We find it incomprehensible that you only advised us – if at all – of the possible harmful side effects of the Contergan substance after signing of the contract, although you had been aware of such side effects long before. In the press conference you organised at the Hotel Alsterhof, Esplanade, in Hamburg on 13 December 1961 you yourselves announced that you had been advised of the first 5 cases of Polyneuritis in the time from October to December 1959. Another 2 cases in September 1960 in England. The press releases by Dr. Frenkel, Königstein, indicate that Dr. Frenkel advised you of his observations in 21 patients in August 1960.

We, therefore, deeply regret that we have to assert our claims in this form, however we hope that you do not close yourselves off to our statements and request your early comments.

GRT.0001.00063.0040: 13 February 1962 Letter Mueckter (Grt) to Kobyletzki (Univ. Giessen)

Dear Dr von Kobyletzki,

Your kind letter dated 1.2.1962 has been forwarded to me for commenting. We have recently been working on the questions whether thalidomide (Contergan) can cross from the mother to the foetus via the placenta. Enclosed are our findings in the form of a brief statement.

We are also generally interested in these questions regarding our other products; I would be very grateful if you could send my your results of the demethylchloretetracycline study for confidential viewing. As far as we know from scientific literature, the question of diaplacentar transfer has been examined for numerous substances. Generally the results indicated that low-molecular compounds can cross easily, only high-molecular compounds seem to be hindered or blocked from crossing. We do not have access to all relevant literature and I assume that you would have no difficulty in looking up these studies in the libraries of the University of Giessen. Please contact us if we can be of assistance in any other way.

GRT.0001.00064.0056: 28 February 1962 Letter to Syrian Arab Republic from GRT

Dear Mr Redacted,

We confirm receipt of your letter dated 13. June 1962, from which we must learn to our sincere regrets that your 2-year old son was born with deformities of the arms. You ascribe this deformity to the taking of Contergan. We would like to point out that the causality of Contergan for deformities in newly born is not proven. We must therefore emphasise that our company cannot accept any liability whatsoever, no matter which misfortune has affected your family, and must therefore refute any allusion that is targeted at insinuating that Contergan had been released to the market negligently. We only realized, despite thorough and many years of testing of the medication, for the first time in November 1961, that the suspicion of a possible

connection between the taking of Contergan and the deformities in new born exists. Thereupon we voluntarily withdrew Contergan from the market within a few days. Even under the greatest care, the possibility of a causing of the deformities through Contergan was not foreseeable.

For these reasons all legal prerequisites for any claim for compensation are absent. Pursuant to this we cannot, as much as we are aware of the hardship of your case, recognize a liability for damages.

As far as the sale of Thalidomide-containing preparations in Syria is concerned, we have of course directed our representatives to withdraw all Thalidomide-containing medications from trade. Our agency has complied with this request and has also already confirmed this towards us at the beginning of the year.

Archive number: 4 April 1962 Memorandum titled "Peracon-Contergan Contract with KALI-Chemie AG"

As correctly stressed by Mr. Viehöver it would have been obvious to mention individual reports by doctors regarding Polyneuropathies during the discussions on 14.7.1960 regarding the side effects. Even if one does not believe in the accuracy of these reports, it would have been only fair not to conceal them in the course of such a contract negotiation.

The same applies in principle for the written negotiations during the following six months, based on which the contract was signed by us on 6 January 1961. As mentioned in the Memorandum of 30.3.1962, we had at that point received approx. 80 reports of Polyneuropathies. It should be difficult for us to convince the gentlemen of KALI-Chemie under these circumstances – without acting maliciously – that we were convinced these reports had been reported entirely without reason and were therefore not worth mentioning during the contract negotiations. Based on the duty of allegiance principally resulting for both parties by conducting these contract negotiations, it would certainly have been our duty to advise KALI-Chemie of the objective facts, i.e. the reports regarding the approximately 80 cases of Polyneuropathies. (In this connection we would still have been free to point out that we were convinced of the inaccuracy of those reports).

