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**PFIZER FILES CHALLENGE TO IMPROPER NIGERIAN GOVERNMENT REPORT
IN TROVAN CASES**

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***Lawsuit claims report was biased, denied company due process,
ignored 19 pieces of contrary evidence; Nigerian government
should be prevented from using it in Trovan cases***

NEW YORK, July 31 - Pfizer said Tuesday that it was granted permission to file a lawsuit in federal court in Abuja, Nigeria, charging that a report in which the Nigerian government has based many of its claims in litigation against the company is illegal, inaccurate, and should be quashed.

The lawsuit states that, in 2001, the Nigerian Ministry of Health constituted an investigative committee to look into Pfizer's 1996 Trovan clinical study. The resulting report was never made public until a prominent U.S. newspaper reported excerpts from it in 2006.

The complaint points out that to date "the Federal government of Nigeria has neither accepted the Report, considered the Report in the Federal Executive Council, nor issued a white paper on the basis of the said Report." The lawsuit also states that the committee "acted in excess of its powers," as its job was mere fact-finding and it lacked authority to impose any punishment. Moreover, the complaint alleges that the "proceedings of the committee and the Report were in utter violation of and total disregard of the Applicants rights to Fair Hearing."

The lawsuit contains many serious challenges to the fairness and impartiality of the process by which the report was generated, including that:

- The report was initiated at a time when both the Ministry of Health and Pfizer had been sued in federal court in Nigeria over the Trovan study, and the report was prepared with the intention of exculpating the ministry from liability.
- Dr. Nasidi, Chairman of the Investigation Committee that issued the report, openly stated his objection to the study during a visit to Kano's Infectious Disease Hospital (IDH) with another known critic of the trial, Professor Idris Mohammed. Despite his pre-conceived views, Dr. Nasidi refused to reclude himself from the investigation. Pfizer's objections to Dr. Nasidi's role as committee chairman, due to his lack of impartiality, were ignored.
- Contrary to common sense, logic and law, Dr. Nasidi himself provided evidence to the committee. Hence, he acted as committee chairman, witness and judge in the investigation.
- Pfizer was not given any opportunity to hear the witnesses' testimonies before the committee, nor to cross examine them.
- The conclusions of the committee were based primarily, and almost verbatim, on the evidence provided by Dr. Nasidi.

Furthermore, the lawsuit contends that in the report's recommendations, the committee ignores at least 19 pieces of evidence that favor Pfizer, including the following facts:

- Kano's Ministry of Health and the National Agency for Food, Drug Administration and Control (NAFDAC) approved the Trovan study.
- Several staff members of Kano's Ministry of Health, including Dr. Shehu Yusuf and Mr. Badulkadir, assisted in the study.
- The Trovan study helped save lives; the fatality rate from the epidemic was reduced from 30% to 6% in the group treated with Trovan.
- NAFDAC legally granted Pfizer the authority to import Trovan into Nigeria and approved Trovan for investigational (clinical trial) use.
- Pfizer obtained informed consent from the children's relatives and family.

- The individual who wrote the letter authorizing the importation of the drugs for investigational purposes did so upon being satisfied that the documents supplied by Pfizer were in order.
- At least two witnesses provided contradictory evidence.

In its Statement of Defense in the Kano state civil case - filed on July 16, 2007 - Pfizer maintains that before conducting the Trovan study, the company sought and obtained all necessary approvals from relevant federal and state government agencies in Nigeria. In that regard, Pfizer has at least 12 letters between the company and the U.S. FDA as well as Nigeria's NAFDAC, Ministry of Health and Ministry of Finance, discussing and approving the study. Pfizer also states that the results of the study plainly proved that Trovan helped save lives. With a survival rate of 94.4%, Trovan was at least as effective as the best treatment available at Kano's IDH. The overall survival rate in Nigeria was less than 90%.

Pfizer's Statement of Defense also asserts that at Kano's IDH, parents or guardians of potential study participants were explained the details of the trial, including that participation was voluntary; that local Nigerian nurses explained orally to patients' parents and/or guardians in Hausa the details of the study; that oral consent was obtained before any patient was admitted into the study; and that at no point were the parents or guardians separated from the children.

Pfizer also contends that patients in the Trovan study already had serious symptoms of meningitis before they were treated and that advanced meningitis can lead to brain damage, coma and death. All clinical evidence points to the fact that any deaths occurring during the Trovan study were the direct result of the

illness and not the treatment provided to patients. The company highlights the fact that survivors of meningitis can suffer the very same long term complications unjustly and erroneously attributed to the Trovan clinical trial including, but not limited to, hearing loss, mental retardation, paralysis and seizures.

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