



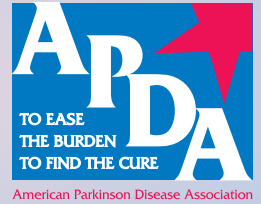
American Parkinson Disease Association
Georgia Chapter and
The Information and Referral Center
at Emory University
P.O. Box 49416
Atlanta, GA 30359

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Parkinson's @ Us

Newsletter

Summer/Fall 2009



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and The Information & Referral Center at Emory University

WHERE DO MEDICINES COME FROM?

By Cheryl A. Cuzzo, MSN, RN

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; for example: 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 five thousand 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 due to issues of safety or metabolism. 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 maintained 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.

MARK YOUR CALENDAR!

Upcoming APDA events:

The next Educational Meetings are located at Clairmont Oaks in Decatur, GA

August 15, 2009

PD Update 2009-2010 by Dr. Jorge Juncos

September 19, 2009

New Therapies with Lee Silverman Voice Therapy by Alma Ownes, CCC SLP

October 17, 2009

Lower Urinary Tract Symptoms in PD by Dr. Camille Vaughan

November 21, 2009

Speaker to be announced

Educational meetings will start at 10:30am. Please come prepared with your questions.

OTHER EVENTS:

September 27, 2009

Polo for Parkinson's, 2pm at Chukkar Farm & Polo Club in Alpharetta, GA

OCTOBER 15, 2009

5th Annual Countrified Rock at Trilogy in Marietta, GA



This newsletter made possible by an educational grant from TEVA

DISCLAIMER

The material in this newsletter is presented solely for the information of the reader. It is not intended for treatment purposes, but rather for discussion with the patient's physician.

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APDA Georgia Chapter
P. O. Box 49416
Atlanta, GA 30359
404-325-2020
www.apdageorgia.org

Emory I & R Center Staff

Jorge L. Juncos, M.D.
Medical Director
Mary Louise Weeks
R.N., B.S.N Coordinator

1841 Clifton Road NE
Room 504
Atlanta, GA 30329
404-728-6552

Newsletter Staff

Mary Louise Weeks
R.N., B.S.N
Editor
Linda McGinn, R.N.
Copy Editor

PRESIDENT'S CORNER

Dear Friends,

First of all, I want to thank all the people who worked so hard to make this year's "Driving Parkinson's Away" golf tournament a success. Yes, it was a difficult year and, yes, the economic downturn has hit us hard, too – but we were still able to meet our fiscal goals for the year.

So, now we enter our new fiscal year starting September 1, 2009 with fresh energy to bring in new donors and sponsors. Remember, if you are interested in working with us on any of our projects, please call me!

Now I have a special request to those of you who are able to respond. Please consider becoming one of the:

FRIENDS OF APDA

American Parkinson Disease Association – Georgia Chapter
A monthly donation for one year by people who believe in the mission of the APDA apdageorgia.org

To continue the high level of service to Georgians with Parkinson's Disease, we need you to become a Friend of APDA. Our Friends donate \$50 per month for one year...that's \$1.66 per day to Parkinson's. With just 100 friends we can generate \$5000 per month to support our services like Caregiver Respite programs and the monthly educational meetings and to publish the Parkinson's & Us newsletter. We wouldn't ask if we didn't need you. Can we add your name to the list?

Please call: 404-325-2020

Thanks to all of you!

Annemarie Schwarzkopf
President
Board of Directors
APDA Georgia Chapter
www.apdageorgia.org

FDA WARNS ABOUT RISK OF WEARING MEDICATED PATCHES DURING MRIs

Certain adhesive patches that deliver medication through the skin have been found to be a risk to patient safety. The patches, if worn while undergoing magnetic resonance imaging scans or MRIs, can cause skin burns, says the U.S. Food and Drug Administration today.

The patches of concern include both brand name and generic products and patches purchased over the counter without a prescription.

The FDA issued the Public Health Advisory on transdermal drug patches after learning that a warning was missing on some patches that contain aluminum or other metals in their non-adhesive backing. The backing is the portion of the patch not in direct contact with the skin. While not attracted to the magnetic field of the MRI, the metal can conduct electricity, generating heat which can cause burns. Users of the patches reported receiving skin burns at their patch site when wearing the patch during an MRI scan.

"The risk of using a metallic patch during an MRI has been well-established, but the FDA recently discovered that not all manufacturers include a safety warning with their patches," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "Because the metal in these patches may not be visible and the product labeling

may not disclose the presence of metal, patients should tell both their health care professional and their MRI facility that they wear a medicated adhesive patch."

The FDA was alerted to the missing MRI warning on Teva Pharmaceutical's fentanyl transdermal system in January. The FDA investigated and found that a similar warning was also missing on a variety of skin, or transdermal, patches delivering medications.

