IN THE HIGH COURT OF KANO STATE
HOLDEN AT KANO

SUIT NO: K/233/2007

BETWEEN

ATTORNEY GENERAL OF KANO STATE PLAINTIFF

AND

1. PFIZER INTERNATIONAL INCORPORATED
2. PFIZER NIGERIA LIMITED
3. WILLIAMS STEERE
4. SAMUEL OHUABUWA
5. A. DOGUNRO
6. SCOTT HOPKINS
7. MIKE DUNNE
8. DEBRA WILLIAMS
9. ROBERT BUHL

DEFENDANTS

STATEMENT OF DEFENCE OF 1ST AND 2ND DEFENDANTS

Save and except as it is hereinafter specifically admitted, the 1st and 2nd defendants (hereinafter the "Defendants") deny each and every material allegation of fact contained in the statement of claim as if each were specifically set out and denied seriatim.

1. The Defendants deny paragraph 1 of the Statement of Claim and in reaction thereto state that the powers of the Plaintiff does not include the commencement of legal actions for matters personal to the citizens of Kano State.

2. The Defendants admit paragraphs 10 and 11.

3. The Defendants specifically deny paragraphs 2, 3,4,5,6,7,8, 9,10,11, 12, 13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35, 36,37,38,39,40 and 41of the Statement of Claim.

4. The Defendants deny paragraph 2 and 3 of the Statement of Claim and aver that Pfizer International Incorporated does not exist, is incorrectly named as the 1st defendant in this suit, and the proper defendant is not before this Court.

5. The Defendants deny paragraph 4 of the Statement of Claim and put the plaintiff to the strictest proof thereof. The Defendants aver further that the Pfizer Nigeria Limited never existed at any time material to this suit or at any time at all.

6. The Defendants deny paragraph 5 of the statement of claim and aver that the 3rd Defendant was never employed by the 1st Defendant. The 1st Defendant did not engage in any illegal conduct and as such, the 3rd Defendant did not at any time approve any illegal conduct as alleged or at all. The Defendants further aver that the 3rd Defendant had no involvement in the design or implementation of the Trovan study and never traveled to Nigeria for the study or for any other reason.

7. With reference to paragraphs 6 and 7 of the Statement of Claim, the Defendants say further that the 4th and 5th defendants were never in the employment of the 2nd Defendant that never existed at all times material.

8. The Defendants admit paragraph 8 of the Statement of Claim only to the extent that the 6th, 7th and 8th Defendants are qualified professionals and were in the employment of the party in interest that is not before this Court at the time of the Trovan investigative study in 1996. The Defendants further deny that the 6th, 7th, and 8th defendants furthered any "dubious" objective of any Defendant. In particular, Defendants aver that the 6th, 7th, and 8th defendants did not in the course of their work take part in any act which may be ascribed or described by the words "dubious objectives" or any act of a nature that may be considered to have been in bad faith. The Defendants further aver that one Dr. Isa Dutse, a qualified specialist medical doctor, was engaged as principal investigator but deny that he was only principal investigator in name. Dr. Dutse never acted under the control and instruction of the 1st, 6th, 7th and 8th Defendants but served as the principal investigator for the Trovan trial in 1996.

9. With respect to paragraph 9 of the Statement of Claim the Defendants aver that the 9th defendant was never employed, but rather was hired on a one-time basis and for a very brief period of time as an independent contractor (a pilot), by party not presently before the Court to perform a very specific task that did not involve administering the Trovan study or caring of patients in any way.

10. Further to paragraph 8 above, the Defendants aver as follows:

    i.) Dr. Isa Dutse was selected as the Principal Investigator because of his qualifications and experience as a physician.

    ii.) At the time of his selection, the Dr. Isa Dutse was a physician at the nearby Bayero Teaching Hospital, Kano State and served as the Deputy Chairman of the Medical Advisory Committee of the Teaching Hospital.

    iii.) Dr. Isa Dutse had previously worked as an Assistant Investigator on an earlier meningitis study in 1986 involving the drug Unisyn and had published the results of this study.

    iv.) He had wide experience in treating meningitis in Kano State.

    v.) He was fluent in Hausa.

The Status of the 6th, 7th, and 8th Defendants

11. The Defendants admit paragraphs 7 and 8 of the statement of claim only to the extent that the 5th, 6th, 7th and 8th Defendants are qualified medical doctors and were in the employment of the party not presently before the Court at the time of the Trovan investigative study in 1996.

12. The Defendants deny paragraphs 13 and 14 of the Statement of Claim and state that the 6th, 7th, and 8th Defendants were at all material times recognized, experienced and highly skilled professionals. In so far as their employer obtained necessary approvals from the relevant government agencies, including but not limited to approval from NAFDAC for investigative study involving the drug Trovan as well as approval from the Kano State Ministry of Health for permission to treat patients in Kano State Hospitals, the 6th, 7th, and 8th defendants were lawfully involved in the study under supervision of Nigerian qualified medical personnel, the study not being traditional medical practice but an investigative study in an emergency epidemic situation.

13. The Defendants further state with respect to paragraphs 13 and 14 that in assisting the Nigerian doctors to manage the patients, the 6th, 7th and 8th Defendants acted in the best interests of the children involved, using the best medical knowledge available.

Meningitis Epidemics and Defendants' Response.

14. With reference to paragraphs 10-14 of the Statement of Claim, the Defendants state as follows:

    i.) Defendants intervened by setting up and conducting an investigative study at the Infectious Disease Hospital in Kano, Nigeria in 1996 during the cerebral spinal meningitis (CSM) outbreak going on at that time.

    ii.) Pfizer's contribution was not limited to treating patients in its study, but extended to the donation of medicines, equipment and materials to Kano State to help fight the concurrent epidemics involving associated diseases such as cholera and measles that were ongoing at the time. In total, Pfizer donated over N18 Million to Kano State. The Defendants shall rely on documents from relevant government agencies inviting the Defendants as well as those acknowledging the donations.

    Background and nature of the Disease of Meningococcal Meningitis

    iii.) Meningitis is a bacterial infection that causes the inflammation of the tissues that cover the brain and spinal cord.

    iv.) Meningococcal Meningitis does not occur in epidemic proportion in the United States and Europe; rather, such epidemics strike impoverished countries in Sub-Saharan Africa where crowded living conditions and dry climates contribute to the spread of disease.

v.) In Sub- Sahara Africa, epidemics of Meningococcal Meningitis occur in seasonal cycles (between November and June) during the dry season.

vi.) The cyclical impact of the disease has earned this area of Africa the name the 'Meningitis Belt'.

vii.) Advanced Bacterial Meningitis can lead to brain damage, coma and death. Survivors can suffer long term complications, including, but not limited to, hearing loss, mental retardation, paralysis and seizures.

