(2002) 01 NCDRC CK 0050

In the National Consumer Disputes Redressal Commission

MOHD.ISHFAQ — APPELLANT

Vs

MARTIN DeSOUZA — RESPONDENT

Date of Decision : 07-01-2002

Acts Referred:

Citation : 2002 0 CTJ 522 : 2002 2 CPC 468 : 2002 2 CPR 151 : 2002 3 CLT 252 : 2003 1 CPJ 116

Hon'ble Judges : D.P.Wadhwa , J.K.Mehra , Rajyalakshmi Rao , B.K.Taimni J.

Final Decision : Complaint allowed

Judgement

1. THIS com-plaint has been filed by the complainant, Mohd. Ishfaq alleging medical negligence on the part of the respondent, Dr. Martin F. D''Souza, leading to his being completely deaf.

2. FACTS of the case are that sometime in May, 1990, the complainant was put on haemo-dialysis in a hospital in Bangkok. On a reference from a friend, the complainant contacted one, Dr. Sonawala, a Urologist in Jaslok Hospital in Bombay for kidney transplant. Since the complainant could not get a related kidney donor and since Jaslok Hospital did not undertake unrelated kidney transplant, the complainant was referred by Dr. Sonawala to the respondent Dr. D''Souza for kidney transplant in Nanavati Hospital. Complainant reached Bombay on 24th April, 1991 and started undergoing haemodialysis twice a week under the respondent in Nanawati Hospital. The complainant had slight fever on 7th May which persisted, upon which the respondent advised the complainant to get admitted in the Hospital. The complainant was admitted in the Hospital on 29th May, 1991. On 30th May, Renal Study was carried out which indicated the following : Normal Range 13.0 mgs. % S. Creatinine 0.7-1.5 mgs. % Blood Urea 180 mg. % 10-50 mgs. % Hemoglobin 4.3 gms. % 11.5-13.5 gms. % Blood and Urinary tests were carried out, the report of which could be available only on 3.6.1991 which showed sensitivity and resistance to specific medicines. The complainant was discharged on 8.6.1991. It is mentioned in the complaint that he was administered Amikacin 500 mg. Injection twice a day and in the

discharge slip was further advised to take Amikacin 500 mgs. Injection twice a day for 10 days. By the time this course was over, the complainant lost his hearing power. During his stay in the Hospital, according to the complainant, he found the respondent utterly indifferent, hence he decided to shift to Prince Aly Khan Hospital where kidney transplant took place on 30th July, 1991. While in Prince Aly Khan Hospital he was referred to Jaslok Hospital by ENT Specialist, Dr. Hakeem. The complainant alleges that he suffered hearing impairment due to use of anti-biotic Amikacin prescribed by the respondent while the complainant was under his care. It is solely on account of negligence on the part of the respondent, that complainant has gone deaf. Had the respondent been more careful, as per literature on the subject, of use/administration of Amikacin, the complainant would have been hale and hearty. He is a Central Government Officer and was working as Export Promotion Officer in the Union Commerce Ministry. His career has been jeopardised on account of the impairment. He contacted several people/organisations for restoration of his hearing capacity. He has been advised Cochlear transplant which at that time was to cost Rs. 4 lakh, even this would have only partially restored his hearing capability. In the circumstances, the complainant prayed for award of Rs. 12 lakh of which Rs. 10 lakh for a surgery in USA leaving for us to compensate him for the mental torture and other sufferings.

In the written statement filed by the respondent besides challenging the complaint on the question of jurisdiction, it is stated by him that there is no material brought on record by the complainant to prove any direct co-relationship between the drugs prescribed by him and the state of his health. It is admitted by him that the complainant came to him on 24th April, 1991 on reference from Dr. Sonawala and the respondent found the complainant to be a patient of chronic Renal failure due to Bilateral Poly Cystic kidneys for which twice a week Haemodialysis was prescribed. On 20th May, the complainant reported with high fever but even on medical advice, refused to be hospitalised. He was again advised to be hospitalised on 21st without any success. The complainant got admitted only on 29th May, 1991 in serious condition with fever of 1040 F. After admission he was investigated for Renal package which showed high creatinine - 13 mg. %, blood urea 180 mg. % and Hemoglobin 4.3 which were caused by serious blood and urinary tract infection. On investigation of ESR on 30th, it was also found to be high. The reports of urine culture showed sensitivity to Amikacin. Blood culture report also showed serious infection on the complainant. According to him, the case papers showed that gastriscopy was done on 4th June, 1991 and Amikacin, even though prescribed on 3rd June, started on 5th and continued till 7th June. The patient''s temperature subrided rapidly and he did not complain of any side effects. The complainant, on account of the inability to find a kidney donor was agitated and wanted to be discharged. He was discharged much against the wishes of the respondent and besides other medicines was prescribed "injection Amikacin 500 mg. twice a day x 10 days" with an advice to come for haemo-dialysis which he did on 11th, 14th, 18th and

20th June, 1991. On 11th June, once the complainant complained of slight tinitus or ringing on the ear, respondent immediately reviewed the treatment, and in the presence of his attendant i.e. his wife, stopped injection of Amikacin and Cap. Augmantline. He did so verbally as well as by marking ''X'' on the discharge card in his own handwriting. Therefore, the complainant could have taken Amikacin only upto the 11th. Even though cash memos show purchase of Amikacin after the date the complainant was taking this against the advice of the opposite party. On 19th June, one of the complainant''s relative informed the respondent of the complainant having high fever for which he advised admission which was not heeded. He did not see the patient on 20th when he came for dialysis. It has also been stated by the respondent that from 18th to 25th June, when the complainant had high fever, respondent does not know as to what medicines/ treatment the complainant took during this period. Later he was admitted to Prince Aly Khan Hospital where also he was treated with the specified anti-biotic Analgestic, Steriods and I.V. Fluids probably for high fever. No fault or negligence could be attributed to respondent as he stopped injection of Amikacin on 11th by marking ''X'' and explaining its meaning to the complainant and his wife. During the complainant''s stay in Prince Aly Khan Hospital, the complainant was administered a dosage called Sandimmum (Cyclosporine). This medicine could cause Ataxia i.e. shaky movement and unsteady gait in kidney transplant patients. The complainant also consulted Dr. Sonawala in July, 1991 where he had a perfect hearing conversation and movement of his body, thus proving that he had no ''hearing'' impairment at that stage. Respondent alleges complainant to be obstinate, rude and self-imposing. There has been no negligence on his part, hence the complaint needs to be dismissed with costs.