The FDA is reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning to patients undergoing an MRI and will alert the public when this information has been added. Until then, the agency recommends that people wearing medicated skin patches, including nicotine patches, talk to a health care professional about their patch at the time they receive their MRI referral. The professional will advise the patient about when to remove the patch before the procedure and about replacing it after the procedure.

Patients should also tell their MRI facility that they are using a patch when they call to schedule their appointment and should repeat this information when filling out their health history questionnaire after arriving for their appointment.

IN MEMORY

Oliver James Chastain, the first president of the Atlanta APDA Chapter passed peacefully, May 13, after a long battle with Parkinson's disease. Oliver was an accomplished Tenor and sang with Robert Shaw and the Atlanta Symphony Orchestra for three years. He also had the privilege of singing our National Anthem at Atlanta Braves games on several occasions. The accomplishment he was most proud of, however, was being chosen to carry the Olympic Torch during the 1996 Games in Atlanta.

In lieu of flowers, donations may be sent to the American Parkinson's Disease Association.

ASK THE MD

By Alan Freeman, MD

1. I have Parkinson's disease and my dad had PD. Will my children inherit PD?

The risk of developing PD some time during life is approximately 2% for the general population. It increases to 5-6% for those with a parent with PD and to 20-25% for those with both a parent and a sibling with PD.

Genetic mutations result in a minority of PD, accounting for 1-3% of typical late-onset PD and perhaps 20% of young-onset PD, and both have autosomal dominant and recessive inheritance. Genetic testing is available for several genes, but is likely to be uninformative because a negative test does not mean that parkinsonisms is not genetic, but that a specific mutation was not identified. For a good review by Lorinez read "Clinical Implications of Parkinson's Disease Genetic", Seminars in Neurology volume 26, 2006 p 492-498.

2. Sometimes I feel an internal tremor. Is this normal for a Parkinsonian?

Patients may describe the feeling of an internal tremor that cannot be appreciated by others and it can occur in about 25% of PD patients. This may be classified as a sensory symptom, which would include other sensations such as paresthesias (tingling), pain and hot/cold sensations.

3. Sometimes I have difficulty urinating when my medication wears off. Is this because of Parkinson's Disease?

If you notice these symptoms when your medications wear off, it would be an 'off' nonmotor symptom (nonmotor fluctuation). Autonomic symptoms such as urinary urgency, frequency and incontinence may occur, typically in later disease. Difficulty urinating can also be caused by medications that treat PD (anticholinergics such as Artane) or an enlarged prostate in men.

4. How common is sexual dysfunction in PD?

Sexual dysfunction can occur for a variety of reasons including lack of mobility, loss of interest or difficulty achieving and maintaining an erection. Loss of sexual interest is commonly reported in PD patients, and both men and women are affected. Depression and various medications can contribute to sexual dysfunction. After discontinuation of potentially offending medications and treatment of depression, a patient complaining of sexual dysfunction should be evaluated by a urologist to exclude other causes and direct further management.

LOUD AND BIG

By Alma Owens CCC SLP

Everyone dealing with Parkinson's Disease wishes for increased independence and improved function. For almost twenty years the Lee Silverman Foundation has been carefully researching methods for speech improvement that lasts many months after treatment. Recently a course of physical or occupational therapy, called BIG, has been added to the more familiar LOUD.

The Lee Silverman Voice Treatment for Parkinson's disease was developed at the University of Arizona. The initial research was funded by the family of Mrs. Silverman and support continues from the National Institutes of Health and other sources. The developers of the program have carefully researched the method and their research has been supported by other investigators all over the world. LSVT is now implemented world-wide.

LOUD training focuses on the single task of speaking louder while re-training to adjust oneself to the louder volume. Many people with Parkinson's Disease hear their own voice as 'loud enough' though their families insist the individual cannot be heard. The training requires high effort, intensive practice combined with increasing complexity, and practical tasks done outside of the treatment session. Research has shown the technique to be effective for persons with Parkinson's, Multiple Sclerosis, Stroke, and Cerebral Palsy.

BIG is based on the principles of the LOUD LSVT program. LSVT BIG trains individuals with

Parkinson's and other neurological conditions to use internal self-cueing to use better movement anywhere anytime. The focus on bigger movement has been shown to enhance faster walking with bigger steps, better balance, and more ability to turn the trunk. BIG is also high effort and intensive with home exercise programs that must be continued. The best candidate for both programs will have memory to recall and implement the techniques to home exercise program and to practical applications. Individuals with less memory will rely on support of family but can still make functional improvement.

Current research will determine the most efficient presentation, whether LOUD and BIG should be done one following the other, both at the same time, or whether the programs can be combined.