The Impact of the 1996 Meningitis Epidemics in Nigeria

viii.) This was the most serious epidemic of cerebral-spinal meningitis ever recorded in Nigeria and it put a significant strain on the healthcare system of the country. The epidemic resulted in 300,000 cases, with Nigeria being one of the most affected countries in subsaharan Africa. The epidemic was not limited to Kano State, but was widespread over many states in Northern Nigeria.

ix.) The specific strain of the bacteria that caused the epidemic was *Neisseria Meningitis;* which had developed resistance and as such it was difficult to mount an effective response to the epidemic.

x.) The meningitis epidemic in Nigeria took the lives of almost 12,000 people over a six-month period. The severity of the epidemic was evidenced in the fatality rate, which was as high as 20% in the first weeks. Eventually, as reported in one source, it decreased to 10.7%.

No Misrepresentations

15. Contrary to paragraphs 13 to 24 of the Statement of Claim, the Defendants state as follows:

i.) The Defendants did not misrepresent or conceal any facts as alleged or at all.

ii.) The Defendants sponsored an investigative study at the Infectious Disease Hospital in Kano, Nigeria. The Defendants' long-term goal was to bring a life-saving and innovative form of antibiotic that could be used effectively in a pediatric meningitis epidemic in a developing country. Trovan was not only extremely effective at treating the meningitis pathogen, its oral form avoided the use of intravenous administration or intramuscular injections. Such alternative methods of administration are difficult to administer in an epidemic setting, can be painful to those receiving the drugs, and in the case of intravenous administration can lead to the spread of other diseases if sterile needles are not used.

iii.) It would be disingenuous to ignore the significant humanitarian aspect of the Defendants' intervention. The Defendants believed Trovan could save lives. It was the Defendants' hope that this new drug would significantly reduce the cost of care and improve the treatment and health of patients in epidemics that cyclically ravage subsaharan Africa, including Nigeria.

iv.) The Defendants acted in the best interests of the children involved, using the best medical knowledge available to treat the patients in the Trovan trial.

v.) All the personnel recruited by Defendants for the job were experts in their respective fields.

vi.) At the material time, Trovan was in late stage development and had been tested clinically in more than 5,000 patients in the United States, Europe and elsewhere for a variety of infections in both oral and intravenous forms. Pre-clinical studies demonstrated that Trovan was effective against several types of bacteria known to cause meningitis. The drug had been shown to have excellent activity against all meningitis pathogens and penetrated very well into the cerebrospinal fluid (CSF) to effectively treat the disease.

vii.) At the material time, Trovan had also been tested on children in two pharmacokinetic (dosing) studies (172-003, 172-004). Interim results of these two protocols demonstrated that Trovan behaved similarly in adults as it did in children.

viii.) Pfizer was ready to start formal meningitis trials in children around the world. This pediatric meningitis study was eventually conducted and the investigators in this study found that Trovan was an effective antibiotic for the treatment of pediatric meningitis and raised no new safety concerns.

Defendants Obtained Approvals from Relevant Government Agencies.

16. The Defendants further deny paragraphs 13-14 and aver that all necessary approvals to conduct the clinical trial and investigative study of Trovan were obtained from relevant government officials and statutory bodies in Nigeria before conducting the trial. Alternatively, the Defendants aver that in participating in any capacity in the Kano epidemic control effort or investigative study they relied on approval letters and exemptions issued by NAFDAC, the Federal Ministry of Finance, the Federal Ministry of Health, all agencies of the plaintiff herein. Accordingly, the Plaintiff is estopped from denying the fact of appropriate approvals and authorization having so represented the defendants individually and or jointly and they having acted upon the representation as aforesaid. The Defendants will rely on a series of written communications (many of which are referenced below) with the relevant agencies as well as correspondences between the agencies themselves, including the U.S. FDA, the Nigerian Federal Ministry of Health, NAFDAC, the Nigerian Federal Ministry of Finance, and Kano State Ministry of Health. The Defendants further aver as follows:

i.) On March 15, 1996, Pfizer by letter to the United States Food and Drug Administration requested an export waiver to export the drug Trovan to Nigeria. The letter stated that: "We are anticipating that Nigeria will forward a Government Request letter to Michelle Limoli within the week which will request emergency shipment of the investigational antibacterial agents trovafloxacin and alatrovafloxacin to be sent to that country to be used in a clinical trial."

ii.) That same day, March 15, 1996, Pfizer sent a letter to the National Agency for Food and Drugs Administration and Control (NAFDAC). The letter stated "the purpose of this letter is to ask that the Nigerian Health Authority submit via facsimile a government request to the U.S. Food and Drug Administration on behalf of Pfizer Central Research for use in an investigational comparative drug trial for the treatment of meningitis. A sample letter containing the necessary information is attached for your convenience." The letter explained that "the studies to be conducted in Nigeria are a part of Pfizer's worldwide development program for trovafloxacin and alatrofloxin" (IV form). The letter attached a form letter of authorization for the Nigerian government to potentially use and return to the U.S. FDA, as well as a one page summary of the protocol entitled "An Open-label Randomized Comparative Study of Alatrofloxacin and Ceftriaxone in Epidemic Meningococcal Meningitis" and a one page document entitled "Summary/Rationale for Use of Trovafloxacin/Alatrofloxacin in Meningitis."

iii.) On March 18, 1996, the 5th Defendant made attempts to see both the Director of NAFDAC and the Federal Ministry of Health to get approval for the Trovan study. The 5th Defendant provided a letter to NAFDAC on March 18, 1996, stating: "We are happy to express our willingness to help the Federal Government and indeed the citizens of this great country to save the lives of several victims." Attached to the letter was the March 15, 1996 letter from the FDA (see para 19 (ii)), as well as a memo from Pfizer explaining the purpose of the Trovan investigative study, including the fact that Pfizer had "finished pharmacokinetic trials in children and adults to show high CSF levels (many times above that necessary to kill the microorganism) and safety and are ready to start formal meningitis trials." The letter further stated: "We think that the current Nigerian meningococcal meningitis epidemic would be an important opportunity to demonstrate the efficacy of a potent new antibiotic in meningitis to help speed the development and ultimate availability of this worldwide....We are proposing to do a 200 patient randomized, comparative meningitis trial in the Kano area."

iv.) The 5th Defendant returned in person on March 20, 1996 and met with Mr. E. U. Usoro, Assistant to the Director General of NAFDAC. The 5th Defendant explained the nature of the study. The study protocol and case report form were provided to NAFDAC at this meeting. The approval from NAFDAC was obtained that day (March 20, 1996). Specifically, NAFDAC forwarded the letter to the U.S. Food and Drug Administration. The letter requested that "supplies of the investigational drugs trovafloxacin and alatrovafloxacin be exported to Nigeria for investigational use"; and further stated that: "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."

