Ambalal D. Bhatt

Vs

The State of Gujarat

Criminal Appeal No. 116 Of 1969

(H. R. Khanna, P. jagmohan Reddy, J, M Shelat JJ)

07.03.1972

JUDGMENT

JAGANMOHAN REDDY, J -

1. The appellant (original accused No. 2), a Chemist Incharge of the Injection Department of Sanitax Chemical Industries Ltd., Baroda (hereinafter referred to as S.C. I. Ltd.), along with five others was charged under Section 304-A, I.P.C. for rashly and negligently manufacturing a solution of glucose in normal saline batch No. 211105 which contained more than the permitted quantity of lead nitrate as a result of which 13 persons, to whom it was administered, died. At the relevant time the first accused K. K. Prabhakaran was the Chief Analyst of the Testing Laboratory, accused R. M. Patel the third accused was the Works Superintendent, S. J. Mehta and fourth accused was Production Superintendent, Manibhai B. Amin, Proprietor of M/s. M. B. Amin & Co., Baroda, the fifth accused was the Managing Director, and H. M. Amin, the sixth accused, the son of the fifth accused was a Director and Partner of S.C.I. Ltd. It was alleged that all these accused were responsible for the manufacture of the aforesaid solution contrary to the provisions of the Drug Control Act and Rules and for the sale of it. The Trial Court convicted the appellant and K. K. Prabhakaran, the first accused and sentenced each of them to rigorous imprisonment of eight months and a fine of Rs. 100/-, in default to serve 15 days' rigorous imprisonment. It acquitted the other accused. Against this conviction and sentence both the accused filed separate appeals before the Additional Sessions Judge, Baroda who acquitted them of the offences with which they were charged. The State of Gujarat appealed against the acquittal of both these accused. The High Court convicted the appellant and sentenced him to eight months' rigorous imprisonment as awarded by the Trial Court but imposed no fine. The first accused was, however, acquitted. Against that judgment this appeal is by certificate under Article 134(1)(c) of the Constitution.

2. A few of the relevant facts as alleged by the prosecution are not really in dispute. S.C.I. Ltd., prepares glucose in normal saline, a solution containing dextrose, distilled water and sodium chloride (popularly known as common salt). It appears that sodium chloride contains certain quantities of lead nitrate but according to the American Pharmacopoeia, which is one of the Pharmacopoeias recognised by the Rules under the Act according to which drugs can be manufactured lead nitrate of five parts in 1 million is the permissible limit, which works out to 000005%. The evidence shows that in order to prepare glucose in normal saline of the standard quality, 5% of dextrose and 9% of sodium chloride are required to be dissolved in distilled water which is absolutely sterile and free from germs and bacteria. The solution thus prepared is meant for being injected into or given by drip to patients. The Production Report, dated November 12, 1962, Ext. 165, shows that 2.34 kg. of sodium chloride and 13 kgs. of dextrose with bidistilled water was utilised for preparing the solution of glucose in normal saline which was filled in 450 bottles, each

of which contained 540 c.c. of the solution. The report further mentions in the column details of Manufacture and Progress Report, the following :

> "In about 70L. boiled bidistilled water 4.0 kg. dextrose dissolved. Stirred well, volume made up to 80L. Similarly two more lots each of 80L. Soln. prepared. 20L. prepared separately. Total 260L. Soln. prepared."

In this way each batch of 80 litres was filled in 100 bottles and the 5th batch in 50 bottles. Out of these 450 bottles some were rejected. Out of the remaining 394 bottles, 8 bottles were taken for analysis on November 13, 1962, and the remainder were packed for sale. The report in respect of the 8 bottles taken for analysis was received on November 29, 1962, from the first accused. It will appear that contrary to the mandatory requirements prescribed in Rule 96(v) of the Drug Rules made under the Drugs Act, 1940, each of the lots of 80 litres of solution manufactured, was not given a separate batch number but all the 5 lots consisting of 394 bottles were given as aforesaid only one batch No. 211105. In view of this, the analysis of only 8 bottles from the several lots could not indicate the quantity of lead nitrate in all the 5 lots. In the normal course, some of the bottles which were sold by the company were purchased by different hospitals, nursing homes and medical practitioners and were administered to several patients of whom 13 persons died. Immediately after these deaths, a report having been made by the doctors who administered that they suspected adulteration or contamination of the solution, that batch was withdrawn and about 125 bottles were sent for analysis by the Government Analyst. Out of these, 51 bottles alone showed the contents to be of requisite standard prescribed under the Drugs Act with permissible deviation from the standards but the remainder disclosed lead nitrate very much over the permissible limits and was dangerous to human life. The High Court after considering the several exhibits regarding the issue of sodium chloride by the Stores to the Injection Department, and the Registers of the Injection Department maintained by the appellant, came to the conclusion that on November 11, 1962, there was only 15 grams of sodium chloride in the Injection Department, and thereafter 5 kg. was received from the Stores Department by the appellant on November 23, 1962. As against this, Ext. 164 shows that he had utilised 2.340 kgs. of sodium chloride for preparing this solution of batch No. 211105. It further held that the production report shows that the 450 bottles were prepared on November 12, 1962, but as a matter of fact, according to Ext. 232, the Injection Batch Book, the entire lot of 450 bottles was not prepared on one and the same day. 106 bottles of that batch were filled and sealed on November 10, 1962, and the remaining 344 bottles were filled and sealed on November 12, 1962. In view of these facts, the High Court observed as follows :

> "The only possible conclusion that one can reach from the material disclosed by the various exhibits was that the appellant had used 2,340 kgs. of sodium chloride from a source or sources unknown as such there was a lack of homogeneity in the solution prepared by him."

3. The explanation of the accused that there was a practice in the company of using the solutions contained in bottles rejected on the ground of dust when goods or drugs of the same kind came to be prepared later on was not accepted as being incompatible and inconsistent with the entries made by him in Ext. 164 and was a pure afterthought. It was further held that the appellant has not been able to show the source from which sodium chloride weighing 2.340 kgs. was obtained by him for preparing glucose in normal saline of batch No. 211105, and that the only possible conclusion of this negligence of the accused is that it was the cause of the death of 12 individuals who, it has been established, died because of the administration of contaminated drug. With respect to the death of the 13th person, there was no clear finding that his death was due to the administration of the

glucose in normal saline of batch. No. 211105.

