UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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RABI ABDULLAHI, *individually and as the natural guardian and personal representative of the estate of Lubabatau Abdullahi*, et al.,

Plaintiffs,

-against-

PFIZER, INC.,

Defendant.

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01 Civ. 8118 (WHP)

ORDER

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AJUDU ISMAILA ADAMU, *individually and as the natural guardian and personal representative of the estate of Yahaya Ismaica*, et al.,

Plaintiffs,

-against-

PFIZER, INC.,

Defendant.

----------X

04 Civ. 1351 (WHP)

WILLIAM H. PAULEY III, District Judge:

The parties are hereby notified that this Court received the attached

correspondence dated January 28, 2011.

Dated: February 3, 2011
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.

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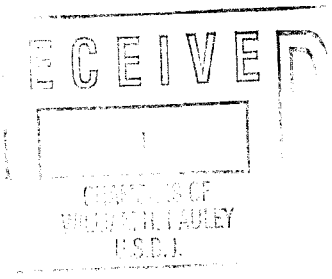
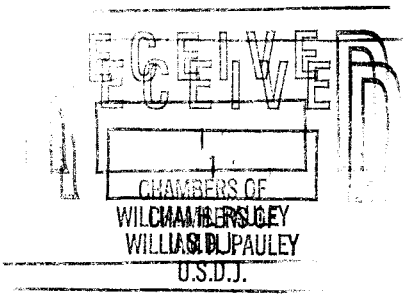


01-28-2011

Judge
William H. Pauley III USDJ
US District Court Southern D NY
500 Pearl Street
New York NY 10007-1312



Re: Amicus curiae for Nigerian Children Plaintiff(s) Including RABI ABDULLAHI, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi, et al. Plaintiffs, against PFIZER, INC., 01 Civ. 8118 (WHP)

Dear Judge Pauley,

While I was taking care of my mother in Germany, Wikileaks broke the news that Pfizer black/back/blackmailed the Nigerians or something to the effect of influencing foreign officials again, and also boldly claimed that their "humanitarian" drug was also used by Physicians Without Borders (MSF) on site.

MSF which is usually apolitical shot back, loud and clear, and the shot was at least heard in Europe.

I assume, that encouraged by this Wikiinformation the German newspaper Sueddeutsche Zeitung – Munich Germany, (and maybe others ?) anonymously received attached document that I had send under Pfizer confidentiality to the CEO, board members and Nigerian Pfizer employees under distress in 2007.

The Sueddeutsche Zeitung law department contacted me immediately (the Walterspiel family is well known in Munich) and asked me for written confirmation that this was my document, which I did (Eidesstattliche Erklaerung)

On Xmas, my relatives informed me that Katja Riedel had published attached article " When Children Die ". I apologize for the German only, but it quotes accurately new information to the public now, from my letter to Pfizer in 2007.

May truth and justice eventually prevail !

But .. this will go on for ever if the ones responsible (and paid for with OUR health care money) can not be touched personally and can continue to be covered by money (peanuts for them and minor cost of doing business) and then "pay without fault, just to diminish the cost of further litigation.

- negligent manslaughter – bribing of foreign officials – falsified docs to the FDA – " humanitarian action to save lives" – fool the FDA everytime you can ... we should be so proud of our largest American pharmaceutical company and support that kind of business skill.

Sincerely,

Juan N. Walterspiel MD, FAAP

Dr.med. Juan N Walterspiel
Hilda Str.57
D 79102 Freiburg
Germany

Aug.06.07
1of 9 pages

Jeffrey B Kindler Esq.
CEO Pfizer
235 East 42nd Street
New York, NY 10017

Documentation of the Trovafloxacin study in Kano, Nigeria 1996 and its implications.

By registered mail with separate copies on 08-06-07and 08-08-07

A discoverable document to be sent by Pfizer in full length (8 pages) and /or by (0) or (0')s counsel to plaintiff attorneys in CT, NY and Nigeria

In time also in similar or abbreviated form to:

- board members of Pfizer
- scholars and historians
- regulatory authorities
- members of congress
- investigators and research facilities
- managers and employees of pharmaceutical companies
- colleagues and ex co-workers

Written after New York and Connecticut courts determined to be unable to attend to African children and the ramifications for clinical research and regulatory oversight in their own country.