3. EVIDENCE in the first instance was led by way of affidavits. In all two affidavits were filed on behalf of the complainant being that of himself and of his wife. Six affidavits were filed on behalf of the respondent being that of Dr. D''Souza, the respondent, Dr. Danbar, a doctor attached to Haemo-dialysis Department of Nanavati Hospital, Dr. Abhijit Joshi, a Resident Senior Houseman attached to the Hospital, Mrs. Mukhta Kolekar, Senior Sister of the Hospital, Dr. Sonawala, the Urologist and Dr. Ashique Ali Rawal, a Urologist who did the kidney transplant on the complainant in Prince Aly Khan Hospital. The respondent also filed three affidavits of Specialists i.e. that of Dr. Kriplani, Dr. Sethi and Dr. Upadhyay. Oral evidence was recorded of complainant, his wife and the two expert witnesses, Dr. Ashok Sareen and Dr. Vindu Amitabh on behalf of the complainant, while oral evidence of the respondent, Dr. Danbar, Dr. Upadhyay, Sister Mukhta Kolekar an Dr. Ashique Ali Rawal was recorded from the witnesses from the side of the respondent. Besides this medical literature on Amikacin and use of Sandimmum, was also cited in their respective support by both the parties. A note on "use of Amikacin - its dosage and administration" issued by Javier L. Clemente, M.D. Section Chief of Nephrology, Fairview General Hospital, Cheveland, Ohio, USA was also brought on record by the complainant as an expert input. It was argued by the learned Counsel for the complainant that the

respondent, Dr. D''Souza has been negligent in the administration of Amikacin to the complainant as the dosage of 500 mg. twice a day given for 14 days to the complainant was excessive resulting in causing bileteral sensori-neural hearing impairment. In his evidence, Dr. Sareen, as an independent witness, produced by the complainant has stated the dosage to be excessive. In fact the respondent himself in his cross-examination admits that Amikacin has to be prescribed carefully and excessive dosage can cause deafness. Physicians "Desh Reference" as also other medical literature states that the dosage ''time gap'' of Amikacin is determined by the level of creatinine multiplied by 9. In this case at the time of admission creatinine level was 13 hence with a multiple of 9 it comes to 117 hours i.e. dosage should have been 38.4 mg. twice a day whereas dosage prescribed/administered obviously was excessive leading to complainant''s deafness. No audiogram was taken or instructed to be taken either before or during the ''Amikacin therapy'' at all by the respondent and daily dosage of Amikacin was not adjusted in accordance with changes in the serum creatinine level. It was argued by the learned Counsel that it is not proved that at the time of admission on 29th May, 1991 the patient was having a life threatening situation. Temperature was not high when the medicine Amikacin was started (tested on the complainant on 3rd June and started on 5th June, 1991), situation was not life threatening as the temperature was not high. It was also argued by her that the opinion of Dr. Ghosh of AIIMS obtained by the Commission should be seen only in a limited context as Dr. Ghosh is an ENT Specialist and not a Nephrologist. It was vehemently argued by her that the contention of the respondent that he crossed out the Injection Amikacin and Cap. Augmentlin on 11th June is not true and correct. The crossing out and circling these medicines were done by the Doctors at CGHS to indicate that these were not readily available and need to be indented. Since, it was prescribed by the respondent Doctor and since they were not available in CGHS, they bought it from the open market for which cash memos have been produced. The story of crossing out these medicines by the respondent is an after-thought to cover his acts of negligence of giving over-dosage to the complainant. These cash memos have been duly certified by CMO of Nanavati Hospital. It was also argued by her that the respondent has tried to pass on his blame to the other medicines especially for the period when he was not under his care, but neither he nor any other witness said anything to prove that deafness could be from other medicines. The material on record is enough to prove that excessive dosage of Amikacin solely was responsible for the deafness suffered by the complainant. It was also argued by her that the allegation of the respondent that the complainant was non-cooperative and rude has not been corroborated by any other witness. On the contrary the two of his witnesses, Dr. Danbar and Mrs. Mukhta Kolekar, the Nurse, quite categorically denied that the complainant was not co-operative or rude or ill-tampered during his stay in the Hospital. All the above material produced and the arguments advanced in support go to show clear negligence on the part of the respondent - Dr. D''Souza leading to the hearing impairment, hence requesting for allowing the complaint and awarding compensation to the

complainant to undergo surgery as well as to compensate him for mental and physical harassment and torture and loss of career prospects as a result of this impairment.

