

**NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION  
NEW DELHI**

**CONSUMER CASE NO. 257 OF 2015**

1. PUSHPA VERMA & 2 ORS.

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.....Complainant(s)

Versus

1. BHARDWAJ NURSING AND MATERNITY HOME  
PRIVATE LIMITED & 9 ORS.

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.....Opp.Party(s)

2. DR. SANJIV BHARADWAJ,

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3. DR. V.A. BHARADWAJ,

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4. FORTIS ESCORTS HEART INSTITUTE

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5. PIYUSH JAIN,

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6. MEDANTA HOSPITAL

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7. NARESH TREHAN,

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8. DR. RAVI KASLIWAL,

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9. DR. YATIN MEHTA, CHAIRMAN

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2. Mrs. Pushpa Verma, Mrs. Shubhra Verma Bhatnagar and Dr. (Mrs.) Rashmi Mathur have filed above complaint, for directing the opposite parties to pay exemplary damage & compensation of Rs.100000000/-; and any other relief which is deemed fit and proper in the facts and circumstances of the case, alleging medical negligence in treatment of Justice J.S. Verma (Retd. Chief Justice Of India), resulting in his death. To pursue the principles of Justice J.S. Verma lived for, the complainants approached this Commission, to ensure that the guilty do not go unpunished. The Complainants intend to put the compensation, if awarded in the present matter in a Trust in the name of Justice Verma, which would be utilized for charitable causes.

3. The complainants stated as follows:-

(a) Late Justice J.S. Verma was the husband of complainant-1 and father of complainants-2 & 3. Justice J.S. Verma retired from the post of Chief Justice of India on 18.01.1998. Thereafter, he worked as Chairman, National Human Rights Commission, India during 1999 to 2003. After Nirbhaya gang rape and brutal murder case, Government of India formed a three members Commission, on 16.12.2012, in which he was chairperson, widely known as Verma Commission, to recommend for amendment in criminal laws for the effective prosecution of the culprit in the rape and sexual offences. After hectic efforts and working continuously for 18 to 20 hours in a day, he submitted report on 23.01.2013. The said report was acknowledged and acclaimed worldwide. Pursuant to the said report, several amendments have been brought in the Criminal Law by the Criminal Law Amendment Act, 2013.

(b) While serving as the Judge, Supreme Court of India, Justice J.S. Verma underwent to a routine cardiology check-up, including coronary angiogram in 1993 and was diagnosed with asymptomatic Coronary Artery Disease. The same was well managed by healthy life style, regular medical check-ups, adherence to medical advice, compliance with intake of prescribed medications, diet and exercise. He was a very active and healthy man, who used to take good care of his health. On advise of Dr Yugal Mishra, a Cardiac Surgeon, who had performed a cardiac surgery of his wife in June, 2012, Justice J.S. Verma underwent to a complete executive check-up i.e. Blood Test, including a Liver Function Test (LFT) at Fortis Escorts Hospital on 30.11.2012, which showed significant abnormal liver functions (out of the normal range blood test results for liver function). Test report was submitted to Dr. Piyush Jain (opposite party-5) of Fortis Escorts Hospital, on 19.12.2012, who just noted it, in the records. He did not advise for any further investigation or medication.

(c) Justice J.S. Verma, developed swelling in his left leg. He consulted with Dr. V. A. Bharadwaj (opposite party-3), who was his family doctor, in this respect, who got him admitted to Bhardwaj Nursing & Maternity Home on 12.03.2013, where he was under treatment of Dr. V. A. Bharadwaj (Medicine) and Dr. Sanjiv Bharadwaj (Cardiologist) (opposite party-2) during 12.03.2013 to 14.03.2013. On examination, atrial fibrillation (irregular heart rhythm) was diagnosed. Dr. Sanjiv Bharadwaj advised various tests including the Liver Function Test and Clotting Tests. The result of these tests reports clearly showed significantly deranged liver function and very significantly abnormal blood coagulation (clotting). Dr. Sanjiv Bharadwaj prescribed the tablet Dabigatran (Pradaxa) with combination of Clopidogrel and Amiodarone and other medicines. He was discharged on 14.03.2013, with an instruction for review after a week. Justice J.S. Verma went for review on

21.03.2013 to Dr. Sanjiv Bharadwaj, who continued the same medicines for a period of three months. Justice J.S. Verma had bleeding in first week of April, 2013. He informed this fact to Dr. Sanjiv Bharadwaj, on telephone, who did not call for any further test and told to continue with same medicines.

(d) Justice J.S. Verma was awarded NDTV Indian of the year award by the Prime Minister on 15.04.2013. He travelled to Mumbai on 16.04.2013 to deliver his lectures in the University. While he was in Mumbai on 16.04.2013, he felt unwell with significant gastrointestinal bleeding, then he took a return flight on 17.04.2013 and directly went to Fortis Escorts Heart Institute from airport, where he was admitted at 15:00 hours on 17.04.2013, under the treatment and care of Dr. Sanjiv Bharadwaj. En-route he had several blood vomiting. At 19:30 hours on 17.04.2013, he had blood vomiting in Fortis Escorts Heart Institute. In order to cover blood loss, six units of blood and six units of plasma were transfused to Justice J.S. Verma. His endoscopy was done in morning on 18.04.2013, by Dr. Rahul Gupta, Gastroenterologist, who orally informed to the family members that bleeding was from an ulcer, which was clipped and not from oesophageal varices. Dr. Rahul Gupta also noted that thereafter there was no further bleeding.

(e) Multiple transfusions of blood and plasma at Fortis Escorts Heart Institute to Justice J.S. Verma, created fluid overload in lungs. As a result, acute breathing problem arose. Citrate in the transfused blood and plasma bound calcium in the blood. ECG showed prolonged QTc interval due to hypocalcaemia. These complications were not properly managed by Dr. Sanjiv Bharadwaj. Ultimately Dr. Sanjiv Bharadwaj, Dr. Yugul Mishra and Dr. Arvind Bharadwaj advised to shift Justice J.S. Verma to Medanta Hospital (opposite party-6). Mrs. Shubhra Verma Bhatnagar talked to Dr. Naresh Trehan, Chairman, Medanta Hospital, Gurgaon, who assured that good care would be taken and on such assurance he was transferred to Medanta Hospital through ambulance on 19.04.2013 at 15:00 hours and subjected to treacherous journey of travelling to Medanta Hospital in Delhi Traffic.

(f) Justice J.S. Verma was admitted to Medanta Hospital on 19.04.2013 at 16:45 hours, The main problems at the time when he was shifted to Medanta Hospital was worsening of fluid overload and a deteriorating cardiac status as a consequence of inappropriate management of complications due to multiple units of blood and plasma transfusions. The suboptimal management (too little too late) at Medanta in four and half hours from the arrival i.e. at 16:45 hours until the cardiac arrest at 21:14 hours, failed to correct the reversible physiological causes that could have produced a different outcome. After cardiac arrest at 21:14 hours, he was intubated and ventilated. He could not survive and passed away on 22.04.2013.

4. The complainants stated that opposite parties-2, 3, 5, 7 to 10 had committed negligence in treatment of Justice J.S. Verma, which resulted into his death. Details of which are as follows:-

(a) Test Report (i.e. complete Blood Test and Liver Function Test) dated 30.11.2012 showed significant abnormal liver function. This report was shown to Dr. Piyush Jain (opposite party-5) on 19.12.2012 at Fortis Escorts Hospital. He did not show even a minimal responsibility and cared to go through it. Significant abnormal liver function being detected, he ought to have advised for Ultrasound or Gastroenterology tests, to ascertain the reason

and proceed with the further effective treatment. The medical protocol for investigation of unexplained abnormal liver function tests as a start is, an Ultrasound Scan of the liver, but no such action was taken to investigate this further. Had Dr. Piyush Jain of Fortis Hospital taken any notice of the reports and advised Ultrasound and referred to a Gastroenterologist, to check his liver, the condition of liver cirrhosis, which was diagnosed in April, 2013, would have been diagnosed 5 months earlier.