v.) That same day, March 20, 1996, the FDA granted Pfizer an export waiver acknowledging in a letter that "this is your authorization to ship immediately."

vi.) On March 26, 1996, the 4th Defendant wrote to the Ministry of Finance requesting that the Ministry of Finance authorize the importation of the various materials for the investigative study. This letter stated that Pfizer has "secured the approval of the National Agency for Food, Drugs, Administration and Control to bring medical supplies including alatrofloxacin and trovafloxacin as life-saving medicines." The letter further requested a "waiver on custom duties to clear these drugs."

vii.) The 4th and 5th Defendants also went to the Federal Ministry of Health in person to meet with Dr. A.E. Ike, Special Assistant to the Honorable Minster of Health to discuss the Trovan study. On March 28, 1996, Nigeria's Federal Ministry of Health and Social Services approved the Trovan study, stating by letter that their approval would "…enable you deliver safely to Nigeria the emergency medical supplies for the Management of the Cerebrospinal Meningitis currently ravaging parts of our country. The products...have been kindly donated by Pfizer Inc. NY to assist Nigeria to [sic] contain the disease."

viii.) Also that same day (March 28, 1996), the Federal Ministry of Health and Social Services sent a letter to Nigeria's Finance Minister, which asked that: "In view of the fact that all drugs and medical consumables are to be donated to government free of charge, I am appealing to you to grant PFIZER PRODUCTS PLC duty exemption certificate to facilitate the clearing of items from the Ports."

ix.) The next day on March 29, 1996, Nigeria's Ministry of Finance granted Pfizer an Import Duty Exemption Certificate. The letter to the Minister of Health and Social Services reads in part: "[A]pproval has been granted for the Federal Ministry of Health and Social Services to import, duty free, through Pfizer products PLC, drugs and medical consumables as indicated...."

x.) The Minister of Finance, Chief Anthony A. Ani (Honourable Minister of Finance), also sent a letter to the Sole Administrator of Nigeria Customs Service, Abuja, the Zonal Coordinator of Customs Service, and the Governor of the Central Bank of Nigeria, and the Pre-Shipment Inspection Agencies, attaching an invoice listing the medicines and supplies being shipped to Nigeria from Pfizer for use in the Trovan investigative study.

xi.) Following approvals by the Federal Ministries and NAFDAC, approval was also obtained from the Kano State Ministry of Health. The 5th Defendant met with Lawan Gadanya at the Kano State Minister of Health, discussed the protocol with her and also explained how Trovan was an investigational new drug. Lawan Gadanya gave her approval for the study. In a letter from Kano's Ministry of Health and Social Services to Pfizer, Lawan Gadanya stated that "Approval is also hereby given for your staff to participate in treating patients at our hospitals."

xii.) The 5th and 6th Defendants also met with the Director of the IDH as well as Idris Mohammed on April 2, 1996 and provided each of them with a copy of the protocol and informed consent form. Both gave their approval to allow the study to go forward.

17. The Defendants further deny paragraph 14 of the Statement of Claim and state that they did not breach the duty imposed on them under Nigerian law having acted based on authorization and approvals given by Nigerian authorities.

18. The Defendants further deny paragraphs 13 and 14 of the Statement of Claim and shall put the Plaintiff to the strictest proof and further aver that they were competent to participate in the investigative study and did validly conduct an investigative study using the drug Trovan as approved by NAFDAC and that in so doing they were not engaged in medical practice, but an investigative study under the supervision of a duly qualified Principal Investigator Dr. Isa Dutse.

The Defendants Engaged In Legal and Ethical Conduct

19. Contrary to paragraphs 15 and 16 of the Statement of Claim, the Defendants did not exercise any inappropriate control over the hospital ward where the investigative study was conducted and state that the ward utilized by the Defendants and the local doctors was duly allocated to them by the authorities of the Infectious Disease Hospital. The Defendants further aver that they did not violate Nigerian Law in administering the Trovan drug. The drug was approved by NAFDAC and other relevant government agencies for investigational purpose. The Defendants only used the drug for the investigational purpose that it was approved for by the Nigerian government. The drug was not sold to anybody or distributed outside the hospital ward where it was used.
Consequently, no question of use of an unregistered drug arose because

investigative study is part of the process of eventually achieving registration of the drug and Nigerian law allows for such a study. Additionally, the informed consent process was transparent and the parents were never separated from their children during the process.

20. Contrary to paragraph 17 of the Statement of Claim, as set forth previously in paragraph 16, Trovan was in late stage development and had been tested clinically in more than 5,000 patients. Likewise, pharmacokinetic (dosing) studies demonstrated that it behaved similarly in adults as in children. Additionally, as set forth in paragraph 17, government approval for the Trovan investigative study had been obtained from the relevant Nigerian government authorities.

21. Contrary to paragraphs 18 and 19 of the statement of claim, the Defendants state that the amount of Ceftriaxone, the comparator drug, given to patients in the clinical study was more than enough to effectively treat the disease. The drug was familiar to the 6th Defendant who, while in the employment of Hoffman-LaRoche, helped to develop Ceftriaxone. The Defendants further state that:

    i.) The fact that its survival rate for children was approximately 94% speaks to how effective Ceftriaxone was at the doses administered.

    ii.) Children receiving Ceftriaxone were initially administered a 100 mg/kg intramuscular injection of the drug. Subsequently, four daily doses were reduced to 33 mg/kg IM in an effort to reduce the significant pain resulting from the 100 mg/kg injection.

    iii.) Even at the 33 mg/kg dosage level, the amount of the drug was approximately 620 times the level required to kill the meningitis bacteria.

    iv.) Indeed, a clinical study sponsored by Doctors Without Borders (also known as MSF) in 2003 confirmed that <u>one 100 mg/kg dose</u> of Ceftriaxone was effective at treating epidemic meningococcal meningitis, a total dose significantly lower than that used in the Trovan study in Nigeria. Mortality rates in the Doctors Without Borders-sponsored study were 5-6%, similar to the outcome for patients in the Trovan trial. The authors of this study conclude that: "Single-dose Ceftriaxone provides an alternative treatment for epidemic meningococcal meningitis – its efficacy, ease of use and low cost favor its use. National and international health partners should consider Ceftriaxone as an alternative first-line treatment to Chloramphenicol for epidemic meningococcal meningitis." The Defendants will rely on this study at trial.

22. It is not true, as alleged in paragraph 19, that the Defendants purposefully used a lower dosage of Ceftriaxone in order to make a dubious claim that Trovan was more efficacious than other drugs in the market.

