Tekst 4

Clinical trials on trial

Osagie K. Obasogie

1 A GREAT deal of scientific research — especially in medicine — relies on human subjects. Protecting volunteers has been a prominent social and legal issue since the 1950s, when the world recoiled from the horrors of Nazi medicine.

2 We have come a long way since then, but it pays to remember that the Nazis did not have a monopoly on atrocities committed in the name of science. One of the worst cases of human subject abuse was perpetrated by American scientists who, between 1932 and 1972, misled hundreds of black people with syphilis in Tuskegee, Alabama, by deliberately leaving them untreated to enable researchers to study the progression of the disease.

3 Tuskegee wasn't an isolated incident. Historian Susan Reverby of Wellesley College in Massachusetts recently uncovered another appalling ethical breach. In the 1940s, researchers from the US Public Health Service deliberately infected Guatemalan patients, prisoners and soldiers with syphilis to test whether penicillin was an effective treatment. In a paper to appear in the *Journal of Policy History*, she describes how in some cases infected prostitutes were paid to have sex with prisoners. This breach happened at almost the same time as Nazi doctors were on trial at Nuremberg for similar abuses.

4 Reverby's revelation led the US to issue formal apologies to the victims and the Guatemalan government. It also prompted President Barack Obama to instruct his Bioethics Commission to turn its focus away from synthetic biology and take a fresh look at the protection of human subjects, so as to "assure that current rules… protect people from harm or unethical treatment". Obama should be applauded. **10** if he and the commission review the rules without examining the broader context in which human research occurs, they may vastly underestimate the depth of the problem. Particularly troublesome is the extent to which research on human subjects increasingly targets vulnerable people.

5 This is seen most clearly in clinical trials. The pharmaceutical industry spends billions of dollars each year testing experimental drugs, with a significant portion of this cost stemming from recruiting and retaining human volunteers.

6 Subjects for research are in high demand. A 2005 Bloomberg Markets report showed that the pharmaceutical industry conducted 36,839 clinical trials between 2001 and 2004 — six times more than in a similar period starting in 1981. This

rapid expansion is causing demand for human subjects to outpace supply. To meet the need for more bodies while keeping costs down, the industry is resorting to extreme measures, and the most vulnerable members of society are in the crosshairs.

7 First, poor people and undocumented immigrants are often targeted to participate in drug trials. The industry-wide practice of paying participants hundreds, and in some cases thousands, of dollars attracts poor people who are simply doing it for the money.

8 As a second trend, drug companies are looking to developing countries, where poverty is extreme and social services non-existent. A 2009 study in *The New England Journal of Medicine* (vol 360, p 816) revealed that one-third of phase III clinical trials sponsored by the 20 largest American drug companies are conducted in foreign countries. Over 50 per cent of all clinical trial sites are outside the US, with India and sub-Saharan Africa ranking first. The study also found that since 2002, the US Food and Drug Administration has seen a 15 per cent annual increase in the number of clinical trial investigators it regulates outside of the US while the number of domestic investigators has fallen by 5.5 per cent overall.

9 While clinical trials may offer the developing world some measure of healthcare, they may also give rise to controversial research practices. For example, Pfizer recently paid $75 million in Nigeria to settle charges ─ without admitting any wrongdoing ─ that it illegally tested an experimental antibiotic on children, leading to 11 deaths.

10 Finally, there is a movement in the US to give researchers easier access to prisoners. Current regulations, stemming from past abuses, severely restrict scientists' ability to recruit prisoners for clinical research. But the Institute of Medicine ─ an influential government advisory body ─ has recommended relaxing these restrictions. While no decision has been made, the once unthinkable idea of reopening prison gates to biomedical and behavioural research is now back on the table.

11 These practices highlight how one of the most crucial ethical debates in science and medicine is not over speculative technologies such as synthetic biology. Rather, it concerns the more basic question of how we treat each other. With an entire research industry becoming increasingly dependent upon vulnerable populations to test experimental treatments, not enough thought has been given to issues of justice. We are not back in Tuskegee territory yet, but this approach to recruiting human subjects may give rise to outcomes that are similarly pernicious.

12 Obama should be commended for instructing his Bioethics Commission to look into ways to prevent further human subject abuses, but its mandate must go beyond checking the rules. **14**, the commission must examine a deeper question: is it ever ethical to ask the most vulnerable members of our society to give their bodies to science?

adapted from *NewScientist, 2011*

Tekst 4 Clinical trials on trial

1p **9** What is the main function of the Tuskegee example?

A to illustrate that medical experiments on humans used to be more brutal than they are now
B to indicate that evil deeds are sometimes necessary to achieve something good
C to point out that conducting medical trials on unconsenting subjects continued after WWII
D to reveal the infamous origin of clinical trials in the United States
E to suggest that vulnerable groups of patients should be given special treatment

1p **10** Which of the following fits the gap in paragraph 4?

A Because
B But
C Even
D Only
E Whereas

1p **11** Which of the following conclusions is in line with the “2005 Bloomberg Markets report” (paragraph 6)?

A Clinical research has shifted its preferred method from demand-oriented to supply-oriented.
B In twenty years’ time human testing has developed into the preferred method of conducting clinical research.
C Past clinical trials proved that weaker members of society are particularly suitable test subjects.
D Recruiting a sufficient number of participants for clinical trials is becoming increasingly difficult.

1p **12** Which of the following is a finding of the 2009 study published in *The New England Journal of Medicine* (paragraph 8)?

1 The American pharmaceutical industry increasingly outsources its medical tests across borders.
2 The Third World is in greater need of appropriate regulatory authorities than the US.

A only 1
B only 2
C both 1 and 2
D neither 1 nor 2

1p **13** What becomes clear from paragraph 10?
The writer is concerned that

A prisoners may fall victim to the medical industry as soon as new rules come into effect.
B prisoners will be granted more leave to meet the increasing demand for thorough medical research.
C scientists will be working with a test population consisting solely of prisoners.
D scientists will manipulate prisoners into accepting money in exchange for participation in clinical trials.

1p **14** Which of the following fits the gap in paragraph 12?

A As a result
B Likewise
C Nevertheless
D Rather