The statements herein may not be protected by employee confidentiality and describe facts and circumstances which may have led to criminally negligent homicide. It is written to prevent similar occurrences in the future.

Names are encoded as consecutive numbers. The code is available from the author.

Introduction:

Pfizer issued the following statement in response to legal action taken against the company by the Nigerian government:

" Pfizer continues to emphasize—in the strongest terms—that the 1996 Trovan clinical study was conducted in a responsible and ethical way consistent with the company's abiding commitment to patient safety. Any allegations in these lawsuits to the contrary are simply untrue—they weren't valid when they were first raised years ago and they're not valid today. It is indeed regrettable that, more than a decade after the meningitis epidemic in Kano, the Nigerian government has taken legal action against Pfizer and others for an effort that provided significant benefit to some of Nigeria's youngest citizens " (www.Pfizer.com accessed 08.06.07)

- **The experiments were performed without consent.**

An experimental oral formulation of trovafloxacin was administered to children as the sole treatment for life threatening meningococcal infection. Pfizer physicians administered the experimental drug without prior data on its gastro-intestinal absorption in pediatric patrients and not knowing whether it would reach sufficient blood and cerebrospinal fluid (CSF) concentrations in children after oral administration.

An oral absorption study with this formulation in children was conducted by (1) only after the study in Kano. The phase I/II, n = 20, study protocol was reviewed for scientific integrity and approved by the Institutional Review Board of a Children's Medical Center in the United States (2) and performed by the US trained investigator (3). The study showed unexpected low absorption rates resulting in low blood and cerebrospinal fluid (CSF) concentrations.

This alarming finding prompted sending the study formulation administered in Kano back and forth between Groton CT and the test site under various travel and temperature conditions. Trovafloxaxin was found to have crystallized into a hitherto unknown form. Absorption studies were repeated in adults revealing that Trovafloxacin was absorbed equally well from either crystal form, and that poor absorption was limited to children.

The study did not need to be registered (phase I) and the investigator (3), was asked by Pfizer to neither present nor publish his findings.

No parent, whether informed in oral or written form, in any culture or language in the world would ever allow for her/his child to be a test "subject" for oral absorption of the only medication given for her/his child's life threatening infection.

No regulatory authority, ethics committee or responsible physician would either.

" Informed " parental consent, regulatory and ethics committee approval was therefore never given.

• Regulatory and legal aspects – including those in the US

The approval for exportation of an experimental drug by the FDA and request for importation by Nigerian authorities was arranged for by (4) and Pfizer Nigeria. The needed request for an experimental emergency medication came back from Nigeria immediately and (5) heard (6) say to(7): "This will haut us. Nigerian authorities could not have read the Trovafloxacin CMC in such a short time and I have concerns to add the oral formulation".

Upon reading about the study in the Washington Post ("The body hunters") San Mateo, CA senator T. Lantos (D) proposed a tracking law, still pending.

While the team was in Kano, (8) and (9), with (8) having refused to participate in the study, received a teleconference phone call from (10) reporting that Nigerian officials had shut down the study, needed to be paid off and that the team was under the threat of arrest. A currier with cash was dispatched by intervention of (9) via KLM through Amsterdam. The study resumed about three days later. The law firm of Millberg Weiss (then presented by attorney Elaine Kusel) is in possession of an affidavit by (8) in respect to this witnessed phone call concerning US federal subject matter bribing of foreign officials.

The study report was submitted to the FDA and prompted an unexpected FDA inspection in Groton lead by FDA agent (11). It led to a series of

frantic preparations. (12) either by accident or not, placed a fax from (13) to (14) on (15')s desk. The fax implored (14) to urgently send him an ethics committee approval from Kano. A falsified document was then presented to FDA inspector (11). (15), concerned about the imminent FDA inspection and Pfizer instructions to be truthful with answers to the FDA as well as to observe any orders and objections from a Pfizer representative who would be present, consulted a labor law attorney in CT. He was afraid to be forced to lie or be dismissed by Pfizer. He was advised to store a copy of the document. Pfizer did not provide (15)'s name, labeling her/him as "not involved" to the inspector now, and in later lawsuits. (15) was not questioned but then personally debriefed by (16) saying, that the inspection found only minor infractions and was benign.

