated that damage to the globus pallidus could reduce the excess nerve sell firing and improve the signs and symptoms of PD. Indeed, destructive lesions of the globus pallidus in animal models of PD have been shown to provide dramatic improvement and relief from parkinsonism.

Based on the above. there has been renewed interest in pallidotomy, a surgical procedure that makes a destructive lesion in the globus pallidus in an attempt to diminish its overactivity. Initial results have been very promising and this procedure is now widely employed as a treatment for PD. However: pallidotomy is associated with several important limitations. These include:

- It is necessary to make a destructive lesion within the brain. This can lead to the development of serious side effects including paralysis and blindness.
- Pallidotomy procedures on both R and L sides are associated with additional side effects including impairment in speech swallowing and thinking. As a result physicians are wary of performing bilateral procedures. This is important because PD effects both sides of the body and bilateral procedures may be necessary to provide a satisfactory benefit.

- A destructive lesion in the brain may preclude rhe possibility of using new and more effective therapies in the future.

Deep Brain Stimulation

Deep Brain Stimulation (DBS) is another surgical technique that shows considerable promise as a treatment for patients with advanced PD. DBS is based on the empirical observation that stimulation of nerve cells in the brain at a frequency of approximately 180 cycles per second replicates the effects obtained with a destructive lesion yet does not cause damage to the brain. The system works by implanting an electrode into the desired target region of the brain (e.g. the VIM, the globus pallidus or the subthalamic nucleus). The electrode is then connected to an **extension** wire which runs under the skin to a pacemaker which is implanted over the chest. The pacemaker can be programmed with respect to a number of parameters including frequency and voltage. Turning on the stimulator induces the benefits associated with a lesion without the disadvantages of damaging the brain. There are several advantages to this system in comparison to other destructive surgical procedures. These include:

- It is nor necessary to make a destructive lesion within the brain.
- The procedure avoids brain damage due to a destructive lesion that could result in paralysis or blindness.
- The pacemaker can be reprogrammed at any time to minimize side effects and maximize benefit.
- The procedure can be performed bilaterally with much greater safety than procedures that necessitate making a destructive brain lesion such as pallidotomy or thalamotomy.

- Target sites in the brain can be chosen for DBS that are not candidates for a destructive lesion because of the high risk of inducing a side effect. An example is the subthalamic nucleus (STN). The STN appears to be the optimal target for in PD but a lesion in the STN can induce a life-threatening involuntary movement disorder known as hemiballismus.
- DBS does nor preclude the possibiiity of using a newer and more effective therapy in the future. There is no permanent brain damage and if a better treatment comes along, the pacemaker can be turned off.

DBS was originally employed as a treatment for tremor. stimulating a target brain region in the thalamus (the VIM). Studies in Europe and in the United States demonstrated dramatic improvement and even elimination of tremor in as many as 80% of patients. During these studies. the relative safety of DBS and its bilateral application were established. Two patients who underwent this procedure recently testified as to its effect on their lives. One was able to dress himself and write a letter for the first time in 10 years. Another spoke of the great pride he felt in not being embarrassed to take his daughter out for dinner and actually being able to sign for the check. Being able to perform simple acts once again that all of us take for granted has had a dramatic effect on the lives of these and other individuals who have had DBS.

However; tremor is not die only problem facing PD patients. Rigidity, slowness, gait disturbance, and failing are more likely to interfere with activities of daily living and independence. These features do not respond to lesions in or stimulation of the thalamus. However, there is

considerable evidence to Indicate that DBS can relieve even these features of PD if stimulation is performed in the globus pallidus or the subthalamic nucleus.

DBS of the Subthalamic Nucleus and **Globus Pallidus**

As mentioned above, a body of scientific information indicates that the dopamine depietion results in excess nerve cell firing in both the globus pallidus and subthalamic nucleus leading to the signs and symptoms of PD. This suggests that destructive lesions in the globus pallidus or subthalamic nucleus to reduce the excess nerve cell firing could improve PD features. Indeed. destructive lesions in these regions have been demonstrated to relieve parkinsonian features in animal models of PD. This has led to the re-emergence of pallidotomy as a treatment for PD and the procedure is associated with dramatic clinical benefit in some patients. However. it is extremely dangerous to perform a pallidotomy on both sides. The subthalamic nucleus is an even more rational target for PD but physicians have been reluctant to destroy this region of the brain because of the risk of inducing hemiballismus. a serious and potentially life threatening side effect. DBS offers the potential to diminish the excess nerve cell firing in the globus pallidus or the subthalamic nucleus bilaterally without rhe need to make a destructive lesion in the brain.