4. We may in passant mention that the learned Advocate for the appellant referred to prosecution of 10 accused including the appellant, the Store Keeper Vaghjibhai and the Chief Analyst Prabhakaran the first accused for the contravention of the Drugs Act. The appellant and the first accused were charged with contravention of Rules 78(c), 109(c), 111, 114(h), 115 and 121(a) which are offences under Sections 18(a)(i) and 18(a)(v) of the Drugs Act punishable under Section 27 of that Act. Vaghjibhai was charged with the contravention of Rule 121(a), an offence under Section 18(a)(v) punishable under Section 27 of the Act. We were also informed that all of them were ultimately acquitted of these charges. Through the charge-sheet has been filed before us, no copy of the judgment has been brought to our notice. That there was a prosecution for the offences under the Drugs Act is mentioned by the appellant in his statement under Section 342, Cr. P. C. to the question that he along with other accused got the drug in question manufactured with with culpable negligence for the purpose of administering to human beings in culpable violation of the provision of the Drugs Act and Rules which he was bound to follow. The learned Advocate for the appellant, however, states that even assuming that there was a contravention of the relevant rules, any lapse on the part of the appellant to conform to them is not the direct cause of the death of the 12 persons so as to make him liable to punishment under Section 304-A.

5. Before we deal with the several aspects of the contentions urged before us, it is necessary to notice that under the Drugs Rules (hereinafter called 'the Rules') made under the Drugs Act (hereinafter termed 'the Act') which were in force during the relevant period when batch No. 211105 was prepared, certain tests have to be carried out, records maintained and inspection was to be allowed to the inspector authorised in that behalf in respect of the preparation of the drug. No drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Under Rule 76, a licence to manufacture for sale of drugs specified in Schedules C and C(1) has to be issued in Form 28. It is not denied that glucose in saline preparation falls under these schedules. Before a licence in Form 28 is granted or renewed, the conditions to be complied with have been set out. Under the conditions the manufacture will have to be conducted under the active directions and personal supervision of competent technical staff consisting at least of one person who is a whole-time employee and who is qualified as provided in (a) to (e) of sub-rule (1). Sub-rule (4) of the rule deals with the maintenance of adequate staff, etc., for carrying out all tests of strength, quality and purity of the substances as may be required to be carried out by him under the provisions of Part X of the Rules, provided that the manufacturing unit shall be separate from the testing unit and that the head of the testing unit shall be independent of the head of the manufacturing unit. Rule 78 says that the licence in Form 28 shall be subject to the special conditions, if any, set out in Schedule F which relate to the substance in respect of which the licence is granted and to the general conditions specified in (a) to (1) of that Rule. Clause (c) states that a licensee shall keep records of the details of manufacture of each batch of the substance which is issued for sale and of the application of the tests thereto in such form as to be available for inspection and to be easily identified by reference to the number of the batch as shown on the label of each container, etc. Clauses (d) and (e) deal with the duty of the licensee to allow Inspectors authorised by the licensing authority to inspect the premises without prior notice and also to inspect all registers and records, etc., maintained under the Rules. Under clause (g) the licensee shall on request furnish to the licensing authority or such other authority as the licensing authority may direct from every batch of substance or from such batch or batches as the licensing authority may from time to time specify, a sample of such amount as the authority may consider adequate for any examination required to be made and the licensee shall, if so required, furnish full protocols of the tests which have been applied. Clauses (h) and (i) deal with

the restrictions to sell or offer for sale any batch in respect of which a prohibition has been imposed by the licensing authority and if so directed, to withdraw the remainder of the batch from sale or recall all issues of that batch in so far as it is practicable. Under clause (j) no drug manufactured under the licence shall be sold unless the precautions necessary for preserving its properties have been observed throughout the period after manufacture. Rule 96 deals with the manner of labelling. Clause (v) of sub-rule (1) of the said rule provides as follows :

> "Every drug manufactured in India shall bear on its label a distinctive batch number, that is to say, the number by reference to which details of manufactures of the particular batch from which the substance in the container is taken are recorded and are available for inspection; the figure representing the batch number being preceded by the words 'Batch No.' or 'Batch' or 'Lot Number', 'Lot No.' or 'Lot' or any distinguishing prefix".

6. Rule 109(1)(c) which is in Part X dealing with the special provisions regarding biological and other special products, is similar to Rule 96(v) and refers to labelling. Schedule F which applies to Rule 78 and Part X gives the tests to be performed in respect of various preparations of which Part IX deals with preparations in a form to be administered parenterally and these are, that the preparation shall be in a container which precludes the access of bacteria; that the composition of the preparation shall be in accordance with the composition stated on the label, such deviation as may be allowed in the composition of the preparation shall be fixed by the licensing authority; that the preparation shall comply with tests for sterility; that the water used in the manufacture of parenteral preparations shall comply with the tests for pyrogens; and that if the container is made of glass, the glass shall pass the tests for limit of alkalinity in glass laid down in the British Pharmacopoeia.

7. A reading of these rules would show (1) that a batch number is to be given for every lot of the preparation; (2) that the preparation has to be tested and analysed and records maintained with the protocols; (3) that they must be properly labelled and the constituents specified therein; (4) that the test should be conducted in accordance with the requirements specified in respect of a particular preparation. Though we have not before us the conditions of the licence to see what special directions have been given thereunder, the effect of all the precautions required to be taken under the rules is that the materials used in the preparation of the solution should also be tested before use. At any rate, as we shall see, the company understood them to impose that duty and the Chief Analyst was required to test the materials before they are issued to the injection department for the preparation of glucose saline solution.

