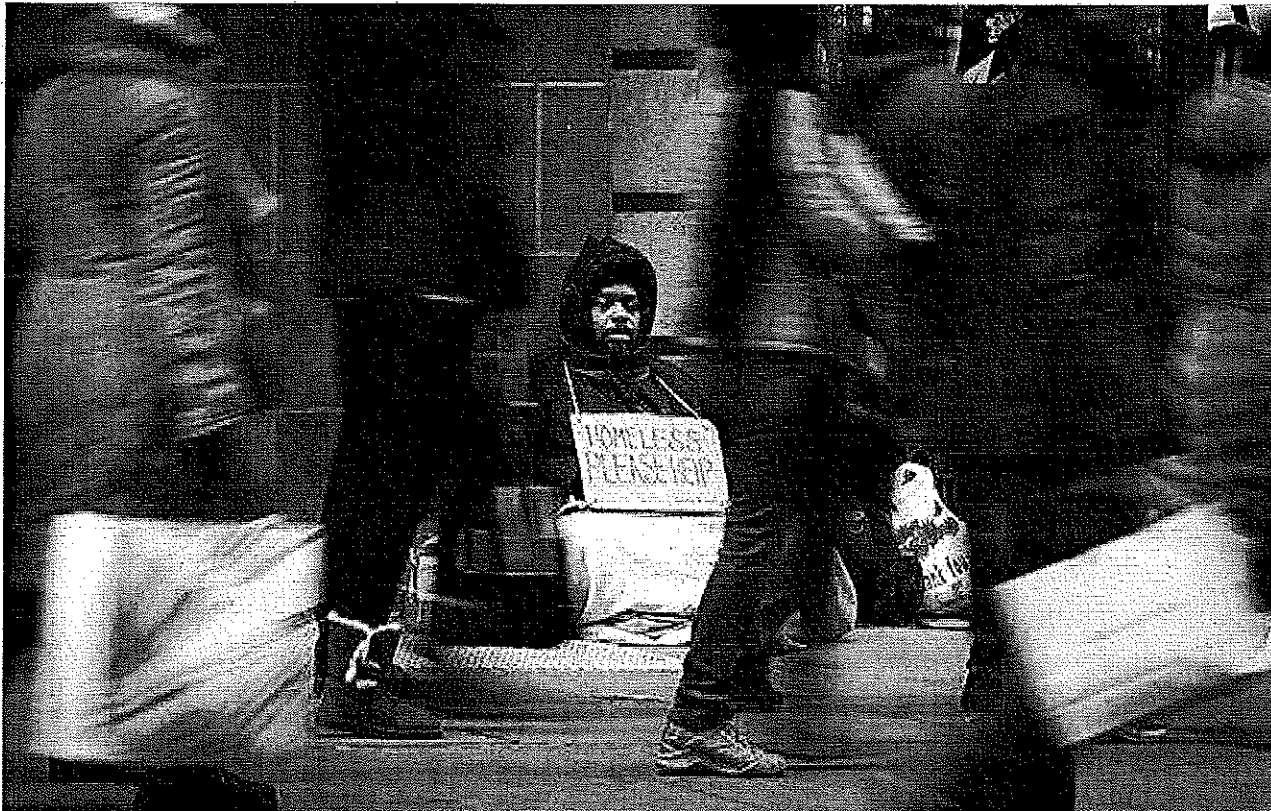


MINNPOST

UCare generously supports MinnPost's Second Opinion coverage; learn why.

Recruitment of homeless people for drug trials raises serious ethical issues, U bioethicist says

By Susan Perry | 08/11/14



REUTERS/Carlo Allegri

Elliott spoke with homeless people around the country who've been recruited into drug experiments.

Homeless people, many with severe mental illnesses, are being actively recruited by contract companies working for the pharmaceutical industry to test experimental drugs, according to University of Minnesota bioethicist Dr. Carl Elliott in a troubling article published recently in the online magazine *Matter*.

