TO EASE
THE BURDEN
TO FIND THE CURE
American Parkinson Disease Association

The American Parkinson Disease Association

FALL 2008 NEWSLETTER

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Where Do Medicines Come From?

By Cheryl A. Cuozzo, MSN, RN
Clinical Study Manager, Pfizer Global Research & Development,
New London, Conn.

When a doctor prescribes medications, it is the final step in a long, complex and expensive process to assure vital drugs get to patients who need them. It is valuable to understand what clinical trials are, and the rigorous phases through which medicines are developed, to appreciate that these drugs are available. This article will discuss each step in detail, starting from the earliest point of discovery, research and development – where drugs begin as an idea in the mind of a research scientist.

DISCOVERY LABORATORIES

Chemists and biologists in discovery labs work to develop drugs that will combat illnesses and diseases in various areas: cardiovascular diseases such as heart conditions, respiratory disorders such as asthma, neurological problems such as Parkinson's disease, or various allergies. The focus begins on understanding the normal and abnormal functions of the body, and learning about a particular disease. Millions of chemical molecules are tested to find a compound that will have promising activity against a particular biological target. For each potential compound there can be 5,000 other compounds that fail this process, never making it out of the lab.

PRE-CLINICAL TRIALS

Most compounds that are evaluated never become new medicines. If a compound shows promise, it will begin the journey down the long road to become a medicine approved by the Food and Drug Administration (FDA). Early tests are performed in cells and in animals to determine if the compound is safe, and to observe what the body does with the drug. Animal testing is necessary to learn if it is reasonably safe to proceed with studies of the compound in humans. This critical phase also helps to find out how the study drug should be made to produce the quantities required for clinical testing later on. Scientists must also eventually be able to formulate the compound into tablets, capsules, or other forms that are easy to administer. It must also be pure and it must contain the correct amount of the active ingredient. Sometimes these efforts fail as well.

About half of the compounds tested in pre-clinical trials are eliminated because of safety or metabolism issues. The discovery and pre-clinical testing process combined can take up to four years.

CLINICAL TRIALS

Clinical trials are planned to prove that the drug will produce a beneficial effect. The main goal is to determine whether the drug is safe and effective for its intended use(s), and whether its benefits outweigh its negative effects.

In all phases of drug development, the safety of the study volunteers is most important. Ethical, scientific and clinical standards are enforced by strict FDA regulations. The purpose of the study and all the risks of participation are thoroughly explained to volunteers during a consent process, and they are required to sign an Informed Consent Document (ICD), acknowledging that they understand the study and its potential risks.

PHASE I STUDIES

If the compound passes pre-clinical

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Dear Reader:

This is my last letter as APDA's president as I turn the gavel – and pen – over to my successor, Joel A. Miele, Sr., who has been a tireless champion of our organization for more than 23 years, most recently as the first vice president.

When I assumed this position seven years ago, there was excitement that a cure for Parkinson's disease was within sight in the next five years. Well, we know those years have come and passed, and we are still working and closing in on that goal. But we should not be disheartened. New medication and surgical therapies have brought great relief to many, and our contributions to research are achieving new breakthroughs every day. The work of organizations like APDA is providing the research funds that our government is not.

APDA has grown to meet these challenges. Today we are operating from a modern new national headquarters to serve better the 1.5 million Americans with PD and their caregivers, and our board of directors is guided by Sarbanes-Oxley mandates and requirements for financial governance. Concurrent with improving our operations, we have created the only national center dedicated to the needs of young onset patients, expanded the numbers and types of programs to ease the burden of patients and caregivers across the country, and are approaching the $40 million mark contributed to Parkinson's research.

Of course, all this progress and, indeed, all progress, is the product of unselfish giving and going the extra mile. The efforts of the hundreds of volunteers who drive our chapter awareness and fundraising events, the contributions of our donors, foundations and corporations, the time and expertise of our board and staff are all testimonies to our determination to "Ease the Burden - Find the Cure."

It is a bittersweet feeling to turn over the reigns of leadership of such a dynamic organization. I do so with moments of pride in what has been accomplished mixed with moments of frustration that there is so much more to do. But I am assured that our very able and accomplished new president will take APDA to even greater achievements, our contributors will generously continue to support our work, and that persons with Parkinson's disease and their families will live as comfortably as possible and with a realistic hope that a cure is close because of it.

I will continue as a member of APDA's board of directors and look forward to being part of the celebration when that scientific breakthrough and clinical application are made and Parkinson's disease is spoken of in the past tense.

Sincerely,

Vincent N. Gattullo
President

POPULATION 65 YEARS OLD & OLDER

According to the U.S. Department of Health, this country in 2005 had 36.8 million persons age 65 and older. The portion of the population over age 65 is rapidly increasing: people 65 and over represented 12.4 percent of the population, but are expected to grow to about 20 percent by 2030. The past century has seen significant increases in life expectancy, and 65-year-olds today can expect to live an additional 18.5 years. Nonetheless, the elderly face greater health care concerns than younger populations.

In 2006, 38.9 percent of non-institutionalized older persons assessed their health as excellent or very good, compared to 65.1 percent of persons ages 18-64.