During the development of Trovafloxacin, (17) was asked by (18) to review and help with a protocol for peri-operative prophylaxis with oral Trovafloxacin. (17) voiced concerns that Trovafloxacin may not be fully absorbed in the presence of antacid preparations which are routinely given to patients prior to surgery, and that an absorption study in the presence of antacids was needed. (18) reported to (19) and was told that the concern was unfounded, would only cause delays, and if valid, (19) would happily risk for this to be picked up by the FDA or an ethics committee but that these would trust a large company as Pfizer to do things right. Speed was of essence and stock options and bonuses at stake. The study was performed without objection from the FDA or the respective ethics committee(s) or investigators. (20) was one among other sites in the US where the study was run. The study failed and several patients developed severe post-operative infections and one women had her uterus removed. Pfizer dispatched risk managers to (20) and asked affected patients and relatives to fill out checks for whatever amount they felt right against their signature to keep the payments confidential.

A statement in the package insert for oral Trovan not to be given with Bicitra testifies to the episode.

At the beginning of the development, the FDA had asked for an effective surveillance plan for detection of the " Temafloxacin Syndrome ".
The Temafloxacin and Trovafloxacin molecules have similarities and Temafloxacin was taken off the market for causing deaths due to hemolysis, (red cell breakdown) kidney and liver failure in 1992. (21) returned from the FDA and announced that he/she had agreed with the FDA upon an

inexpensive and fast solution. Only one test for hemolysis was required and that it was to be a haptoglobin determination. During a meeting (present at least 21,22,23,24,25,26), (26) remarked that haptoglobin is an acute phase reactant that increases with infection, and that in the presence of infection (for which Trovafloxacin was administered), the test results would be "normal". (21) challenged (26) on this. (26) prepared an e-mail with proper documentation. (27) accused (26) of being an irresponsible non-team-player. (26) remembers hearing "can you imagine what would happen if the FDA sees this e-mail". (23) and (18) requested transfer into another group. (26) stored the e-mail.

After approval, when Pfizer spent 1,2 billion dollars to promote the drug, (27) was cited to appear in front of the FDA within 24 hours to explain why the FDA had not been informed that Alatrofloxacin (the IV form) precipitated in normal saline. The phenomenon was well known and (28) had even conducted in vitro experiments in artificial CSF and methotrexate provided from the pharmacy of hospital (29), to rule out precipitation in cerebro-spinal fluid during tests in children.

After (30) ´s travel to Kano, the FDA initiated a criminal investigation into Pfizer regarding issues Trovafloxacin. The investigation was lead by officer (31). Several months into the investigation (32) was informed by (31) that the investigation was halted and that (32) would not be able to understand the complex ways by which the government decides upon such issues.

It would now be reasonable for the FDA or congress to re-open this investigation, as more corroborative evidence emerges from Nigeria and the harm from the peri-operative study and the assumed ignorance on the haptoglobin test justifies the agency's urgent need for independence and personnel to protect research "subjects" and the US public.

- **Ethics, corporate and physician integrity**

- It violated ethical standards to conduct an experiment with an oral formulation in a lethal infection in children without knowing its gastro-intestinal absorption and even less so under the conditions of sepsis and meningitis.

(33) visited Egypt prior to the study and met (34) at an US government/Egyptian military/medical institution to examine the possibility to administer oral Trovafloxacin to malnourished and bacteremic children with meningococcal meningitis. These children would also be treated with IV ceftriaxone and the gastro-intestinal absorption and CSF penetration of Trovafloxacin determined under realistic conditions.

The determination of an appropriate dose for children followed by a professional study would have had the potential to treat thousands of children in the sub-Sahara. Pfizer's premature endeavor caused lasting global mistrust and has prevented medical interventions to be given such as the polio vaccine in northern Nigeria which hampered its worldwide eradication and discouraged further study of other potential antimicrobials such as Gatifloxacin. PATH will hopefully not be hindered to test and deploy its vaccine in northern Nigeria.