Preliminary clinical studies of DBS in PD have been extremely encouraging. The procedure is well tolerated and permits otherwise untreatable disability to be dramatically improved. As the stimulator can be turned off with an external magnet. stimulation related side effects can be eliminated. Leaders in the field of PD have been astounded by the magnitude of improvement and consider DBS to potentially be one of the most important advances in the field of Parkinson

therapeutics. In the studies of Benabid and colleagues from France, remarkable benefits have been documented with minimal adversity. in our own initial studies, we have confirmed the observations of Benabid and agree that DES has tie potential to dramatically improve PD disability and improve the lives of many pariems. The preliminary results of our m&i-center study, performed under the auspices of the FDA, indicate that patients with DBS in the GPi or STN can enjoy remarkable benefits. Taken together, it appears that DBS can provide a benefit that is equal to the best that can be obtained with levodopa but without the side effects (dyskinesia and motor fluctuations) that complicate levodopa therapy. Examples of the kind of benefit that can be derived from DBS is illustrated in the accompanying video tape. Clearly. more extensive studies are required to confirm these findings and to establish the long term safety and efficacy of DBS as well as to determine which patients are the best candidates for the procedure. As the initial results of DBS are so promising and potentially offer relief to so many PD patients who currently suffer from an untreatable disability, it is crucial that well-designed studies be carried out in as expeditious a manner as possible. In addition. a process must exist to permit rapid FDA approval if appropriate.

Role of the FDA

As a physician. I would naturally like IO provide the best treatments available to my patients. The FDA has an important regulatory role in assuring that any new- treatment has a satisfactory risk/benefit ratio and that adverse events have been adequately defined. However, it is essential that this be accomplished in as short a time as possible. It is my understanding that the FDA has made a substantial effort in recent years to reduce the time required for approval of new

treatments such as DBS. Nonetheless, despite these efforts, the development and review time for new products continues is increase. It is important for the committee to appreciate that treatments such as DBS offer PD patients with intolerable disability an opportunity to experience meaningful clinical benefit and to return to something like a normal life. In many instances, such a treatment is life saving. Impaired mobility as occurs in advanced PD can lead to potentially fatal complications such as aspiration, deep vein thrombosis, pulmonary embolus. and pneumonia. Based on the then available results and the unmet medical needs in patients with advanced PD. DBS was approved in Europe in 1995 as a treatment for tremor. In the United States, despite even more data. the treatment continues to await FDA approval for this indication. We are particularly concerned that this same pattern will emerge with regard to DBS of the globus pallidus and subthalamic nucleus which offer even greater promise for patients with disabling PD. In the current environment, new therapeutic development in the United States consistently lags behind that in Europe. This denies our patients access to innovative and promising treatments such as DBS and has encouraged industry to conduct investigations of new medical and surgical therapies in other countries. In the case of DBS for STN and GPi, the FDA would *not* allow our study to continue despite significant clinical benefits and lack of significant adversity in the initial 10 patients. Without reviewing this data, the FDA asked for changes to the previously approved protocol which reflected a lack of understanding of the specific disease process. After 6 months, the study was resumed with no fundamental change. While we applaud the good intentions of the FDA, this delay was unnecessary We have had to send patients to Europe to have DBS because we could not perform the procedure in this country during this bureaucratic delay. We recognize the importance of carefully defining the benefits and adverse events associated with any new therapy. However, it is unconscionable to spend one day longer

than is absolutely necessary to accomplish this goal. Patient's quality of life and even their lives hang in the balance. Congress must introduce legislative reform to ensure that the development and approval process for new therapies is expedited and that wasted time and unnecessary studies are eliminated. It is hard enough to develop innovative therapies such as DBS. We can not create a regulatory environment where patients are denied access to such treatments because of unnecessary delays in the approval process.

In summary, PD is a progressive disorder and a source of disability to hundreds of thousands of individuals in this country. In the coming years it is likely that the incidence of PD will dramatically increase leading to an increasing burden on PD patients. their families and society It is essential thar new therapies such as DBS be made available to patients as quickly as is reasonably possible both to relieve individual suffering and to diminish the cost that PD imposes upon the society as a whole.

