

Britain to update its drug trial rules

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Britain is planning a major revision of pharmaceutical drug trial regulatory rules after an incident that nearly killed six men.

The trial of a new immune system drug in a London hospital earlier this year left the young men in intensive care for weeks. Physicians say they will suffer from severely damaged immune systems the rest of their lives -- but the drug companies involved in the trial have refused to cover any of their medical expenses or provide compensation, The New York Times reported.

A subsequent investigation revealed loopholes in Britain's drug testing system that, investigators said, in some instances seemed devised more to bring drugs to market rather than protect human safety, the newspaper reported.

Since the incident, the British Health Department, the U.S. Food and Drug Administration and the Association of the British Pharmaceutical Industry have issued revised recommendations for testing new medicines, particularly those aimed at essential biological pathways.

"The lesson learned is that now when we see a molecule like this -- one with a novel mechanism -- we need a very different approach," Dr. John Jenkins of the FDA told the Times. "Now that we've seen this episode, we will be very cautious going forward."

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