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**CONTACT:** Chris Loder  
(212) 733-7897

## **Kano's High Court Orders Nigerian Governments to Produce Documents That Show Governments' Approval of 1996 Trovan Clinical Study**

**NEW YORK** - The High Court of Justice of Kano, Nigeria, has ordered the Kano State and federal governments to produce more than 12 letters between Pfizer and the two governments in connection with the 1996 Trovan clinical study. The letters show that, contrary to the governments' allegations, Pfizer sought and obtained the governments' approval to conduct the study before undertaking it. The Court's April 24 order was in response to a request by one of the individual defendants in the case to subpoena the letters.

"Government approval is at the heart of these cases. Pfizer has said all along that both the Kano State and federal governments were fully aware and approved of the Trovan clinical study. Now, the Nigerian people can confirm that with their own eyes," said Pfizer spokesman Chris Loder.

One of the subpoenaed documents is a March 20, 1996, letter from Nigeria's National Agency for Food and Drug Administration Control (NAFDAC) - the Nigerian authority responsible for approving clinical studies - to the U.S. Food and Drug Administration (FDA), providing approval for Trovan to be used as part of a clinical study. The letter reads in part:

1. We have been supplied with adequate information about the drug and its proposed investigational use by the sponsor.
2. The drug will be used for investigational use only.
3. The drug may be legally used by the investigators in Nigeria."

Years later, in response to an inquiry by a federal government committee investigating the matter, NAFDAC again confirmed that it had approved the Trovan clinical study. "Available evidence show that in 1996, NAFDAC legally granted permit to Pfizer Plc., to import the un-registered drug, Oral Trovan, into Nigeria, for the purpose of clinical trial investigations," says the January 5, 2001, letter.

Other letters between Pfizer and federal authorities show: (1) the federal government's invitation to Pfizer to come to Nigeria; (2) an exchange between the federal ministries of Health and Finance seeking to facilitate the entry of Pfizer medicines and medical supplies into Nigeria via the ports; and (3) the authorization to import Pfizer medicines and other medical supplies duty free.

The letters between Pfizer and Kano State authorities also address various issues, including the state's authorization for Pfizer doctors to treat patients. "Approval is also hereby given for your staff to participate in treating patients at our hospitals," reads a letter from Kano's Ministry of Health to Pfizer Products Plc. dated April 2, 1996.

Pfizer stands by its clinical study, which was conducted with the full knowledge and approval of the Nigerian government, consent of the participants and consistent with Nigerian laws.

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