4. ON the other hand, it was argued by Mr. Banerjee, learned Counsel for the respondent that the complainant at the time of admission to the Hospital on 29th May, 1991 had fever as high as 1040 F and on 30th May, after investigation was found to have serum creatinine levels of 13 mg.%, blood urea 180 mg.% and Hemoglobin of 4.3 mg. thus making it clear that he was in bad shape. E.S.R. test on the same day showed a rate of 140 - a sign of massive infection i.e. life threatening infection. Amikacin was prescribed after obtaining blood and urine culture reports on 3rd and 4th June, 1991 which showed that the complainant was resistant to various sorts of antibiotics, save and except Methz. Mendalate and Amikacin. It is in these circumstances, injection Amikacin was prescribed to be administered to the complainant. Dr. Ashok Sareen, Expert Witness concedes that in such position, as obtained in the complaint, that he probably would give this drug. Expert witness also concedes that he would prescribe Amikacin when other drugs are not available. It is his case that the dosage administered initially i.e. 500 mg. twice a day was necessary and cannot be said to be so excessive as to hold doctor guilty of negligence. He relied upon the opinion of Dr. Ghosh of AIIMS, an Expert, whose opinion on this case was called upon by this Commission; who opined that "in life threatening infection, the adult dosage may be increased to 500 mg. every 8 hours but should neither exceed 1.5 gm/day nor be administered for a period longer than 10 days, the maximum total adult dosage of 15 gms. should not be exceeded". The dosage of 500 mg. twice a day is within the limit. It is admitted by the learned Counsel for the respondent that it is true that in the case of patient with renal failure, care is to be taken as per literature on record. He relied upon the evidence of Dr. Kirti Upadhyay who in his cross-examination states that an initial loading dose of 750-1000 mg. for serious illness could be prescribed and then goes on to a maintenance dose upto two weeks. Hence, it needs to be seen that correct dosage was prescribed - given the facts and circumstances of this case; and goes on to add that Amikacin was discontinued on 11th June, 1991 though initially it was prescribed for a period of 10 days. This discontinuation was occasioned by the complainant complaining of tinitus ringing during his visit on 11th June. ON this basis Amikacin and Augmentlin both were ''circled'' and ''crossed'' out and this was explained to the complainant in the presence of his wife, the doctor in-charge of dialysis and the nurse. The latter has been confirmed by Dr. D''Souza, Dr. Danbar and Mrs. Mukhta Kolekar in their affidavits and cross-examination. He argued that it is admitted by Dr. Sareen, the expert witness that deafness comes gradually, whereas the complainant wishes us to believe that he had the ringing on 19th June and lost his hearing completely on 20th. It is not possible. The fact that he had not lost his hearing even when he went to Prince Aly Khan Hospital is corroborated by the evidence of Dr. Ashique Ali Rawal and Dr. Kirti Upadhyay who state that they used to have normal conversation with him. Hence, it is not

believable that the complainant lost his hearing on 20th June, 1991. It may be that the complainant continued to take Amikacin injection of his own accord after 11th June, 1991 for which respondent doctor cannot be faulted. It was also argued by him that deafness could be on account of any medicine(s) taken by the complainant when he was not under the respondent''s care, which is also supported by the opinion of Dr. Ghosh who opined that there could be many causes for deafness on patients facing renal disease. Eight factors have been mentioned in this regard by him. No direct co-relationship has been established by the complainant between administration of Amikacin and deafness, thus not proving any negligence on the part of the respondent, hence complaint need to be dismissed. The complainant was also administered Sandimmum which is a traditional name of the drug called "Cyclosporine" whose known effects an unbalanced gait. This was prescribed after his kidney transplant by the Prince Aly Khan Hospital. Respondent had nothing to do with this. In any case the claim of Rs. 12 lakh is excessive and wholly arbitrary and inflated. The complainant has failed to prove the extent of damage suffered by him. We have gone through the material on record and heard the arguments. Admittedly, the whole case hinges and depends entirely on issue related to administration and dosage of Amikacin. The case of the complainant is that he was given an over-dosage of Amikacin contrary to the literature on the subject and was administered injection Amikacin 500 mg. twice a day X 10 days, unmindful of parameters necessary to determine the dosage and periodicity of each injection. His case is that lower dosage than prescribed should have been given to him directly relatable to serum creatinine levels and no audiogram was taken when he complained of ringing in his ears. As is usual in such cases evidence on record is sharply divided along known lines i.e. whether it is brought on record by the complainant or by the respondent. The case of the respondent is that based on the urine and blood culture reports and other parameters of S. creatinine levels, hemoglobin and blood urea the respondent perceived it to be a life threatening situation and since the culture reports showed Amikacin as one of the antibiotic to which the infection was sensitive, hence it was administered; when the complainant decided to leave the Hospital against medical advice on 8th June, Injection Amikacin was prescribed to be continued for 10 days. When on 11th, during the visit of the complainant for dialysis he complained of ringing in the ears, he crossed these injection/ medicines to not to be administered/taken. Whatever dosage was administered till 11th June was within limits and did not cause deafness. It could have been on account of any medicines taken by him when he was not under his treatment (18th to 25th June, 1991). Before going on to the question of dosage and periodicity of administration of Amikacin, it is, in our view, necessary to go into the question of crossing out the Injection Amikacin and Cap. Augmentlin on 11th June as alleged by the respondent very vehemently and equally vehemently rebutted by the complainant. The case of the complainant is as soon as he came to know of ringing in the ears as complained by the complainant on 11th June, 1991, he crossed it out in the Discharge Summary on which these were prescribed. In the written statement filed by the respondent he states : "On the

11th June, the complainant complained to opposite party of slight tinitus or ringing in the ear. Opposite party immediately reviewed the treatment on discharge card in possession of the complainant and asked the said complainant and also made his attendant i.e. his wife to understand and asked her also to stop Injection Amikacin and Capsule Augmentline verbally as well as marked ''X'' on the discharge card in his own handwriting i.e. on 11th June, 1991 i.e. three days after discharge..."