As Elliott notes, "Most people think of pharmaceutical research as highly technical activity that takes place in world-class medical centers. The reality is somewhat different. ... Pharmaceutical

companies now typically outsource clinical studies to contract research organizations like South Coast [Clinical Trials], which run trials faster and at lower cost than universities do. Their job is simply to follow the instructions of their sponsors. This formula is working: The contract research industry has grown steadily since the early 1990s and may now generate over \$100 billion in annual income."



Dr. Carl Elliott

Most people also assume, adds Elliott, that medical research studies are tightly regulated by the government to ensure the safety of the people participating in the studies. Again, that's not the case.

"In the 1970s, after a series of notorious research abuses, legislators pushed for a central federal agency with the power to protect human research subjects," Elliot explains. "The medical research establishment fought this idea, however, and when the National Research Act was passed in 1974 a very different alternative followed: a patchwork system of small ethics committees known as Institutional Review Boards. The boards were originally located in hospitals and medical schools, but clinical research has since moved into the private sector. Many are now for-profit companies that review studies in exchange for a fee."

'An extraordinarily profitable class of drugs'

Elliott spoke with homeless people around the country who've been recruited into drug experiments. (None of his stories are from Minnesota.) Some of the people he interviewed, like a middle-aged Californian named Steve, were glad to be participating in the studies — and, in fact, were repeat participants.

"I love this place," Steve told Elliott, referring to the South Coast clinic where he had just begun an outpatient study of Depakote, a seizure drug sometimes prescribed for bipolar disorder. "It's awesome. They don't treat you like you have a mental illness."

Yet, reports Elliott, Steve's hands were trembling so violently that he spilled his coffee on the floor. Tremors are a common side effect of Depakote.

Many of the drugs that have been tested on the homeless are antipsychotics, "an extraordinarily profitable class of drugs," writes Elliott. Once reserved only for people with schizophrenia or other serious mental illness, the newer "atypical" antipsychotics — drugs like Risperdal, Zyprexa, Seroquel and Abilify — are now broadly prescribed for an array of conditions, such as insomnia, depression, anxiety, bipolar disorder, anxiety, autism and attention deficit hyperactivity disorder (ADHD).

The atypicals remain in wide use despite the fact that a large 2005 federally funded study found

them to be no more effective at improving patients' quality of life than the older (and much less expensive) antipsychotics and despite the fact that they can cause potentially dangerous or disabling side effects, including muscle stiffness, tremors, extreme restlessness, and tics.

"The most notorious is tardive dyskinesia, a writhing, twitching motion of the mouth and tongue that can be permanent," writes Elliott.

Elliott repeatedly observed symptoms of dyskinesia and other drug side effects among the homeless study participants he met.

Antipsychotics can also cause heart arrhythmias, which can lead to a life-threatening condition called torsade de pointes. Elliott describes the case of one 47-year-old military veteran who had been diagnosed with paranoid schizophrenia and a potential heart problem before being recruited into a study of an experimental antipsychotic drug called ASP2314 in 2007. The doctors in charge of the study misdiagnosed the man's symptoms of a heart attack as an anxiety attack. The veteran died while at the study's clinic.

'They'll say yes to anything'

Drug study recruiters often approach homeless people on the sidewalks outside of shelters. As a chaplain who works with the homeless in Philadelphia told Elliott: "These guys have no job, no home, and a [illegal drug] habit. You have people at their lowest state, and they'll say yes to anything."

That was certainly the case with, Ed Burns, a Philadelphian man interviewed by Elliott.

Burns and his wife had been on the street for over two years when we spoke; he said they had trouble getting space in shelters, even though his wife is pregnant and Burns has bipolar disorder and depression. "I was on Depakote and I almost killed someone out of anger," he said. "It made me a wrecking machine."

Burns was living in a shelter when he got a message saying that someone from the Veterans Affairs hospital was waiting outside for him. But when he went outside, he said, he was met by a representative of a research company known as CRI Worldwide.

"I was tired, I was hungry, and half an hour earlier the police had treated us like crap," Burns said. "And this woman is saying, 'Imagine, in 40 days you'll have \$4,000!' The recruiter made testing drugs sound like a vacation in a five-star hotel, Burns said. "It's like a resort selling time shares. They talk about all the benefits first, and it sounds great, but then you start to ask: What do I have to do?"