The majority of older persons has at least one chronic condition. Older women outnumber older men by more than one-third.

About 3.6 million elderly (9.8 percent) lived below the poverty level in 2004.

Another 2.3 million (6.7 percent) were classified as near poor, with incomes between 100 percent and 125 percent of the Federal poverty level. ■

Abstracted from the 2007 National Healthcare Disparities Report of the Agency for Healthcare Research and Quality, Department of Health and Human Services USA

Innapropriate Medication Use by the Elderly

Appropriate use of medications is important for the elderly, since they use more medications than younger people. The National Healthcare Disparities Report tracks the percentage of adults age 65 and over who used at least one prescription from a list of 33 medications considered usually inappropriate for this age group.

Persons with basic mobility or other basic personal-level functioning and complex (ability to participate in community life) activity limitations were significantly more likely than persons with neither limitations to have used one of the 33 inappropriate medications.

Approximately 23.9 percent of those with basic activity limitations and 26.8 percent of those with complex activity limitations have used one of the 33 inappropriate medications, compared with 12.9 percent of those with neither.■

Abstracted from the 2007 National Healthcare Disparities Report of the Agency for Healthcare Research and Quality, Department of Health and Human Services USA

Dear Reader,

There is a popular radio commercial in the New York area about a manager wanting someone to fill a former worker's shoes. "Good luck," says the second worker, "that man has the biggest feet I've even seen." Well, I've never checked how big Vincent Gattullo's feet are, but I certainly know that he left very big shoes to fill, and it is with both a sense of humility and of excitement that I begin my administration as APDA president. Much has been accomplished during his seven years, and I am proud to have worked with him during the transition to our new headquarters, as we increased our research funding and launched our organizations modernization effort.

As a former New York City commissioner, of agencies both large and small, and as a retired naval officer, I intend to call upon my years of administrative experience to continue the legacy of my predecessors, including the Esposito and Springer families, John Pillarella and our first president, Rabbi Eugene Cohen. The contributions of these people have created a strong foundation, and with the support of our board, staff and volunteers, I look forward to building upon it. Finally, as a professional engineer and licensed planner, I intend to draw upon my varied areas of expertise in leading our devoted staff.

APDA has held an important place in my volunteer life for the past 23 years. I have been part of the excitement when our funded research made major - and even minor-breakthroughs, and attended our annual conferences to see the interaction between the national office, the coordinators and chapter presidents who are the very lifeline of our organization. I have truly marveled at our Scientific Advisory Board's annual meeting, observing the country's leading scientists and neurogolists discuss every aspect of the disease and how institutions and individuals are trying to identify the causes and find a cure for this disease.

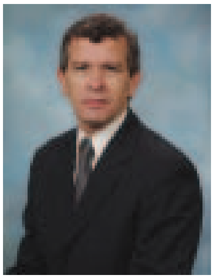
As each of my predecessors has wished, I hope that my tenure is shortened because a cure has been found, and I vow to do everything in my power to assist those who can find a cure and provide comfort and support for those who are now afflicted.

I invite you, as a reader and someone equally dedicated to the eradication of PD, to share your questions, concerns and thoughts about our work with me directly via surface mail or via my e-mail, jmiele@apdaparkinson.org.

Sincerely,

Joel A. Miele, Sr.
President

Dennis Dickson, MD, Named 2008 Springer Award Winner



Dr. Dennis Dickson

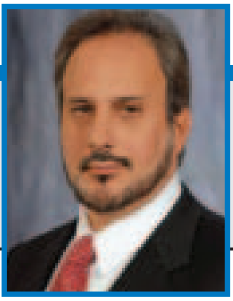
Dr. Dennis Dickson's almost life-long fascination with brains and the human nervous system has established him as a recognized authority on neuropathology. Dr. Dickson is the director of the Mayo Clinic, Jacksonville, Neuropathology Laboratory, which also serves as the brain bank for the Udall Center for Excellence in Parkinson's Disease. He is also the center's Principle Investigator and leads one of three NINDS-funded research projects there. A past president of the American Association of Neuropathologists, recipient of the 2001 Metropolitan Life Award for his contribution to medical research, and member of the APDA Scientific Advisory Board, Dr. Dickson was honored with APDA's 2008 Fred Springer Award during the organization's annual meeting in New York. The award is presented annually in memory of Fred Springer, APDA president and treasurer for more than 20 years, to a physician or scientist in recognition of his or her overall contributions to PD research.

APDA-Funded Scientists Receive Million Dollar NIH Grants

Gary Miller, PhD (Emory University) and Marie-Françoise Chesselet, MD, PhD (UCLA) are two of three recipients of National Institutes of Health grants totaling $21.25 million. Dr. Miller received an APDA research grant in 2006 and Dr. Chesselet is the director of APDA's Center for Advanced Research at the UCLA School of Medicine, and a member of the Scientific Advisory Board.

The grants were awarded through the National Institute of Environmental Health Sciences over a five-year period to study how environmental factors contribute to the cause of PD and related disorders.

BY ENRICO FAZZINI, DO, PhD
Associate Professor Neurology
New York University, New York
University of Nevada, Las Vegas
N.Y. Institute of Technology, Old Westbury



Q: What are the criteria for Deep Brain Stimulation? Why has it not been used more extensively? What are the benefits and/or side effects? Your response is very much appreciated.

