

The New York Times

Health

Search All NYTimes.com

ING DIRECT
Member FDIC

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION ARTS STYLE TRAVEL JOBS REAL ESTATE AUTOS

RESEARCH FITNESS & NUTRITION MONEY & POLICY VIEWS HEALTH GUIDE

Coit Cleaning Services is **Booming.**
find out more >Start
Booming™

OPEN

Search Health 3,000+ Topics

Go

Studies Halted at Brain Lab Over Impure Injections

By BENEDICT CAREY
Published: July 16, 2010

[Columbia University](#) has quietly suspended research at a nationally prominent brain-imaging center and reassigned its top managers after federal investigators found that it had routinely injected mental patients with drugs that contained potentially dangerous impurities.

The investigations found that the center — regarded by experts as the nation's leader in the use of positron emission tomography, or PET, for psychiatric research — repeatedly violated [Food and Drug Administration](#) regulations over a four-year period.

“Failure to promptly correct these violations may result in legal action without further notice,” the agency wrote to Columbia in December 2008, citing lax internal quality control and sloppy procedures for formulating drug injections.

F.D.A. investigators returned in January 2010 and found that many of the center's lab's practices had not changed, and cited a long list of specific violations, including one instance in which the staff hid impurities from auditors by falsifying documents.

“They raided the place like it was a crime scene, seizing hard drives,” said one former lab worker, who requested anonymity because he feared reprisals from the university.

In a statement, the university said on Friday that it had conducted its own investigation of the lab at the request of the F.D.A. had and reported to the agency on July 6 that it found no evidence of harm to patients. The F.D.A. did not publicize its investigations; The New York Times learned of them from doctors who were familiar with the lab's problems.

The office under fire, the [Kreitchman PET Center](#), on West 168th Street in Manhattan, has attracted millions of dollars in research funds from the federal government and pharmaceutical companies to study drug actions and the biology of brain disorders, among other things.

Many of its studies focus on patients with disorders like schizophrenia and severe depression, who are especially vulnerable to poorly prepared imaging drugs because the compounds can act on brain receptors involved in their illness.

“We acknowledge serious shortcomings of quality control in the manufacturing process and record-keeping at this lab,” said David I. Hirsh, Columbia's executive vice president for research. “That is why we are fundamentally reorganizing the lab's management and operations in response to what the F.D.A. told us.”

To perform a PET scan, doctors must first inject patients with a radiotracer, a drug engineered to accumulate in the area of the body being studied and to emit low-level radiation detectable by a scanner.

Using Your Phone to Lose Weight

July 16, 2010

Summer Salads as the Main Attraction

July 16, 2010

A Personal Approach to Primary Care

July 15, 2010

Phys Ed: The Men Who Stare at Screens

July 14, 2010

Talking to Kids About Your Drug Use

July 12, 2010

SIGN IN TO E-MAIL

PRINT

REPRINTS



Get the Opinion Today E-Mail



Sign up for the highlights of the day in Opinion, sent weekday afternoons.

Sign Up

[See Sample](#) | [Privacy Policy](#)

One man,
His cello,
90'000 children's lives saved...
every year!

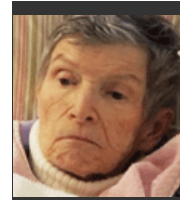
Find out more!

Health & Fitness Tools



BMI Calculator

What's your score? »

What are the signs of
Alzheimer's Disease?

LEARN MORE »

nytimes.com/health

MOST POPULAR - HEALTH

The compounds are considered very safe. But because they degrade quickly, many laboratories produce them themselves, under protocols agreed upon with the F.D.A.

The agency regulates the allowable radiation levels and the purity of the drugs. If a drug contains too many impurities — unknown chemicals that may or may not be related to the tracer itself — then its effects in the body are unpredictable.

“There could be a patient safety issue, for one,” said Dr. Barry Siegel, chairman of the radioactive drug research committee at Washington University in St. Louis. “And there could be a scientific validity issue. If you’re exposing people to radiation and getting garbage data, then that becomes an ethical problem.”

That is particularly true when it comes to psychiatric research. Radiotracers that target receptors in the brain, as used in many of the Columbia studies, are more prone than other PET drugs to be biologically active — to affect mood or behavior, especially in those who already suffer from severe depression or other mental problems. “You have to have additional quality-assurance procedures if you’re using agents that bind receptors in brain,” said Dr. Dennis P. Swanson, chairman of the radiation safety commission at the University of Pittsburgh.

The F.D.A.’s latest investigation, which took place from Jan. 5 to Jan. 21, listed six categories of violations. It found that since 2007, “at least 10 batches” of drugs had been “released and injected into human subjects” with impurities that exceeded the level the lab had agreed to set. At least four injections “had impurity masses that more than doubled the maximum limit implemented.”

The report highlighted an equation that the lab routinely used, resulting in injections that exceeded the limit for acceptable impurities. The lab did not adequately check “the identity, strength and purity of each active ingredient prior to release” for injection into patients, the report said.