8. The learned Advocate contends that even if one batch number was given to several lots prepared on November 12, 1962, as was done in respect of batch no. 211105, the evidence discloses that this was not an isolated case but such practice was uniformlly followed in S.C.I. Ltd., for which the appellant could not alone be held liable. In the circumstances the non-compliance with the rules for giving a batch number to every lot does not make the act of the appellant the causa causans of the death of the persons who were injected with glucose saline prepared by him because it was not only the duty of the Analyst Prabhakaran to test the materials before they are issued to the injection department but also to test the solution in such a way as would trace lead nitrate in the sodium chloride content of the solution. As Prabhakaran had not applied the proper test and that too knowing fully well that several lots were given one batch number, he cannot be absolved of his responsibility to take representative samples for testing them instead of testing only one bottle out of 450 bottles comprising batch No. 211105. On this premise it is contended that though Section 304-A

covers various fields of activity, an offence is committed only if a person charged is shown to have neglected to take to avoid injury to others and that such reasonable steps that are expected to be taken by him should show that there was a failure to take such elementary steps it was necessary for him to take. Inasmuch as in all cases under Section 304-A there is a causal chain which consists of many links, it is only that which contributes to the cause of all causes, namely, the causa causans and not cause sine qua non which fixes the culpability. In other words, it is submitted that it is not enough for the prosecution to show that the appellants' action was one of the causes of death. It must show that it is the direct consequence, which in this case has not been established. On the other hand, according to the learned Advocate the appellant is separated by two important steps which intervene before the glucose saline is sold for being administered to the needy. These are : (1) that not only should the materials be tested by the solution should be tested properly to detect the dangerous components of the preparation which was the duty of the Chief Analyst; and (2) that the production report and the analysis report have to be seen by the Production Superintendent who is to satisfy himself that proper tests have been carried out before certifying them for sale. The persons who are directly responsible for the saline solution to be certified for sale are the Chief Analyst as well as the Production Superintendent and not the appellant.

9. It is, however, the case of the respondent State that had the appellant not given a single batch number to all the four lots which he prepared the offending glucose saline, the analysis by the Chief Analyst would have certainly discovered the heavy deposits of lead nitrate in the sodium chloride and the lot which contained this would have been rejected. As the appellant has been negligent in conforming to the rules, the deaths were the direct consequence of the negligence.

10. It appears to us that in a prosecution for an offence under Section 304-A, the mere fact that an accused contravenes certain rules or regulations in the doing of an act which causes death of another, does not establish that the death was the result of a rash or negligent act or that any such act was the proximate and efficient cause of the death. If that were so, the acquittal of the appellant for contravention of the provisions of the Act and the rules would itself have been an answer and we would have then examined to what extent additional evidence of his acquittal would have to be allowed, but since that it is not the criteria, we have to determine whether the appellant's act in giving only one batch number to all the four lots manufactured on November 12, 1962, in preparing batch No. 211105, was the cause of deaths and whether those deaths were a direct consequence of the appellants' act, that is, whether the appellants' act is the direct result of a rash and negligent act and that act was the proximate and efficient cause without the intervention of another's negligence. As observed by Sir Lawrence Jenkins in Emperor v. Omkar Rampratap, ((1902) 4 Bom LR 679) the act causing the deaths "must be the causa causans; it is not enough that it may have been the cause of sine qua non." This view has been adopted by this Court in several decisions. In Kurban Hussein Mohammedali Rangwala v. State of Maharashtra, ((1965) 2 SCR 622) the accused who had manufactured wet paints without a licence was acquitted of the charge under Section 304-A because it was held that the mere fact that he allowed the burners to be used in the same room in which varnish and turpentine were stored, even though it would be a negligent act, would not be enough to make the accused responsible for the fire which broke out. The cause of the fire was not merely the presence of the burners within the room in which varnish and turpentine were stored, though the circumstance was indirectly responsible for the fire which broke out, but was also due to the overflowing of froth out of the barrels. In Suleman Rehiman Mulani and Another v. State of Maharashtra, ((1968) 2 SCR 515) the accused who was driving a car only with a learner's licence without a trainer by his side, had injured a person. It was held that that by itself was not sufficient to warrant a conviction under Section 304-A. It would be different if it can be established as in the case of Bhalchandra alias Bapu and Another v. State of Maharashtra, ((1968) 3 SCR 766) that

deaths and injuries caused by the contravention of a prohibition in respect of the substances which are highly dangerous as in the case of explosives in a cracker factory which are considered to be of a highly hazardous and dangerous nature having sensitive composition where even friction or percussion could cause an explosion, that contravention would be the causa causans.

11. Bearing these principles in view, what we have to see is : (1) Whether there was a contravention of the rules ? If so, to what extent that contravention by the appellant contributed to the non-discovery of lead nitrate in sodium chloride content of the glucose saline in batch No. 211105 ? (2) Whether sodium chloride from which the said solution was prepared was obtained by the appellant from sources other than the Stores of S.C.I. Ltd. ? and (3) Whether the method adopted in testing the said batch by Prabhakaran would have, but for the contravention of the rules requiring the giving of one batch number to each lot, detected the presence of lead nitrate when he analysed samples of the offending batch of glucose saline prepared by the accused. The answers to these questions will determine whether the appellant's act is causa causans or has there been a cause interveniens which has broken the chain of causation so as to make his act, though a negligent one, not the immediate cause or whether it amounts to an act of gross negligence or recklessly negligent conduct. In this context it may be observed that in a case of this nature where as many as 12 persons lost their lives as a result of the parenteral administration of the drug comprised in batch No. 211105, prepared by the appellant, those deaths however shocking and regrettable they may be, ought not to allow the mind to boggle while appreciating the evidence which must necessarily be free from any such consideration.