23. It is not true, as alleged in paragraphs 13 and 14 of the statement of claim, that the Defendants misrepresented its primary motive in seeking to participate in giving care and rendering assistance to 200 persons out of over 200,000 children afflicted with the disease during epidemic. While Defendants did sponsor an investigative study, the Defendants' contribution was not limited to providing assistance to and collaborating with local physicians to treat patients in the study, but also extended to the donation of medicines, equipment and materials to the Kano State Government to help fight the concurrent epidemics that were ongoing at the time. This included medicines, such as unasyn and cefroid, microscopes, refrigerators, a laboratory incubater, centrifuges, and other laboratory supplies. In total, Pfizer donated over N18 Million worth of goods to Kano State. The Defendants will at the trial rely on letters of appreciation written by the governments.

24. Further with respect to paragraph 10 of the Statement of Claim, the Defendants aver that from available publications, particularly a publication reported by Dr. Idris Mohammed, that about 109,580 people were afflicted by the deadly meningitis and that about 11,717 of the children (over 10%) died.

25. Further with respect to paragraph 10-11 of the Statement of Claim, the Defendants further state that Trovan's survival rate of 94.4% was at least as good as the best treatment available at IDH. For patients who did not participate in the Trovan investigative study, the survival rate was slightly less than 90%.

26. Further to paragraph 24 above, Pfizer also donated medicines and materials worth over N18 million to the Kano State Government. The Defendants shall rely on letters of appreciation written by these governments.

The Defendants Were Not Negligent

27. The Defendants deny paragraphs 20-29 of the Statement of Claim and put the plaintiff to the strict proof of the alleged acts of negligence.

28. Contrary to the untrue averments in paragraph 20 to 29 of the Statement of Claim, the Defendants state categorically that they were not in any way negligent in their actions and/or in the discharge of their professional duties to the victims of the epidemic. Defendants state that their acts met the standards required of professionals in the circumstance and that they exercised all due care in the treatment of the patients in the study. Specifically, the Defendants:

    a. The protocol approved by relevant authorities for the study anticipated the risks associated with the study and stated detailed procedure to manage those risks, which the Defendants endeavored to comply with within the limitation of the circumstances.
    b. Took adequate measure to study, analyze and diagnose the specific ailments the victims presented;

    c. Ensured that the medications, treatments and standards were safe and adequate;

d. The patients responded well to the treatment with Trovan, as the survival rate for Trovan was 94.4% while that of Ceftriaxone was 93.8%. The death rate for this epidemic was at times averaged as high as 20% and tragically it took the lives of almost 12,000 in Nigeria alone making the rate of survival within the study a significant improvement in mortality as compared to the epidemic as a whole.

e. The Defendants aver that the patients already had serious symptoms of meningitis before the arrival of the Defendants and that Trovan was not responsible for their serious condition.

f. The Defendants aver emphatically that none of the patients died as a result of the application of Trovan. All clinical evidence points to the fact that any deaths were the direct result of the meningitis illness and not the treatment provided during the clinical study. Tragically, the epidemic took almost 12,000 lives, many of them children. A number of patients were very sick and deaths occurred with all the treatments. But Trovan's survival rate of 94.4% was at least as good as the best treatment available at Infectious Disease Hospital. For patients who did not participate in the Trovan investigative study, the survival rate was slightly less than 90%.

g. Prof. Idris Mohammed, the purported Chairman of the National Taskforce on the Epidemic, was given the protocol and he expressed satisfaction with it. He only withdrew his approval when the Defendants refused to accede to his request that the materials and equipment used for the trials should be given to him personally for use in his private hospital.

h. As part of the safety measures adopted by them, the Defendants conducted a series of micro-biology tests to ensure that the clinical diagnosis of meningitis was consistent with laboratory results.

i. The treatment provided by Doctors Without Borders (a.k.a. MSF) was oily chloramphenicol, an injectable drug that was not approved for use in Nigeria and the United States and caused significant pain to patients.

j. Local Nigerian nurses at a triage desk at Kano's Infectious Disease Hospital informed the sick children's parents or guardians that they could choose between treatment by MSF and the Trovan investigative study. Before participating in the Trovan investigative study, oral informed consent was obtained. Local Nigerian nurses explained orally to the patients and/or their parents in Hausa the details of the study. The patients and/or their parents gave their consent orally in the native language of Hausa.

k. Additionally, the informed consent process was transparent and the parents were never separated from their children during the process.

l. Prior to the first dose, each patient was physically examined to determine whether he or she presented with the symptoms of meningitis.

m. Additionally, prior to receiving drug treatments, a diagnostic lumbar puncture was performed.

n. Patients were randomized to receive either Trovan or Ceftriaxone but after the randomization, it was revealed which treatment the patient was to receive, then each patient was given a bracelet and a pink identification card, both of which stated which drug he or she had received.

o. Trovan was administered for the most part in oral form. However, some patients received the drug intravenously.

p. Ceftriaxone was administered intramuscularly as the comparison drug; a small portion of ceftriaxone was also administered intravenously.

q. Prior to the Kano study, Trovan had been tested clinically in more than 5,000 patients in the United States, Europe and elsewhere for a variety of infections. Pre-clinical studies demonstrated that Trovan was effective against several types of bacteria known to cause meningitis.

r. Prior to the Kano study, pharmacokinetic (dosing) studies had also been done in children. These studies demonstrated that the drug behaved similarly in children and adults.

s. Numerous scientific articles published prior to 1996 expressly supported the testing and use of quinolones (the class of drugs that Trovan is part of) in children as "medically indicated and ethically justified," including but not limited to the following:

i. A 1990 article by R. Stahlmann entitled "Safety Profile of Quinolones" concluded that "Today the possibility of using quinolones in pediatric infections has been discussed by several authors (*e.g.* Fontine, 1989). **'A careful prospective evaluation of the efficacy and safety of new quinolones for the treatment of childhood infections (particularly pseudomonal infections)' has been judged as 'both medically indicated and ethically justified' (Adam, 1989).**" (Emphasis added.)

ii. A 1992 article by Chemother entitled "Lack of Quinolone-Induced Arthropathy in Children" reported that "because of obvious advantages of fluoroquinolones **and absence of joint pathology in follow-up studies of children treated with nalidixic acid**, many pediatricians have started to prescribe such anti-bacterial agents for patients

on a compassionate use basis. **By early 1992, published data on fluoroquinolone use in children included over 1000 pre-pubertal patients. These studies reported good to excellent efficacies, and usually mild and always reversible adverse effects**. (Emphasis added; internal citations omitted.)

iii. A 1993 book chapter by DC Hooper et al entitled "Adverse Effects" in Quinolone Antimicrobial Agents, 2nd ed., reviewed the prior studies and reported that the "extent to which arthropathy will pose a limitation to fluoroquinolone therapy in children is unclear."

iv. A 1996 article by DB Bethell et al entitled "Effects on Growth of Single Short Courses of Fluoroquinolones" expressly "**support[s] the use of short course fluoroquinolone treatment in childhood typhoid, especially when caused by strains resistant to other antibiotics.**" The article, which is based on a two-year follow-up study of children who received a single short course of either ofloxacin or ciprofloxacin during a typhoid epidemic in southern Viet Nam in 1993, reports that "**this large study supports the accumulating data from studies in cystic fibrosis that the fluoroquinolone antibiotics are safe in children**." The article also notes that these medications "offer distinct advantages over other antibiotics when used for treatment of Gram negative infections because of their acceptability, rapid oral absorption, good intracellular penetration, and speed of action." (Emphasis added; internal citations omitted.)

v. A 1996 article by Gootz, "Fluoroquinolone Antibacterial: SAR, Mechanism of Action, Resistance, and Clinical Aspects," is still another article concluding that fluoroquinolones "**should be more widely tested in children.**" (Emphasis added.) Thus, the article reports that "**Recent pediatric studies with ciprofloxacin have not provided evidence of [joint cartilage] damage in human joints, suggesting that these agents should be more widely tested in pediatric populations.**" (Emphasis added.)