(b) On examination of Justice Verma, on 12.03.2013 at Bhardwaj Hospital, atrial fibrillation (irregular heart rhythm) was detected for which he was admitted, in the Hospital. He was under the treatment of Dr. V.A. Bharadwaj (Medicine) (opposite party-3) and Dr. Sanjiv Bharadwaj (Escort's Cardiologist) (opposite party-2). Dr. Sanjiv Bharadwaj advised various tests including the Liver Function Tests and Clotting Tests. The tests reports clearly showed significantly deranged liver function and very significantly abnormal blood coagulation (Clotting). In utter disregard with the medical condition of Justice Verma and without thoroughly analysing the reports Dr. Sanjiv Bharadwaj negligently prescribed a tablet Dabigatran (Pradaxa) along with a combination of Clopidogrel and Amiodarone. If he had shown even a minimal responsibility and cared to go through the said reports, no competent doctor could have advised the aforesaid medicines to a patient with abnormal liver function and impaired blood clotting. Dabigatran (Pradaxa), an Anticoagulant, was started while Justice Verma was already taking Clopidogrel, which is an antiplatelet. In addition, he was prescribed Amiodarone, on admission, which is associated with hepatotoxicity (liver toxicity). Amiodarone is also known to have drug interaction with the anticoagulant Dabigatran, by increasing its plasma concentration with the risk of causing fatal bleeding. He was discharged on 14.03.2013 from the Hospital saying everything was taken care of and that he should come back for reappraisal in a week. On 21.03.2013, Justice Verma, was examined by Dr. Sanjiv Bharadwaj, as an outpatients at Bharadwaj Hospital. But Dr. Sanjiv Bhardwaj again advised Justice Verma to continue with the same drug combination. In the first week of April, 2013, Justice Verma contacted Dr. Sanjiv Bharadwaj on phone, informing him of what he thought was bleeding piles since the time he had started taking Dabigatran (Pradaxa). However Dr Sanjiv Bharadwaj once again carelessly reiterated his advice to continue taking Dabigatran. Dr. Sanjiv Bharadwaj even at this point did he not consider it necessary monitoring or advising Justice Verma's blood sample to be checked for Full Blood Count including haemoglobin. The minimum prudence which they were required to observe is, that they should have at least gone through the test reports before prescribing any medicine, but they miserably failed to do so. The deranged liver functions and coagulation were apparent from the liver function tests report. Had the Liver function and coagulation tests been reviewed and aforesaid combination of drugs not commenced, fatal outcome would not have occurred. The combination of drugs (Amiodarone, Dabigatran (Pradaxa) and Clopidogrel) commenced by Dr. Sanjiv Bharadwaj resulted in fatal bleeding causing multiple organ failure, which ultimately led to the death of Justice Verma. A low haemoglobin clearly indicated that Justice Verma was bleeding internally as a consequence of treatment with Dabigatran. Justice Verma was not advised to stop Dabigatran before the catastrophic bleed requiring admission to Fortis Escorts on 17.04.2013 despite Justice Verma having complained and being concerned of increased risk of bleeding.

(c) Significant gastrointestinal bleeding was started to Justice J.S. Verma on 16.04.2013. On his admission to Fortis Escorts Hospital on 17.04.2013 at 15:00 hours, Justice J.S. Verma

was under the treatment and care of Dr. Sanjiv Bhardwaj with severe upper gastrointestinal bleeding. In spite of the continuous bleeding only after approximately 16:00 hours of his hospitalization, an endoscopy was done on 18.04.2013 in morning. In which for the first time, it was detected that he had oesophageal varices and an ulcer which was bleeding, as recorded by Dr. Rahul Gupta in his report. Further scan showed the diagnosis of Liver cirrhosis. The Gastroenterologist Dr Rahul Gupta orally informed his family members that the main source of bleeding was not from oesophageal varices but the ulcer. Dr Rahul Gupta also recorded in his report on the same day at 16:00 hours that Justice Verma did not have further episode of bleeding. Instead of detecting the source of bleeding and clipping it, Dr. Sanjiv Bharadwaj administered six units of blood and six units of plasma negligently. Multiple transfusions of blood and plasma at Fortis Escorts Heart Institute to Justice J.S. Verma, created fluid overload in lungs. As a result, acute breathing problem arose. Citrate in the transfused blood and plasma bound calcium in the blood. ECG showed prolonged QTc interval, due to hypocalcaemia (low calcium levels) which is a precursor of fatal cardiac rhythm abnormality. Dr Sanjiv Bharadwaj failed to recognise these complications that occurred as a consequence of multiple blood and plasma transfusions. Till Justice Verma was shifted to Medanta Hospital on 19.04.2013 at 15:00 hours, he was not administered a single intravenous calcium injection. Justice Verma had developed breathlessness which was obviously due to fluid accumulation in his lungs. The same is well documented in the nursing notes, but the same was also not properly recognised and taken care of by the doctors in their progress notes while Justice Verma was in ICU at Fortis Escort's Hospital. This is apparent from the Doctor's Progress Notes of 17th, 18th & 19th April, wherein the Doctors at Fortis Escorts had repeatedly recorded that the chest condition was normal, no added sound and B/L EAE (Bilateral equal air entry). Further, apart from one injection of Lasix 20 mg, which was advised by Dr. Rahul Gupta at 16:00 hours on 18.04.2013, no other treatment, as per the established medical practice, like diuretics (flush the excess accumulated body fluid through the kidneys by giving Lasix injections) or hemofiltration (to clear the lungs and blood of excess fluid and other toxins by slow dialysis) was carried out to correct his breathlessness or fluid overload. Fluid overload is a complication which is easily prevented and corrected. There was no recognition of this complication in the doctor's progress notes in the ICU at Fortis Hospital. Even the injection of Lasix was not followed up. On 19.04.2013, the family was strongly advised by Dr Sanjiv Bharadwaj, Dr Yugul Mishra and Dr. V. A. Bharadwaj to shift the patient to Medanta Hospital at Gurgaon. Decision to shift to Medanta when no active liver management was necessary or planned at the time and without consultation with the treating Gastroenterologist Dr Rahul Gupta, on the premise that proper care for the Liver could be taken at Medanta only, was a complete apathetic decision. The main problem at the time when he was shifted to Medanta Hospital was worsening of fluid overload and a deteriorating cardiac status as a consequence of inappropriate management of complications of multiple blood and plasma transfusions.

(d) Dr. Naresh Trehan, Chairman, Medanta Hospital, Gurgaon personally assured complainant-2 that good care would be taken of Justice Verma, and on such assurance in a critical state, Justice Verma was subjected to the treacherous journey of travelling to Medanta Hospital in Delhi Traffic which further deteriorated his condition. Justice Verma was admitted to Medanta Hospital at 16:45 hours on 19.04.2013 at Medanta Hospital. Suboptimal management (too little too late) at Medanta in four and half hours from the arrival i.e. at 16:45 hours until the cardiac arrest at 21:14 hours, failed to correct the

reversible physiological causes that could have produced a different outcome. Considering his critical condition and as assured by Dr. Naresh Trehan it was expected that the specialist doctors would have expeditiously attended to and taken care of the health condition of Justice Verma. First documented cardiology review was at 18:00 hours by Dr. Balbir Singh an hour and 15 minutes after Justice Verma was admitted to ICU at Medanta Hospital. It is documented by Dr. Balbir Singh that an episode of TdP - Torsade's de Pointes was seen. He prescribed Injection Magnesium which is documented as given at 19:00 hours (significant delay in such a critically unwell patient), in the running chart but not documented in the records of stat medications (to be given immediately) or in the nursing notes. There was no further repeat dose of Magnesium given as was required, as per the recommendation for prevention and management of TdP Torsade's de Pointes. This was not repeated until after at 21.14 hours on 19.04.2013. Justice Verma had cardiac arrest due to failure to provide adequate treatment for TdP Torsade's de Pointes, reversible cause. The standard regimen consists of 2 gm IV bolus of 50% Magnesium Sulphate over 1-2 minutes followed in 15 minutes by another such bolus and even a 3-20 mg/min continuous infusion if required. I V Magnesium Sulphate is a first line therapy, being highly effective for both the treatment and prevention of recurrence of long QTc related ventricular ectopic beats or TdP. The benefit occurs without shortening of the QTc interval and is seen even in patients with normal Serum Magnesium at baseline. Dr Balbir Singh documented that 1 episode of non-sustained TdP was seen and has, apart from Injection Magnesium 2g I/V TDS, also advised Injunction Esmolol at 18:00 hours on 19.04.2013. In spite of being advised by the cardiologist at 18:00 hours, injection Esmolol was given only at 19:30 hours (1hr 30 min later than advised). All this while he was admitted in the critical care unit and assured best possible care by none other than Dr. Naresh Trehan. It is claimed that the delay in giving injection Esmolol was due to Justice Verma being haemodynamically compromised with pulse- 149/min & BP 90/50 mm of Hg. Acute therapy of TdP in such patients with haemodynamically unstable TdP, requires prompt non-synchronised electric defibrillation. If Esmolol was not given as the patient was haemodynamically unstable then electrical defibrillation should have been considered. As is mentioned above, one dose of Injection Magnesium as claimed by illegible documentation was given at 19:30 hours and the second dose at 21:30 hours, which is recorded in Stat Medication, signed by both the doctors and nurses, after the cardiac arrest at 21:14 hours, when it was already too late.