A: The procedure known as deep brain stimulation (DBS) involves placing an electrode in a circuit, which is overactive as a consequence of the lack of dopamine which occurs in patients with Parkinson's disease (PD). The best candidate is a patient who has severe "on/off" fluctuations in response to medications used to treat PD. It is important that the patient have a least some time during the day at which time he/she is almost normal. This is known as "on" time without dyskinesia. Often the best candidates are exquisitely sensitive to small changes in the amount of L-Dopa taken during the day with too much L-Dopa leading to abnormal writhing movements and too little L-Dopa leading to extreme stiffness and slowness. DBS will increase the "on" time without dyskinesia. The complication rate of DBS can be up to 40 percent so it is important that only those patients who cannot be managed with medications receive the surgery. Patients with atypical forms of PD who do not respond to L-Dopa, and patients with PD who have dementia or severe balance impairment are not candidates for DBS.

Q: Is PD hereditary?

A: We still do not know the cause of PD. Patients who develop PD before the age of 40 often do have genetic history, but the vast majority of patients do not have a clear inheritance history. It is thought that a combination of genetics and environment leads to the development of PD. If you have a parent and a sibling with PD the chance of developing PD is about 25percent. If you only have one parent with PD, the chance of developing the disease is about 5 percent. There is nothing that has been proven to lessen the risk of developing PD if you have a positive family history.

Q: What are the pros and cons with gene therapy?

A: Clinical trials have been conducted using viruses to implant the genetic material: 1) to make dopamine, 2) to inhibit overactive circuits, which exist as a consequence of too little dopamine and 3) to stimulate the growth and sprouting of the remaining healthy dopamine neurons. Potential problems are: 1) unregulated growth of virus, 2) unregulated expression of gene and protein, 3) immune reactions, 4) benefits not yet confirmed in double blind trials and 5) a risk of unanticipated side effects like dyskinesia, tumors or cancer. Gene therapy is an experimental and unproven therapy for patients with PD. ■

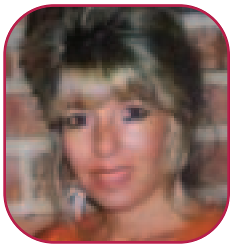
Two New Dosages of Stalevo Approved

Novartis Pharmaceuticals Corporation announced at the end of October FDA approved the use of two new dosage strengths of Stalevo® (carbidopa, levodopa, and entacapone). Stalevo is indicated for certain people with Parkinson's disease who experienced end-of-dose "wearing off". These new 75 and 125 mg dosage tablets added to the previously approved 50, 100, 150 and 200 dosages provide physicians with options that may enable more customized approaches to treating people with Parkinson's disease.

BY K.G. WHITFORD

APDA Honors Its Own

Among the highlights of APDA's 2008 Coordinators Conference in Charleston, S.C. was the farewell awards dinner. In addition to three Salvatore Esposito, Sr. awards given to coordinators for outstanding performance, Donna Diaz,Connecticut coordinator, RN, and Bea Cordero, RN, Far Rockaway, N.Y. coordinator, received Stuben Glass Big Apples for 20 years of service. (Bea, who could not be present, received her award at the APDA annual meeting this month in New York.)



Salvatore Esposito Sr. Awards for Service

Brenda Allred, RN, joined APDA in 2005 and led efforts on behalf of Parkinson's patients throughout her state of Mississippi during, and in the aftermaths of, hurricanes Katrina and Rita. A proven self-starter, Brenda had retired from nursing to be a full-time grandmother and had started a home-based business but jumped at the opportunity to be the APDA Mississippi coordinator. When the first hurricane hit and her center was severely damaged, she organized a support network to help PD patients get their medications, printed and distributed flyers with information for dislocated patients, and worked from her home until the center was up and running again.

Julie Garofalo, RN, has been the coordinator at St. Catherine of Siena Medical Center in Smithtown, N.Y. for eight years, as well as the Parkinson Therapy Center director there for 11 years. Her drive to support PD research and her love of animals make her a perfect co-director of the annual APDA Paws for Parkinson Dog Walk-a-thon on Long Island, where she also likes to take long walks along the beach.

Gigi Gilcrease, RN, had a really great conference. In addition to her APDA award, the preceding day her husband, retired U.S. Army Lt. Col. William Gilcrease, also a nurse, was discharged after 44 years in the military, including two Viet Nam tours and an Iraq tour. Gigi became interested in PD while working as neurologist's assistant in the '70s, and for many years was an executive with the Parkinson's Outreach Program. She has been the APDA coordinator for the southeast coast of Florida for five years.

Big Apple Awards

Bea Cordero, RN, transferred from the rehab nursing department to the family health center at Peninsula Hospital Center, Far Rockaway, N.Y. in 1988, and her experience in an Alzheimer's group immediately singled her out as the right candidate for the APDA coordinator's vacant position. Her appointment coincided with that year's conference, which served as her orientation as well. Bea received the Esposito Award in 2001. She credits her family and especially her husband, Fred, for their support of her activities and looks forward to another 20 years with APDA.