- It violated ethical standards to give trovafloxacin to children with joint manifestation from meningococcal infection (about 40 % of the Kano patients at that stage of the epidemic), as quinolones (the class of antibiotic that Trovafloxacin belongs to) are known to cause permanent articular cartilage damage in juvenile animals. An arthritis / immunreaction + Trovafloxacin study in animals should have preceded the Nigeria study. The circumstances deliberately chosen during the epidemic in Kano did not allow for long term follow up or diagnostic procedures such as x-ray, magnetic resonance and accurate hearing studies. These were demanded by other countries in a later IV administration-only meningitis study where patients with existing joint manifestations were excluded from enrollment. According to the study report there was a statistically significant increase in joint manifestations in the Trovafloxacin arm, as calculated from public data by (35).

- It violated ethical standards to test a new drug almost simultaneously in a large number of "subjects". This precludes halting a study after the first indication of severe adverse events and limiting damage to others.

- It violated ethical standards to conduct a study under circumstances which did not allow for adequate laboratory support to detect toxicity in a timely fashion. Trovan was later removed from the European market and restricted in the US because it causes lethal idiosyncratic liver reactions.

- It violated ethical standards for Pfizer physicians to assume the incompatible simultaneous role of physician to their "subjects" and the stance of impartial investigators, as noted in the Belmont report.

Patient safety and study outcome were open to influence and incentives such as stock options, bonuses, career advancement and the group dynamics of a small number of people finding themselves wrong and under severe stress in a hostile and unfamiliar environment. (36) reported, that a machine gun was emptied over their heads.

- It violated ethical standards for the Pfizer physicians to abandon their patient(s) and not change the experimental treatment in this open label study when patients did not do well. According to study report, "Subject" 0069 was simply left to die and continued on oral Trovafloxacin when she developed hemiparesis. The replica of the slave ship Amistad, build in Mystic, in the vicinity of the Groton facility, and based in New Haven CT, now carries plaques in her memory.

- It violated professional and legal standards for the Pfizer physicians to practice medicine without license in a foreign country with limited experience in treating and evaluating pediatric patients with meningitis. It was noticed that the Glasgow coma score in the case report form was in inverse order, that they were unskilled in placing IV lines, and after the first two patients, resorted to open label oral Trovafloxacin and painful IM Ceftriaxone administration. Only two of the three Pfizer physicians seemed to have held a US state license and practiced a few days a month at a respiratory clinic at a medical school. The dean of that medical school (37) asked faculty member (38) about the full circumstances of the study in Nigeria and what he could have avoided. He was briefed in writing with copy to (39) but had a conflict of interest after previous high level contacts with Pfizer and responsibilities for the product.

- It was unethical and violated scientific standards for Pfizer physicians to openly select and assign the patients to the treatment arms themselves. The FDA inspection report obtained through (40)states, that there was lack of adequate documentation for some patients to have had meningitis. After the interruption of the study by the Nigerians, patients with more favorable symptoms were enrolled into the Trovafloxacin arm compared to the ceftriaxone arm. The change in enrollment is evident from the data in the study report.

- It violated ethical and scientific standards for the Pfizer physicians to alter the protocol without prior outside review and approval during the course of the study. Any such changes i.e. who would receive oral or IV and the reduction from the original IM dose of ceftriaxone due to pain and limping, had a direct impact on patient safety and the validity of the study results. Significant changes in clinical study protocols have to undergo prior written approval by a full quorum ethics committee and notification of regulatory authorities.

- It compromised the reliability of the study results for Pfizer physicians and employees to not only select the patients themselves, but also performed diagnostic laboratory evaluations, as well as treated patients, and observed and recorded the findings. This must be done independently from a vested sponsor and entries into the patient chart are later compared with those made by the investigator(s) in the case report form for accuracy and completeness by a process called "source documentation and verification".

The veracity of the study results, i.e how many died, how many had meningitis or bad or good outcomes, as well as the identities of most of the patients is now in question. Investigative teams must now use the souvenir pictures taken by the Pfizer team, that were presented to a private audience of opinion-leaders in New Orleans, LA and an audience of employees in Groton CT.