12. There can be no doubt that in this case there has been a total disregard of the provisions of Rules 96(v) or 109(c) by the company and its officers in not giving the correct batch number to the preparations made in that company and the gross negligence of the Drug Inspector to check and bring to book the offending company and its officers with the full knowledge that the rules in respect of batch number were being openly flouted by them. The accused S. J. Mehta, Production Superintendent of S.C.I. Ltd., in his statement to the Drug Inspector said that all the batches of glucose in normal saline manufactured by S.C.I. Ltd., were prepared in 3 or 4 lots and one batch was given to the several lots and sterilisation was also made in three or four lots. More lots had to be made because they had a small vessel for preparing solution in which it is not possible to prepare a lot larger than that of 80 liters. As the capacity of autoclave is small they could not sterilise the whole batch at one time. The fact that one batch number was given to several lots is also amply borne out by the admission of K.M. Shah, P.W. 34, the Drug Inspector who says that from 1960-1962 in respect of 105 production reports of gluciline 31 of glucose, 47 of glucose in saline, 46 with glucoline with B6 there is not a single instance of the production report showing that different lots manufactured on the same day were given different batch numbers. He further states that in that company previously they used to give one batch number for the drug manufactured on different days but their Department had pointed out that defect but it is had never objected to the system of giving one batch number to different lots manufactured, on the same day. This Drug Inspector as well as the Department seem to have been fully aware that the solution vessel of S.C.I. Ltd., is of 80 litres only and each bottle of glucose in normal saline was 540 ml. In the certificate of analysis forwarded to them he admits the company was mentioning the number of bottles and size of each bottle manufactured by them and that if experienced Drugs Inspector looks at the certificate of analysis, then from the numbers of bottles and size bottles stated therein, he can make out the amount (quantity) of Drug manufactured if he concentrates on that point. Though he was directed by his Assistant Director when he took minutely about the prescribed test only, he says that he is not supposed to nose all details of certificate of analysis with concentration. The witness says that one of the objections against giving one batch number to different lots would be that each lot would not

be separately tested, and that if each lot is not separately tested then public health would be endangered. He also says that this danger would be there whether different lots are manufactured on the same day or on different days and yet says that it was not his duty to see whether the drug is manufactured in one lot of different lots, from the certificate of analysis sent to him. After this answer it was quite justifiably suggested that he was telling a lie to escape from the charge of dereliction of duty. There can, therefore, be no doubt that the Drugs Inspector has been grossly negligent in his duties and totally oblivious of the dangerous consequences to health and human life by his failure to perform his duties with care and caution. In view of these statements can it be assumed that Prabhakaran, the Chief Analyst did not know that several lots manufactured on the same day were given one batch number. We think, he must have known, though no questions were asked of him about this aspect because this practice seems to have been not only current for a long time but also appears to be well known.

13. On the facts of this case, it appears to us that the appellant was only carrying on a practice prevalent in that company of giving one batch number to the entire lot manufactured on any particular day, a practice made possible by the Drugs Inspector turning a blind eye to a serious contravention of the Drugs Rules. It is also evident that the Production Superintendent whose duty it was to check the Analyst's report and the Production Report and order the release of the preparation for sale, not only knew of the practice as admitted by him, but considered the solution safe to be sold to the public. Even according to the statement of Prabhakaran to the Drugs Inspector, a copy of his report was sent to the Drugs Inspector for obtaining release order and that after the release permission was received, one copy was sent to the injunction department. As admitted by the Drug Inspector, he has not come across any written document wherein the appellant was directed not to give same batch numbers to separate lots manufactured on the same day. When the Drugs Inspector himself knew fully well that this was the practice going on and had not lifted his little finger to prohibit the practice, to hold the appellant responsible for the contravention of the rule would be to make an attempt to somehow find a scapegoat for the deaths of the 12 persons.

14. The High Court as we stated earlier was of the view that the appellant had used 2.340 kg. of sodium chloride from source of sources unknown because according to the Stores Register considered along with the Registrar of the Injection Department maintained by the appellant, there was no sodium chloride in the stores during the relevant period from 8th to 23rd November, 1962, and that the appellant has not been able to show the source from which he got the 2.340 kg. sodium chloride for preparing glucose in normal saline of batch No. 211105. In this view, it concluded that the appellant was negligent and this negligence was the cause of the death of 12 individuals.

15. Vaghjibhai Chhotabhai Patel, P.W. 53, was the Store-Keeper of S.C.I. Ltd., in whose charge various raw materials including dextrose, sodium chloride and lead nitrate were kept. It was his duty to supply materials on requisition slips issued by different Departments, and he maintained a register. With respect to the supply of dextrose and sodium chloride to the Injection Department, he says the appellant had issued about 12 slips for sodium chloride and dextrose. R. M. Patel was directing him to send materials for testing. It appears that the materials in stores had to be tested before they were sent to the Department and the testing was done by the first accused, K. K. Prabhakaran, who was the head of the Laboratory. He used to sign samples of raw materials with two forms of bulk material test report. The witness had sent sodium chloride on June 7, 1962, and it was certified to be of standard quality by the first accused as per Ext. 151, only on November 19, 1962, and another lot on November 23, 1962 which was also tested and certified to be of standard quality as per Ext. 152. Both these test reports were given only after batch No. 211105, was prepared. According to the witness the appellant had demanded 3 kgs. of sodium chloride on

October 1, 1962, but he supplied him only 2 kgs. on that day and changed the figure 3 in the requisition slip to 2. He further states that from November 8, 1962, there was no stock of sodium chloride in the store. In cross-examination he states that stores balance is struck when the goods are issued, that at times requisition slip was coming late after the material was supplied. The material has to be supplied on the date of the receipt of the slips, not later so that goods would be debited in the account books on the date of requisition slip. On December 30, 1962, certain materials are debited to make good the shortage in actual stock and then the ledger was balanced. He also says that there was no practice of writing batch numbers of sodium chloride in ledger but after the investigation was started they had written batch numbers in the ledger on referring to the invoices. He denied the suggestion that the material of requisition slip, dated October 1, 1962, was not given on that day and that it was given on November 12, 1962, to the appellant, Regarding the purchase of raw materials he says that generally raw materials of standard quality were purchased and admitted that he had supplied sodium chloride for the batch referred to without getting it tested under the instructions of R. M. Patel. It is, therefore, the case of Vaghjibhai that he only supplied raw materials on the requisition slip on the date when that slip was received, nonetheless he did admit that sometimes the material is supplied earlier and the requisition slip is sent later.

16. The appellant has, however, denied that the requisition slip given by him on October 1, 1962, for 3 kgs. out of which as stated by Vaghjibhai 2 kgs. were supplied to him on that day but he states that it was in fact supplied to him on November 12, 1962, when he had to prepare another batch of glucose saline injections. This is what he states :

> "On November 12, 1962, I had to prepare batch of G.N. Saline injections. I then again went to the stores, whereupon Vaghjibhai was on that day on duty told me that 2 kg. of Nacl. of my requisition slip No. 249, dated October 1, 1962, which was not delivered to me was lying in the store and that I can take it and utilise it. He changed my slip from 3 kg. to 2 kg. He gave me the four packages of 0.5 kg. They were of the B. No. 2-A 1525 of Sarabhai Merck Ltd., extra pure variety. I brought them and prepared out of them B. No. 211105.
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> The suggestion of prosecution witnesses that on October 1, 1962, Mr. Vaghjibhai had delivered to me 2 kgs. of Nacl. is false. His account books are not reliable."