Donna Diaz RN joined APDA 20 years ago and is a state nursing review board instructor in New Haven, Conn. Patients and their families, her profession, and APDA have all been beneficiaries of her time and talents. She lectures extensively, develops programs oversees 21 support groups, and administers a respite-care program and fitness and educational programs. Donna is a past Esposito award recipient, serves as co-chair of the annual APDA conference, is a member of the APDA editorial board, and a leader of the coordinator mentoring program. Her roles of wife and the mother of three have brought her into numerous community and youth-programs leadership roles.

F.Y.I. is a guide to the efforts and successes and recognition of the hundreds of volunteers and staff who work daily to help ease the burden and find a cure for millions of persons with Parkinson's disease and their caregivers across the United States.

IN THE NORTHEAST

APDA's first regional chapter presidents' conference was held in Shilton, Conn., in August with a full agenda prepared by the host state's president Gladys Tiedemann. Each of the seven presidents talked about the history and work of his/her chapter, heard a presentation by New England Community Health Charities, learned about liability insurance and discussed the functions and accomplishments of the national organization.


Northeast chapter presidents, (l-r) front row: Mary Sontz (Maine); Athol Cochane (R.I.), Gladys Teidemann (Conn.), second row: Michael O'Connor (Vt.), Ben Yip (N.J.); Marueen Chamberlaine (N.H.); and Keith Circone (Mass.) get together before their first regional conference.

•The New Jersey Chapter has launched APDA's first scholarship program for children, grandchildren and legal wards of people with Parkinson's disease (PD). The prototype program provides two $1,500 scholarships to New Jersey high school juniors or seniors and may be used for tuition or books, computers and/or school fees. The winners will be announced in April.

•The Rhode Island Chapter had a busy season with its spring symposium, launching a successful golf tournament and its popular Race, Walk & Roll in scenic Goddard Park in September

•Dr. Stephen Reich, MD, Baltimore Information & Referral Center medical director, has been named the first Claire Zamoiski Segal and Thomas H. Segal endowed professor in Parkinson's disease at the University of Maryland School of Medicine. The $1.5 million endowment to support PD research and education was given to honor Dr. Reich's outstanding care for patients and will continue as long as he is on the university's facility.

•It was another sellout crowd for Pittsburgh's 10th annual Three Rivers Seminar and Cruise in September. The popular event mixes educational lectures by Drs. Susan Baser, I&R Center medical director, and Donald Whiting with family fun including a juggler and lunch while cruising the Allegheny, Monongahela, and Ohio rivers.

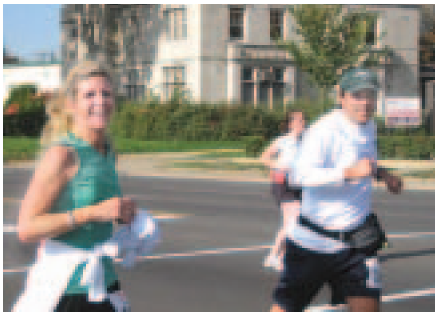
IN THE SOUTH

After 15 years as the Arkansas I&R Center medical director, Dr. Richard Pellegrino has turned the reigns over to Dr. R. Paul Tucker, a Hot Springs neurologist and former Air Force pilot. A U.S. Naval Academy graduate, Dr. Tucker completed his medical education at the University of Oklahoma, training at the Universities of Michigan and Arkansas, and is on the staffs of St. Joseph's Regional Health Center, National Park Medical Center and Levi Hospital, all in Hot Springs.

IN THE MIDWEST

They walked, they ran, they swam and they biked in the Midwest this season to bring both awareness about the disease and funds to support research toward finding a cure.

•In Chicago Peter Kruen participated in his second Accenture Chicago Triathlon in honor of both his mother and his best friend's father. Peter swam just under half a mile, biked 13.5 miles and ran a little more than 3 miles to complete the course.


Megan and Bill Brown

•Megan and Billy Brown crossed the US/Canadian border twice during their 26.2 run in the Detroit Free Press /Flagship Marathon. They ran in honor of Megan's dad.

•And in Des Moines, Iowa, I&R coordinator Sam Irwin was one of the three persons with PD who completed the Des Moines Register Marathon – all 26.2 miles. Sam and team captain LaDona Molander walked and Rick Wyatts, a center volunteer, biked the 5K course and walked across the finish line. The entire 63-member PD team completed the course. A tired and sore ("I ache in places I didn't know I had.") Sam in seven hours and 43 minutes, reported that the newspaper interviewed the team for a full-page placement.

•But it was volleyball that captured the imagination in Nebraska. The Weitz Company's Fifth Annual Volleyball Challenge brought $35,000 in pledged proceeds. The company began the tournament in 2002 as a way to help a Weitz employee who was diagnosed with PD. More than $112,000 has been raised to date.

IN THE WEST

The Utah I&R Center's new location in the University of Utah's new Brain Health Learning Center is part of a collaborate effort to better serve families dealing with memory loss and Alzheimer's, Multiple Sclerosis, and Parkinson's disease. Coordinator Sylinda Lee attended the center's grand opening and ribbon cutting on Sept. 5 in Salt Lake.