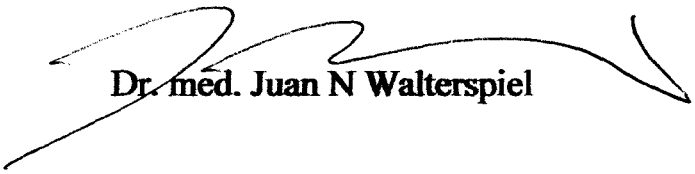
Pfizer could have appointed an independent observer to avoid this.

Pfizer, in spite of the critical report from the FDA inspection and the scientific and ethical shortcomings of the study, wrote to the FDA (40) that a non approval would jeopardize US children, US travelers and Homeland Security.

Pfizer retracted the submission only after a "no prejudice " deal was struck with the FDA.

The opportunity for an immediate six month patent extension for a drug expected to generate billions of Dollars, and the planned PR coup to advertise a new drug name with a safe, benevolent and heroic image saving children's lives in Africa, was lost.

A careful study of the clinical development of Trovafloxacin, the psychological factors involved, the lack of enforceable international laws, and the managerial structure and incentives in a pharmaceutical company, may prevent for this to repeat itself in the future.



Dr. med. Juan N Walterspiel

ton, Connecticut, in denen Forscher des US-Pharmakonzerns Pfizer Wirkstoffe erforschen. „Amistad“ heißt der historische Schiffsnachbau. Als Symbol gegen Sklaverei und die Ausbeutung des schwarzen Kontinents segelt er um die Welt. 1839 hatten auf der echten Amistad afrikanische Sklaven rebelliert. Der Nachbau lief nur wenige Kilometer entfernt von Pfizers größter Produktionsstätte vom Stapel, im Städtchen Mystic. Mit an Bord: eine kleine Metallplakette, darauf die vier Ziffern 0069. Angebracht von einem, der diese Ziffern nicht vergessen will. Weil 0069 nicht mehr rebellieren kann.

„Subject 6587-0069“, so steht es im Untersuchungsbericht der amerikanischen Food and Drug Administration (FDA), war ein zehn Jahre altes, dunkelhäutiges Mädchen. An Tag eins kam es mit Meningitis, einer bakteriellen Hirnhautentzündung, in ein Krankenhaus in Kano, Nigeria, wo ein Team des Konzerns Pfizer ein neuartiges Medikament testete. 0069 bekam täglich 56 mg des Antibiotikums Trovan, die es oral einnahm. An Tag zwei der Behandlung verschlechterte sich seine Meningitis dramatisch und es war halbseitig gelähmt. An Tag drei der Behandlung mit Trovan war 0069 tot. Die Dosis hatte niemand erhöht.

Das war im April 1996, während einer Meningokokken-Epidemie, an der 115 000 Menschen erkrankten und etwa 12 000 starben. Bis heute ist umstritten, warum Subject 0069 und zehn andere Kinder aus Kano, die an einer Medikamentenstudie mit 200 kleinen Patienten teilnahmen, gestorben sind. Zahlreiche weitere Kinder trugen schwere Schäden davon. Sechs der Kinder, die später starben, hatten ein herkömmliches Mittel bekommen, fünf Trovan. Trovan, das vorher an Kindern nicht ausreichend getestet war. Von dem man nicht wusste, ob Kindermägen es so gut aufnehmen, dass die Konzentration in Blut und Rückenmarks-Hirnflüssigkeit hoch genug ist, um die Bakterien abzutöten. Trovan, das in der EU seit 1999 verboten ist, weil es zu schweren Leberschäden führte.

Die Betroffenen dürfen jetzt auch in den USA klagen, entschied der Supreme Court.