5. WHAT we see on the discharge certificate is not only ''X'' marked against Amikacin and Augmentlin, but they are also ''encircled''. The latter has not been stated in the written statement. We also do not see the reason for its crossing out (X); we are unable to appreciate as to what prevented the Doctor, who, according to him, wrote in his own handwriting on 11th June, to note about the complainant''s complaint of tinitus or ringing in the ears as well as explaining the reason for discontinuation of medicines by way of marking it with (X) ? Why encircle ? Why not delete and initial ? After all it was a record. There is no such mention on the record. There are also tick marks () against other medicines. It is not his case that he tick marked against the rest of the medicines. In these circumstances, we are inclined to agree with the complainant''s argument that the marking was done by CGHS Doctors. This is further corroborated by the cash memos produced duly endorsed by Nanavati Hospital of having purchased Amikacin on 3rd, 5th, 7th, 8th, 11th, 14th, 17th and 18th June. These have not been challenged. Case of the respondent is that he had stopped the administration of injection of Amikacin on 11th June; for any administration of Amikacin after 11th June, respondent cannot be held responsible. It is an admitted fact that the complainant is literate person and was holding a middle level job in Government of India in Ministry of Commerce. So to expect him to continue with the injection even after the alleged ''crossing'' out and explaining it to the complainant and his wife, escapes common sense. We will find it very different to believe that any patient in such a situation shall continue with the medicine which is stopped by the treating Doctor. The respondent in this regard wishes to rely upon the evidence of Dr. Danbar and Mrs. Kolekar. Both of them state that once the complainant complained of ringing in the ears, respondent Doctor D''Souza called for the discharge certificate and put a cross in the prescription (Discharge Card) against the said Injection/Cap. Augmentlin on the Discharge Card. Mrs. Kolekar also adds that "Dr. D''Souza immediately deleted Injection Amikacin and Cap. Augmentlin and put a cross...". We see no deletion on the Discharge Slip. It is germane to note that encirclement of these injection/ capsule have not been mentioned in their affidavits. Their parroating of one (crossing out of Amikacin in Discharge Summary) and absence of other (encirclement of the same) by all could not be co-incidental. The effort on the part of the respondent to build his case on the marking ''X'' seems to have been merely repeated by the supporting affidavits. Anyone can see both ''X'' and encirclement of these two. If the respondent Doctor had only put a cross then who encircled them. The move we see the more we get convinced that

''crossing'' out and ''encircling'' is not the doing of the respondent Doctor. The other two witnesses have only blindly repeated what respondent Doctor stated in his written statement. Had they seen the Discharge Slip and had independently given out their statement on oath, they would have mentioned both the facts i.e. of ''X'' and ''encirclement''. Keeping in view the above discussion, we are clearly of the view that ''X'' and encirclement was not done by the respondent Doctor. There is no mention of cause of crossing them out ? Ringing in ear is not noted. It is not initialed. No date is indicated. Tick marks on other medicines is not explained. If a medicine is to be discontinued it is deleted, we do not see this in the instant case. This is not even the case of the respondent that he prescribed any other anti-biotic drugs in lieu of Amikacin to control/check the infection. There are cash memos of purchase of Amikacin till as late as 18th June, 1991 duly endorsed by Nanavati Hospital. It is very important to note that in spite of clear mention "that the respondent never asked me or the complainant to stop taking Amikacin injection" in the affidavit filed by the complainant''s wife and the reference to. "The Medical Officer marked ''X'' on the discharge card against Amikacin Injection and Cap. Augmentlin as they were not available in the dispensary and were, therefore, to be indented" in the affidavit filed by the complainant, the whole issue of crossing out was not touched in the cross-examination of complainant or his wife, who were alleged to be present when the respondent crossed out the medicines. In these circumstances, we are unable to sustain the contention of the respondent Dr. D''Souza that he stopped Injection Amikacin on 11th June, 1991 by crossing it out.

6. THERE is no disputing the fact that over-dosage of Amikacin can lead to hearing impairment. In his written statement respondent states that Injection Amikacin was administered on 5th, 6th and 7th June, 1991 after a test dose on the evening of 3.6.1991, in his cross-examination he makes a categorical point that ''I do not know where it was actually administered for the first time''. In the absence of hospital record, which was not produced by the responden, we are no wiser as to when did it start ? Though not stated in his written statement, the respondent in his cross-examination states that the dosage (of Amikacin) is adjusted according to patient and the extent of dysfunction of the organs such as kidneys. He also states that "I do not remember having filed the hospital record in this case" and goes on to add that dosage also depends on ''factors like dehydration. In this case he was having severe infection so he was hyper catabolic dehydration than also because of vomiting and diarrhea and other things'' but we do not find these facts mentioned in the discharge slip. In the absence of hospital record we are unable to take a view on this subject. It is admitted by the respondent - ''one has to be careful while administering the Amikacin and it cannot be administered for a very long time''. The date 21st June is very important in this case as the complainant complained of hearing loss on 20th. In his cross-examination he states that "I presumed from records that he received his last dialysis on 20th June, 1991. I have seen the photocopy of the receipt of 21st June issued by Nanavati Hospital and agrees he could have came