The Emory Center for Rehabilitation Medicine offers both BIG and LOUD therapy. Currently both are offered four days a week for four consecutive weeks. Elizabeth Fordyce, physical therapist, and Alma Owens, speech pathologist, are certified clinicians in LSVT. A physician's prescription is required. Medicare insurance covers both treatment programs at their usual 80% rate. Individuals should confirm whether their secondary insurance covers the remaining 20%.

You can visit, www.lsvtglobal.com to find a therapist near you.

WHERE DO MEDICINES COME FROM? (CON'T)

By Cheryl A. Cuzzo, MSN, RN

Phase I Studies

If the compound passes pre-clinical 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 suffer from the disease or condition for 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 selected patient volunteers meeting study criteria.

Once volunteers are consented, screened and approved, they are enrolled in the study and are closely monitored under controlled environments or circumstances. Each volunteer receives medication over a pre-determined period of time. The drug is tested for safety and effectiveness by whether or not 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 under the supervision of their physician, who serves as a clinical investigator. Patients have 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

POLO FOR PARKINSON'S



"Grab those fancy hats and dig out your divot-stomping shoes! Wilkins Media Company and Solvay Pharmaceuticals will be hosting the second-annual Polo for Parkinson's fundraiser event on Sunday, September 27th at 2pm at Chukkar Farm & Polo Club in Alpharetta, GA. This fun afternoon in Atlanta's beautiful horse country will include an exciting polo match, halftime divot stomp, delicious food, silent auctions, and even a "Best Hat" contest for the ladies. Tickets are \$10 for children 12 and under and \$50 for an adult ticket, which includes food and drinks (sodas, water, beer & wine). All of the net proceeds from this event will go to Team Fox, the Michael J. Fox Foundation's regional fundraising effort. Of those proceeds, 84% are then allocated

to PD research. Last year's event raised over \$70,000! Limited sponsorships are available. For complete information or to donate, sponsor, or purchase tickets, please visit www.poloformparkinsons.com or call Kris Hall at 770-804-1818."

2009 COUNTRIFIED ROCK FOR RESEARCH

A FUNDRAISER FOR PARKINSON'S RESEARCH

THURSDAY, OCTOBER 15, 2009

THE EVENT WILL BE HOSTED BY OUR EAST COBB NEIGHBOR'S AT

Trilogy

Entertainment provided by

JEFFREY STEELE

Your ticket price will include buffet dinner and passed hors d'oeuvres

Soft Drinks - Coffee

AN EXTENSIVE SELECTION OF SILENT AND LIVE AUCTION ITEMS

Please visit <http://www.teamcantore.org> for complete information

URINE STUDY

If you have Parkinson's Disease and suffer from trouble with your bladder...

The Atlanta VA Geriatric Research, Education, & Clinical Center is conducting a research study for persons with Parkinson's disease and difficulty controlling their bladder entitled:

“Behavioral Therapy for Urinary Incontinence in Parkinson's Disease”

To qualify for the study, you must:

- Have Parkinson's disease
- Have unintentional urine leakage
- Be able to attend clinic appointments
- Be willing to participate in behavioral therapy training

Each person will be seen privately for a full evaluation at the Atlanta VA Continence clinic. Persons who qualify will be treated with behavioral therapy for 8 weeks. Clinic visits will occur every two weeks and will last up to 90 minutes.

For more information, contact the principal investigator: Dr. Camille Vaughan at (404) 321-6111 ext 5080

HELP IS HERE FOR CAREGIVERS!

Are you feeling exhausted? Don't know how you will make it another day? Can't seem to find the time to go to the grocery store, hair appointment or doctor's office?

The APDA Information and Referral Center and Georgia Chapter are here to help by offering the Respite program. This program was designed with the caregiver in mind. Respite provides relief to the caregiver while their loved one is in professional hands. Partnered with the Visiting Nurse Health System, a trained aide is sent to your home seven hours a month free of charge. Through donations to our program we are able to provide this service for those who qualify. Seven hours a month may provide an opportunity to take care of the caregivers' needs, a necessary component of long-term care and care giving. If you feel you would benefit from the Respite Program please call 404-728-6552.

WHERE DO MEDICINES COME FROM? (CON'T)

By Cheryl A. Cuzzo, MSN, RN

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 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 twelve years and costs approximately \$1 billion dollars! 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.