•The founder of the country's first young onset I&R center, Arlette Johnson, was the keynote speaker at the APDA Young Onset Parkinson's West Coast Retreat 2008. Coordinators Linda O'Connor, Martha Gardner, Debbie Baires, and Viviane Tondeur planned the two-day retreat for young onset families and included hikes, indoor and outdoor sports, wellness sessions, lectures and special programs for teens and night owls.

•Former West Coast regional representative Bob Dolezal was the subject of a week-long series about living with PD published in the Arizona Sun. (See our Web site, www.apdaparkinson.org) to read the entire inspirational series. ■

APDA Board Member Dr. Robert Meeker Dies

Robert Meeker, PhD, joined APDA's board of directors in 1996 when he was president of the Arizona Chapter. He was buried Aug. 30, 2008 wearing his APDA pin.

Dr. Meeker was a physical chemist and corporate executive with Shell Oil Co. for 21 years and with T.R.W. for 10 years until his PD necessitated his early retirement. He and his wife, Dorothy, relocated to Tucson, where he remained active in church, civic and interest clubs. "Bob was a valued member of the APDA family," said executive director Joel Gerstel. Our sympathy goes to Dorothy and his daughters, Julie Meeker Rossi, MD, and Laurie Meeker Gamel." ■

National Young Onset Center Publishes New Handbook

APDA's new Young Parkinson's Handbook is now available. The publication culminates the efforts of more than 20 contributing authors, many experts in researching and/or treating Parkinson's disease, and others able to offer counsel on a variety of subjects that young people with PD may encounter.

The book begins with a review of "The Basics," providing a disease overview and traditional, as well as alternative treatment options. It also contains an in-depth description of many physical, psychological, and social aspects of living with YOPD such as relationships (developing or maintaining them), employment, and financial security that can be as distressing to patients and their families as the motor symptoms of the disease.

This handbook is unique in its content, design, and format. It is versatile and offers a great deal of flexibility and can be read as a book, with sections and chapters flowing into the next; as a reference book to flips from one section or resource to another; and as a manual, to inspire helpful discussions with physicians, healthcare providers, family members and friends.

Individual copies are available free by calling the National Young Onset Center at 877-223-3801 or via our Web site: www.youngparkinsons.org. ■

Whatever He Gives, He Gives the Best

APDA's greatest funding resource is people, who find more creative ways to help "Ease the Burden – Find the Cure." A recent effort is being made by Brooklyn-born professional singer/songwriter Marc Ribler, who has played to sellout audiences at New York City's Towne Hall, has had more than 30 cuts by recording artists and has written and produced many songs that have charted in North America and abroad.

Having survived a life-threatening illness himself, and watched a beloved family member succumb to complications of PD, Marc has placed the APDA logo on the home page of his Web site, www.marcribler.com, encouraging donations to help meet the mission. ■

RECEIVE FREE E-NEWSLETTER

APDA will launch a free monthly e-newsletter in January as part of its goal to provide timely news about the progress in the search to finding a cure for PD. The newsletter will included updates on research and therapies, APDA's efforts to raise awareness and research funds, and helpful hints for patients and caregivers to ease the burden of living with PD. To subscribe send your e-mail address to enews@apdaparkinson.org. You can cancel your newsletter at any time by clicking the "Unsuscribe" button in every issue. ■

Where Do Medicines Come From

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testing, an Investigational New Drug (IND) application is submitted to the FDA. If granted, the drug graduates to clinical trials for initial human testing, beginning with Phase I. These trials are usually made up of 20 to 100 healthy volunteers.

The drug will be further tested for safety, tolerated dose range, side effects, and interactions with other drugs. Extensive studies reveal what the body does with the compound (pharmacokinetics), what the compound does in the body (pharmacodynamics), as well as how the body absorbs, distributes, metabolizes and excretes the compound. Medical teams coordinate and carry out the procedures of the clinical trials according to the specifics of the study's protocol.

Once volunteers consent to participate and are screened, those who qualify are usually housed in the clinical research unit where the study is being run, for various lengths of time. Under the supervision of physicians, very low doses of the drug are administered. Gradually, doses are increased while the participants are constantly and carefully monitored to determine how their bodies react to the compound, whether it is sufficiently absorbed in the bloodstream, and which dosage levels are safe. Various safety assessments are made, and blood and other samples are analyzed. Approximately one out of three INDs fail during Phase I studies, which require about one year to complete.

PHASE II STUDIES

If a compound passes the requirements of Phase I clinical trials, it moves into Phase II testing. This phase usually consists of 100 to 300 patient volunteers who have the disease or condition which the compound is intended to treat. Patients are recruited through hospitals and other centers. The sponsoring drug company teaches the physicians (called clinical investigators) about the study, who in turn educate the selected volunteers meeting study criteria.

Once volunteers give their consent, they are screened, enrolled in the study and are closely monitored under controlled circumstances. Each volunteer receives medication over a pre-determined period of time. The drug is tested for safety and effectiveness by whether it produces a measurable improvement in the patient. This will determine the most effective dose with the least number of side effects. Phase II studies take approximately two years to complete.