on 21st June, 1991" and goes on to state - ''even after his discharge from the hospital, he continued to have dialysis under my supervision'' and further goes on to say in the later part of the cross-examination "it is incorrect to suggest that the patient met me on 21st June, when he came for haemo-dialysis". Dr. Danbar also in his cross-examination states "I do not remember whether the complainant came for the dialysis on 21st June, 1991". The principal i.e. respondent doctor D''Souza concedes that he could have come on June 21st, 1991 but the doctor working in Dialysis Department denies the same and so does the attendant Nurse, Mrs. Kolekar "I do not remember whether the complainant came for dialysis on 21st June". Their memory appears to be very sharp as to what is alleged to have happened on 11th, 14th, 17th and 20th June, 1991 but develops selective amnesia for 21st June, 1991 as it is the critical day i.e. the date on which the complainant alleges of hearing loss. It gives us an impression that whatever the latter two i.e. Dr. Danbar and Mrs. Kolekar have stated in their affidavits is a reproduction of whatever is stated by respondent, Dr. D''Souza driving us to draw an adverse inference on the veracity of their averments. We have on record the evidence of four expert witnesses. The two experts from the side of the respondent i.e. Dr. Kriplani and Dr. S. Seth did not come in the witness box but their opinion is on the record by way of affidavit. Dr. Kriplani''s short affidavit states that drug "Amikacin" as prescribed by the respondent doctor was absolutely indicated to eliminate urinary pathogen. Since the complainant was suffering from life threatening infection, therefore, "Amikacin" could not have been avoided. The prescribed medicine was absolutely right in his opinion. Dr. Seth states in his affidavit : "I state that in the circumstances of the case when Klebsiella Organism was found resistant to all powerful drugs inclusive of Augmentlin with the exception of Amikacin any Nephrologist of a reasonable standard of proficiency would have prescribed "Amikacin" drug in measured doses as a life saving drug despite the well-established fact that this drug might cause "tinnitus" or partial hearing impairment which is reversible, to almost complete extent in most of the cases after discontinuation of the drug as soon as any of the above symptoms makes its appearance. I state that in this situation, "Amikacin" could not have been avoided if the danger to the life of the patient had to be "Thwarted". The diagnose of Dr. M.F. D''Souza and the line of treatment adopted and administered to the said Shri Mohd. Ishfaq, who was suffering from a renal failure in addition to above specific infections, appears to be correct."

There is not a word in their affidavit about varying the dose of "Amikacin" on known parameters.

On the other hand two expert witnesses, i.e. Dr. Sareen and Dr. Vindu Amitabh were produced for examination in witness box without any affidavits having been filed on their behalf.

7. DR. Sareen, a Nephrologist in his examination states that "Amikacin" has a standard dose but have to be careful in the case of kidney failure patient''s. Dose

has to be titrated according to glomerular filtration rate, functioning of kidney or the Serum Creatinine level. DR. Sareen states that he uses this drug with extreme caution and only when other anti-biotic have failed, then he will give "Amikacin" 500 mg. injection to such a patient for 3-4 or 5 days. He further states that Nephrologist use this medicine at wide intervals and when absolutely necessary. They use it after dialysis when creatinine levels are low and then give it after 3-4 days. He further states that "when we give this drug we estimate their blood level, i.e. Amikacin level after administration of the drug in the patient. The drug can cause impairment of hearing. He goes on to indicate three parameters for administrating "Amikacin" namely patient should be well hydrated, use Amikacin when absolutely necessary and estimate serum levels of Amikacin through blood levels and titrate the dose accordingly. When "Amikacin" is prescribed then he needs constant watch by way of blood levels of Amikacin and audiogram, if possible. In his cross-examination he admits that he will use Amikacin for life saving, when he feels that other drugs are not going to do the job. He does not agree that patient can have high level of creatinine (13) after dialysis. Shown the status of the patient on 29th and test results on 3rd and 4th June, the witness says "Yes, probably I would use this drug". The witness says that after kidney transplant in Bombay, the complainant is under his treatment for transplant irregularly; he lost hearing when he was in Bombay and denies that Cyclosporine administered to the complainant after kidney transplant can cause deafness. Shown the report of DR. Ghosh of AIIMS, whose opinion was sought by this Commission, the witness says that he fails to understand how transplant by itself could cause ''deafness'' and goes on to state "I do not say that it (Amikacin) was wrongly prescribed but whatever the dosage is said on record, I would have prescribed it differently". High fever is not life threatening - Not even 105, just bring it down with cold water. The other expert witness is Dr. Vindu Amitabh - a Medical Specialist and looking after Nephrology in Safdarjung Hospital. He states that Amikacin is given in a restrictive dose in chronic renal failure patients. "Amikacin" is given 5 to 7.5 per kg. of body weight, twice a daily for a period of 5-7 days. Dosage has to be monitored according to serum level, blood analysis has to be done, if that facility is not available then it has to be given in relation to serum creatinine level. Serum level multiplied by 9 is the dose. In the initial stage i.e. bolus dose should be 500 mg. for a patient with creatinine level of 13 and subsequent dose depends upon whether he is undergoing haemo-dialysis or not ? If yes, then dose should be given post-dialysis @ 60 x 5 mg. (sixty being the body weight of complainant in the instant case). Serum analysis is done immediately and audiometry also should be done. Normally "Amikacin" should be given for 5-7 days. In severe circumstances it could be given more depending upon the patient not developing any complication. He goes on to state in his cross-examination that urinary tract infection is not a life threatening entity. In view of sensitivity tests, he would have given Amikacin but not in the same doses, but in a modified dose. If the treatment continues for more than 7 days audiometry has to be done. Dosage was too high on the days he was getting dialysis. Complainant was coming to

him for post transplant care and he use to deal with him through a third person. Complainant uses to write his version. It is true that Cyclosporine was administered to the complainant, can cause ataxia and not ear problem only. On the basis of record before him he can say that "subsequent to his loaded with Amikacin, he develops problem in his gait and in his hearing... I have just seen it. So it is just conjecture that it could have been the effect of that". Another witness, Dr. Ashique Ali Rawal, the Urologist who did the kidney transplant on the complainant in Prince Aly Khan Hospital in July, 1991, supports the contention and states "the said medicine is prescribed even for 5-7 days after getting the urine for culture and sensitivity test; at the same time patient is monitored with serum creatinine. On the hearing problem - on the one hand he states that he conversed with the patient and avoids the question about the deafness and does not remember to have seen the report of Dr. Hakeem, ENT man at the same hospital who had done audiogram on 26.6.1991. On the slightest pretext, he claims that he does not have the record and then goes on to say that "I cannot exactly say what was the condition of the patient when I examined him". Selective memory gain and loss appear to be symptomatic in this case. It was for them to produce the record. We can only draw adverse inference from this. Then there is the opinion of Dr. Ghosh, Professor and Head of ENT at AIIMS dated 24.12.1993 given on the request of this Commission. Dr. Ghosh found him totally deaf 95 db at 500 Hz. and more than 100 db at 100 Hz. on the right side and on the left side more than 100 db at 100 Hz. Then he goes on to theorize the contributory facts in renal disease which can cause hearing loss. He goes on to enumerate eight factors : 1. Immunologic 2. Dialysis 3. Drug Potentiation 4. Aminoglycosides (Amikacin as in this case) 5. Diuretics, especially loop ons. 6. Diabetes mellitus 7. Transplant 8. Other unknown factors.