Noch jetzt, 14 Jahre später, sorgt Studie 154 -149, sorgen die toten, gelähmten, tauben oder blinden Kinder für Schlagzeilen, beschäftigen Gerichte und, wie die Enthüllungsplattform Wikileaks kürzlich veröffentlichte, auch die internationale Diplomatie: Im vergangenen Jahr hatte Pfizer für geschädigte Kinder und Angehörige 75 Millionen US-Dollar an die nigerianische Justiz überwiesen, um ein Gerichtsverfahren zu stoppen. Wikileaks enthüllte einen Bericht von US-Diplomaten, die schrieben, Pfizer habe auf den nigerianischen Staatsanwalt Michael Aondoakaa private Ermittler angesetzt, um dadurch Druckmittel zu bekommen und höhere Forderungen abzuwenden. Pfizer bestreitet dies – genauso wie jegliches unethische Verhalten in Kano. Auf Entschädigungen von zwei Milliarden US-Dollar hatte Nigeria Pfizer 2008 verklagt. Befriedet wurden nicht alle Geschädigten. In diesem Sommer entschied das höchste US-Gericht, der Su-

Im nigerianischen Kano leiden viele Jugendliche unter den Folgen der Meni
blind oder taubstumm, so wie Abubakar Hussaini. Ob auch Trovan daran sch

zerne aus – nach Indien, Osteuropa, Russland, China, Thailand, nach Südamerika oder auch in afrikanische Staaten. Sogenannte Contract Research Organisationen wie Covance und Quintiles organisieren die Forschung vor Ort. Für die Pharmafirmen ist das billiger, für die betref-

te, die ihm sonst verwehrt wären, wie die niederländische Organisation Wemos in ihrer Studie „Eine bittere Pille“ beschreibt. Zwar haben sich sowohl die europäische Zulassungsbehörde EMEA als auch die nationalen Stellen harte ethische Vorgaben auferlegt. Doch was an-

erben

ria das neuartige Mittel Trovan an Kindern getestet. Pfizer bestreitet das. Der Fall beschäftigt die Gerichte

sandten Dokument entnehmen lässt, das die *Süddeutsche Zeitung* erreichte. Darin hat der ehemalige Pfizer-Forscher, Infektiologe und Kinderarzt aus dem Trovan-Entwicklungsteam, Juan Walterspiel, die Vorgänge aus seiner Sicht dokumentiert. Es sind schwere Vorwürfe, die Walterspiel in dem Dokument bereits 2007 notiert und an den Pfizer-Vorstand und an nigerianische Angestellte versandt hat. Eigentlich ist Walterspiel zum Stillschweigen verpflichtet. Der SZ hat er jetzt auf Anfrage die Echtheit jenes Dokuments eidesstattlich bestätigt – und seine schweren ethischen Bedenken bekräftigt. Bedenken, die ihn von „fahrlässiger Tötung" sprechen lassen.

Die Geschichte, die Walterspiel erzählt und die zahlreiche Indizien stützen, ist ein Drama in vielen Akten. Dass in Kano eine Meningitis-Epidemie ausbricht, erfährt die Welt zum ersten Mal am 10. Februar 1996, in einer Meldung der Agentur AP. Bald häufen sich die Nachrichten in Zeitungen und Internet, und so erfährt auch das Trovan-Team in Groton davon. Binnen weniger Tage entscheidet Pfizer, nach Nigeria zu gehen, um das erfolgversprechende Trovan zu testen – das zuvor, intravenös verabreicht, gute Werte erreicht hat. Ungewöhnlich schnell liegt eine Anforderung der nigerianischen Regierung vor. Später wird der dortige Studienleiter öffentlich erklären, er habe die Genehmigung des Ethikkomitees „rückdatiert".

Walterspiel, der den Versuch als Kinderarzt hätte mitleiten sollen, meldet Bedenken an – und entscheidet, nicht teilzunehmen. Auch, weil zuvor nicht getestet wurde, ob Kindermägen Trovan ausreichend aufnehmen können, denn Kinder haben weniger Magensäure. Eine Studie zur oralen Aufnahme bei Kindern wurde erst Monate nach dem Versuch in Kano in Auftrag gegeben. Walterspiel berichtet von ersten Rohdaten, die nach Informationen der SZ aus Studiendaten in einem chilenischen Krankenhaus gewonnen wurden: Diese hätten unerwartet niedrige Absorptionsraten gezeigt, schreibt er – ein „alarmierendes Ergebnis". Als Phase I/II-Studie mussten die Ergebnisse nicht veröffentlicht werden; auch der Forscher schwieg.