Period of treatment

t. Patients received 5 days of treatment and were monitored in the hospital or out patients' clinic depending on the status of each patient's heath. Patients were treated with either Trovan or Ceftriaxone for 5 consecutive days.

u. Dr. Isa Dutse performed rounds twice daily in the clinics and was assisted by residents from Bayero Teaching Hospital.

v. The Defendants aver that the conditions of the patients were already serious before the arrival of the Defendants and that Trovan was not responsible for their serious condition. The Defendants aver that despite the serious condition of the patients, the Defendants acted in the best interests of the children involved, using the best medical knowledge available to treat the patients in the Trovan trial that was provided by well-qualified professional doctors.

w. Additionally, the Principal Investigator recruited competent Nigerian doctors and Nurses to assist him in the Trovan investigative study.

x. Defendants provided adequate follow-up. During the study, patients who required care beyond what was available at the Kano IDH were sent to the best medical facilities available in the area at Defendant's expense. At the end of the trial, any child who required additional attention was transferred to a local Kano hospital for continued care. Four weeks after concluding the study -- on May 15, 1996 -- a follow-up exam of study participants was conducted. Of the patients who returned for exam, no unusual side-effects unrelated to meningitis were noted.

29. The Defendants deny paragraph 30 of the Statement of Claim and shall put plaintiff to the strictest proof and further aver that it procured all necessary approval for the investigative study and that the report of the Investigation Committee was void.

Conduct and Practices of the Defendants Had No Adverse Effect on Patients

30. Contrary to paragraphs 20 to 32 of the Statement of Claim, the Defendants aver that the disorders, i.e. deafness, muteness, paralyses, brain damage, loss of sight, slurred speech and deaths are complications or sequelae of the disease of Meningitis and were not caused by the Drugs administered by the Defendants. The Defendants further state (as stated above) that patients were admitted to the study on the basis of their own consent and the consent of their respective parents/guardians. The Defendants will, at the trial, rely on the video of the investigative study and follow-up conducted in the hospital. Defendants will also rely on at the trial medical literature documenting the complications of the disease of meningitis.

31. Contrary to paragraphs 23 and 24 of the Statement of Claim, the Defendants aver that the Drug had been tested on humans, including adults and children, before the investigative study was conducted in Kano.

32. The Defendants deny paragraphs 23 and 24 of the Statement of Claim and repeat paragraphs 14 and 15 above and specifically aver as follows:

i.) The investigative study was done pursuant to approval of relevant government authorities and was not unproven having been the subject of study with over 5000 patients in United States, Europe and elsewhere.

ii.) The purpose of the study was to prepare the drug for registration if study result was positive and as such it need not be registered having received approval for study purpose.

iii.) Dr. Idris Mohammed is not an approving authority for investigative studies in Nigeria and had no authority to approve such a study. Consequently, his action in interfering with the study duly approved by NAFDAC by way of suspension of the study was *ultra vires* of his powers, if he had any, and in any event was overruled by the Kano State Ministry of Health who were very much interested in the potential benefit of the study in preventing similar epidemic in the state in future.

iv.) The Defendants deny that Dr. Idris Mohammed had any statutory authority to act with respect to the 1996 Trovan trials in Kano.

v.) The Protocol approved by relevant authorities for the study anticipated the risks associated with the study and stated detailed procedure to manage those risks, which the Defendants endeavoured to comply with within the limitation of the circumstances as narrated above.

vi.) Notwithstanding his lack of authority, Dr. Idris Mohammed was provided a copy of the test Protocol at the start of the study and he orally approved it after studying it and gave his go ahead for the study.

33. Further, contrary to paragraph 24 of the Statement of Claim, the Defendants state that the patients in the study were not exposed to any unusual risks associated with the Drug, and the Defendants observed the standard medical procedures and obtained necessary approvals before conducting the investigative study. The Defendants state further that the actions of Dr. Idris Mohammed, which led to the abrupt suspension at one stage of the investigative study was done in bad faith and was condemned by the relevant authorities subsequently. A copy of the letter from the Minister, Ministry of Health condemning Dr. Idris Mohammed will be relied upon at the trial and the Plaintiff is put on notice to produce the original at Trial.

34. Further, contrary to paragraph 24, the Defendants did not unlawfully disregard the suspension order of Prof. Idris Mohammed. The Defendants continued the treatment after the Kano State Government gave authorization for Defendants to continue treatment.

35. The Defendants also deny paragraph 24 of the statement of claim and state that Dr. Juan Walterspiel did not travel to Nigeria to participate in the Trovan investigative study and thus had no personal knowledge of the clinical investigative trial. The Defendants further aver that the alleged statements by Walterspiel are untrue. In fact, Dr. Walterspiel co-authored an article supporting the use of quinolones in children entitled “Quinolone

Arthropathy in Animals Versus Children," published in volume 25 of Clinical Infectious Diseases (1997). It states: "**Prospective controlled studies in children are justifiable in view of a continuing lack of correlation between findings in juvenile animals and those in children and because of the selected therapeutic advantages of the current and newer quinolones.**" (Emphasis added.)

36. The Defendants further aver that Dr. Walterspiel discontinued working for Pfizer for reasons unrelated to the Trovan investigative study itself.

The Defendants Did Not Contravene Customary International law or Any Law

37. The Defendants deny paragraphs 26-29 of the Statement of Claim and put the plaintiff to the strictest proof of the averments therein.

38. The Defendants further to the last preceding paragraph aver that international customary law and conventions are only enforceable in Nigeria so far as they have been domesticated under section 12 of the 1999 Constitution. In so far as the conventions, treaties, declarations, codes and international customary law have not been passed into law by the National Assembly they are unenforceable and inapplicable to this case. With respect to the NAFDAC guidelines for Clinical Trial 1996, the Defendants aver that the guidelines were not gazetted and did not have the required force of law and that in any event that the Protocol approved for the study was in accordance with the guideline and its implementation met the obligations imposed therein. As for compliance with local laws, we repeat that the Plaintiff is estopped from denying compliance with all local laws in view of the representations of its relevant agencies approving the study.