PHASE III STUDIES

Phase III clinical testing is the most time-consuming and expensive phase of the development process. This phase can involve 1,000 to 10,000 patient volunteers in hospitals and medical centers worldwide, creating a large database to meet the requirements of the FDA, as well as the requirements in other countries where the drug may eventually become available. The diversity of volunteers helps to identify adverse effects that may be present in only a few patients out of thousands.

After the consent process, the patient volunteer is enrolled in the study. Monitoring is done to confirm the drug's effectiveness, to check for side effects and to compare it to current treatments. Patients take the IND drug under the supervision of their physician, who serves as a clinical investigator. Patients make regular visits to the physician for physical exams, lab and diagnostic tests or other assessments, but otherwise lead their lives in a typical manner. This phase usually lasts about three years.

NEW DRUG APPLICATION AND APPROVAL

Following the completion of all three phases of clinical trials in humans, the drug company analyzes all of the data. If the trials have successfully proven the drug's safety and efficacy, a New Drug Application (NDA) is filed with the FDA, which will include all of the scientific information collected. On average, NDAs contain 100,000 pages or more. The NDA review and approval process can take up to two and one-half years. If the NDA is approved by the FDA, the new medicine becomes available to patients. The company continues to provide the FDA with periodic reports on the drug and its safety. Additional testing (Phase IV studies) is performed to evaluate long term safety and efficacy, new dosage forms, or new use indications for the drug.

CONCLUSION

Out of every 5,000 compounds evaluated in pre-clinical testing, five enter clinical trials in humans. Out of those five, only one compound will be approved for use in patients. The whole process takes an average of 12 years and costs approximately $1 billion! Clearly, pharmaceutical research and development is a lengthy, challenging and financially risky process where the end result is never guaranteed. We all can appreciate the value of this process and the positive benefits that drugs have on patients who rely on these life-saving medications for their health and well-being. ■

Counterfeit Drugs

In consideration of the increasing trend in ordering medicines using online pharmacies, it is advisable to bring to the attention of our readers an article which appeared in the Summer 2008 Issue of EPDA Plus, a magazine published in Europe for health care professionals.

When one considers that counterfeit medicines are regularly shipped covertly across a range of international jurisdictions and frequently traded via unofficial and uncontrolled websites, it gives an outsider a small glimpse of the terrible problems facing authorities today.

We know that the industry is growing rapidly, and latest intelligence on the incursion of counterfeit medicines reveals there were over 50 percent more seizures of counterfeit medicines in 2007 than in the previous year.

The Center for Medicine in the Public Interest (CEPI), based in the US, predicts that counterfeit medicines sales will reach approximately 55.5 billion euros globally by 2010 - an increase of more than 90 percent in just five years.

A large number of these counterfeit medicines find their way into the hands of European patients through illegal online pharmacies. Many of the illegal websites sell prescription medicines, or unsafe counterfeit versions, directly to members of the public without a valid prescription or consultation with a healthcare professional.

This is the most dangerous aspect of the online medicines trade, as consumers cannot know what is in the products they receive, or whether the medicine they are ordering is appropriate for their condition.

In response to this trend, the European Alliance for Access to Safe Medicines (EAASM) produced The Counterfeiting Superhighway - a comprehensive research report examining the dangerous practices of illegal online pharmacies.

It reveals a frightening 62 percent of medicines purchased online are fake or substandard, including medicines indicated to treat serious conditions, such as cardiovascular and respiratory disease, neurological disorders and mental health conditions.

Expert visual and chemical analysis of prescription-only medicines purchased online compounded the desk research findings. Many of the medicines arrived without boxes or patient information leaflets - and those that did were in a number of different languages.

Among the most alarming was the blister pack of unauthorized generic 'Plavix' (clpoidogrel) that arrived wrapped in a copy of Indian newspaper, with free unauthorized generic 'Viagra' (sildenafil) taped on top.

It is alarming that a patient seeking medication for a heart condition would be sent unsolicited, unprescribed and unauthorized medicine without any medical assessment or guidance. Apart from possibly being fake, this 'bonus' medicine could interact dangerously with the clopidogrel contained in the same package, or could exacerbate a pre-existing medical condition.

"The report findings are shocking and the story it tells demands action," said Jim Thompson, chair of the EAASM. "Consumers are susceptible to fake medicines that could harm their health, and in extreme cases be deadly. The EAASM calls on all stakeholders, including search engines, credit card companies, patient groups and regulators, to take action and halt this dangerous trend. ■

PD and Skin Cancer

By Kristine Twomey, RN, BSN,
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Symptoms of malignant melanoma include a change in the size, shape, color, or feel of an existing mole. Most melanomas have a black or blue-black area. Melanoma also may appear as a new mole. It may be black, abnormal, or "ugly looking."

According to one study people with PD may be 2 to 10 times more likely to develop malignant melanoma skin cancer than the general population. While the reason for this is still not clear, it is important to know what you can do to decrease your risk of developing skin cancer. Here are a few recommendations:

1. Begin by being aware of the moles and freckles on your skin and note any change in color or size and report it to your doctor.