17. This statement of the appellant that the account books were not reliable and that 2 kgs. of sodium chloride in respect of requisition slip given by him on October 1, 1962, was supplied to him on November 12, 1962, is borne out by other evidence. The evidence of the Assistant Director, Drugs Control Administration, Savantilal Mohanlal Shah P.W. 48 supports the appellant's case that the Store Keeper's registers were not reliable. He says, accounts are not properly maintained and that it is not possible to calculate from store ledger alone as to how much sodium chloride was issued to Injection Department from January 1, 1962 to December 31, 1962, for there are entries of issue of sodium chloride to other departments. In cross-examination he also states that it is not possible to find out the exact quantity of sodium chloride issued by the store department to Injection Department in 1962 from the available records. On the other hand, we find that the accounts maintained by the appellant appear to have been more reliable. Injection Department's ledger Ext. 163 from January 1, 1962 to December 31, 1962, would show the balance on a particular date, the receipt thereof and the issue of sodium chloride for using in that Department. We have checked up these entries and found that up to November 11, 1962, the opening balance is correctly shown after taking into consideration the receipt and the issue of that material. Entries for the months of October and November, 1962, need alone be considered critically to ascertain whether the appellant had in

fact stocks of sodium chloride, from which he could prepare the offending batch of glucose saline solution. On October 1, 1962, there was a balance of 2.102 kg. Nothing was received on that day. The entire stock was issued for preparing batch No. 210101. The next day there was no balance but the injection department received 5 kgs. and there was no issue. On October 10, 1962 on the day when 2.160 kg. was issued to prepare batch No. 210107, the balance was 5 kg. on October 12, 1962, the balance shown is 2.840 kg. which is the amount of sodium chloride after deducting 2.160 kg. used for preparation on October 10, 1962. On October 23, 1962, it got .5 kg., probably left out of the balance of what remained after the use in preparing batch No. 201117. On November 1, 1962, it started with .5 kg. There is no receipt and no issue. On November 6, 1962, 5.0 kg. was received and, therefore, the balance was 5.5 kg. On the same day 2.160 kg. was issued for preparing batch No. 211101. On November 8, 1962, it shows a balance of 3.340 kg. No sodium chloride was received but out of that quantity 2.160 kg. was issued for preparing batch No. 211103. On November 10, 1962, there was a balance of 1.180 kg. was received from the Laboratory so that on October 10, 1962, there was 1.68 kg. from which 1.665 kg. was issued to prepare batch No. 211104. On the relevant date, i.e., November 11, 1962, the Injection Department had only 0.015 kg. It received 5.0 kg. against which the date was shown as November 23, 1962. from this amount 2.340 kg. was issued to prepare batch No. 211105. In the month of November up to 11th, the register shows 10.5 kg. of sodium chloride out of which 9.25 kg. was issued for preparing batch Nos. 211101 to 211105, so that the allegation that the appellant did not have sufficient sodium chloride available in his laboratory from November 8, 1962, to November 23, 1962, cannot be correct and is only explicable on the basis of what the appellant says, namely, that he got 5 kg. on November 12, 1962, for which he had issued a requisition slip on October 1, 1962, on which date there is no entry of 5 kg. having been received by the injection department from the store.

18. The appellant in his statement to the Drug Inspector said that he had manufactured glucose in normal saline batch No. 211104 from the balance of 1.18 kg. together with .5 kg. brought from the laboratory without asking anybody while it was lying on the work bench. This packet was the product of Sarabhai Merck. On November 11, 1962 he says he had .015 kg. of sodium chloride with him and 5 kg. was sent for from the stores. This 5 kg. is shown in the receipt column in the register on November 11, 1962 which he thought must have been brought on November 10, 1962 or on November 12, 1962 as against this 5 kg. He gives as probably due to the fact that he had sent the requisition slip for that quantity to the stores on November 23, 1962. In respect of Issue Slip No. 294, dated November 24, 1962, he says that it is for the same amount. Out of these 5 kg. he says he used 2.340 kg. in preparing glucose in saline batch No. 211105. He explains entry of November 24, 1962 that after preparing batch No. 211105 he had done a mistake in not deducting it and consequently that was brought forward up to the entry of December 31, 1962. It appears to us that though there may be one or two minor discrepancies in this register, if fairly represents the stock of sodium chloride in the injection department on the several days to which we have referred. At any rate, there is no reason to conclude that the appellant must have bought 5 kg, from outside because he had no interest in going out of his way to do something which was not his duty nor was he expected to purchase materials from outside other than getting them from the stores. That the stores register maintained by Vaghjibhai, Exhibit 149 does not reflect the true position is clear from the fact that on August 8, 1962 an issue of 5 kg. was shown but the injection department does not show that it has received that quantity. It may be that the 5 kg. was issued by the stores to some other Department or it may be in respect of an issue to the injection department on November 6, 1962. Again on October 1, 1962 there is an issue of 2 kg. but there is no corresponding receipt of this quantity shown in the injection department's register nor is there any entry in the stores register that 5 kg. was issued to the injection department as indeed the latter register shows. If no sodium

chloride has been issued on October 2, 1962 by the stores it is difficult to explain how the injection department received that quantity except on the basis that the stores register does not reflect a contemporaneous entry of stock issued to the injection department. This is also evident from another entry which shows that on January 1, 1962 the injection department received 7 kg. of sodium chloride of Emork but a reference to the corresponding entry of the stores register does not contain any entry of that date either. The only entry in the stores register which shows any issue of sodium chloride is of January 27, 1962 which is 7 kg. Now this clearly shows that long prior to there being any controversy, the stores department was issuing material and making entries subsequently when it received requisition slips or that it may have received requisition slips on the date when sodium chloride was issued but did not make any entry on that date. Vaghjibhai's explanation that sometimes the material was issued first and requisition slips were received later would explain the incorrectness of the entries in the stores register to which we have referred. There are two other slips Exhibit 205 of August 8, 1962 and Exhibit 206 of September 17, 1962 issued by the first accused Prabhakaran for sodium chloride which does not find an entry in the store register. The first is in respect of 2145 (whether grams or kilograms is not evident) and the second for 2 lbs. against which the date May 17, 1963 is shown. Nor does the requisition of 5 kg. by the appellant by Exhibit 255, dated May 10, 1962 find a place in the store register on that date.