8. DR. Ghosh admits his handicap of assessing the case "I do not find any audiogram taken before the treatments were instituted for the kidney ailment..". Statistically significant risk factor are a higher total dose of "Amikacin and a history of aminoglyoside therapy... But in this case a very gross impairment of balancing function has perhaps been wrought by a combination of factors and goes on to say" the organisms were sensitive to Amikacin. So it appears that it was not blindly used on a speculation or as clinical experiment. In the literature on Amikacin, it has been mentioned that in a life threatening infections and/or those caused by pseudomonas aeruginosa, the adult dosage may be increased to 500 mg. every 8 hours but should neither exceed 1.5 gm./day nor be administered for a period longer than 10 days. The minimum total adult dose of 15 gm. should not be exceeded. Perhaps in the case of Mr. Ishaq the physicians continued the therapy with Amikacin since they noticed steady improvement with this treatment. In conclusion, it may be opined that "in this case the impairment of hearing and balancing function are of multi-factorial origins and it is not possible to ascertain as to what percentage of this impairment is due to Amikacin and what percentage due to the other factors outlined above. Both have possibly exerted summation and potentiation to the ototoxic effect". Singular silence on

the parameters of dosages in administration of Amikacin is clearly perceptible in the report. One of the possible explanation for this could be that it is on account of the fact that he is an ENT Specialist and not a Nephrologist. We get an impression from the written statement filed by the respondent, evidence adduced by him and nature of cross-examination by his learned Counsel of the expert witnesses produced by the complainant that the respondent is out to prove that use of Amikacin was the only alternative and use of Cyclosporine could cause ataxia. Having gone through the record repeatedly we are clear in our view that the case of the complainant is not based on effects of Cyclosporine resulting in ataxia. He had this phenomenon for sometime and then it was cured. The two expert witnesses, Dr. Sareen and Dr. Amitabh are quite categorical that Cyclosporine are not known to cause any ear/hearing problems. So we would like to exclude this from our discussion. It is also not the case of the complainant that Amikacin should not have started at all. Even though expert witnesses do not consider high temperature as life threatening or for that matter low hemoglobin of 4.3 as life threatening, what is being challenged is the line of dosage, period and total length of period for which it could be administered and the accompanying parameters. When it is conceded that in the judgment of treating doctor it was life threatening situation and he started injection of Amikacin 500 mg. twice a day in the initial stages but what is under challenge is continuation of Amikacin for 10 days after initially being given for 4 days in the hospital and that too at the same dose i.e. 500 mg. twice a day without taking into consideration the accompanying parameters which go to determine the dosage and periodicity. Any witness examined on behalf of the respondent including his own affidavit are silent on this point. In his cross-examination the respondent concedes that the dosage is adjusted according to the patient and the extent of disfunctioning of the organs such as kidneys'' but we find no such material on record to help us appreciate the case of the respondent. All expert witnesses say that dosage has to be monitored through blood levels of Amikacin and audiogram (Dr. Sareen). The best thing is that the serum analysis should be done immediately and audiometry also should be done because it can cause toxicity and the serum level should be done (Dr. Amitabh). It is clear that after initial dosage of 500 mg. twice a day, then the dosage should have been reduced to body weight multiplied by 5 mg. i.e. Amikacin 300 mg. especially after haemo-dialysis and that too for 5-7 days. Even the respondent in his cross-examination admits that one has to be careful while administering the Amikacin and it cannot be administered for a long time". He also states that "In those days, there was no facility for evaluation of Amikacin levels...". It is no one''s case that Amikacin levels should have been measured when allegedly facility was not there. But, it is not denied that measuring serum creatinine level was not there. Why was this not done to regulate the dosage of Amikacin. It is not denied that facility for measuring serum creatinine level was not there. We have no material on record to show that even this was ever done after 30th May, 1991 to monitor the situation of the patient for the purpose of modifying the dose of Amikacin to be administered to the complainant. This is also supported by statement of Dr.