(e) Arterial blood gases done at 16:50 hours soon after arrival at Medanta Hospital showed low levels of Calcium 0.98 (normal 1.15-1.29). The ECG showed significant changes, with QTc prolongation, changes consistent with low blood calcium levels which are a precursor of impending cardiac arrhythmias (catastrophic irregular heart rhythm), and also with evidence of ischemia suggesting reduced blood supply to the heart. There were poor attempts at correcting the hypocalcemia. As recorded in the nurse's reports, first injection of calcium chloride was given at 16:45 hours and second injection at 20:10 hours. Despite the claim that Calcium was given twice at interval of more than 3 hours, the ionised Ca remained very significantly low and uncorrected at 0.75 mmol/l at 21:18 hours at the time of the cardiac event, leading to the cardiac arrest. Due to failure to correct the reversible factors, in spite of an opportunity being available for four and a half hours, after admission to Medanta Hospital, Justice Verma at 21:14 hours developed sudden severe ventricular arrhythmia (catastrophic irregular heart rhythm). At this time his repeat blood gases showed an ionized corrected Calcium of 0.75 (normal-1.15-1.29). This episode of life threatening ventricular

arrhythmia occurred due to failure to correct severe hypocalcaemia and TdP - Torsade's de Pointes, especially in a patient of liver disease. Despite an opportunity that was available for four and a half hours, these reversible factors were not recognized and corrected in time, as a result of which he developed catastrophic ventricular arrhythmia which resulted in cardiac arrest at 21:14 hours.

(f) Aforesaid amounts to negligence on the part of the doctors at Medanta Hospital also which claims to be a Super Speciality hospital, that in spite of the patient being in the intensive care unit in a life threatening condition. Haemodynamically compromised state (pulse- 149/min & BP 90/50 mm of Hg), and in spite of being advised by the Cardiologist, potentially lifesaving medications and treatment such as nonsynchronised electric defibrillation were not given in an attempt to correct and prevent fatal ventricular arrhythmia. The same not only reflects poor management by the "specialist team" but also exhibits apathy in the management of their patients. The resuscitation at the Medanta Hospital after Justice Verma had cardiac arrest, did not follow ALS (Advanced Life Support) guidelines effectively, which clearly mentions that chest compression is an integral part in management of resuscitation. As stated by the medical personnel present at the time, 27 shocks were given. According to the eyewitness accounts high quality of minimally interrupted chest compression were not given as there was a group of doctors and other staff, who rushed out of the room after each shock, with no obvious person continuing chest compressions. Inappropriate CPR was performed without any efforts for effective chest compression and this resulted in ineffective attempt at Cardiopulmonary Resuscitation. Not only, no attempt was made to correct easily reversible factors like TdP - Torsade's de Pointes low calcium and magnesium levels prior to this catastrophic event, the effort at resuscitation was carried out very reluctantly by the doctors at the scene. There was poor coordination between the specialists at Medanta Hospitals after the transfer from Fortis Escort's to Medanta. It was made clear to the family that specialist Cardiologist, Intensivist and Gastroenterologist would be available on Justice Verma's arrival, to oversee and monitor his care. The transfer was agreed to after Dr Naresh Trehan telephoned and gave complete assurance. Dr Randhir Sud was the only specialist available until 19:30 hours, from the 3 Specialist doctors who should have attended to Justice Verma after admission. Dr. Sud left the critically ill patient, who was essentially admitted under his care at 19:30 hours, saying that since now the problems are cardiac, they will be managed by the cardiac team. There was lack of responsibility, coordination and ownership in coordinating the care associated with apathy. Justice Verma was reviewed by the named cardiologist Dr. Ravi Kasliwal only after the prolonged catastrophic events, much later in the night after repeated complaints by friends and family present there. Only from subsequent review of the medical records provided later to the family members it shows an entry by a cardiologist to show that a cardiologist attended at 18:00 hours. This is surprising as despite repeated reminders by the family even after 18:00 hours and much later the family members were constantly being informed that the cardiologist will review him soon. The entry into notes of a cardiology review that had taken place at 18:00 hours came to the family members as a big surprise, as at no time did the family and friends, who were constantly present at the ICU demanding a cardiologist review, notice, or were informed that this review has already taken place. On 22.04.2013, Justice Verma following the cardiac event, was intubated and ventilated from the 19th April evening until 22nd April evening, when he eventually passed away, with



worsening condition, from factors which if treated appropriately and in time were preventable and reversible.

(g) Subsequently, after his death, the family has been subjected to severe mental trauma and distress due to attempts by Dr. Naresh Trehan's breach of patient privacy and confidentiality and issue concerning compliance with Medical Ethics. Dr. Naresh Trehan, on the national TV in CNN IBN "Face the People" live telecast on 09.10.2013, against the professional code of conduct and ethics, divulged the detailed medical diagnosis, detailed treatment and Justice Verma's previous medical history. If he had a disagreement with the statement by the family, he should have said that he disagreed and await a detailed investigation. His language too was unprofessional by statements such as "anybody who knows a b c of medicine should know.....", "how dare they sit in judgment....." All his comments and demeanour reflected an attitude of vengeance since the family had spoken out in spite of his earlier warning, at media's request and insistence to know the concerns around medical negligence that had resulted in Justice Verma's Death. Dr. Trehan had previously warned a family member that he would go public with the medical details, with an implicit intention to stigmatize, if the media was made aware of the medical negligence. In fact even immediately after Justice Verma's death, none at the Medanta hospital made any attempt to speak to the family, before releasing the news in the media. The entire family including complainant-1 was in the ICU. The news was released without any courtesy, consideration to speak, discuss or inform the family. Following Justice Verma's death, the family tried to speak to Dr Sanjiv Bharadwaj in the early afternoon on the 27.04.2013, to ascertain the details. But to shock and surprise he was in an inebriated state. It was not possible to have any conversation at all. This was highly unprofessional and a cause for concern, for his patients as he is supposed to be an interventional cardiologist. Dr. Sanjiv Bharadwaj then called between 5-6am the next morning and accepted that he had indeed overlooked and failed to even see the blood reports of the patient he had been treating.

5. Dr. Dilip Mathur (husband of complainant-3) made a complaint before Medical Council of India, on 24.06.2013, against above mentioned erring doctors for the negligence and professional misconduct for not exercising due care while treating Justice Verma which was referred to Delhi Medical Council. Delhi Medical Council dismissed it on 10.06.2014. The complainants filed an appeal against the same before Medical Council of India on 23.06.2014. This complaint has been filed on 10.04.2015.

6. Bhardwaj Nursing and Maternity Home (opposite party-1) has filed separate written reply and Dr. V.A. Bhardwaj (opposite party-3) has filed his separate written reply in same terms and stated that Justice J.S. Verma, after his retirement from the post of Chief Justice of India, shifted to Noida, since then he was taking medical care of Justice J.S. Verma and his family. Justice J.S. Verma was patient of Coronary Artery Disease, Double Vessel Disease, (AIIMS (1999), significant lesions in LCX and RCA, non-critical lesion in LAD. Justice J.S. Verma had a long standing history of hypertension on Tablet Nebicard, Diabetes Mellitus on Glyciphage SR, dyslipidaemia on Statins for last 14 years. He was also known case of bleeding piles. He was ex-tobacco chewer. Justice J.S. Verma had been on regular check-ups at AIIMS by Cardiologist and Endocrinologist. His reports used to be reviewed by his daughter Dr. Rashmi Verma Mathur and son-in-law Dr. Dalip Mathur also, who are highly qualified doctors practicing in U.K. Justice J.S. Verma reported uneasiness on 12.03.2013 at Bhardwaj Nursing and Maternity Home. His ECG showed Atrial Fibrillation as such he was

admitted in ICU and a cardiology consultation was taken from Dr. Sanjiv Bhardwaj and he was put under his treatment with fast ventricular response and hypotension. Injection Heparin was started. Such patient needs long term blood thinner for which Tablet Pradaxa 110 mg (Dabigartan) was recommended by Dr. Sanjiv Bhardwaj. He personally contacted Dr. Rashmi Verma Mathur on her telephone on 13.03.2013 and explained everything in detail, who also approved Pradaxa 110 mg (Dabigartan). Dr. Sanjiv Bhardwaj also consulted with a Electrophysiologist at Fortis Escorts Hospital, who also approved Pradaxa 110 mg (Dabigartan). Subsequent to admission, his investigations reveals anaemia Hb 11.4 gm, LFT SB2.1, Dir 0.8 (asymptomatic unconjugated hyperbilirubinemia), SGOT 73, SGPT 37, PTTK control -28 sec and test-48 sec, PT 13/18, INR 1.3 on Heparin, HbA1C 7.2, Serum Creatinine 0.9. SGOT is found in liver, heart and skeletal muscle. SGOT was elevated more than SGPT. Deranged LFT as labelled if serum transaminases are less 3 times (Upper limit of normal) (40). In liver disease transaminases should be elevated 5 to 10 times the upper normal limit. Typical reference range for PTTK is between 30-50 sec. depending upon the laboratory. Deranged clotting parameters if PTTK is more than 3 times the normal value. He was shifted to the room next day and he was haemodynamically stable and was put on tab Amiodarone 200mg OD. His condition was fit and he was discharged on 14.03.2013 with instruction for review after a week. Thereafter, Justice J.S. Verma never consulted him.