19. It also appears that all the slips relating to the several issues of sodium chloride to injection department have not been produced, except about 11, namely, Exhibits 255 and 153 to 163 between January 25, 1962 to December 24, 1962. There is one Exhibit 162 which is for 5 kg. of sodium chloride without a date. In the sense of all the requisition slips, it is difficult either to verify the correctness of the statement of Vaghjibhai or to discredit that of the appellant. From the injection department's store register it is evident that there are at least 14 occasions when sodium chloride was received by it and according to the stores register there are 16 occasions on which this substance was issued between January 1, 1962 and December 31, 1962. At any rate, one thing is clear which is, that the store register does not show the correct stocks on any particular date. The evidence to which we have referred, however, inclines us to the view, disagreeing with the findings of the High Court, that the sodium chloride which has been used for preparing glucose solution in normal saline of batch no. 211105 was issued from the stores department of S.C.I. Ltd. Whether the stores department purchased any sodium chloride other than that of Sarabhai Merck cannot be ascertained from the material on record but having regard to the fact that a large number of glucose saline in question was found to contain lead nitrate, an inference may legitimately arise that the company has been purchasing sodium chloride manufactured by others or that the sodium chloride which was issued got contaminated by lead nitrate in the stores. This conclusion becomes plausible from two circumstances, firstly, that large quantities of lead nitrate were found in batch No. 211105 which could not have been from the sodium chloride of Sarabhai Merck as that has been tested and found to be free from this substance, secondly, that the materials issued by the stores which had to tested before issuing them to the injection department, have not been tested for a long time as admitted by the store keeper. Vaghjibhai says that sodium chloride sent by him on June 7, 1962 was tested in the laboratory on November 19, 1962 and from June 7, 1962 to November 23, 1962 no sodium chloride was tested in the laboratory, that he had sought instructions from R. M. Patel as to what he should do as raw materials were not tested in time and were supplied without testing, and that R. M. Patel had given instructions to the first accused, K. K. Prabhakaran but even then the raw materials remained untested till November 23, 1962. Exhibit 182, dated September 4, 1962 would show that Vaghjibhai is writing to R. M. Patel who was incharge of the laboratories thus :

> "You have not sent above store sample analysis, from last 5 months and no chemist comes in stores for stores samples last six months, and material used without

analysis.

You have not given any information for rejecting the goods so as you do needful in this matter, with Supdt of M. D.

#(Sd.) V. C. Patel##

Shri Prabhakaran please report why in spite of decision it is yet not started.

#(Sd.) R. M. Patel##

Please advise whether we should take store sample first finished samples.

#(Sd.) Prabhakaran##

Shri Vaghjibhai

Please give the sample of Calcium Glucerophosphate for analysis and then issue to the patent.

#(Sd.) S. J. Mehta."##

20. Again Exhibit 184 would show that Vaghjibhai had complained on July 1, 1962 that the analysis was not done so necessary arrangement should be made. He also sought instructions from R. M. Patel in that memo as to whether he should issue materials in such circumstances. R. M. Patel in the Exhibit 185 asked Vaghjibhai to supply the list which he supplied in Exhibit 186.

21. This evidence shows that there has been a total dereliction of duty by the Chief Analyst, the first accused who had to test the raw materials nor has R. M. Patel exercised an effective control and supervision in seeing that the raw materials were analysed before being issued to the injection department in spite of the lapses being brought to his notice. The learned Advocate for the appellant suggested that the Analyst was over worked and the company did not want to engage another analyst because of increase in the establishment expenditure. If this is the reason, it is all the more regrettable because the consequence of the omission to test the raw materials had fatal results, but there is no evidence to conclude that the submission made on behalf of the accused has any justification. Whatever the reason, it is undeniable that the materials were not tested before their issue to the injection department. It also appears from the evidence of the Drugs Inspector K. M. Shah, P.W. 34 that he had found in the store poisonous drugs like barium hydroxide and sodium sulphacetamide stored in open drums along with drugs of dextrose. In such circumstances the necessity to test and analyse the raw materials would be all the more imperative. It would thus appear that this brazen disregard of the safeguards prescribed for testing the raw materials to ascertain whether they are of standard quality, or at any rate, the omission to test the sodium chloride during the relevant time when that element was used for preparing batch no. 211105 is certainly one of the factors which has contributed to the non-detection of lead nitrate in glucose solution before its sale to the public.

22. One other aspect which is pertinent is that even if one batch number was given to each lot whether the method adopted by Prabhakaran would have indicated the presence of lead nitrate without other additional tests being undertaken and if not, could the appellant be held culpable for merely giving one batch number to several lots ? As already indicated, the Production Report (Exhibit 165) given by the appellant discloses that he prepared 260 litres of solution in 4 lots for