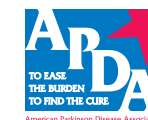
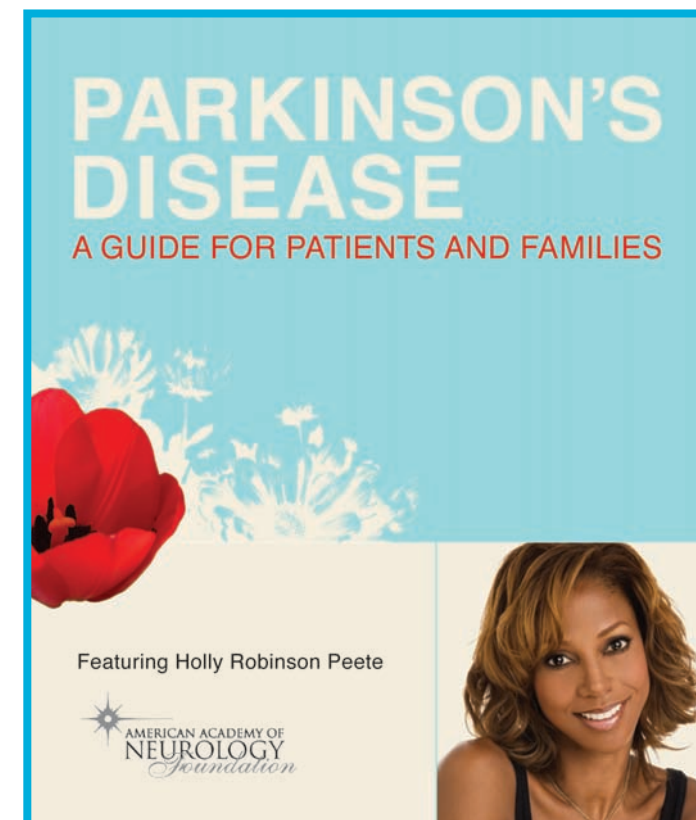
This article was originally published in the Fall 2008 APDA National newsletter

INFORMATION CORNER

The American Academy of Neurology has launched a new patient education video starring actress Holly Robinson Peete. For more information check out www.thebrainmatters.org

Other reputable websites for information on PD include:

- www.apdaparkinson.org
- www.michaeljfox.org
- www.parkinsonsaction.org
- www.thepi.org
- www.wemove.org
- www.pdtrials.org



DISABILITY NOT DIAGNOSIS

By Cari M. Schwartz and Megan F. DiTolla

People often have the misconception that disability entitlement is based on a diagnosis. This is not the case. While the Social Security Administration (“Administration”) requires that an individual have a severe medically determinable impairment, what is most important is the limitations that an impairment imposes.

The Administration recognizes that Parkinsonian Syndrome is degenerative and progressive in nature. However, they also recognize that many people who have Parkinsonian Syndrome do work and can maintain a work schedule for many years following a diagnosis. The Administration must determine at what point a person becomes vocationally disabled. Essentially, the Administration will grant benefits when an individual is unable to complete a normal work week due to his/her symptoms.

The Administration uses many tools to make such a determination. First, they will examine a claimant’s medical records for clinical and laboratory evidence indicating disability. The Administration will see if the records indicate rigidity or tremors which interfere with fine and gross manipulation or gait and station. They may also look to see if there are any cognitive impairments evidenced in the medical documentation. Second, the Administration may request an opinion from a treating physician as to an individual’s

limitations and capabilities. Third, the Administration, at their own initiative and cost, may send an individual to a consultative examination with a doctor for an evaluation of limitations. Finally, the Administration may solicit the help of a vocation expert to determine whether an individual can maintain employment in spite of his/her limitations. This is just some of the analysis that goes into determining whether an individual is capable of working. However, it is illustrative of the Administration’s reliance on limitations, opposed to a diagnosis, in determining disability. While the diagnosis is important, a diagnosis alone will not entitle a person to disability benefits

Attorneys Cari M. Schwartz and Megan F. DiTolla have 10 years experience handling SSDI claims at all levels of the administrative and judicial process. Co-founders of West Coast Disability Law Group, LLP, which provides legal services for the disabled, but also focuses on community outreach and education, they have conducted over 1,700 Social Security Disability benefit and Supplemental Security Income hearings before Administrative Law Judges all over the United States. To contact Cari or Megan, call (800) 459- 3017, or e-mail them at info@westcoastdisability.com

4TH ANNUAL ALLGOOD PEST SOLUTIONS CYCLE



The 4th Annual Allgood Pest Solutions Cycle for Parkinsons at Georgia Gwinnett College on June 28, 2009 was a great success. For the weekend we had 400 race entries. It was a very good race day on campus - even though it was quite hot, we had a nice breeze and lots of shady trees along the Start/Finish line. No serious injuries (a few skinned knees and elbows) and the help of Georgia Gwinnett College volunteers to marshal the race course made for excellent results. The

racers ranged from 10-12 year old juniors to women to 40+ masters to the pros. Sunday’s criterium (a loop that is less than a mile) race ranged from 20 minutes for the young juniors to 90 minutes for the pro racers all done at top speeds.

Frazier Cycling and the Georgia Chapter of the APDA team up with the Gwinnett Sports Commission and Florida-based Top View Sports to hold this event each year to raise public awareness about



Parkinson’s Disease. Georgia Gwinnett College has for the past four years provided the race venue. This race is highly ranked by the cycling community as one of the best run races in the region.

Corporate Sponsors:

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