7. Dr. Sanjiv Bharadwaj (opposite party-2) has filed his written reply and stated that Justice J.S. Verma was about 80 years old elderly gentleman. He was a known case of Coronary Artery Disease, old MI, Double Vessel Disease, (AIIMS (1999), significant lesions in LCX and RCA, non-critical lesion in LAD. He had multiple co-morbidities such as (a) Long standing hypertensive on nebicard. (b) Long standing diabetes mellitus on Glyciphage SR. (c) Long standing Dyslipidemia on Statins (Simvastatin) for last 14 years. (d) Known case of bleeding piles grade III and (e) Ex-tobacco chewer. Despite long CAD in last 14 years, there was no treadmill test (TMT) or stress thallium report available to document any progression of CAD, revealing no evidence of ischemia. His Blood Test report was reviewed on 05.12.2012 by him. At that time he was detected to have carotid atherosclerosis 20% lesion in LICA. His investigation revealed mild anaemia HB 11 gm, Serum Bilirubin 2.1, SGOT 84, SGPT 53. There was no report of clotting parameters like PTTK, INR. His Echo revealed normal LV function. Justice J.S. Verma was admitted at Bhardwaj Nursing and Maternity Home (opposite party-1) under Dr. V.A. Bhardwaj (opposite party-3) on 12.03.2013, for uneasiness. Dr. V.A. Bhardwaj was his family physician for last many years and knew his medical condition. At the time of admission, the patient had documented Atrial Fibrillation (irregular heart rhythm with fast ventricular response and hypotension). Therefore a cardiology consultation was taken from him (Dr. Sanjiv Bhardwaj) for management of Atrial Fibrillation. At the time of review, his BP was 80/60; pulse 180/min, irregular. He did not have any evidence of angina or congestive heart failure. He was admitted to ICU and Dr. Sanjiv Bhardwaj prescribed IV fluids Injection, Cordarone Injection, Heparin to control his Atrial Fibrillation. Subsequent to admission, his investigations reveals anaemia Hb 11.4 gm, LFT SB2.1, Dir 0.8 (asymptomatic unconjugated hyperbilirubinemia), SGOT 73, SGPT 37, PTTK control -28 sec and test-48 sec, PT 13/18, INR 1.3 on Heparin, HbA1C 7.2, Serum Creatinine 0.9. SGOT is found in liver, heart and skeletal muscle. SGOT was elevated more than SGPT. Thus there was no evidence of abnormal liver function test of the patient. Deranged LFT is labelled if serum bilirubin is greater than two times the upper normal limit and serum transaminases is more than three

time the upper normal limit. All other non-cardiac related disorders were being reviewed by Dr. V.A. Bhardwaj. The patient had minor elevation in serum transaminases and S. Bilirubin for many years and the patient himself attributed to the long term statin therapy. During his stay in hospital, there was no evidence of any bleeding from piles, no gastrointestinal symptoms, no past history to suggest any liver impairment.

**8.** Fortis Escorts Heart Institute (opposite party-4) has filed its reply and stated that Justice J.S. Verma was reviewed on 19.12.2012 by Dr. Piyush Jain at OPD. At that time he was detected to have carotid atherosclerosis 20% lesion in LICA. His investigation revealed mild anaemia HB 11 gm, Serum Bilirubin 2.1, SGOT 84, SGPT 53. In the work up there was no report of clotting parameters like PTTK, INR. His Echo revealed normal LV function. Thereafter, Justice J.S. Verma was admitted to Fortis Escorts Heart Institute on 17.04.2013 with history of hematemesis and melena for last two days. At the time of admission, he was haemodynamically stable with BP 130/80, pulse 80/min. His investigations revealed Hb 7.6, S.Cr 1.1, PT 11.8/21.3, INR 1.84, PTTK 26/51, SG OT 119, SGPT 61, serum bilirubin 1.9. As noted he had stopped Dabigartan for last 2 days and his clotting parameters Prothombin Time/ PTTK were within normal limit. To attribute bleeding to Dabigartan, the aforesaid parameters should have been deranged but the patient was haemodynamically stable. Upon admission, urgent Gastroenterology consultation and Critical Care Team consultation was done and treatment was started. 4 units of packed RBC and 2 FFP were transfused on 17.04.2013 over 24 hours. His ultrasound revealed cirrhosis liver, chronic liver disease, Cholelithiasis, ascites, which were documented for the first time and no such symptom relating to chronic liver disease were recorded earlier. Daily ABG was done, which revealed serum ionized calcium 0.9 which is normal and a better indicator than serum calcium. Upper GI Endoscopy was done on 18.04.2013, which revealed grade III bleeding Oesophageal varices, portal HT, gastritis and duodenitis. There was only active bleeding grade III from Oesophageal varices and no other site and band ligation of varices was done. Investigations revealed PT 11.8 INR 1.54, Hb 10.4. Hepatitis B antigen reactive. As his INR were below 2. From which, it was proved that dose of Dabigartan was low and all cannot be attributed to Dabigartan. Subsequently he has 2 episode of melena-passing of black stools signifying bleeding in upper gastrointestinal track. The patient was transfused two unit packed RBC and 2 units FFP on 18.04.2013. There was no interaction with calcium due to FFP. Daily ABG revealed Serum Ionised Calcium as 0.99 mmol. On 19.04.2013, the patient was Haemodynamically stable, BP 110/80, pulse 100/min. He was in atrial fibrillation. Investigation revealed Hb 9.3, S ionized calcium 0.9, ABG ph 7.45, PO2 126, PCO2 43, SB 5.72, SGOT 407, SGPT 93, INR 1.5. The family of the patient decided to shift the patient to Medanta Medicity Gurgaon and on their request patient was discharged on 19.04.2013 at 15:00 hours. During stay at Fortis Escort Heart Institute there was no sign of fluid overload because he was Haemodynamically stable, CVP was within normal limits, ABG normal, chest clear, X-ray chest within normal limits. No sign of Hypocalcemia was found. At the time of shifting, the patient was conscious, oriented BP 110/68, pulse 100/min and was not on any inotropic support.

**9.** Dr. Piyush Jain (opposite party-5) has filed his written reply and stated that Justice J.S. Verma had met him for the first time on 05.12.2012 at Fortis Escorts Heart Institute and informed that he had coronary artery disease but he was asymptomatic on medical therapy. He was advised for a complete cardiac check-up on a later date as he was not in a fasting

state on that day. Thereafter, Justice J.S. Verma reported back on 19.12.2012 to share a set of investigations conducted at Bhardwaj Nursing and Maternity Home, nearly three weeks back. The reports were examined and documented in OPD booklet and advice was given on the basis of these reports. In the liver panel, SGOT (AST) level (84 u/L, reference range 0-40 u/L) and SGPT (ALT) level (53 u/L, reference range 0-40 u/L) were borderline raised beyond reference range. A rise in liver enzymes less than 3 times above upper limit of normal are considered to be clinical insignificant. Mild rise in indirect bilirubin was also noted (serum total bilirubin 2.1 mg/dl), which is also known to occur on statin therapy, particularly simvastatin, that the patient had been taking. Despite all evidence contrary to active liver disease, the patient was asked to follow up review after six months. A positive diagnosis of chronic hepatitis can only be made when abnormal liver function tests, particularly transaminase elevation, persist for at least 6 months. Abdominal ultrasound was not suggested because it is recommended in patient with asymptomatic liver transaminases (SGOT/SGPT) elevations when:- (i) The patient presents with cholestatic picture and (ii) When the patient has chronically abnormal liver tests (of clinical significance) of hepatocellular pattern and other investigations are negative (normal) at follow up.

**10.** Dr. Naresh Trehan (Opposite Party-7) has filed his written reply and stated that on 19.04.2013, the family members of Justice J.S. Verma had informed him that the patient (Justice J.S. Verma) was being shifted to Medanta as recommended by his treating team at Fortis Escorts and decided by the family members. Then he stated that the doctors at Medanta would do their best. On admission at Medanta, the patient was attended by the team of senior most doctors of each relevant speciality, viz (i) Dr. Randhir Sud, Chairman, Digestive and Hepatobiliary Sciences, (ii) Dr. Yatin Mehta, Chairman, Critical Care medicine, (iii) Dr. R.R. Kasliwal, Chairman, Division of Clinical and Preventive Cardiology and (iv) Dr. Balbir Singh, Chairman Division of Electrophysiology. Justice J.S. Verma was admitted at Medanta on 19.04.2013 at 16:45 hours, suffering from multiple diseases. The team of doctors attending the patient did all the best efforts to reverse the critical condition of the patient. Details of treatment given to the patient are matter of record and detailed in the written reply filed by the treating doctors. The complainants filed complaints before various authorities including Prime Minister of India, in which, material and crucial facts relating to medical condition and course of treatment of the patient were concealed. The family members divulged similar facts to the media CNN-IBN on the programme "Face the People", making serious allegations against the doctors of Medanta who treated the patient and the answering opposite party. Several print and electronic media has published concealed and incorrect version of the complainants. Thereafter, the media CNN-IBN Channel interviewed him on such incomplete facts on 09.10.2013 and recorded his statement. 34 eminent citizen signed a letter, asking for an inquiry against Medanta. In the light of accusation on the basis of incorrect and incomplete facts, the answering opposite party placed correct facts relating to medical history and treatment of Justice J.S. Verma and voluntarily did not give press release.