which he used 2.340 kg. sodium chloride which works out to 9 per cent. strength of that component in the solution. The analysis report given by the first accused Prabhakaran (Exhibit 167) disclosed that the samples of the above batch which he tested contained..... 8869 per cent. of sodium chloride which was within the permissible limit of .97 indicated in column 2 of that report. In his written statement given to the Drugs Inspector (Exhibit 181) which was before any action for prosecuting him was taken, he says that on November 13, 1962 he had drawn a sample of bottles of glucose in normal saline batch No. 211105 from the injection department as shown in the entry book of the said department which he signed. Five bottles were first subjected to sterility test and then one of them was used for estimation of glucose and sodium chloride contents. He had also taken three more bottles of the same batch from the injection department on the day pyragen test was to be performed on November 21, 1962 but the sampling of the three bottles was not shown in the entry book (Exhibit 166) through over-sight. After the analysis of the batch was over, he made a report on November 29, 1962 and two copies of the same were sent to the Drugs Inspector, Baroda for release permission. After release permission was received, one copy of the report was sent to the Injection Department. A copy of the report No. 1-183, dated November 29, 1962 which was shown to him by the Drug Inspector is the one he admitted having sent to the Department and signed by him, i.e. the Report to which we have referred (Exhibit 167). It is obvious, therefore, that Prabhakaran had tested only one bottle out of the eight taken by him as sample for testing and that too only for an estimation of glucose and sodium chloride contents. Evidently, he did not analyse the sodium chloride content for impurities or to ascertain whether there was any lead nitrate and if there was, whether it was over the limits permissible under the U. S. Pharmacopoeia (hereinafter called the U.S.P.) or any other pharmacopoeias referred to under the rules. According to the report he seems to have subjected the five bottles to sterility test between 21st to 29th November, 1962 and during that period he analysed one of them for glucose and sodium chloride contents. On November 21, 1962 he took another three bottles for pyrogen test which was to ascertain whether it contained any foreign protein or toxic substance formed by micro-organisms which cause rise of temperature when injected into human or animal body. It may be mentioned that even distilled water may have pyragen and for quateneously, intraveneously or by any route other than by way of the digestive track has to be immediately followed by sterilisation otherwise it causes severe rigours and rise in temperature when the water is injected into human beings or animals. For this reason also, the Production Department has to use both bidistilled water and subsequently filter it with asceptic filteration unit and sterilise the filled bottles by authoclav method for half an hour which according to the report (Exhibit 165), the appellant seems to have done.

23. That the test made by Prabhakaran could not have disclosed contents of lead nitrate which it was stated was likely to be found in sodium chloride, whether in the form of lead or nitrate salts or as lead nitrate, is evident from the report of the analysis of the 125 bottles of batch No. 211105 sexed after the fatal deaths from various shops by the Drugs Inspector. All the 125 bottles and some other bottles were analysed by the Government Analyst, Jayantilal Popatlal Ganatra, P.W. 40. According to him two bottles A and B were first handed over to him a week after January 1, 1963 by one Shri Shastri for analysis. He analysed them and gave his report Exhibits 208 and 209. In one bottle 0.0183 per cent. and in other 0.04424 per cent. of lead nitrate was found. The lead nitrate in the first bottle marked 'A' was 0.02939 per cent. and in the second bottle it was 0.07071 per cent. A reference to the report Exhibit 208 in respect of bottle 'A' would show that the salt content (Nacl.) in the sodium chloride was .8904 per cent. which is 98.95 per cent. Similarly, in bottle 'B' the content of salt Nacl. was 0.8876 which is 98.63 per cent. Both these were within the permissible limit of 95 per cent. to 105 per cent. as given in the British Pharmacopoeia (hereinafter referred to as 'the B.P.'). On January 1, 1963 he says he was given two bottles of glucose in normal saline of Sanitex for

analysis. The first bottle contained 0.1096 per cent. of lead equivalent to 0.1753 per cent. of the lead nitrate and in the second bottle he found. 08913 per cent. of lead equivalent to 0.1424 per cent. of lead nitrate. The reports in respect of these two bottles are Exhibits 210-211 which show that they are from batch No. 211105. Exhibit 210 discloses that the sodium content in the two bottles were .9 per cent. in 100 ml. which is 9 per cent. The witness further states that on January 5, 1963 he was given five bottles of glucose in normal saline of batch No. 211105. Of these, two bottles serial Nos. 2 and 3 in the report contained 0.13087 per cent. of lead which is equivalent to 0.2091 per cent. of lead nitrate and in the other bottle there was found 0.1260 per cent. of lead equivalent to 0.20147 per cent. of lead nitrate. In respect of this analysis he gave a report Exhibit 212. The content of sodium chloride in these bottles is the same, i.e. 0.9 kg. in 100 ml. The detailed results of the analysis would show that the samples in the 1st, 4th and 5th bottles had salt contents of 0.9095 per cent., 0.91317 per cent., 0.92987 per cent., equivalent to 101.0 per cent., to 101.5 per cent., and 101.3 per cent., respectively. These were within permissible B.P. limits of 95 to 105 per cent. In none of these bottles the presence of lead nitrate was detected. In the other two bottles, namely, bottles 2 and 3, the salt content was much less than the permissible limits. In bottles 2 it was 0.7324 per cent. or 81.39 per cent. and in bottle 3, 0.7342 per cent. or 81.55 per cent. In these bottles as already stated, there was evidence of lead and lead nitrate.

24. On June 29, 1963 the witness states that he was given 123 bottles of glucose saline of Sanitex and he analysed those bottles in the presence of the parties concerned and their pleaders from July 2, 1962 to July 11, 1962. His report concerning this analysis is Exhibit 173. A reference to this report discloses near uniformity in that in bottles containing 0.89 per cent. or above of saline there are absolutely no traces of lead nitrate and in bottles containing less than that quantity of sodium chloride ranging from 0.8824 to 0.8832 (Items 14, 15, 17, 58, 59, 69, 77, 92, 93, 97, 107 and 121) there is found lead nitrate except in one bottle, item 17, which has salt content of 0.886 per cent. in which there was no trace of lead nitrate.

