Understanding the Drug Approval Process

A recent article in a newsletter from the Pharmaceutical Research and Manufacturers of America stated the following regarding new drugs...according to a 1993 report by the Congressional Office of Technology Assessment, it takes 15 years on average to bring a new drug to market at an average cost of $359 million. The U.S. system of new drug approvals is very rigorous.

Once a new compound has been discovered, laboratory and animal studies are conducted to determine the drug's safety and effectiveness against the targeted disease. Once this data has been compiled, an Investigational New Drug Application (IND) is filed with the Federal Drug Administration (FDA) to obtain permission to begin tests on humans. If the FDA does not reject the application within 30 days the testing can begin. These tests are called clinical trials.

Clinical Trials, Phase I These tests study the safe dosage range, determine how a drug is absorbed, metabolized, excreted, and the duration of its action. Usually 20 to 80 normal, healthy volunteers are involved.

Clinical Trials, Phase II In this phase 100 to 300 volunteers with the disease, test the drug to assess its effectiveness.

Clinical Trials, Phase III In this part of the study, between 1,000 and 3,000 patients are involved in clinics and hospitals, usually in several sites around the country. Physicians monitor these patients closely in order to identify any adverse reactions and of course to determine how well the drug works.

When these studies have been completed and the data analyzed, the company will file all this information with the FDA. This filing is called a New Drug Application or NDA. Because it must contain all the information gathered, a NDA typically runs 100,000 pages or more.

Understanding Good Bowel Health

From time to time, bowel problems affect us all. Constipation especially can be troublesome for some individuals. According to Pauline Chiarelli, author of Let's Get Things Moving: Overcoming Constipation, there are many self-help strategies which can be tried. It is well worth the effort of taking a look at your diet and adjusting the fiber level.

Some simple ways to increase your fiber intake include: eat whole meal or whole grain bread, choose a breakfast cereal with high bran content, eat fruit and vegetables every day, choose brown rice instead of white, eat potato skins and do not overcook your vegetables. You may prefer to purchase an over-the-counter fiber supplement.

People who suffer from bladder control problems often cut down on their fluids to stop leaking or having to rush off to the toilet every ten minutes. This is not only bad for the bladder, but also bad for the bowel. The bowel also needs fluid to help keep the stool soft. If you do not drink enough liquids, plan to increase your fluid intake gradually.
THE ASSOCIATION OF REHABILITATION NURSES RELEASES INTERVENTIONS AND OUTCOMES MANUAL...

This new manual is designed to guide nurses involved in assessing, planning, evaluating, and documenting the rehabilitation care they provide. This reference book, Twenty-One Nursing Diagnoses: A Guide to Interventions and Outcomes, is available for $25. Call 800-229-7530

A NEW EXPOSITION IS ANNOUNCED...

KNOW NO LIMITS Expos, Inc. announces new assistive technology expositions designed to enable healthcare professionals and end-users to gain hands-on experience with numerous assistive technology products and services. These exhibits will appear on a rotating basis.

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☐ $5000. Corporate Sustaining Membership
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Your annual membership will begin with the next edition of The Informer. Contributions and membership in the Simon Foundation are tax deductible.

The Simon Foundation for Continence
P.O. Box 835, Wilmette, IL 60091

Drug Approval

continued from front

By law, the FDA is allowed six months to review an NDA. After approval, the company must continue to submit periodic reports to the FDA on such data as adverse reactions plus accounts of the company’s quality control records.

Drugs are not the only medical product to go through this process. Many medical devices must also be tested in a similar manner. Patients who volunteer for clinical trials to test either drugs or medical devices play an important role in this process, helping to guarantee that the general public’s safety is protected.
Letters to the Editor

Dear Simon Foundation:
I have suffered with urinary incontinence for years, including some in the Marine Corps. Enuresis has been a problem since earliest childhood. I have learned to live with and around these inconveniences, but now I have come to a situation I don’t know how to deal with. Perhaps you or some of your readers may have suggestions.

For the first time in 25 years, I am single and not in a serious relationship with a lady. I am only 49, so I am not ready to become a hermit. Where do I look for a lady willing to have a relationship with a guy who wets the bed or wears diapers not to?

Suggestions will be greatly appreciated. I’d like to be included in the The Informer pen-pal section.

Mike Zacker
Post Office Box 82423
San Diego, CA 92138-2423

Dear Mr. Zacker:
We’re happy to add your name to our pen pal list. Your letter exemplifies so many we receive from adults who have nocturnal enuresis. My best advice is to look for women who share your common interests, enjoy life, seem well balanced emotionally, and treat their friends and family with respect. Such a person will probably be a lot more interested in who you are than in what you wear to keep the bed dry. Readers, any further advice?

Dear Informer:
My incontinence has been increasing. Where it used to be mainly at night, it is now frequent during the day.