**11.** Opposite parties-6, 8, 9 and 10 have filed their joint reply. They stated that Justice J.S. Verma, aged about 80 years was admitted to Medanta Hospital on 19.04.2013 at 16:43 hours. Medical history of Justice J.S. Verma as noted in Medanta Hospital at the time of his admission on information of his family members are that (i) Pre-existing history of Coronary Artery disease with critical Double Vessel involvement, diagnosed in 1993 at AIIMS along

with history of Paroxysmal Atrial Fibrillation with Fast ventricular rhythm. (ii) Diagnosed with Hepatitis B related Decompensated Chronic Liver Disease with Cirrhosis of Liver with Portal Hypertension leading to massive Oesophageal variceal bleed and Ascites. (iii) Hypertension, Diabetes Type II, Hiatus Hernia, Haemorrhoids, Dyslipidemia, Cholelithiasis and Migraine. (iv) Due to decompensated chronic liver disease and portal hypertension, he had massive bleed from Oesophageal varices on 17.04.2013. The bleed was severe which would be evident from the fact that multiple units of blood transfusion along with plasma were administered to stabilize his vitals at Fortis Escorts hospital. Endoscopic variceal ligation was done at Fortis Escorts on 18.04.2013. However he was developing encephalopathy. (v) In spite of treatment at Escorts hospital, his condition was deteriorating as he was becoming stuporose, breathless and had developed Atrial Fibrillation with fast Ventricular rate.

At the time of admission, the patient was in a state of drowsiness /delirium, malena (blood in stools). He was having Grade I to II Hepatic Encephalopathy; and was also hypotensive and required vasopressors. He was having Atrial Fibrillation with fast Ventricular rate and was in respiratory distress requiring oxygen. The aforesaid condition was indicative of critical illness where variceal bleed had precipitated hepato-cellular failure and aggravated a pre-existing Coronary Artery disease. There was a dilated IVC confirming fluid overload as the cause of his breathlessness.

After admission, the patient was shifted to Intensive Care Unit, where he was immediately attended by a team of doctors namely Dr. Randhir Sud, Chairman, Digestive and Hepatobiliary Science, Dr. Yatin Mehta, Chairman, Critical Care Medicine, Dr. Deepak Govil, Associate Director of Critical Care Medicine and Dr. Balbir Singh, Chairman, Division of Electrophysiology. His condition was discussed with Dr. R.R. Kasliwal on telephone, as he was in Medanta City Clinic at Defence Colony, New Delhi at that time, who ordered for an urgent Echocardiography. In ICU, his pulse was 126 per minute and irregular due to atrial fibrillation, blood pressure was 102/57 mmhg on infusion of Inj. Noradrenaline, his SPO2 was 93%; and respiratory rate of 22 per minute on 5 litres of Oxygen through face mask. The patient was given injection Somatostatin, which were continued and injection Monocef was changed to injection Cefatoxim.

The patient's Blood Gases were taken at 16:50 hours, which showed hypoxemia with Pao2 of 66 mmHg (range 83-108) and high Lactate levels of 2.9 (rage 0.5-1.6), ionic calcium level of 0.98 mmol/litre. That 2gm of calcium chloride was administered to the patient in 50 ml of infusion immediately after admission before 17:00 hours. The patient had an episode of unsustained Torsade's de Pointes (TdP) (Ventricular Rhythm Disturbance) with pulse at 149/minute. It was advised to start injection Esmolal and injection Magnesium Sulphate to maintain the Serum Potassium. The patient passed malenic stools at 17:00 hours. At 18:00 hours, 2 gm of Magnesium was given.

At 17:19 hours, tests of (i) Complete Blood Count, (ii) Renal Function Test, (iii) Alpha-fetoprotein, (iv) Activated Partial Thromboplastin Time, (v) Prothrombin Time/INR (vi) Liver Function Test, (vii) Serum Calcium (viii) Magnesium and Phosphorus, (ix) Arterial Ammonia, (x) Blood Culture and Sensitivity, (xi) Urine Culture and Sensitivity, (xii) Urine Routibe and Microscopic, (xiii) X-ray chest, (xiv) Ultrasound Abdomen, (xv) Blood Gas Analysis, (xvi) Echocardiography, (xvii) Blood grouping and antibody screening, (xviii)

Aerobic C&S Blood, (xix) Nasal Swab, (xx) Auxiliary Swab, (xxi) Groin Swab and (xxii) Urine Analysis and ECG were done.

The lab report showed Magnesium Serum and Potassium to be within normal range. The chest X-ray showed bilateral opacities in mid & lower zones, possibly Aspiration Pneumonitis. At 19:00 hours, the episode of TdP got resolved and the pulse was restored to 107/minute, as compared with 149/minute at the time of admission. After Blood Pressure of the patient was stabilised at 20:00 hours, injection Esmolol and injection Calcium Chloride were administered. Around 20:00 hours, report of blood samples was received, which showed Serum Calcium level of 7.0 mg/dl with Serum Albumin of 2.5 mg/dl, Arterial Ammonia of 66 umol/litre, High Alpha-fetoprotein 49.1 IU/ml (reference range 0.00-7.22) was also noted. His urine sample was turbid with 4-6 pus cells along with presence of Bacilli.

Around 21:30 hours, the patient had non-sustained intermittent Ventricular Tachycardia with hemodynamic compromise (pulseless VT). At this point of time, the patient was given D.C. Shock by Dr. Sachin Gupta and Cardio Pulmonary Cerebral Resuscitation (CPCR) was started by Dr. Jagadeesh K.N. till return of systemic circulation. The patient was intubated and was given bolus of injection Adrenaline in presence of Dr. Balbir Singh. Other supportive medicines like injection Betaloc, Xylocard, Calcium Chloride, Potassium Chloride, Sodium Bicarbonate, Cordarone were given. With repeated D.C. Shocks (12-14) and continued Cardiac massage (in accordance with ACLS protocol) along with medication, the patient's blood pressure was stabilised around 22:00 hours but the patient remained critical and was maintained on artificial ventilation and medications prescribed. His pupil's were reacting. Echocardiography revealed the ejection fraction of left ventricle of heart around 40-45%. As his Haemoglobin in ABG was on lower side, it was decided to transfuse packed Red Blood Cells. Ryle's tube was also placed to assess on going GI bleed if any and was utilised to give oral medication.

On 20.04.2013, in morning, the patient was conscious and oriented although still on ventilator. His heart rate was stable at 80 beats per minute, in sinus rhythm. His blood pressure was maintained at 99/52 mmHg with infusion of injection Noradrenaline, Xylocard, Cordorene, Pantocid and Insulin. Tablets Rifagut, Entecavir and syrup Lactulose were started. Lactulose enema was also given. Blood test performed in morning on 20.04.2013, revealed rise in total Leucocyte Count to 16.45, rise in Serum Creatinine to 1.1, rise in Serum Bilirubin to 4.4, C-Reactive Protein to 52.7 (range 0.0-10.0), Procalcitonin 0.57 (range 0.00-0.05), Arterial Ammonia 73 (range 9-30), Troponin-I 20.100 (range 0.000-0.120), Creatinine Phosphokinase 237 (range 55-170), CKMB 61 (range 0-25), NT Pro-BNP 15600 (range 0-450). During the day time, higher doses of Noradrenaline to maintain his blood pressure and infusion of Dobutamine was started. The patient continued on the ventilator but was responding to verbal commands.

In the evening of 20.04.2013, the blood test showed a decrease in Arterial Ammonia to 35, the Troponin-I and CKMB showed downward trend, while his total Leucocyte Count increased marginally to 17.63. During night the patient remained critical and required increase of doses of vasopressors to maintain his blood pressure and also his urine output was decreasing.

In morning on 21.04.2013, the chest X-ray showed bilateral consolidation in mid to lower zones with rising trend of TLC, CRP and Procalcitonin. Gram stain of Endotracheal secretions showed gram negative cocci for which injection Colistin nebulation was added. Injection Meropenam and injection Targocid were added. His INR was 1.75, total Bilirubin of 5.1 and Arterial Ammonia of 85. The patient was continued on mechanical ventilation and to hemodynamics, infusion of injection Vasopressin was added to infusion of injection Noradrenaline, Dobutamine, Xylocard and Cordarone. During the day, his urine output fluctuated, requiring intermittent diuretics. He passed malenic stools requiring transfusion of one unit packed Red Blood Cell and two units of Fresh Frozen Plasma.

