



RUSH UNIVERSITY
MEDICAL CENTER

PARKINSON NEWSLETTER

Regulation of Human Research in the United States

Kathleen M. Shannon, M.D.

Part 2: The Food and Drug
Administration



The mission of the Food and Drug Administration (FDA) is: to promote and protect public health by helping safe and effective products

to reach the market in a timely fashion, to monitor products for continued safety, and to help the public get accurate information needed to improve health.

The push for national oversight of food and drugs in the United States began as a result of the industrial revolution. This resulted from movement of workers away from the agricultural setting and into cities as well as the addition of preservatives, coloring and other adulterants (impure mixtures) to the food chain.

Harvey Washington Wiley was an early crusader for food standards. He was chief chemist at the Department of Agriculture. His concern about the safety of additives led him to form the "Poison

Squad," a group of 12 men who tested the safety of food preservatives by themselves eating the food.

Still, food safety did not get the attention it needed until Upton Sinclair published *The Jungle*, his novel detailing deplorable safety and cleanliness in Chicago meat packing plants. The Food and Drug Act and the Meat Inspection Act were passed in 1906. While the Food and Drug Act prohibited interstate commerce in misbranded and adulterated food, drink and drugs, the manufacturer need only show that he personally believed the products to be safe. The legislation was enforced by the Bureau of Chemistry, until 1927, when the Food, Drug, and Insecticide Administration was founded. Attempts to strengthen the legislation failed until a tragedy occurred.

In 1937, the S.E. Massengill developed a liquid form of sulfanilamide, an antibiotic used to treat streptococcal infections. The base for the drug was diethylene glycol, which lent the product a nice appearance and pleasant taste. Unfortunately, diethylene glycol (antifreeze) is highly toxic, causing a prolonged and horrible death with kidney failure, severe abdominal pain, nausea, vomiting, coma and convulsions. 107 people, many of them children, died from this therapeutic misadventure.

Investigators for the FDA eventually tracked down most of the distributed medicine and removed it from the market.

The Federal Food, Drug and Cosmetic Act of 1938 added cosmetics and therapeutic devices to the list of regulated products; required scientific proof of safety and effectiveness before the products were marketed; prohibited or controlled the addition of poisonous substances to foods; created the authority to inspect factories; created food standards; and instituted federal court jurisdiction for violations was created. Later amendments included the Pesticide Amendment (1954); the Food Additives Amendment (1958) and the Color Additive Amendment (1960).

Another drug tragedy highlighted the importance of good safety oversight. Thalidomide was a drug commonly used after 1958 in Europe to treat insomnia and morning sickness. An application for approval was submitted to the FDA and assigned to a new employee, Frances Kelsey. Kelsey had been involved with the collection of tainted sulfanilamide in the 1930's and carefully reviewed the application. Concerned that the drug worked differently in animals than it did in humans, she requested more

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Digital Stream

I write this
digitally
so I can read
what I write
so I remember
what I wrote
when I read
what I wrote
in the morning

I walk slowly
cautiously
because my foot hurts
because I'm not so sure
about that step
about that crack
in the sidewalk
if my next
step will be
a footfall or
freefall

Sometimes
I say "reach"
and I don't
"move"
and I can't
"think"
and
nothing
happens

Words taste
like styrofoam
pens feel
like pipe cleaners
a steering wheel
like a gyroscope
I'm a park monument
listing slightly
to the left

At home
a couch is a bed
a bed is a slab
a book
is a sleeping pill

In public
a crowd feels
like a mob
an avalanche
of voices
a big bowl
of eyeballs
watching

I do
what I do
because I
still can
because it
feels right
because it
must be done
because it fits
because I can't
hold on
or it's time
to let go

I need
to move

I know

I need a foam suit
airbags
to beep beep beep
when I back up

Still
mostly
I'm fine
free lucky spoiled
I'm rich!

Mike McGowan
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Welcome To Our Group



Deborah A. Hall, M.D., Ph.D.

Dr. Hall was awarded her M.D. degree at Indiana University and completed her internship, neurology residency, and movement disorders fellowship at the University of Colorado. Dr. Hall's research interests are in Fragile X tremor ataxia syndrome and in the clinical aspects of movement disorders.



Brandon R. Barton, M.D.