I found an absolutely wonderful medical person who has been working with me. She is a physician’s assistant in my family practice group. She has been very open, a good listener, and not afraid to try new things. Because of her, I began self-catheterizing, and regularly taking a bladder relaxer medication. This has helped. Since I am very comfortable with catheterizing, she also suggested that I could use a Foley or indwelling catheter for a day or two at a time when the incontinence was particularly bad or for my own convenience at work, in a social situation, or while traveling.

I now use a Foley and collection bag a couple of times a week and have found that being catheterized for this time seems to relax my bladder and reduces overall incontinence. It is also a real blessing to be free of diapers and pads for a time too.

This points out how important it is to find a medical practitioner who is willing to work with you to try different management approaches, even if they are considered a bit unconventional or non-conservative. I have decided that I am in charge of my medical situation and care. It is refreshing to find someone, such as my practitioner, who is willing to go along with this “radical” idea.

Florida

Dear Florida:

Many people write to us with the fear that their incontinence will worsen in time. Thanks for telling our readers the hope that can result from becoming actively involved in one’s own medical care. Finding a professional who is interested and knowledgeable about treating incontinence is the first step and one which may take some perseverance. Being open to new treatment and management routines is also necessary, as medical research and product developments are constantly changing the modalities available for incontinence care.

Keep informed. We at the Simon Foundation appreciate your updates.

Dear Cheryle:
One of the things which attracted me to the Simon Foundation is a desire to find out more about this condition and, perhaps more importantly, to make contact with others who share the same feelings.

I am nearly 50, happily married with three lovely children. I am a senior executive and have just completed an MBA degree. My problems began with a back operation for a ruptured disc in 1993. For several years prior to the operation I had been having incontinence problems. Finally a myelogram disclosed a ruptured disc pressing on various nerves including those which controlled the bladder. I have been partially incontinent ever since the back operation. However, I was told that had I not had the

continued on back

Bowel Health

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Following are some ideas which may help. Keep a large covered glass on the sink and take a few sips each time you pass. Keep chilled or mineral water in the refrigerator. Use your finest glassware - there is no one more “special” than you. Try using mugs which hold more than cups for hot drinks. Keep a stock of your favorite beverage on hand (but watch out for the calorie content). Include fruit with high fluid content such as watermelons, grapes, and oranges in your diet.

Increasing your activity level can also help alleviate constipation. Physical activity has a definite and positive affect on the bowel. Ms. Chiarelli also recommends massage to her readers. Your hands should be warm and their pressure firm.

The colon begins in the lower right hand corner of the abdomen. This is where the massage should begin. Your abdomen should be bare. Using a firm, gentle pressure, make large stroking movements up your right side, across under the rib cage and down the left hand side of the abdomen. This is the direction of movement along the colon.

These stroking movements can be followed by small circular movements, always following the same direction as the bowel contents. Repeat each small circular movement about six times before changing your hand position. Continue the massage for about ten minutes. If you feel discomfort, stop immediately.

Although an uncomfortable topic for many people to talk about, your doctor or nurse is accustomed to discussing bodily functions. Remember to ask for their suggestions regarding good bowel health and always inform your physician of any changes in your bowel habits.
operation I might not have continued to walk. On balance, I would much rather be able to walk and ‘leak’ once in a while than not walk at all.

My greatest problem is nocturnal incontinence or bedwetting. It’s strange, but I never think of it as bedwetting which I associate with children. Perhaps it is just a question of semantics, but I prefer to think of it as adult incontinence which occurs at night.

Although I don’t run through public places proclaiming my situation, I am, for the most part comfortable with it. I have exhausted all medical avenues aimed at relieving the condition and have decided, with the wonderful understanding help of my wife and family and a few close friends, that my “ailment” is nothing to get too upset about.

Over the years I have experimented with various combinations and types of cloth diapers, disposable diapers and protective waterproof pants. If I need protection during the day I usually wear a child-sized disposable held snugly in place by stretchy, close-fitting, ladies underpants. I know what you’re thinking but you’re wrong; I was told about them by a physiotherapist who said that many men wear this type of women’s stretchy pants for this purpose simply because they work and there is not a male equivalent! My wife doesn’t mind and thinks it’s a practical idea.) Over the underpants I wear a pair of plastic waterproof pants. This is undetectable and works very well.

At night, as you know, more care has to be taken. I usually wear a small towel folded like a diaper and held in place with a pair of stretchy underpants. Over that goes a disposable diaper held in place by another pair of stretchy underpants. I finish off with a pair of plastic pants. This may not be everyone’s “cup of tea,” but it works well for me and my situation.

My very best wishes to you and the Simon Foundation for the splendid work you and it are doing to bring this problem out of the closet after so long.

South Archer, England

Dear England:

If you have not already discovered your local continence advisor, please make the effort. People in England with the problem of incontinence have long had the privilege of seeking help from nurses whose total focus is incontinence. They have a wealth of experience regarding incontinence. Today, more research is being done regarding the treatment of incontinence so check with your doctor periodically to inquire if anything new would be of help in your specific case.