A change in ethical standards

As Elliott explains, offering money to drug study subjects used to be considered unethical.

“Paying any volunteer was seen as problematic, even more so if the subjects were poor, uninsured, and compromised by illness,” he writes. “Payment, it was argued, might tempt vulnerable subjects to risk their health. As trials have moved into the private sector, this ethical calculus has changed. First came a hike in the sums that volunteers could be paid: Many clinical trial sites now offer over \$6,000 for an inpatient drug study. Eligibility requirements have changed, too. For years, trial sites paid only healthy volunteers, mainly to test new drugs for safety. These days, people with asthma, diabetes, kidney disease, liver disease, and other conditions can be paid to take part in trials.”

Of course, many people still view this kind of recruitment as a breach of medical ethics.

“The main ethical issues here ... are the competence and judgment of the prospective subjects,” writes Elliott.

Current federal guidelines governing the selection of research subjects contain a deep conceptual flaw, he contends. Here’s why:

In the notorious research scandals of the 1960s and ‘70s, the common element was exploitation. With the Tuskegee syphilis study, it was exploitation of poor black men in Alabama; with the Willowbrook hepatitis study it was exploitation of the disabled, institutionalized children; with the Holmesburg Prison experiments it was exploitation of prisoners. In each case, researchers with power took advantage of vulnerable populations, getting them to “volunteer” for studies that most people would refuse.

Yet you will not see the word “exploitation” in the federal guidelines governing research. Nor will you see it in the Declaration of Helsinki, a foundational ethics document first signed in the Finish capital in 1964, or more other codes of research ethics. What you will see instead are instructions to avoid “coercion” and “undue influence.”

Concepts like “coercion” and “undue influence” are poorly suited for economic transactions, however. Offering desperate people money to take risks to their health may be wrong, but nobody is being coerced. No one is threatening to harm people if they refuse to become test subjects. One parallel would be sweatshop labor. The ethical problem is not that people are coerced into working in sweatshops — people are desperate to work there, under horrific conditions, for pennies. The ethical

problem is whether it is acceptable to take advantage of their desperation.

You can read Elliott's article in full on Matter's website. Matter is an online publication specializing in long-form articles about science, technology, medicine and the environment. Elliott also wrote about this topic in 2008 for the New Yorker.

Get MinnPost's top stories in your inbox

First Name

Last Name

Email address

☒ Daily newsletter

☒ Sunday review

☐ Greater Minnesota newsletter

☐ D.C. Memo



RELATED CONTENT:

Bad Pharma

Ben Goldacre
Bestselling author of *Bad Science*

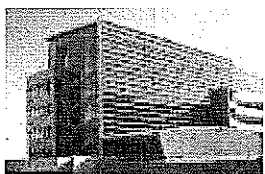
Why drug companies
mislead doctors and
harm patients

SECOND OPINION

Release of 'Bad Pharma' in U.S. may help spur clinical-trial reforms

BY SUSAN PERRY | 02/06/13

"What sets this author apart from most other writers is his charisma, his energy, and his unfiltered comic bluntness," writes the U of M's Dr. Carl Elliott.



SECOND OPINION

'Lone wolf' FDA investigator says 'clinical trial system is broken'

BY SUSAN PERRY | 12/10/13

"Drug companies have turned into marketing machines," Dr. Thomas Marciniak said. "They've kind of lost sight of the fact that they're actually doing something which involves your health."

Related Tags:

ABOUT THE AUTHOR:



Susan Perry

Susan Perry writes Second Opinion for MinnPost, covering consumer health. She has written several health-related books, and her articles have appeared in a wide variety of publications.

COMMENTS (1)

Recruitment of Homeless People 4 Drug Trials

SUBMITTED BY ANITA YAWSON ON FEBRUARY 24, 2017 - 5:22PM.

Hello Ms. Perry,

Thanks for writing this informative article. I'm aware of such studies but didn't realize that participants would not be covered for medical care in the event of any resulting problems.

I also like to extend thanks to Dr. Carl Elliot for his participation!

Sincerely,
Anita

MinnPost | 900 6th Avenue SE | Minneapolis, MN 55414 | 612.455.6950