Upadhyay who supports the proposition that body weight is an important factor for calculation of dosage. He also states that the complainant did complain of hearing problem even though he communicated with him. Excessive dosage of Amikacin can cause deafness. Complaint was seen by ENT Specialist of the Hospital, he is not aware of the details. There is no material on record to show what were his creatinine levels and other parameters after the initial investigation on 30th May and 3rd and 4th June. Complainant was in Hospital till 8th of June and admittedly he came again on 11th, 14th, 17th and 20th June and on 21st June also. No material is on record before us to show as to what were his serum creatinine levels after the dialysis leaving us with a hollow thought that this was not being done, leading us to doubt the very competence and capability of the respondent Doctor. To leave a patient after blindly prescribing Amikacin 500 mg. twice daily for 10 days and not caring to monitor the dosage at least on the days of visit to the Hospital, to modify the dosage as per literature on the subject, itself tantamounts to medical negligence. Even the opinion of Dr. Ghosh is clear on the subject.... "dosage may be increased to 500 mg. every eight hours but should neither exceed 1.5 gm/day nor be administered for a period longer than 10 days". Literature on the subject makes it clear that adult dosage of 15 gm. is meant for heavier patients. Even though the respondent does not come clean on the number of days on which Amikacin was administered (See his cross-examination referred to earlier)... it can be presumed, based on the written statement filed by the respondent, that a test dose was administered on 3rd June and then 500 mg. twice a day was administered on 5th, 6th and 7th June and then prescribed further for 10 days - thus exceeding the maximum period of 10 days given out by Dr. Ghosh and also in the literature on this subject. We wonder if the respondent was even aware of that. No defence/explanation whatsoever was given by the respondent on the subject. It is no one''s case that Amikacin should not have been prescribed/ administered in the first instance. It is the dosage and length of time of administration which is in question. Pamphlet for Medical Practitioners given out with Injection Amikacin states : "In patients with impaired renal function the daily dose should be reduced and/or the intervals between doses increased to avoid accumulation of the drug. One suggested method for estimating dosage in patients with known or suspected diminished renal function, is to multiply the serum creatinine concentration by 9 and to use the resulting figure as the intervals (in hours) between doses i.e. if the serum creatinine is 2 mg. the recommended dose should be administered every 18 hours. As renal function may alter appreciably during therapy, the serum creatinine should be checked frequently and the dosage regimen modified as necessary."

9. IN both these aspects the respondent has failed to satisfy us. All the witnesses/ evidence adduced by the respondent before us is silent on the question of audiometry. The first audiometry report is of Jaslok Hospital dated 29.6.1991 which states the patient has "Bil. profound sensori neural hearing impairment" IN Goodman and Gilaman''s the Pharmacological Basis of Therepeutics (Sixth

Edition) Macmilcan Publishing House, New York. It is stated : "Since the incidence of nephrotoxicity and ototoxicity is directly related to the concentration to which an aminoglyocide accumulates, it is critical to reduce the maintenance dosage of these drugs in patients with impaired renal function. It is recommended that patients receiving aminoglycosides be carefully monitored for ototoxicity, since the initial symptoms may be reversible; however, deafness may occur several weeks after therapy is discontinued."

10. IN the book "drug - facts and comparisons" Media Centre St. John & West Shore Hospital, West lake - OH 1990 Edition, published by "A division of J.B. Luppincot and Co. Philadesphia, Toronto it is stated that "The usual duration of treatment is 7 to 10 days. Do not exceed 15 mg./kg./day. If treatment beyond 10 days is considered, monitor renal and auditory functions daily". Treatment of heavier patients should not exceed 1.5 mg/day. IN UTI, use 250 mg. twice daily. Opinion obtained by the complainant from Chief of Nephrology at Fairview General Hospital, Cleveland Ohio, which is part of the record is as follows : "Dosage guidelines should be continuously followed taking in consideration the patients weight and adjustment made according the renal function since Amikacin is 92% renally excreted within 8 hours and 98% within 24 hours in patients with normal renal functions (1, 2). A patient weighing 60 kg. with normal renal functions e.g. serum creatinine of 1 mg% (100% function) should receive 450 mg. every 12 hours. A patient with a serum creatinine of 13 mg.% (about 5.6% function or even less) should receive 450 mg. every 117 hours (5 days) or 34.6 mg. every 12 hours as clearly explained in the enclosing information (1, 6, 7). The dose should be altered in patients with renal failure of any degree regardless of a life threatening condition to prevent ototoxicity and further nephrotoxicity (5, 1, 7). A dose of 500 mg. every 12 hours for 14 days, for a patient weighing 60 kg., having a serum creatinine of 13 mg.% (renal function of less than 6%) is excessive and would he highly ototoxic and furtherly rephrotoxic (1, 2, 3, 4, 5, 6, 7). This case made out by the respondent is that he discontinued administration of injection Amikacin and Cap. Augmentin on 11th June and the complainant went to Prince Aly Khan Hospital on 25th June. IN between this period what medicines he took respondent does not know. There was no deafness on 11th and no deafness was reported to him till 20th or 21st June. Hence, he could not be held accountable for any medicines he took during this period 11th to 20th June, 1991 which might have been responsible for the alleged deafness. As discussed we are not satisfied that the respondent discontinued injection Amikacin on 11th June, 1991. Even if it is accepted for argument sake that this was done, was it not the duty of the respondent to refer the complainant to ENT Specialist in the same hospital. This is not even alleged by the respondent or his two unacceptable witnesses, Dr. Danbar and Mrs. Kolekar that at any time during the subsequent visits for dialysis, the complainant was asked if he is still getting titinus or ringing in the ears. Record shows that the complainant did go for audiogram on 29.6.1991 in Jaslok Hospital, where hearing impairment is noticed, still the witnesses from that

hospital i.e. Dr. Upadhyay and Dr. Rawal go on to say that they were conversing with him normally. Audiogram contradict their affidavits on this aspect clearly and definitely. However, it must be said to the credit of Dr. Upadhyay that he admits of the complainant having complained of hearing problem yet evades reply on the Audiogram report carried out on reference from Dr. Hakeem of the same Hospital i.e. Jaslok Hospital. It is not denied by Dr. Upadhyay that the complainant was under his direct care during this period of his admission for the period from 25.6.1991 to 13.8.1991. We are inclined to believe that the first warning bell on hearing problem ran on 11th June, as admitted by the respondent leading to serious gradual hearing impairment result of which is available the Audiogram of 29.6.1991. Amikacin especially in excessive dosage can lead to deafness. As following discussion will show respondent was negligent on that count thus leading to hearing impairment."