2. Have your skin examined by a doctor regularly.

3. No TANNING.

4. Wear sunscreen of SPF 15 or greater.

5. Wear a hat with a wide brim.

Malignant melanoma is 100% curable with early diagnosis and prompt treatment. If you have a suspicious mole or concerns about a lesion on your skin please talk to your healthcare provider.

This letter was adapted from the Spring 2008 APDA Neenah, WI I&R Center Newsletter ■

Hallucinations in Parkinson's Disease

By Jacob Sage, MD, Professor of Neurology
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Parkinson's disease (PD) traditionally has been classified as a motor system disease. The diagnosis has relied on three major motor symptoms and signs, resting tremor, rigidity and bradykinesia (slowness).

Additional signs of motor system involvement include diminished fine motor coordination, abnormalities of gait including dragging of a leg, shuffling and freezing, disturbances of posture and postural stability, problems with balance, flattening of facial expression and softness of speech. This emphasis on the motor system abnormalities was reinforced in the late 1960s with the successful introduction of levodopa therapy. Levodopa which is converted in the brain to the neurotransmitter dopamine ameliorated many, but not all the motor signs and symptoms of of PD. In the very first few months after treatment with levodopa began in the 1960s it was even thought that it might be a cure for PD. Quickly however motor fluctuations and dyskinesias appeared as significant side effects of treatment and it was realized that a cure would have to be found elsewhere. But the idea that PD was simply and solely a motor-system disease persisted for decades.

In the past decade it has become increasingly evident that PD should be regarded as a more generalized disorder rather than a strictly motor disease. In addition to the major signs and symptoms referable to the motor system, autonomic, sensory and cognitive issues play major roles in the discomfort and disability of PD patients. In fact some of the most common problems occur in the cognitive/psychological arena with depression and hallucinations being major sources of disability. In this article, we will focus on the issue of hallucinations in patients with PD.

An hallucination is defined as a perception of something in the environment that is, in fact, not there. Hallucinations in PD patients come as three major types: olfactory, auditory and visual. Visual hallucinations are by far the most common. They range from mild to severe. Mild hallucinations often start with the patient reporting a sensation that there is a shadow off to one side of the visual field. These sensation are intermittent. Some patients report that they look at an object in the distance and think they see a person or animal, but the object turns out to be a fire hydrant or telephone pole, etc. These are more correctly termed illusions or delusions but for our purposes can be classified with the hallucinations. As hallucinations get more serious, patients report seeing people, often children, animals or insects. These hallucinations are not precipitated by looking at an object but seem to occur for no reason at all. Severe hallucinations are those which are accompanied by paranoia or are frightening in some other way. The patient is afraid that the people in the hallucination are going to harm him in some way. Patients sometimes react violently to such hallucination or may call the police or in some other way act irrationally.

The processes of advancing disease in PD patients make them prone to develop hallucinations. In fact, certain forms of parkinsonism with more early diffuse involvement of the Lewy body pathology in the brain may get hallucinations early in the course of the disease. In most patients hallucinations are prone to be a factor late in the disease. The important thing to remember is that some of the medications used to treat the motor symptoms and signs of PD tend to make hallucinations worse.

The first treatment to try and decrease hallucinations is medication reduction, where this is possible. Reducing and eliminating medications should start with the drugs most likely to worsen hallucinations. Depending on circumstances, most patients reduce the anticholinergic medications (Artane®, Cogentin®) and the direct acting dopamine agonists (Requip®, Mirapex®, Neupro®) first. After that the catechol-omethyltransferase inhibitors (Comtan®) can be decreased and discontinued. Finally levodopa reduction may be necessary. It is often hard to decrease levodopa because it is so essential for controlling the motor symptoms of PD. In that case, drugs like quetiapine can be added. This agent acts directly to reduce the tendency to have hallucinations.

It is important to recognize hallucinations and to report them to the doctor. They are nothing of which a patient need be ashamed. If left unchecked, hallucinations can lead to irrational and antisocial behavior that can be very difficult on patients and families. ■

Model Curriculum for the Training of Interdisciplinary Rehabilitation Teams in Parkinson's Disease

With support from the APDA, researchers and clinicians from The Center for Neurorehabilitation at Boston University and the Parkinson's Disease and Movement Disorders Center at Boston University Medical Center teamed up to develop an educational curriculum for interdisciplinary health care teams (nurses, physical therapists, occupational therapists, speech language pathologists and physicians) consisting of the most current, evidence-based, innovative rehabilitation treatments available for people with Parkinson's disease.

The curriculum was developed by Cathi Thomas, RN, MS; Terry Ellis, PhD, PT; Marie Saint-Hilaire, MD; Tami Rork, PT; and Donna Diaz RN, MS using a "train-the-trainer" model. The goal is that participants of this program will return to their health care settings and will educate other members of their health care team in the rehabilitation of people with Parkinson's disease. By accomplishing this, well-qualified health care practitioners will directly impact patient access to current rehabilitation information and services. "This initiative will enhance our ability to ease the burden by improving the quality of life of greater numbers of people with Parkinson's disease," states Dr. Saint-Hilaire, the director of the APDA Center for Advanced Research at Boston University Medical Center.