Dr. Barton was awarded his M.D. degree from the Medical College of Wisconsin. His internship, residency, and fellowship were completed at Rush. He splits his time between Rush and the Veteran's Administration. Dr. Barton's research interests are in clinical trials in movement disorders and impulse control disorders.



Sachin Kapur, M.D.

Dr. Kapur is our new Movement Disorder Fellow. Dr. Kapur joins us after completing his Neurology residency at the University of Illinois.

Evelyn Perez

Evelyn is our new Medical Assistant. She assists the nurses in the clinics and with research study visits.

Michelle Heicher and Julie Saldana

Michelle and Julie are the new faces you see in the front clinic. Both Michelle and Julie work with medical records and with correspondence from patients.

Sara St. John

Sara was an intern in our department from Northern Illinois University and is now our new administrative assistant. She videotapes patients and assists with our databases.

Direct-to-Consumer Stem Cell Treatments Fabulous or Fraudulent?

Kathleen M. Shannon, M.D.

Hardly a clinic day goes by without a question about progress in stem cell research to treat Parkinson's disease and related disorders. Interest in this type of "brave new world" treatment has achieved a level rarely seen for a specific therapeutic intervention. So, it is no surprise that glitzy websites advertising available stem cell treatments for PD are garnering quite a bit of attention in the community. Several of our patients have traveled overseas to obtain these treatments, at considerable personal expense. This article summarizes the findings of a review of how stem cell medicine is portrayed in these direct-to-consumer appeals.

Darren Lau and colleagues from the University of Alberta, Edmonton, Alberta, Canada reviewed 19 websites claiming treatment of human disease using stem cells. All advertised centers treat patients with many different diagnoses (including Parkinson's disease, Alzheimer's disease, spinal cord injury, cerebral palsy, multiple sclerosis and others). Most sites use stem cells normally found in the patient's own bone marrow and inject the stem cells into the spinal fluid by means of a spinal tap, though some sites inject cells directly into the brain or spinal cord for some diseases. Most sites either do not mention or describe as trivial any potential side effects of the treatment. For the most part, these stem cell treatments are portrayed as effective and safe. Pictures of high-tech equipment and patient testimonials are used to support the claims of successful therapy.

Why then, should these treatments be discouraged? Before offering treatments to patients, we have a moral obligation to subject the treatment to a series of rigorous experiments in animals and then in people. These experiments are subject to very strict oversight both at the level of the university and the federal government (in the United States, the Food and Drug Administration) and are necessary to establish safety and effectiveness of the potential therapy. Although a growing literature in animal research supports the potential of stem cells for a variety of diseases, there are no published human clinical studies of any type of stem cell (embryonic, adult, etc.) in PD. Therefore, there is absolutely no evidence that stem cell therapy of any kind is safe or effective for the treatment of PD. One poignant story brings home the danger of unregulated treatments. A 13-year-old boy with an inherited brain disorder (ataxia telangiectasia) was treated with fetal stem cells into the brain and spinal cord on several occasions in Moscow. Four years later, he developed headaches, and several tumors were found in the brain, and along the spinal cord. DNA studies confirmed that the tumors arose from the stem cell tissue.

At the present time, it is abundantly clear that human treatments with stem cells should not be performed until they are found safe and effective in well-designed animal and human studies. Until that time, pursue these treatments at your peril!
Verdict: fraudulent!

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information before it could be approved. While the application was delayed in the United States, its use was widespread in Europe. In 1960, 83 European children were born with birth defects, and by 1961, 5,000 German babies with malformed limbs had been born. The drug was withdrawn from the market before it could be approved, but not before 3,000 women in the US had been given the drug in a clinical research test, resulting in a handful of cases of birth defects in the US. In an article on July 15, 1962, the Washington Post ran an article explaining that thalidomide could have legally been approved in the US. This led to passage of the Drug Amendments of 1962, which addressed drug safety testing in humans. In 1976, FDA authority was extended to medical devices. FDA oversight extends to drug marketing and advertising.

Unfortunately, the FDA has had a number of recent mis-steps including failure to recognize or act quickly on drug side effects after marketing (Bextra, Crestor), failure to ensure the quality of imported drugs (heparin), and food safety concerns (peanuts).

Monthly Educational and Support Program

WHEN: Second Saturday of each month, 10:00 am to 12:00 noon

LOCATION: Oak Park Hospital (Back of Cafeteria)

May 8:	Dr. Katie Kompoliti	July:	Summer Break
June 12:	TBD	August:	Summer Break

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