39. The Defendants will contend that contrary to paragraphs 25 to 31 of the Statement of Claim, the Defendants state that they did not contravene any law in conducting the investigative study of the Trovan Drug, and state further as follows:

i.) That the approvals of the relevant government agencies were obtained before the investigative study of Trovan began.

ii.) That the oral consent of the patients and their parents and/or guardians were obtained before they were allowed to participate in the trial.

iii.) That Hausa nurses recruited to assist the Defendants explained the entire process for conducting the trial to the participants in Hausa.

iv.) Before conducting the trial, the participants were informed of the alternative treatment being provided by MSF and they were allowed to decide between the two.

v.) The drug was in late stage development and had been tested in clinical studies on more than 5,000 patients prior to the study. Pharmacokinetic (dosing) studies had been conducted in both

adults and children and showed that the drug behaved similarly in adults as it did in children before the Kano trial was conducted.

vi.) That the trial was conducted in the open as parents were allowed to remain with and see their children when going through the treatment.

vii.) The protocol used for the trial was appropriate, comprehensive, and acceptable.

viii.) Likewise, the study was carried out in a way that was appropriate, comprehensive and acceptable. The Defendants always acted in the best interest of the children involved, using the best medical knowledge available that was provided by well-trained medical professionals.

ix.) Additionally, the Principal Investigator recruited competent Nigerian doctors and Nurses to assist him in the Trovan investigative study.

x.) The Defendants continued with the trial because in spite of Prof. Mohammed's alleged stop order, the Kano State Government gave their go ahead for the trial to be continued as Professor Mohammed's objection was based on unfounded accusations.

xi.) Additional outside physicians also visited the IDH while the trial was ongoing and indicated their verbal approval of the study, including a representative from the World Health Organization and a representative from the U.S. Centers for Disease Control.

xii.) After the trial Idris Mohammed sent another letter in 1997 complaining about the trial to the Minister of Health and the 5th Defendant responded. After reviewing both the complaint and the response, the Minister held that there was nothing wrong with the study.

xiii.) Defendants conducted adequate follow-up treatment on the patients. During the clinical study, patients who required care beyond what was available at Kano's IDH were sent to the best medical facilities available in Nigeria at the Defendants' expense. At the end of the trial, any child who required additional attention was transferred to a local Kano hospital for continued care. Four weeks after concluding the study - on May 15, 1996 – Pfizer team returned to Kano for follow-up exam of study participants. Of the patients who returned for the exam, no unusual side-effects unrelated to meningitis were noted.

xiv.) Defendants did not destroy any medical records. All the patients were registered with the IDH and the records showing the sex, age, diagnosis, date of admission, date of discharge or death as well as other records were left with the hospital.

The Defendants Did Not Fraudulently Procure Ethical Committee Clearance to Conduct the Investigative Study

40. Further to paragraph 39 above and in response to paragraph 30 of the Statement of Claim the Defendants aver that the true position is as follows :

i.) There was no regulation or law in Nigeria requiring ethical committee approval before conducting clinical trial or investigative study and therefore there was no need to obtain what the law did not require.

ii.) There was no formal ethics committee sitting at either Kano Infectious Disease Hospital or at nearby Bayero Teaching Hospital.

iii.) The Defendants contend that there is no law in Nigeria at the relevant time, which was contravened by failing to obtain a formal ethics board approval not required by law.

iv.) Importantly, there were numerous other forms of approval by local physicians and government officials authorizing the study to go forward, including but not limited to the head of the IDH Hospital as well as Idris Mohammed.

v.) Patient care was not compromised in any way.

The Defendants Did Not Conduct An Illegal Trial

The Defendants deny paragraph 31 of the Statement of Claim and state further that the investigative study was not illegal at all. The Defendants did not obliterate any evidence. All the patients were registered with the IDH and the records showing the sex, age, diagnosis, date of admission, date of discharge or death as well as other records were left with the hospital.

The Defendants deny paragraphs 15 and 32 of the Statement of Claim and further aver that it is not correct that parents /guardians of patients and government officials did not have access to the patients. Neither is it true that Kano State Government medical personnel experienced any difficulty providing medical assistance to the patients during and after the trial as during the trial the Pfizer team attended to their medical needs and after the trial did post trial examination and the patients did not require further attention from the state.

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41. The Defendants further deny paragraph 32 of the Statement of Claim and aver further that the Defendants acted in the best interest of the children involved, using the best medical knowledge available. Trovan's survival rate of 94.4% was at least as good as the best treatment available at Infectious Disease Hospital in Kano. For patients who did not participate in the Trovan investigative study, the survival rate was slightly less than 90%.

42 The Defendants further deny paragraph 32 of the Statement of Claim and vehemently deny that it was Trovan that caused any of or a combination of deafness, muteness, paralysis, brain damage, loss of sight, and slurred speech by any of the patients. The Defendants put the plaintiff to the strictest proof of this claim.

43. Further to paragraph 42 above, the Defendants aver that Trovan and Ceftriaxone performed better than the alternative treatment available at the IDH.

44. With particular reference to paragraphs 23, 30 and 33 of the Statement of Claim, the Defendants aver that the report of the Federal Ministry of Health was unconstitutional, null, void and of no effect in so far as it purports to indict the Defendants without affording them opportunity to be heard as provided under the 1999 Constitution and in breach of their constitutional right to fair hearing upon the following grounds:

PARTICULARS

(i.) The Chairman of the Committee is one Dr. Nasidi. See pages 2 and 95 of the record.

(ii.) The Chairman of the Committee Dr. Nasidi had expressed opposition to the trial in 1996 prior to his appointment into the Committee in 2001.

(iii.) The Chairman of the investigation committee has strong bias against the Defendants because of his closeness to Prof. Idris Mohammed who developed aversion to the investigative study midway when his request was not met.

(iv.) The Committee was set up at a time when both the Federal Ministry of Health and the Pfizer were parties to an action by alleged victims as defendants with intention of exculpating the Ministry from liability.

(v.) No allegation was made against the Defendants and Defendants were not given the opportunity to present their case or cross-examine the witnesses before the Committee.

(vi.) Although the committee was set up for fact finding and investigations, The Committee proceeded to make findings proposing sanctions against the Defendants in breach of the provisions of the 1999 Constitution.

(vii.) The committee preferred mere oral testimony of its chairman and few others to documentary and scientifically proved testimonies of the Defendants.

(viii.) As Chairman of the Committee, and contrary to common sense, logic and law, he gave copious evidence thereby constituting himself a judge in his own cause and recorded his own evidence at Pages 69-72 of the record.