Mount Sinai

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Steering Committee - C. Warren Olanow, M.D.
Approved: Funding pending

C. W. Olanow, M.D., F.R.C.P.C.
Professor and Chairman

CWO/jw

BIOGRAPHICAL SKETCH

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EDUCATION

University of Toronto	Pre-Med	1961
University of Toronto	M.D.	1965

RESEARCH AND PROFESSIONAL EXPERIENCE

1965-66	Rotating Internship, Toronto General Hospital, Toronto, Canada
196647	Resident in Medicine, Queen's Hospital, Honolulu, Hawaii
1967-68	Resident in Neurology, Toronto General Hospital, Toronto, Canada
1968-71	Resident in Neurology, Neurological Institute, Columbia Univ. NY, NY
1971-77	Lecturer in Neurology & Neuroanatomy, McGill University, Montreal, Canada
1977-84	Assistant Professor of Medicine (Neurology), Duke Univ. Durham, NC
1984-86	Associate Professor of Medicine (Neurology), Duke Univ, Durham, NC
1986-94	Professor of Neurology. University of South Florida, Tampa, FL
19X8-94	Professor of Pharmacology, University of South Florida, Tampa, FL
1992-94	Professor of Psychiatry, University of South Florida, Tampa, FL
1986-92	Director, Movement Disorder Center, University of South Florida, Tampa, FL
1992-94	Director, Centre for the Study of Neurodegenerative Disorders, USF. Tampa. FL
1994-	Professor and Chairman, Department of Neurology, Mt. Sinai School of Medicine, NY, NY

HONORS & SOCIETIES

1970	Royal College of Physicians, Canada Fellow
1990-97	National Institute of Health, Ad Hoc Reviewer
1992-93	President, International Society of Movement Disorders
1992.94	Treasurer, Movement Disorder Society
1987-	United Parkinson Foundation-Scientific Advisory Board
1991-95	American Parkinson Disease Association-Scientific Advisory Board
1994	Scientific Secretariat IIIrd International Congress of Movement Disorders
1994-	Association for Research in Nervous and Mental Disease-Board of Trustees
1994-	Henry P. and Georgette Goldschmidt Professor, Chrmn, Neurology, Mt. Sinai School of Med

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JOY M. VASS

WRITTEN STATEMENT

ON

MEDICAL DEVICES AND PATIENT/PROVIDER PERSPECTIVES

SUBCOMMITTEE ON HEALTH AND ENVIRONMENT

HOUSE COMMITTEE ON COMMERCE

APRIL 30. 1997

Hello, my name is Joy Maria Vass and I appreciate the opportunity to be with you, and to tell you my story. Approximately 12 years ago, I had my first heart attack while watching the evening news. At that time. the doctors discovered that I have Coronary Artery Disease-Hypoiipothermia -- a dual congenital disease in which extremely high levels of cholesterol collects in the arteries causing blockage. As a result. the heart suffers from a lack of blood and oxygen. which leads to severe angina, heart attacks, or death.

At the time of my first attack I was 25 years of age, and working in a relatively stress-free job in Virginia Beach. When my parents rushed to my bedside. doctors informed them that my cholesterol level was nearly 800 -- it should have been less than 200. I was immediately placed on a low fat diet. which I have followed consistently since that time; and was prescribed cholesterol-reducing pills. powdered drinks. beta blockers. and diuretics. I was told that I would live a relatively "normal" life. and although I had three angioplasties from 1986 to 1991. life was as "normal" as it could be, However. in 1991, I began to show signs of the onset of angina and the possibility of a major or fatal heart attack I was rushed to the hospital where doctors held a conference with my parents and myself. We were told that I needed immediate bypass surgery

On March 3, 1991, I underwent a quadruple bypass procedure I recovered in record time and proceeded with my life. which included securing a master's degree from the University of Mississippi graduating in the top 10 percent of my class, Shortly thereafter. my health began to deteriorate and I soon found myself again watching the shadows of twirling red and blue lights from the back of an ambulance. Doctors were astounded to find that after a cardiac catheterization only eighteen months earlier, three of my bypassed graphs were again more than 90 percent blocked. I was once again scheduled for yet another bypass in March 1993.