25. In this connection it may be pointed out that the evidence of J. P. Ganatra, P.W. 40, the Government Analyst shows that in most of the bottles whatever quantity of lead nitrate was found, content of sodium chloride was found less to that extent, i.e. the sum total of lead nitrate and sodium chloride (salt) in each bottle was coming up to the requisite quantity of sodium chloride. By reference to Exhibits 208, 212, and 173 he stated that the highest quantity of lead nitrate found was 0.3022 per cent. and the sodium chloride in that bottle was found to be 0.6223 per cent. This evidence indicates, firstly, that the salt content and lead nitrate content are equal to the quality of sodium chloride and secondly that the less the content of salt, the more the impurities. In other words, the lead nitrate content seems to go up when the percentage of sodium chloride (Nacl) in sodium chloride constituent in the samples of batch No. 211105 in which lead nitrate was detected was less. It further appears that some of the glucose saline bottles from batch No. 211105 and one bottles from batch No. 211103 were sent for analysis to Bombay and were analysed By R. N. Advani under the supervision of Kodagnalliar Ganapati Anantnarayan, P.W. 6 officer in-charge, Analytical and Central Laboratory, Haffkin's Institute. According to P.W. 6, the Drugs Inspector K. M. Shah had sent him three bottles of glucose in normal saline out of batch No. 211105 which were received by him on January 2, 1963. His report with protocols is Exhibit 53. According to the evidence of this witness, out of these three bottles, sodium chloride content in two bottles was less than the 95 per cent. to 105 per cent. the limits prescribed by B.P. and lead salt was found in solution. Of these two, one bottle contained 81 mgs. of lead per 100 c.c. and the other contained 70 mgs. of lead per 100 c.c. of solution. The limit prescribed as per U.S.P. for lead salt (heavy metal) in dextrose and sodium chloride is 5 parts per million, whereas in the above two bottles it was 700 and 810 parts per million as such this was found in great proposition. The reports with the respect to

these two bottles are Exhibits 54 and 55 which were signed by R. N. Advani and initialled by P.W. 6. The sodium chloride was estimated by one Jagadoss which was done under his supervision and this is shown in Exhibits 56 and 57, signed by the Jagadoss and initialled by him. The report in Exhibit 53 shows that 50 c.c. of above glucose in normal saline sample bottle was injected to each rabbit and both had died and this fact has been noted in the protocols. The witness further states that he received ten bottles of glucose in normal saline manufactured by Sanitex from Shri K. M. Shah on January 8, 1963 out of which nine bottles were of batch No. 211105 and one was of batch No. 211103. Out of ten bottles, in three bottles sodium chloride was more than the prescribed limit and in those three bottles lead salt was there in appreciable amount. One contained 120 mgs. of lead per 100 c.c. of solution and the other two contained 140 mgs. lead per 100 c.c. solution. This exceeded the U.S.P. limits in that lead salt was found to be 1200 and 1400 parts per million. From all the above three bottles 50 c.c. was injected to each rabbit and all the three rabbits had died. The report is Exhibit 58. The estimation of lead salt and sodium chloride was made by Advani under his supervision which was installed by him. A reference to Exhibit 53 would show that the test for sodium chloride content does not indicate the presence of lead nitrate, for the ascertainment of which additional tests have to be done as specified in detail in the quantitative analysis by Garrot (p. 286). It may also be noticed that the salt content of the three bottles is 99.3 per cent., 78 per cent. and 76.7 per cent. respectively of the sodium chloride which was within the B.P. limits. In the first of these bottles in which the salt content was 99.3 per cent. of the labelled amount of sodium chloride no lead nitrate was found. The rabbit which was injected intravenously with 75 ml. of that sample, though observed for ten days, had no untoward reaction nor did death occur, while in the other two in which the salt content was 78 per cent. and 76.7 per cent. of the labelled amount of sodium chloride (which was less than the B.P. limits), the led nitrate was as stated by the Analyst, 81 mg. and 70 mg. per cent. of the lead and both the rabbits injected with 50 c.c. of solution from each samples, died, the first one within 18 hours and the second one after having convulsions within five minutes. Exhibit 58 would show that out of the ten bottles the 1st, 3rd and 5th bottles contained 140 per cent., 232.2 per cent. and 251.1 per cent. of salt in the sodium chloride which were far in excess of the permissible B.P. limits of 95 to 105 per cent. while in the other seven bottles, the salt content was over 100 but under 105 per cent. It is only in respect of the three bottles in which the salt content was far in excess of the upper limit of 105 per cent. that the rabbits injected by those samples died within 18 hours while in the other samples where the salt was above 100 but below 105 per cent. no lead nitrate was found and the rabbits injected did not show any untoward signs. This evidence further indicates that where were the slat content is .89 per cent. and over but did not exceed the permissible B.P. limit the lead nitrate has not been detected though we are not in a position to say that if it is within the permissible limit according to U.S.P. whether it has been ignored and shown as not present. But where the salt content is less than the minimum limit of 95 per cent. or far in excess of the upper limit of 105 per cent. lead nitrate has been found. We have referred to the evidence in detail only to show that by merely determining the sodium chloride content to be 0.8869 per cent. as disclosed in the analysis report of Prabhakaran (Exhibit 167) though it is said to be within the permissible limit, it does not indicate without the additional test that the one bottle out of batch No. 211105 which he analysed does not contain lead or nitrate salts or lead nitrate. We had earlier seen that as many as 11 bottles in which the sodium chloride ranged between .8824 per cent. and .8882 per cent. in which range the analysis of one bottle by Prabhakaran in his report Exhibit 167 had shown .8869 per cent. is included, there was a large quantity of lead nitrate which was a danger to human life. In our view, therefore, the test of the sample as per exhibit 167 is not by itself sufficient to determine the impurities. This test might have been safe if the raw materials used in the making of the solution of batch No. 211105 had been earlier tested as should have been but as we have seen that test was not undertaken in spite of the

repeated reminders by Vaghjibhai. In other words, if the materials used in the preparation and prepared the solution had been properly tested, lead nitrate would have been detected at any rate even before the solution was prepared by the appellant. In this view, we cannot hold that the negligence of the appellant in giving one batch number to several lots was the direct cause of the deaths nor can his act be declared to be grossly rash and negligent. After this judgment had been finalised a copy of the judgment of the High Court in the criminal prosecution dismissing the appeals of the State against the acquittal of S. J. Mehta, the appellant and K. K. Prabhakaran accused Nos. 7, 8 and 10 respectively was circulated. It merely confirms what has been stated at the Bar, namely, that S. J. Mehta, the appellant and K. K. Prabhakaran, accused Nos. 7, 8 and 10 respectively in that case who were convicted by the Trial Court along with the S.C.I. Ltd., were acquitted in an appeal which was confirmed by the High Court. Both the appellate court and the High Court were of the view that under the Act and the Rules made thereunder only the manufacturer was liable and not its servants. These findings do not in any way affect our conclusion.

26. In the view we have taken, we allow the appeal and set aside the conviction and sentence. As the accused is on bail his bail bond is directed to be cancelled.

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