(ix.) The Defendants protested vehemently against the appointment of Dr. Nasidi as the Chairman of the Committee because of his known opposition to the trial. The objection was overruled. See page 59 of the report.

(x.) The conclusions of the committee were based primarily and almost verbatim on the evidence of the said Dr. Nasidi, the Chairman.

(xi.) There was evidence of Nasidi's closeness to Prof. Idris Mohammed who initially agreed to the trial but changed when the Defendants disagreed to give him the equipment used for the trial for use in his private hospital.

(xii.) In making the so-called recommendations, Dr. Nasidi's committee ignored all the evidence that favoured the Defendants such as Appendix V (the authority given by NAFDAC)

(xiii.) The team leader of Pfizer (Mr. Tade) also expressed fears that the Washington Post would get a copy of committee's report before it is released. His fears were eventually confirmed as the Washington Post got and published selected portions of the report.

(xiv.) As a matter of fact up until June 2007, Defendants were not provided a copy of the report until the Defendants applied to court in Suit No FHC/ABJ/CS/309/2007 to order the plaintiff therein (Attorney General of the Federation) to release the report to Defendants'counsel. Therefore, but for the order of the court, the plaintiff was not prepared to give the Defendants or their counsel a copy.

(xv.) The report of the Committee was never presented to or accepted by the government through a white paper.

(xvi.) No proper investigation by a duly authorized investigation authority in Nigeria has been conducted.

PARTICULARS OF FAVOURABLE EVIDENCE NOT CONSIDERED

(i.) Defendants aver that the following points below illustrate favourable evidence and facts that were summarily dismissed by the Government Committee, although Defendants make no representation as to the accuracy of each statement.

(ii.) Page 21 (Paragraph 8) reads:- ***"When Prof. Idris Mohammed was given the protocol, he commended it as being well written and asked them to go-ahead with the trial."***

(iii.) The Kano State Ministry of Health gave written permission to Pfizer Staff in Kano State Government hospitals response to request by Pfizer – See Page 21 (xxii)

(iv.) The trial of Trovan saved many lives as the case fatality in the epidemic proportion of 30% came down to 6% in the group treated with Trovan. Page 22(xxiii)

(v.) Unlike Nigeria, Ghana and South Africa had benefited from Pfizer development programme and therefore Pfizer wanted Nigeria to benefit also and did all that was necessary.....(Page 21 iv)

(vi.) That response to Trovan treatment was promising and results were remarkable. (Page 23 xxiii)

(vii.) That the staff of Kano State Ministry of Health participated in the drug management including Dr. Shehu Yusuf and one Badulkadir of Kano State Ministry of Health in response to application by Pfizer. (Page 30)

(viii.) That there were 21,739 cases of meningitis and about 1000 deaths and in the IDH there were 6,133 cases and a mortality of 247.

(ix.) That the situation overwhelmed the State Government making it necessary to seek assistance from federal government and international agencies. (Page 30)

(x.) That there was a request by Pfizer to Kano State government to participate in the treatment of patients.

(xi.) That the Kano State Ministry of Health set up a committee led by Dr. Kura to look into the petition.

(xii.) That the Committee found evidence that the trial did take place and that the Federal Ministry of Health and NAFDAC approved it. (Page 31 (xiv)

(xiii.) It is noteworthy that the evidence of the witness (Dr. Sanni) contradicts that of Alhaji Aliu Mukthar who is the CMD at page 29 in all material particulars.

(xiv.) That when the epidemic escalated the MSF, Pfizer and Niger Republic and other NGOs came to assist. (Page 33 (v).

(xv.) That the Task Force supervised all those that contributed to the control activities (Page 34(x)

(xvi.) That Pfizer's donation to the State Government was very helpful during the epidemic.

(xvii.) That NAFDAC legally granted Pfizer the authority to import the drug Trovan into the country. (Page 43 (vii)

(xviii.) That approval was given by NAFDAC for clinical trial and that clinical trial and investigational use mean the same thing. (Page 43)

(xix.) That informed consent would be provided for minors by relatives and family and that Pfizer obtained informed consent. (Page 43)

(xx.) It is noteworthy that this evidence is totally at variance with the evidence of Sule at page 39 who said that there was no application by Pfizer.

(xxi.) This evidence was corroborated by E.U. Usoro at P.48 and he was the person who actually wrote the letter authorizing importation of the drugs for investigational purposes upon being satisfied that the documents supplied by Pfizer were in order.

45 It is not true that the test caused the medical conditions of deafness, muteness, paralysis, brain damage, loss of sight, slurred speech on the patients. These are common side effects of the disease of epidemic meningitis. The Defendants will rely on the medical literature demonstrating the above.

46. Contrary to paragraph 34 of the Statement of Claim, the Defendants repeat paragraphs 14, 15 and 16 above and in addition aver that the sample size of 200 was deliberate standard clinical research practice intended to control the study as set out in the approved protocol for the study.

47. The Defendants deny paragraphs 35, 36, and 37 of the Statement of Claim and shall put the Plaintiff to the strictest proof and aver that neither the Plaintiff nor the Kano State government he claims to represent provided any medical assistance to the patients who participated in the investigative study. In particular the majority of the patients were completely healed during the period of the study. At the follow up visit in May 1996 of those patients who returned for follow-up, the majority were recovering very well from the symptoms of the disease. It is repeated that no injury outside the normal ravages of the epidemic was caused by the Defendants or at all and the medical conditions listed as suffered by the patients are indeed symptoms of post meningitis prognosis and not side effects of treatment with Trovan.

48. Contrary to paragraph 34 of the Statement of Claim, the Defendants state that it is not true that the investigative study was illegal and that it was motivated solely and exclusively by desire for profit. The Defendants' long-term goal was to bring a life-saving and innovative form of antibiotic that could be used effectively in pediatric meningitis epidemic in developing countries.

49. The Defendants hoped that the drug would provide a more effective treatment for meningitis over currently available treatments. The effectiveness of the drug was born out by the fact that it recorded a lower mortality rate than other alternative treatments available at the IDH.

50. The Defendants further deny paragraph 34 of the Statement of Claim and aver that at all times material to this suit, the Defendants had no undue interest in pursuit of financial benefit over and above advancement of

science, providing affordable treatment and health care delivery and other ethical corporate values. In particular, they state that Pfizer had been committed to addressing solutions for diseases prevalent basically in Africa and other less developed countries with a very low GDP. There was no motivation for financial benefit in pediatric use in meningitis in Africa as distinct from adult use for various purposes in the United States.

51. The Defendants further aver that the Defendants' intervention is not limited to the treatment of 200 patients as it provided other medicines, materials and equipments to the government to assist them in the treatment of the other patients who did not participate in the trial. The Defendants will rely on letters to and from the Kano State government documenting the medicines, materials and equipments donated to the Infectious Disease Hospital and the Kano State government.