On 22.04.2013 around 1:45 hours, the patient developed Atrial Fibrillation with fast ventricular rate for which synchronised cardio-version was done. In spite of all supportive therapy, the patient developed increasing Metabolic and Lactic acidosis with rising Ammonia, Procalcitonin and CRP levels. The continuous renal replacement therapy was started on 22.04.2013, in view of these events. By afternoon his hemodynamics started deteriorating further, requiring increase in vasopressors. Metabolic acidosis persisted. CXR showed bilateral consolidation with pleural effusion. His ventilatory requirements also went up requiring high FiO<sub>2</sub> and high PEEP. His endotoxin level had become high. Toraymixin hemofiltration was done afternoon. Despite all these measures, his hemodynamic instability worsened and infusion of injection Adrenaline, Dopamine, Phenylephrine, Sodab carbonate were added. At 20:58 hours, the patient had Bradycardia followed by asystole. Immediately CPR was started. Despite best efforts, the patient could not be revived and passed away at 21:45 hours on 22.04.2013 due to Multi-organ failure, De-compensated Hepatitis B, related chronic liver disease with upper GI bleed, Post Endoscopic Variceal Ligation status, Diabetes Mellitus, Hypertension, Double Vessel Coronary Artery disease.

**12.** The complainants filed their separate Rejoinder Replies to all the written replies of the opposite parties. The complainants filed Affidavit of Evidence, Additional Affidavit of Evidence of Shubhra Verma Bhatnagar and documentary evidence. The opposite parties filed Affidavits of Evidence of Mrs. Shruti Bhardwaj, Dr. Sanjiv Bhardwaj, Dr. V.A. Bhardwaj, Dr. Kausar Ali Shah, Dr. Peeyush Jain, Dr. Awadhesh Kumar Dubey, Dr. Naresh Trehan, Dr. Ravi R. Kasliwal, Dr. Balbir Singh, Dr. Randhir Sud and documentary evidence. All the parties have filed their short synopsis.

**13.** Dr. Dilip Mathur (husband of complainant-3) filed a complaint before Medical Council of India against the erring doctors of Bhardwaj Nursing & Maternity Homes, Fortis Escorts Heart Institute (except Dr. Peeyush Jain) and Medanta, The Medicity, for taking disciplinary action against them on 24.06.2013 (received on 16.08.2013). Medical Council of India referred the complaint to Delhi Medical Council, vide letter dated 03.09.2013, for consideration and taking action. The Disciplinary Committee of Delhi Medical Council, after hearing the parties, by its order dated 03.06.2014, exonerated all the treating doctors from the charges. The order was approved by Delhi Medical Council in its meeting dated 04.06.2014 and order dated 10.06.2014 was passed accordingly. Dr. Dilip Mathur filed an appeal from the order dated 10.06.2014, before Medical Council of India. The appeal was placed before Ethics Committee. Ethics Committee, without disclosing the name of the patient, sought for an expert opinion of (i) The Head of Department of Cardiology, All India Institute of Medical Sciences, New Delhi. (ii) The Head of Department of Cardiology, G.B. Pant Hospital, New Delhi. (iii) The Head of Department of Cardiology, Postgraduate

Institute of Medical Education & Research, Chandigarh, and (iv) The Head of Department of Intensive/Critical Care Medicine, AIIMS/PGI, Chandigarh. Prof. Yash Pal Sharma, Head of Department of Cardiology, Postgraduate Institute of Medical Education & Research, Chandigarh, vide letter dated 04.04.2015, gave his opinion. However, other members did not give their opinion. Ethics Committee Therefore formed another Sub-Committee of (i) The Head of Department of Cardiology, All India Institute of Medical Sciences, New Delhi. (ii) Prof. B. Ramesh, Department of Cardiology, Sri Jayadeva Institute of Cardiology, Bangalore. (iii) Prof. D. Rajasekhar, Department of Cardiology, Sri Venkateswara Institute of Medical Sciences, Tirupati. (iv) Prof. B.P. Singh, Head of Department of Cardiology, Indira Gandhi Institute of Medical Sciences, Shekhpura, Patna and (v) Prof. R.K. Gokhroo, Department of Cardiology, Jawaharlal Nehru Medical College, Ajmer, Rajasthan. Sub-Committee in its meeting decided to form another committee consisting of specialist of different disciplines and formed other Sub-Committee consisting of (i) Prof. D. Rajasekhar, Department of Cardiology, Sri Venkateswara Institute of Medical Sciences, Tirupati. (ii) Dr. J.V. Divatia, Professor of Anaesthesia & Critical Care, Tata Memorial Centre, Mumbai. (iii) Prof. Rupam Borgohain, Department of Neurology, Nizam Institute of Sciences, Punjagutta, Hyderabad. (iv) Dr. Nitin Kumar Kabra, Professor of Cardiology, Gandhi Medical College, Hyderabad. (v) Prof. Prabhakar B., Head of Department of Gastroenterology, Osmania Medical College, Koli, Hyderabad. Out of whom, Dr. J.V. Divatia, Prof. Rupam Borgohain and Dr. Nitin Kumar Kabra attended the meeting dated 24.06.2015 and held that the treating doctors had not committed any negligence. Ethics Committee approved the opinion of the Sub-Committee, in its meeting dated 6<sup>th</sup> & 7<sup>th</sup> July, 2015, which was approved by Executive Committee on 21.09.2015 and the appeal was dismissed.

**14.** Dr. Dilip Mathur and the complainants challenged the order of Medical Council of India dated 21.09.2015, in Writ Petition (C) No.2710 of 2016, before Delhi High Court, which was disposed of vide order dated 11.10.2017, directing Medical Council of India to constitute a three members Committee of Head of Departments in the subject of Cardiology, Gastroenterology and Anaesthesia of All India Institute of Medical Sciences or PGI Chandigarh to give its opinion on the issue “Whether the drug Dabigatran ought to have been administered to a patient suffering from chronic liver disease?”. In compliance of the order dated 11.10.2017, Medical Council of India formed a three members Committee consisting of (i) Prof. A. Saraya, Head of Department of Gastroenterology, (ii) Prof. S. Rajeshwari, Head of Department of Anaesthesia and (iii) Prof. R. Narang, Cardiology, all of All India Institute of Medical Sciences, New Delhi. They submitted their report dated 14.08.2019. Ethics Committee in its meeting dated 02.11.2019, accepted the report and exonerated the treating doctors, which has been approved by Board of Governors, in supersession of Medical Council of India, by letter dated 24.02.2020. Dr. Dilip Mathur has filed CM No.5614 of 2020 in Writ Petition (C) No.2710 of 2016, challenging the report dated 14.08.2019, decision of Ethics Committee in its meeting dated 02.11.2019 and decision of Board of Governors, In Supersession of Medical Council of India, dated 24.02.2020.

### **Observations and Discussion:**

**15.** We have considered the arguments of the counsel for the parties and examined the record. Let us go through the health record and the chronology of treatment taken by of



Justice J.S.Verma from November, 2012 till his death. For the convenience Justice J.S.Verma is referred to be as 'Patient')

**15.1** Admittedly, on 30.11.2012, Justice J.S.Verma underwent **complete Executive Check-up at Fortis Escort Hospital (OP-4)**. The complainants alleged the Liver Function Tests (LFT) showed significant abnormal liver functions. On 19.12.2012 aforesaid reports were seen by Dr. Peeyush Jain (OP-5) at Fortis Escorts Hospital, though significant abnormal LFT being detected, he ought to have advised for Ultrasound or Gastroenterology tests, to ascertain the reason and proceed with the further effective treatment. He did not show a minimal responsibility and cared to go through it. Dr. Peeyush Jain (opposite party-5) has denied these allegations and stated that the patient met him for the first time on 05.12.2012 at OP-4 and informed that he had coronary artery disease but he was asymptomatic on medical therapy. He was advised for a complete cardiac check-up on a later date as he was not in a fasting state on that day. Thereafter, he reported back on 19.12.2012 to share a set of investigations conducted at OP-1 (Bhardwaj Nursing and Maternity Home) nearly three weeks back. The reports were examined and documented in OPD booklet and advice was given on the basis of these reports.

15.1.2 We have perused the LFT report. It revealed SGOT (AST) 84 u/L (reference range 0-40 u/L) and SGPT (ALT) 53 u/L (reference rage 0-40 u/L). The values were raised mild to borderline beyond reference range. According to the literature liver enzymes less than 3 times above upper limit of normal are considered to be clinical insignificant. There was mild rise in indirect bilirubin (2.1 mg%) which is also known to occur on statin therapy, particularly Simvastatin, that the patient had been taking. Despite all evidence contrary to active liver disease, the patient was asked to follow up review after six months. Abdominal ultrasound (USG) was not suggested because it is recommended in patient with asymptomatic rise in liver transaminases (SGOT/SGPT) if patient show cholestatic picture and has chronically abnormal liver tests. In the instant case there was marginal rise of liver enzymes and bilirubin due to statin therapy which the patient had been taking. A positive diagnosis of chronic hepatitis can only be made when abnormal liver function tests, particularly transaminase elevation, persist for at least 6 months. As Justice J.S. Verma was continuously taking medicines of coronary artery disease as such increase of bilirubin, SGOT and SGPT were due to the drug effect. He was advised to follow-up after six months. Therefore, in our considered view, negligence cannot be attributed to Dr. Piyush Jain (OP-5).