IN view of the above discussion, we like to examine what is "Negligence". Halsbury''s Law of (ED-3 Vol. 26. P 17-18) explains "Negligence in following terms : A person who holds himself out as ready to give medical (a) advice or treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person, whether he is a registered medical practitioner or not, who is consulted by a patient owes him certain duties, namely a duty of care in deciding whether to undertake the case : a duty of care in deciding what treatment to give (a), a duty of care in his administration of treatment (b). A breach of any of these duties will support an action for negligence by the patient. The above explanation has also been relied upon by the Hon''ble Supreme Court in the case of Laxman v. Trimbak Bapu Godbole & Anr., AIR 1969 SC 128 (Vol. 56C 27). IN Spring Meadows Hospital v. Harjot Ahluwalia, AIR 1969 SC 123, Hon''ble Supreme Court, quoted Lord Eraser thus : "The true position is that an error of judgment may or may not be negligent; it depends upon the nature of error. It is one that would not have been made by reasonably competent professional man possessing to have the standard and type of skill that the defendant held himself out as having and acting with ordinary case, than it is negligence."

IN Bolan v. Friegu Hospital Management Committee, (1957) 1 WCR 582 All; ELR (1957) All ER (Queen''s Prince Division), Lord Justice McNair said : "Before I turn that I must explain what in law we mean by "Negligence". IN the ordinary case which does not involve any special skill, negligence in law means this. ''Some failure to do some act which a reasonable man in the circumstances would do, or doing some act which a reasonable man in the circumstances would not do; and of that failure or doing of that act results in injury, than there is a cause of action.....''. I myself would prefer to put it in this way. A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical man skilled in that particular art."

In the instant case, what is supported by all qualified witnesses is that in a life threatening situation, Amikacin is to be given especially when culture reports

support this proposition. This is not disputed. What has not been accepted - in other words disputed by all, is, that Amikacin can be given indiscriminately. Amikacin levels in the blood after administration of drug need to be monitored. Serum creatinine levels need to be monitored to vary the dose and generally given for a period of 5-7 days. Dr. Ghosh, ENT Specialist AIIMS opines that it cannot be given for more than 10 days the other limitation being in all 15 gm. Literature on the subject says that this upper limit of 15 mg. in all, is for heavier patients. Be that as it may, in the instant case serum levels of Amikacin through blood levels are not known to have been monitored. No record of S. Creatinine after 30th May is available on record which could have helped in regulating the dosage; dosage was not prescribed keeping in view the body weight; the very fact that after administering Amikacin for four days in the Hospital, still another 10 days administration of injection Amikacin is prescribed, this making it in all to run for 14 days, which no professional or medical literature on the subject supported. The main issue was tried to be deflected by introducing "ataxia" as a result of administering Cyclosporine in Prince Aly Khan Hospital, which as per expert evidence of Dr. Sareen and Dr. Amitabh are not known to cause hearing impairment; a serious attempt is also made to sully the conduct of the complainant by showing him to be ill-tempered and self-imposing which the two important witnesses i.e. Dr. Danbar and Mrs. Koleker rebut in their cross-examination. In fact no expert evidence was led in his support by the respondent in favour/support of challenged excessive dosage or their being no requirement for its moderation based on known accompanying monitoring parameters. As per expert witnesses, especially Dr. Sareen, whom the learned Counsel for the respondent was can- did enough to call a balanced witness - as well as the literature on the subject referred to earlier, it was imperative on the part of the respondent to ensure audiometry tests of the complainant as part of the overall monitoring of health of the complainant as one of the serious adverse fall out of Amikacin is hearing impairment. This was not only not done but not even advised. It will not be an exaggeration to say that this was not even thought of by the respondent leading us to doubt his competence. Has this been done, then hearing impairment, which as per medical literature on this subject, is reversible in the initial stages, could have prevented the final out-come deafness of the complainant. It is admitted by the respondent that the complainant did complaint of titinus i.e. ringing in ears on 11th June, 1991, which was perhaps an early symptom of impending hearing impairment. What did he do ? Nothing - no suggestion or advice or referal to ENT Specialist to ascertain the status of his hearing. What is more galling in that not even once the respondent tries to find out the hearing status on 11th, 14th, 18th and 21/21st June, 1991, was it not his duty to find out this fact especially when Amikacin had been prescribed by him. He takes no action on this point on 11th June when admittedly respondent was informed of the problem nor on any subsequent dates when respondent met him during the complainant''s visit to Hospital for dialysis under his charge. This is what he ought to have done but failed to do so leading to complete deafness of the complainant for which respondent alone could be held to be responsible by

his series of acts of negligence, staring with prescribing Amikacin 500 mg. twice a day for 10 days when the patient had already taken this injection for four days prior to this, not modulating the dosage based on the well-established parameters, not doing the audiogram before the treatment, during the treatment or after the treatment. Thus we find respondent Dr. D''Souza negligent in discharge of his duties, which was expected of a Doctor possessing ordinary skills on the subject at issue. Respondent, in our view, clearly failed in his duty of care expected from a Doctor to whom the patient in all good faith goes with that confidence. In these circumstances, we allow the complaint.

As per literature on the subject, it may not be possible for him to gain fully his hearing facility, but material on record indicate that in India it would have costed Rs. 4 lakh in 1991 for a cochlear implant surgery. Since then as a result of development of science on this subject cost of surgery must have undergone a change but we have no up-to-date figure on record. In the circumstances we direct the respondent to pay Rs. 4 lakh with interest @ 12% from 1.8.1992 i.e. date of filing the complaint till the date of payment which must be made within 8 weeks of passing of this order, with the hope that this shall suffice for the implant surgery to regain hearing capability at least partially. Respondent is further directed to pay Rs. 2 lakh as compensation of mental agony and harassment along with cost of Rs. 5,000/-. Since no details have been made available, we are unable to award anything for compensating the complainant for loss in career prospects on account of hearing impairment. Complaint allowed.