Agency investigators also found a forged document, a hard copy record that had been altered to hide a drug impurity that showed up clearly in the computer records.

Former employees, speaking on the condition of anonymity because they worked in the imaging field or hoped to, said those practices were not only commonplace but also condoned. They described a center under such pressure to produce studies that it papered over and hid impurities in drugs to stretch its resources and went ahead with business as usual despite F.D.A. warnings.

“These are not the actions of a rogue, but instead are systematic forgeries condoned and approved by the lab director,” wrote one employee in a 2009 resignation letter addressed to Dr. Ronald L. Van Heertum, the PET center’s co-director at the time.

Columbia’s internal audit concluded that this and other charges had “sufficient substance to warrant an investigation,” according to documents obtained by The Times. Among the charges was one that the lab replaced a compound it was testing for the drug maker Eli Lilly with one it was testing for Novartis — and did not mention the switch in its report to Eli Lilly.

Neither Dr. Van Heertum, a radiologist, nor his former co-director, Dr. J. John Mann, a psychiatrist, returned calls seeking comment on Friday.

In his statement, Dr. Hirsh said, “When manufacturing resumes under new leadership, it will meet the strictest standards and best practices for ensuring the quality” of the PET drugs.

He said the center’s clinical, nonresearch side was not affected by the suspension, adding that it was “fully approved and operational” and remained open for patient care.

A version of this article appeared in print on July 17, 2010, on page A1 of the New York edition.

Times Reader 2.0: Daily delivery of The Times - straight to your computer.

E-MAILED BLOGGED VIEWED

1. Recipes for Health: Spicy Quinoa, Cucumber and Tomato Salad
 2. Mind: Accepting That Good Parents May Plant Bad Seeds
 3. Studies Halted at Brain Lab Over Impure Injections
 4. Drug Trials Test Bold Plan to Slow Alzheimer's
 5. Doctor and Patient: Putting Patients at the Center of the Medical Home
 6. Patient Money: Losing Weight the Smartphone Way, With a Nutritionist in Your Pocket
 7. Consults: Are Sleeping Pills Addictive?
 8. Recipes for Health: White Beans With Pesto
 9. Recipes for Health: Quinoa, Corn and Edamame Salad
 10. Recipes for Health: Curried Brown Rice and Wheatberry Salad
- [Go to Complete List »](#)



Granola muffins

ALSO IN HEALTH »
[Talking to kids about your drug use](#)
[Follow the Well blog on Twitter](#)

nytimes.com HEALTH

ADVERTISEMENTS

Find your dream home with
The New York Times Real Estate



Follow The New York Times on Twitter

Watch today's top videos

See the news in the making. Watch
TimesCast, a daily news video.

Unshaven Women:
Free Spirits or Unkempt? ▶
nytimes.com
Where the conversation begins.



Subscribe for just \$4.62 a week.

SIGN IN TO E-MAIL

PRINT

REPRINTS

SHARE

Ads by Google

what's this?

Board Certified Physician

Same day appts. Family practice Insurance and cash accepted.

www.WestValleyCare.com

Ads by Google

what's this?

Gout Medication

Learn About A Medication That Helps Manage Gout.

TheGoutMed.com

Related Searches

[Columbia University](#)

[Brain](#)

[Laboratories and Scientific Equipment](#)

[Radiation](#)

[Get E-Mail Alerts](#)

[Get E-Mail Alerts](#)

[Get E-Mail Alerts](#)

[Get E-Mail Alerts](#)

INSIDE NYTIMES.COM

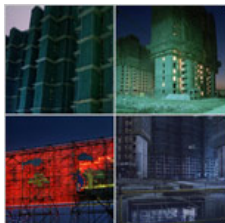


N.Y. / REGION »



[For the Homeless, a Ministry Steps Outdoors](#)

OPINION »



[Living Rooms: China's Instant Cities](#)

FASHION & STYLE »



[State Secret: Chelsea Clinton's Wedding Plans](#)

ARTS »



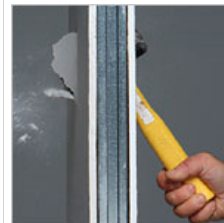
[One-Man Whirlwind Visits Broadway](#)

OPINION »

Bloggingheads: A Great Year to Die

Mark Schmitt of The American Prospect and Stephen Spruiell of National Review debate the estate tax.

REAL ESTATE »



[The Fall of Temporary Apartment Walls](#)

[Home](#) | [World](#) | [U.S.](#) | [N.Y. / Region](#) | [Business](#) | [Technology](#) | [Science](#) | [Health](#) | [Sports](#) | [Opinion](#) | [Arts](#) | [Style](#) | [Travel](#) | [Jobs](#) | [Real Estate](#) | [Autos](#) | [Back to Top](#)

[Copyright 2010 The New York Times Company](#) | [Privacy](#) | [Terms of Service](#) | [Search](#) | [Corrections](#) | [RSS](#) | [First Look](#) | [Help](#) | [Contact Us](#) | [Work for Us](#) | [Advertise](#) | [Site Map](#)