Es ist offenbar nicht das einzige unangenehme Resultat, das unveröffentlicht blieb. Nur ein Satz in der US-Packungsbeilage von Trovan erinnere noch an Komplikationen, die bei einer weiteren Studie auftraten, sagt Walterspiel: Trovan sollte nicht gemeinsam mit irgendeinem Magensäure neutralisierenden Mittel wie „Bicitra" gegeben werden, heißt es dort. Die dazugehörige Studie, die an Kliniken in den USA stattgefunden haben soll, habe zu schweren Infektionen nach Operationen geführt. Pfizer wollte zu diesen und weiteren Einzelvorwürfen Walterspiels auf Anfrage der SZ nicht Stellung nehmen. Dessen Anstellung habe 1998 geendet. Er sei nicht mit nach Nigeria gereist und habe deshalb „kein per-

ginnt das Team mit der Studie, verabreicht Trovan, aufgrund der Zustände vor allem oral.

Nebenan verabreicht die Organisation „Ärzte ohne Grenzen" für das nigerianische Gesundheitsministerium ein erprobtes Medikament. Dieses ist patentfrei und wird auch in Entwicklungsländern produziert. Nicht nur Ärzte ohne Grenzen, auch WHO und Rotes Kreuz sind vor Ort. Pfizer agiert auf eigene Faust. Dem Team helfen zwei lokale Krankenschwestern, die die Landessprache beherrschen. Laut Pfizer klären sie die Eltern mündlich über den Versuch auf. Schriftlich halten sie das Einverständnis nicht fest. Ob die Krankenschwestern den Eltern sagen, dass das Medikament, wie Walterspiel sagt, noch niemals von einem Kind geschluckt wurde, ist nicht dokumentiert. Auch nicht, ob sie auf Alternativen hinweisen.

Die Protokolle weisen zahlreiche Unregelmäßigkeiten auf, stellt die FDA später fest. Nicht jedem Kind wird Gehirn-Rückenmarksflüssigkeit entnommen, obwohl dies als einzig sichere Diagnose gilt. Lassen sich keine Meningokokken nachweisen, wird in einigen Fällen „not done" notiert, „nicht untersucht". Möglicherweise hatte also nicht jedes Kind Meningitis. Die Patienten bekommen Nummern. Adressen und Namen werden selten erfasst. Bis heute muss über DNS-Untersuchungen ermittelt werden, wem eine Entschädigung zusteht.

Möglicherweise hatte nicht jedes Kind, das behandelt wurde, Meningitis.

Denn nicht nur die Familien der toten Kinder, auch Überlebende wollen entschädigt werden. Viele der 200 Kinder aus der Trovan-Studie haben schon Gelenkschmerzen, als sie in die Studie aufgenommen werden – obwohl Tierversuche gezeigt hatten, dass hochwirksame Quinolone wie Trovan bei jungen Lebewesen Gelenke irreversibel schädigen können. Das Studienprotokoll zeigt, dass in der Trovan-Gruppe Gelenkbeschwerden zunehmen. Bewegungsstörungen führen die betroffenen Nigerianer heute auf Trovan zurück, Pfizer spricht dagegen von Meningitis-Spätschäden.

Während das Team in Kano arbeitet, hält Walterspiel in seinem Büro die Stellung. Dort wird er Zeuge eines Anrufs. Ein Teammitglied habe berichtet, nigerianische Behörden hätten die Studie gestoppt, müssten darum bezahlt werden, anderenfalls drohe dem Team die Verhaftung. Kurze Zeit später geht der Versuch weiter. Walterspiel hat dies in einer eidesstattlichen Erklärung niedergeschrieben, die er auf Antrag einer New Yorker Anwaltskanzlei übermittelt hat und die der SZ vorliegt. Die Kanzlei vertritt nigerianische Mandanten. Eine Merkwürdigkeit zeigen auch die Studienprotokolle: Während anfangs auch Kinder, die sehr schwach sind, in die Trovan-Gruppe aufgenommen werden, ändert sich das ab einem bestimmten Punkt. Plötzlich scheinen neu aufgenommene Kinder sehr viel gesünder zu sein.

Nach der Rückkehr aus Nigeria präsentiert das Team seine Ergebnisse auf einem Meeting in New Orleans. Später