**15.2** Secondly on 12.03.2013 the patient was admitted in OP-1 Bharadwaj. He was examined by the physician Dr. V.A. Bharadwaj (OP-3) and Cardiologist Dr. Sanjiv Bharadwaj (OP-2) who detected atrial fibrillation (irregular heart rhythm). Various tests including the LFT and Clotting Tests were performed. It was alleged that despite significantly deranged liver function and abnormal blood coagulation (Clotting) the OP-2 Dr. Sanjiv Bharadwaj negligently prescribed a tablet Dabigartan (Pradaxa) along with a combination of Clopidogrel and Amiodarone. It was the failure of duty of care from the OP-2. The Clopidogrel is known to be antiplatelet drug and Amiodarone is associated with hepatotoxicity (liver toxicity). Amiodarone is known to have drug interaction with the anticoagulant Dabigatran, by increasing its plasma concentration with the risk of causing fatal bleeding.

15.2.1 Dr. Sanjiv Bhardwaj (OP-3) stated that at the time of admission, the patient had documented Atrial Fibrillation (irregular heart rhythm with fast ventricular response and hypotension). His BP was 80/60; pulse 180/min, irregular. He did not have any evidence of angina or congestive heart failure. He was admitted to ICU and he prescribed IV fluids Injection, Cordarone Injection, Heparin to control his Atrial Fibrillation.

15.2.2 We have carefully perused the LFT report dated 12.03.2013. It showed mild rise in bilirubin and liver transaminases (SGOT & SGPT). The coagulation profile did not show gross abnormality. Admittedly as discussed before the patient was on the long term Statin therapy. Moreover, during hospitalisation in OP-1 hospital there was no evidence of any bleeding from piles, no gastrointestinal symptoms.

15.2.3 It is pertinent to note that on 12.03.2013 as there was no evidence of abnormal liver function and impaired blood clotting. His BP was 80/60; pulse 180/min, irregular and Hb 11.4 gm%; in order to control Atrial Fibrillation, medicine Dabigatran (Pradaxa) was advised. After discharge from hospital on 14.03.2013, the patient was reviewed on 21.03.2013. The patient did not complain any upper GI bleeding or from piles.

15.2.4 From the documented literature and the text books on Cardiology, Internal Medicines and Pharmacology, the drug Dabigartan is metabolized in Kidney, therefore as far as there is no severe liver impairment, it can be given in full dose.

15.2.5. The Dabigartan is a direct thrombin inhibitor and a very safe drug, half-life of twelve hours, eight percent renal clearance; Dabigartan has the largest and longest experience. The said drug has advantages over warfarin like rapidly effectively, does not interact with any food/medication, does not require monitoring and associated with lower risk of ischemic stroke.

15.2.6. Amiodarone is a class-III anti-arrhythmic agent and is a very safe drug and liver toxicity occurs at a rate of 0.6% annually and only on long term Amiodarone therapy. No contraindication to Amiodarone in the patients who have marginally raised transaminases. Amiodarone has no drug interaction with Dabigartan and it does not cause any increased risk of bleed as documented in RELY trial. No requirement of dose adjustment with Amiodarone.

15.2.7. It is pertinent to note that in the RELY trial, Dabigartan 110 mg BD lowest dose was non-inferior to warfarin with significantly lower risk of bleeding compared to higher dose of Dabigartan 150mg BD. In patients who are on Dabigartan there is no need to monitor any coagulation parameters like PTTK and PT. Since the patient's renal function was normal there was no requirement of adjusting the patient's dose and the patient was on the lowest dose of Dabigartan 110 mg which is effective for preventing stroke with no risk of bleeding. Dabigartan is a very safe drug.

Thus, at the relevant stage we do not find any negligence on the part of OP-1 and the treating doctors OP-2 & 3.

**16.** The Complainants alleged third incidence of negligence during hospitalisation to Fortis (OP-4) on 17.04.2013 till his shifting to Medanta Hospital (OP-6).

16.1 On 17.04.2013 admission to Fortis (OP-4) at 15:00 hours, the patient was under the treatment and care of Dr. Sanjiv Bhardwaj with severe upper gastrointestinal bleeding. It was alleged that endoscopy was delayed in spite of the continuous bleeding. An endoscopy was done in morning on 18.04.2013 i.e. after 16 hours of his hospitalization. Dr. Sanjiv Agrawal, stated that at the time of admission, the condition of patient was not fit for endoscopy, haemoglobin was 7.6 mg, therefore endoscopy was delayed.

16.2 The medical record revealed that at Fortis Escorts (OP-4) after admission on 17.04.2013, urgent Gastroenterology consultation and Critical Care Team consultation was done. The treatment was started with 4 units of packed RBC and 2 FFP were transfused on the same day over 24 hours. His ultrasound revealed cirrhosis liver, chronic liver disease, Cholelithiasis, ascites, which were documented for the first time and no such symptom relating to chronic liver disease were recorded earlier. Daily ABG was done, which revealed serum ionized calcium 0.9 which is normal and a better indicator than serum calcium. On 18.04.2013, when haemoglobin was increased to 10.4g%, then Upper GI Endoscopy was done which revealed grade III bleeding Oesophageal varices, portal hypertension, gastritis and duodenitis.

17. The next point for our consideration is that instead of taking steps to detect the source of bleeding and clip, Dr. Sanjiv Bharadwaj administered negligently six units of blood and six units of fresh frozen plasma (FFP). Thus, the multiple transfusions at Fortis Escorts (OP-4) caused fluid overload in lungs. It resulted in acute breathing problem. The Citrate in the transfused blood and plasma bound calcium in the blood and led to hypocalcaemia ( low Calcium level). ECG showed prolonged QTc interval, due to hypocalcaemia which was a precursor of fatal cardiac rhythm abnormality.

17.1 The daily ABG estimation revealed serum ionized Calcium 0.9 (normal 1.15-1.29), is not very low. The patient was transfused packed RBC to increase Haemoglobin while Fresh Frozen Plasma was infused to dilute the side effect of Dabigatran as at that time there was no antidote of Dabigatran. On 19.04.2013, the patient was haemodynamically stable, BP 110/80, pulse 100/min. He was in atrial fibrillation. There was no signs of fluid overload. The patient was shifted to Medanta on 19.04.2013 and at time of admission the patient had difficulty in respiration, which does not mean fluid overload only. Therefore in our view there was no negligence at OP-4 during treatment.

18. The complainants alleged negligence at Medanta and the treating doctors (opposite parties-6 to 10) as below:

18.1 There were poor attempts to correct the hypocalcemia. As recorded in the nurses reports the 1<sup>st</sup> injection of Calcium Chloride was given at 4:45 PM and 2<sup>nd</sup> at 8:10 PM. Despite the claim that Calcium was given twice at interval of more than 3 hours, the ionised Ca remained very significantly low and uncorrected at 0.75 mmol/l at 9.18 pm at the time of the cardiac event, leading to the cardiac arrest.

18.2 The another allegation was the failure to intubate on arrival. Arterial blood gases done at 4.50 PM soon after arrival at Medanta Hospital showed low levels of Calcium 0.98 (normal 1.15-1.29). The ECG showed significant changes, with QTc prolongation, changes consistent with low blood calcium levels which are a precursor of impending cardiac

arrhythmias (catastrophic irregular heart rhythm), and also with evidence of ischemia suggesting reduced blood supply to the heart. There were poor attempts at correcting the hypocalcemia.

18.3 We note that the first documented cardiology review was done at 6 PM by Dr Balbir Singh; an hour and 15 minutes after patient was admitted to ICU at Medanta Hospital. It is documented by Dr Balbir Singh that an episode of Torsade's de Pointes (TdP) was seen. He prescribed Injection Magnesium which given at 7 pm, but it was to be given immediately. There was no further repeat dose of Magnesium given as was required, as per the recommendation for prevention and management of TdP. It was not repeated until after at 09.30 pm on 19.04.13 after already patient had the cardiac arrest due to alleged failure to provide adequate treatment for TdP, a reversible cause.

18.4 There was failure to repeat Magnesium bolus doses and start the infusion. Only one dose was given at 7 pm after it was prescribed at 6 pm. The standard regimen consists of 2 gm IV bolus of 50% Magnesium Sulphate over 1-2 minutes followed in 15 minutes by another such bolus and even a 3-20 mg/min continuous infusion if required. IV Magnesium Sulphate is a first line therapy, being highly effective for both the treatment and prevention of recurrence of long QT related ventricular ectopic beats or TdP.

19. In response the Opposite party-6 to 10 stated that after admission, the patient was shifted to ICU, where he was immediately attended by a team of doctors namely Dr. Randhir Sud, Chairman, Digestive and Hepatobiliary Science, Dr. Yatin Mehta, Chairman, Critical Care Medicine, Dr. Deepak Govil, Associate Director of Critical Care Medicine and Dr. Balbir Singh, Chairman, Division of Electrophysiology. Patient's condition was discussed with Dr. R.R. Kasliwal on telephone, who ordered for an urgent Echocardiography. His pulse was 126/min and irregular due to atrial fibrillation, blood pressure was 102/57 mm of Hg on infusion of Inj. Noradrenaline, his SPO2 was 93%; and respiratory rate of 22 /min on 5 litres of Oxygen through face mask. The patient was given injection Somatostatin, which were continued and injection Monocef was changed to injection Cefotaxime.