One week before surgery, doctors called to request a meeting between my parents and whomever else we deemed necessary As we sat around a beautiful mahogany table, the doctors began a “show and tell” using my x-rays. Very reluctantly, but very candidly, the chief cardiologist told us there had been a change in the program. My surgery was being canceled because they didn’t feel that additional surgery would benefit me to any great degree. The discussion ended like a Dear John letter... “forgive us. but there really isn’t anything else we can do for Joy.” After fifteen seconds of silence, tears barely touching my face as they fell. my father (a high school principal who is now deceased), cleared his throat and said: “How do you tell my 32-year- old daughter who has been on the honor roll since the fourth grade. who went to Rlississippi where she knew no one and became the first black female dorm director, who graduated from Ole Miss in exactly ONE year with a dual major and with all As and one B. who can walk into a room and immediately illuminate it. that all of this no longer matters?” But the doctors would not change their minds.

Consequently. for two years. I was on IVs. and heavily medicated with various heart medications. nitro pills which I took like Tic-Tats. nitro spray, nitro patches. and pain killers, In shon. MY LIFE WAS HELL! The final blow came when my insurance carrier “dismissed me,“ I was forced to become labeled as “totally disabled” and had to collect Medicaid and Pubic Assistance. I further had to allow myself to be degraded by individuals of these organizations who snarled at me as if to say “Heart disease, yeah right, only old folks have that. Who do you think you’re fooling?” Since I was now on Medicaid. my mother. who is a retired nurse on disability. did some research, and from an old acquaintance. found a hospital that had the guts to try to make her sick child well again.

Around this time. I became pregnant and engaged. Naturally, given my condition, my doctors immediately advised me to abort I refused because I truly knew how precious the gift of life is. I was willing to forfeit my own life for that of my unborn child, and I even signed papers that stated "IN THE EVENT OF MY DEATH" with my mother as a witness. But now I was in constant pain and could no longer shower alone. I had little or no daily mobility, and eventually became wheelchair-bound. Mercifully, God had another plan and after eight months of pregnancy, I delivered my stillborn son Kyle.

By now. my health was critical. My mother -- bless her heart -- remained the greatest trooper of them all She was forced to endure double duty as her husband lay dying on the third floor of the hospital while her daughter was dying on the fourth floor, I was hospitalized off and on for months. slowly slipping away My cardiologist refused to let it be over. and decided that it was time to introduce me to doctors who were working on an experimental surgery called TMR or transmyocardial revascularization. If I was willing. they would test me to see if I was an eligible candidate for the procedure In doing so. it ensured that I could become the first qualified candidate in the Washington Metropolitan Area to receive the new laser surgery.

In brie!: the idea for the procedure stems from the alligator and the way its heart functions, Instead of the heart relying upon the arteries for passage of blood. a laser is used to create tiny holes in the heart, thereby resulting in the heart receiving its necessary blood and oxygen through the holes instead of through the conventional human method.

In later November 1995, I was told that I would be the first TMR recipient. but because the surgery was pending approval from the Food and Drug Administration, there were some insurance problems At 6:00 a.m December 13, 1995. the morning of my surgery my loved ones and I brayed

the frigid temperatures and lack of sleep. That morning we learned that the final word had come from my insurance company and they would not contribute any financial resources because of the surgery's experimental status.

Believe me. I get "Joy" when I think about the doctor and nurses standing at the door of the family waiting room. searching the faces of my family and Friends and saying something to the nature of "this one is on the house," This is how I am able to speak to you today without becoming totally winded, and not from the whoppie cushion of my wheelchair.

I am now a part-time supervisor at Sears Department Store and am engaged to a new and wonderful man who understands that there have been times. when in the words of Langston Hughes. that "Life for me ain't been no crystal stair." I'd promised my niece, who was malnourished and neglected. that if I survived the surgery and God granted the energy to just "Feel like Going on." that I would adopt her She's been with me since Christmas of 1995 and is here today with the *real* soldier -- my hlom -- and a few other of my nearest and dearest

Thank you for allowing me to share my story with you. I seek no personal gratification or sympathy. and. although another TMR is inevitable. my only purpose here today is to help extend to others who are suffering the words of the Reverend Jesse Jackson. "Keep Hope Alive." Again. don't cry for me. but shed tears for those who are not as fortunate as I to have family and a medical team that will go to the extremes of unconditional love and caring,

Finally, I hope that I will leave you today pondering about those individuals' whose lives are dangling somewhere between the stages of experimentation. red tape, FDA approval. insurance discrepancies. paper shuffling and death. Again. thank you for this opportunity. and always remember, when in doubt listen to your heart; for it beats the truth.