"There is a growing body of literature supporting the benefits of rehabilitation and exercise for people with Parkinson's disease," reports Dr. Ellis, clinical associate professor in the Physical Therapy Department at Boston University. She notes that these recent advances assist people with Parkinson's disease to reach their maximum potential in order to improve day to day function and quality of life. A recent NIH-funded trial conducted by Linda Tickle-Degnen, PhD, OTR; Robert Wagenaar, PhD; Ellis; Thomas, and Saint-Hilaire revealed improved quality of life in people with Parkinson's disease following participation in a rehabilitation program consisting of exercise and strategies to optimize independence. Although the research demonstrates the benefits of exercise, Ellis states that it is important for people with PD to participate in exercise over the long term. To enhance participation in exercise programs, the team at Boston University and Boston Medical Center has developed "Community Wellness Programs" for people with PD. These Community Wellness Programs consist of exercises and strategies which have been demonstrated in the research to benefit people with PD. The goal is to expand the development of these programs so that greater numbers of people with PD can participate and reap the benefits. The curriculum delivered to interdisciplinary health care teams is designed to teach these teams how to implement Community Wellness Programs in their local communities.

This curriculum was offered at Boston University during March of 2007 and 2008 and more than 100 health care professionals participated in the two day course. To date, more than 30 Community Wellness Programs have been implemented in the New England area providing access to more than 250 people with Parkinson's disease. "The participants and their families are extremely pleased with these programs", reports Ms. Thomas, coordinator of the APDA Information & Referral Center at Boston Medical Center.

"It is important to have well-qualified rehabilitation professionals in PD", says Thomas, "so people can have access to high quality care in their local communities."

The team at Boston University and Boston Medical Center plans to offer its curriculum to health care professionals on an annual basis. The next course is scheduled for March 2009. They are looking forward to updating their curriculum to bring the most current information available on evidence-based rehabilitation to interdisciplinary health care professionals. ■

IRA Charitable Rollover Extended

Congress has extended the IRA charitable rollover as part of the Emergency Economic Stabilization Act of 2008 allowing older Americans to make a gift directly from their IRAs to a charity such as APDA without the withdrawal being taxed as income.

The tax-free donation must meet the following criteria:

- the gift is made in 2008 or 2009
- the IRA holder is age 70 1/2 or older
- the gift totals $100,000 or less each year.
- the charity is a 501c3 organization
- the withdrawal goes directly from the IRA to the charity

This information is not intended to serve as legal or tax advice, and APDA suggests those wishing to donate to consult their tax advisor or attorney.

Educational Material

Single copies of the following publications may be obtained free of charge by writing to the national APDA office or by calling 1-800-223-2732, faxing to 1-718-981-4399, or contacting any of the 62 APDA Information and Referral Centers throughout the United States.

BOOKLETS

1. Parkinson's Disease Handbook - Symptoms, causes, treatment (English, German, Italian,Spanish)
2. Young Parkinson's Handbook - A new edition written by a variety of specialists and edited by Michael Rezak, MD, PhD, Susan Reese, RN, LCSW and Julie Sacks, LCSW (English).
3. Be Active - An exercise program for people with Parkinson's disease recently written by Terry Ellis, PT, PhD, NCS, Tami Rork, PT, MSPT and Diane Dalton, PT, DPT, OCS of the Center for Neurorehabilitation, Sargent College, Boston University (English)
4. Be Independent- Equipment and suggestions for daily living activities (English-Revised Edition)
5. Speaking Effectively - Speech and swallowing problems in Parkinson's disease (English)
6. Good Nutrition (English)
7. Aquatic Exercise for Parkinson's Disease - A new edition prepared in cooperation with the Aquatic Exercise Association and edited by Julie See, BS (English)
8. My Mommy Has PD... But It's Okay! - booklet for young children (English)

The Next Step After Your Diagnosis: Finding Information and Support - A U.S. Government publication that can be obtained by calling 800-358-9295 and requesting booklet AHRQ Publication No. 05-0049

SUPPLEMENTS

The Family Unit; Hospitalization of a Parkinson Patient; Fatigue in PD; Healthy Aging; Keys for Caregiving; Medications to Be Avoided or Used with Caution in PD; Neuro-ophthalmology and PD; Medical Management of PD and Medications Approved for Use in the USA; Depression and PD.

BROCHURES

A. Basic Information (English, Spanish, Chinese)
B. How To Start a Support Group (English)
C. National Young Onset Parkinson Disease (English)

DVDS

Managing Parkinson's - Straight Talk and Honest Hope, 2nd Edition
Created by the Washington State Chapter of APDA for newly diagnosed Parkinson's patients and their loved ones.

"Next Step After Your Diagnosis/Tips for Taking Medication Safely"
DVD No. AHRQ 07-M025 can be obtained, free of charge, from the Agency for Healthcare Research and Quality by calling 800-358-9295, or 888-586-6340 (hearing impaired only) or by e-mailing ahrqpubs@ahrq.hhs.gov

WEB SITES

www.apdaparkinson.org for APDA I&R Centers, Chapters, support groups, education and information material, meeting dates, medical abstracts, clinical trials and research application guidelines.
www.wpda.org. A weekly updated source of world news from the web site from the World Parkinson Disease Association

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