The Plaintiff Did Not Incur Any Cost on Patients

52. Contrary to paragraphs 35 to 40 of the Statement of Claim, the Plaintiffs did not spend any money on the patients who participated in the trial.

53. Specifically, defendants deny paragraphs 35 and 36 of the Statement of Claim and shall put the Plaintiff to the strictest proof and further aver that Kano State government did not spend the sum of $25m (twenty five million dollars) or $350m (three hundred and fifty million dollars) or any sum whatsoever to provide support to the alleged victims of the study as there were no such victims in existence who suffered any injury other than those associated with the disease itself and definitely not as a result of the actions of the Defendants drug Trovan. Further if any such sum was spent, which is denied, it is averred that it is too remote from the conduct of the study to flow naturally from it.

54. The Defendants further put the plaintiffs to the strictest proof to provide documentation of the medical records documenting the health of the participants in the study, as well as record of the money expended by the Plaintiff in treating the participants in the Trovan investigative study. The Defendants further put the Plaintiff in strictest proof of all appropriations made by the House of Assembly in respect of the alleged expenditure mentioned in paragraph 35 and 36 of the Statement of Claim.

55. The Defendants aver that the Plaintiff had no cause to continue to spend money on those children who unfortunately died of the disease and were buried the same day sometime in 1996, nor did they have cause to spend money on those who recovered from meningitis as a result of the effective treatment provided.

56. The Defendants deny paragraphs 37, 38, 39 and 40 of the Statement of Claim and shall put the Plaintiff to the strictest proof. In particular the Defendants aver that the provision of primary health care is the constitutional duty of the local government. Further, there are other factors responsible for challenges in delivery of health care to rural dwellers and these include corruption, illiteracy, ignorance, lack of infrastructure, etc. The Defendants specifically deny that apathy to vaccinations is as a result of the Trovan trial and state that the alleged apathy towards vaccinations and other medical interventions cannot be connected with the study in question.

57. The Defendants aver further that if the plaintiff had any cause to spend any money at all on any patient, it was not one of the patients treated by the defendant. The Defendants put Plaintiff to the strictest proof to provide records that any expenditure is linked to the conduct of Defendants.

58. Contrary to paragraphs 37, 38, 39 and 40 of the Statement of Claim, the Defendants deny that Plaintiff has expended and continues to expend huge sums of money in excess of $200m (two hundred and fifty million dollars) on public enlightenment. The Defendants put Plaintiff to the strictest proof to provide records that any expenditure are linked to the conduct of Defendants. Further the Kano State government has constitutional responsibility in delivering secondary health care to the citizens including public enlightenment.

59. The Defendants will before or at the trial of this suit, contend that the action is statute barred and that the court has no jurisdiction to entertain the matter on the following grounds:

i.) The 1st Defendant was improperly named and joined.

ii.) The 2nd Defendant was improperly named and joined.

iii.) The alleged Trovan treatment, the subject matter of this suit took place in April 1996 **(about 11years ago).**

iv.) The damage suffered if any occurred in April 1996 and the legal cause of action was complete in April, 1996.

v.) The claims are based on legal consequences and not legal causes of action.

vi.) The writ not having been issued until more than 3 (three) years after 1996 the action is statute barred.

vii.) Additionally, in 1996, during the Trovan study, Idris Mohammed raised objections to the study and informed the Kano State Minister of Health, who allowed the study to continue. Accordingly, the writ not having been issued until more than 3 (three) years after 1996, the action is statute barred.

viii.) Idris Mohammed again raised these objections again in 1997 with the Federal Ministry of Health. Accordingly, the writ not having been issued until more than 3 (three) years after 1997, the action is statute barred.

ix.) The *Washington Post* published an article in December 2000 stating alleged wrongdoing on the part of Pfizer in conducting the Trovan investigative study. These allegations were also published in numerous articles in Nigerian newspapers. Accordingly, the writ not having been issued until more than 3 (three) years after December 2000, the action is statute barred.

x.) In January 2001, the Federal government instituted a committee to investigate the allegations brought against Pfizer.

xi.) The report relied upon by the Plaintiff dated March 2001 also did not revive the action which is statute barred the writ having not been issued within 3 (three) years of the accrual of the cause of action.

xii.) By the Limitation Laws of Kano State, this action is statute barred the writ having been issued outside the 3 (three) year limitation period.

xiii.) Even if the legal cause of action continued after 1996 (which is denied), the Plaintiff's cause of action is statute barred by reason of the Committee Report of March, 2001.

xiv.) Moreover, the Federal Government was party to a suit initiated in March 2001 in Federal High Court by private plaintiffs involving substantially similar allegations to those alleged here. Accordingly, the writ not having been issued until more than 3 (three) years after April 2001, the action is statute barred.

xv.) The Defendants contend that the Honorable Court lacks jurisdiction to entertain this suit as the Plaintiff has not disclosed any reasonable cause of action against the Defendants.

60. The Defendants shall contend that the instant suit is incompetent having been commenced without requisite compliance with the provisions of the relevant statutes and rules of court governing service of processes of this Honourable Court consequently denying the court of personal jurisdiction over the defendants herein.

61. The Defendants contend that the Honourable Court lacks jurisdiction to entertain this suit as the Plaintiff lacks locus standi to institute this action by virtue of the provisions of section 6 subsection 6 of the 1999 Constitution.

62. The Defendants shall contend that as concerns that 3rd to 9th Defendants herein the suit against them lacks merit as they were agents of a disclosed principal.

63. The Defendants shall contend that the Plaintiff's claim is an abuse of the processes of this Honourable Court same being based on rights and alleged damages suffered by individual citizens of Kano State and not the Kano State government itself and shall urge the Honourable Court to dismiss same with substantial cost.

64. The Defendants shall contend that the doctrine of estoppel is applicable by virtue of the provisions of the Evidence Act to prevent the Plaintiff from denying that it duly authorized and approved the Trovan trials in Kano in 1996 or that necessary Federal Government approvals were obtained.

WHEREFORE the Defendants contend that this action is unmeritorious, frivolous, vexatious, embarrassing and constitutes a gross abuse of the process of the court and should therefore be dismissed in its entirety.

Dated this..... ..... day of July, 2007.

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FOR SERVICE ON:

1. **THE PLAINTIFF**
   ATTORNEY GENERAL KANO STATE
   MINISTRY OF JUSTICE
   AUDU BAKO SECRETARIAT
   KANO

2. **THE 3RD, 6TH – 9TH DEFENDANTS**
   C/O THEIR SOLICITOR
   MOHAMMED B. ADOKE SAN
   FIDELITY BANK BUILDING 2ND FLOOR
   56 IBRAHIM TAIWO ROAD
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3. **4TH AND 5TH DEFENDANTS**
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   10 ATBARA STREET OFF CAIRO STREET
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