19.1. The Arterial Blood Gases (ABG) were done at 16:50 hours, which showed hypoxemia with Pao<sub>2</sub> of 66 mmHg (range 83-108) and high Lactate levels of 2.9 (rage 0.5-1.6), ionic calcium level of 0.98 mmol/litre. That 2gm of calcium chloride was administered to the patient in 50 ml of infusion immediately after admission before 5 PM. The patient had an episode of un-sustained Torsade's de Pointes (TdP) (Ventricular Rhythm Disturbance) with pulse at 149/minute. It was advised to start injection Esmolol and injection Magnesium Sulphate to maintain the Serum Potassium. The patient passed malenic stools at 5 PM and at 6 PM Magnesium was given. The patient's blood was taken further several investigations, culture and sensitivity of urine and blood were done. Also ECHO, USG abdomen, ECG and X-ray chest were done.

19.2 The lab reports showed Magnesium and Potassium to be within normal range. The chest X-ray showed bilateral opacities in mid & lower zones, possibly Aspiration Pneumonitis. At 7 pm the episode of TdP got resolved and the pulse was restored to 107/min, BP was stabilised at 8 pm. The injection Esmolol and injection Calcium Chloride were administered. The following chart shows the details of Mg & Ca administration.

Investigation	Reports	Levels	Medication administered
Magnesium	0520 PM	1.9 mg/dl (range 1.6 - 2.3)	On infusion
	0230 AM	2.7 mg/dl	
Calcium	0450 PM	0.98 mmol/L (range 1.15- 1.29)	Inj.Calcium Chloride: - 2 gm given before 0500 PM; - 2 gm given at 0800 PM; - 1 gm given at 0930 PM.
	0800 PM	7.0 mg/dl (range 8.4 -10.2)	
	0918 PM	0.75 mmol/L (range 1.15 - 1.29)	
	0934 PM	1.38 mmol/L (range 1.15 - 1.29)	
Potassium	1240 AM	1.56 mmol/L (range 1.15 - 1.29)	On infusion
	0520 PM	3.6 mmol/L (range 3.5 - 5.1)	
	0230 AM	4.4 mmol/L (range 3.5 - 5.1)	

The Lab Reports & Medication Chart and ICU flow sheet:

## 20. Opinion of Professional Regulatory bodies:

20.1 The Delhi Medical Council (DMC) and Medical Council of India (MCI) have considered all the aspects on two occasions and found that there was no negligence on the part of the treating doctors at any stage as alleged.

20.1.1 The Delhi Medical Council vide its Order dated 10.06.2014, held that no negligence can be attributed on the part of the doctors of the Bhardwaj Hospital, Fortis Escorts Institute and the Medanta Hospital, in the treatment administered to the Patient.

20.1.2. The Order dated 10.06.2014, was challenged by the Complainant before the MCI . The MCI vide Order dated 10.10.2015, rejected the appeal filed by Dr. Dilip Mathur and upheld the decision of the Delhi Medical Council.

## 21. Law on Medical Negligence:

In the catena of judgments of the Hon'ble Supreme Court and courts worldwide medical negligence has been discussed. The Hon'ble Supreme Court in **Jacob Mathew<sup>[1]</sup>, Malay Kumar Ganguly<sup>[2]</sup> and Kusum Sharma<sup>[3]</sup>** cases it was held that, no negligence in case of any deviation from normal practice or any accident, any error of judgement through any professional or any patient does not favourably responded to the treatment. The doctor would not be held liable for negligence if his diagnosis is different from other fellow doctor or he treats patient from other method and taking any higher element of risk but could not save patient.

21.1 To bring successful claim the victim or victim's family bringing the action must prove **all** the “**four D's**” against the erring doctor/hospital. The **4 D's** of medical negligence stand for ‘**Duty**’, ‘**Dereliction/Deviation**’, ‘**Direct (proximate) Cause**’ and ‘**Damages**’. In the instant case the complainant's failed to prove the dereliction of duty of care from the OPs and the same was not a proximate cause of death of Justice J.S. Verma.

21.2. In the instant case, Justice J. S. Verma was Class-I indication for Dabigartan because he suffered atrial fibrillation and he was at a very high risk of stroke because of his multiple co-morbidity HT, DM, bleeding piles, carotid artery disease. Moreover, Dabigartan was given in the lowest dose of 110 mg BD as recommended and the patient had only marginally raised transaminases and PTTK was within normal range. No interaction of Dabigartan with Amiodarone and clopidogrel. Therefore, in our view, the bleeding occurred was not due to Dabigartan, but it was due to chronic liver disease (asymptomatic) and grade 3 esophageal varices and caused active bleeding. Subsequently, the patient developed multiple organ failure.

21.3. As per our calculation from lab reports, the Calculated GFR of the patient at that point was 65, it was better; despite that the Dabigartan was prescribed in lower dose of 110 mg BD, which will never cause any side effects. This cannot be an incriminate the higher dose. It should be borne in mind that due to Atrial Fibrillation, there are more chances of patient suffering from stroke due to left atrial thrombo-embolism. The (CHADS<sub>2</sub>) score<sup>[4]</sup> is used to predict the need for oral anticoagulation for stroke prophylaxis in patients with atrial fibrillation. The CHADs score related to the patient's Congestive heart failure, Hypertension, Age ≥ 75 years, Diabetes mellitus, Stroke, Vascular disease, Age 65–74 years. Thus it the CHA<sub>2</sub>DS<sub>2</sub>-VASc score alters anticoagulation recommendations. In our considered view, prescribing two anticoagulants to the instant patient was an accepted reasonable standard. Thus, there was no negligence.

21.4. The increased Alpha-Fetoprotein (AFP) values were due to Chronic Liver Disease and cirrhosis. Thus patient bled due to esophageal varices.

21.5. On perusal of ECHO shows the evidence of Cardiac Dysfunction. The LVEF was 45. The blood investigations dated 20/04/2013 revealed very high **NT Pro BNP 15600 pg/mL** (normal 0 – 450), the high **Creatinine phosphokinase (CPK) – 237 u/lit**. The **Tropinin I was 20,100 ng/mL** (normal upto 0.120).

21.6. Moreover as discussed above for citrate toxicity, adequate doses of IV Mg & Ca were given. The patient developed systemic infection, which was evident from high-procalcitonin

(0.57 ng/mL), high C-reactive protein (52.7 mg/ ltr.)

22. We would like to rely upon the case - **Achutrao Haribhau Khodwa and others V State of Maharashtra and others**<sup>[5]</sup>, wherein the Hon'ble Supreme Court held that:

“The skill of medical practitioners differs from doctor to doctor. The very nature of the profession is such that there may be more than one course of treatment which may be advisable for treating a patient. Courts would indeed be slow in attributing negligence on the part of a doctor if he has performed his duties to the best of his ability and with due care and caution. Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient, but as long as a doctor acts in a manner which is acceptable to the medical profession, and the Court finds that he has attended on the patient with due care skill and diligence and **if the patient still does not survive or suffers a permanent ailment**, it would be difficult to hold the doctor to be guilty of negligence.”

22.1 In the recent judgment of the Hon'ble Supreme Court in the case of **Chanda Rani Akhouri vs M.S.Methusethupathi Mithupathi**<sup>[6]</sup>, it was held that:

27. It clearly emerges from the exposition of law that a medical practitioner is not to be held liable simply because things went wrong from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference to another. In the practice of medicine, there could be varying approaches of treatment. There could be a genuine difference of opinion. However, while adopting a course of treatment, the duty cast upon the medical practitioner is that he must ensure that the medical protocol being followed by him is to the best of his skill and with competence at his command. At the given time, medical practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field.

23. In the instant case, the standard medical protocols being followed by the all opposite parties, it was neither failure of duty of care nor any deficiency from the OPs. Prescribing Dabigartan was not wrong decision (*refer para- 23*), it was in the interest of the patient to save him from the cerebral stroke. Justice J.S.Verma, who was elderly (80 yrs) with multiple co-morbidities including Chronic Liver Dysfunction and mid-range ejection fraction (40-45%), Grade III esophageal varices; all these factors contributed to mortality. The death of Justice J.S.Verma was not attributable to the act of OPs. We have deep sympathies with the death of Justice J S Verma, but it cannot be ground for liability.

The Complaint fails, it is dismissed. The parties shall bear their own costs.

The Registry is directed to send free copies of this Order to the Complainant and the Opposite Parties within one week from today.

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[1] (2005) 6 SSC 1

[2] (2009) 3 SCC 663

[3] (2010) 3 SCC 480

[4] Am J Med. 2012 Jun;125(6):603.

[5] (1996) 2 SCC 634

[6] (2021) 10 SCC 291

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**DR. S.M. KANTIKAR**  
**PRESIDING MEMBER**

.....J  
**RAM SURAT RAM MAURYA**  
**MEMBER**

.....  
**DR. INDER JIT SINGH**  
**MEMBER**