The fact that we omitted such a clarification – which in all fairness could have been expected from a serious business partner -, now exposes us to the accusation of fraudulent intent by KALI-Chemie. I consider the risk of litigation in the present matter to be quite significant. In addition, a lawsuit with KALI-Chemie in the present moment would mean having to accept another heavy loss of prestige. It seems reasonable to suppose that such a lawsuit would also have serious consequences regarding our ongoing membership in the German Pharmaceutical Industry Association, and finally a lawsuit with KALI-Chemie about this matter would mean another significant weakening of our position in the criminal proceeding.

Based on the afore-mentioned reasons, it is therefore strongly recommended to reach an agreement with KALIChemie,as already suggested by Mr Viehöver, to the effect that:

1.) we take back the 32.3 kg of CONTERGAN substance, and
2.) KALI-Chemical for their part expressly relinquish any further claims of any kind.

t is recommended to discuss this matter verbally with KALI-Chemie in the near future. From our side, the same gentlemen should participate who conducted the negotiation with KALI-Chemie at the time in 1960 and January1961!

2 March 1962 Letter from Dahs (legal adviser to Grt) to GRT

Dear Colleague,
To my astonishment I understand from the documents forwarded to me that several interim injunction proceedings have been instituted. These proceedings may be highly significant to the criminal trial. This particularly applies to the Fränkel matter. From this the prosecutor will specifically deduce when you were notified of injuries by Fränkel. Many passages in the files of these proceedings can assume grave importance for the criminal trial.

Having worked on the matter for several months in conjunction with fellow lawyer Mr Gruissen, and given my shared responsibility for the criminal trial, I can hardly reconcile that, without prior consultation, court proceedings are instituted which may become significant for the outcome of the matter, and can potentially bring significant disadvantages. I would be grateful to you if you could ensure proper coordination of the four parties (you, the lawyers Gruessen and Kiessler, the Grünenthal company and the undersigned) involved in the work. To serve its purpose, correspondence is also conducted in accordance with consistent considerations. I personally feel that it would be right to correspond exclusively with you in future, and to forward copies for their records to colleague Gruessen and to the client.

GRT.0001.00063.0191:27 March 1962 Note – 'Re General Contergan Situation' prepared by Grt Legal Department

Re General Contergan situation

The following are deliberations which aim to serve as a basis for discussion of the question what measures are appropriate to take in the area of civil law.

I Time prior to launch

To assess whether pharmaceutical and clinical testing prior to launch were sufficient, we rely entirely on the Schulemann assessment. There is a danger, of course, that another expert will come along with a differing assessment. If one arrives at the conclusion that Grünenthal should have carried out more extensive or different kinds of pharmacological or clinical investigations in various areas, we lacked the knowledge at the time that failure to do so might

lead to bodily injuries. We can lean on the fact that despite broad introduction to the market of the drug, virtually nothing negative occurred over a course of three years, even in areas which may require testing prior to launch. The onus is on us to prove, however, that a degree of failure on our part is not the cause. The proof of this should be the unreservedly positive response to the drug here and abroad over years.

Result: No relevance of possible neglect on our part under criminal law. (Under criminal law it is the task of the prosecutor to prove neglect as the cause of bodily harm).

A minor trial risk exists under civil law in as much as neglecting to carry out pharmacological and clinical trials (e.g. chronic toxicity) may be taken as causative in view of the absence of proof to the contrary.

II. Timeframe of Launch till October 1959

1. 'Completely non-toxic'

Professor Elbel considers the terminology of 'non-toxic' justified if, even in the case of grossly exceeding useful boundaries of quantitative limits for the use of a drug, no damage is caused that might have reasonably been expected.

As a sleeping pill, taken frequently on an ongoing basis, Contergan is objectively ~~not~~* non-toxic based on current knowledge according to this definition.

* Translator's comment: the word 'not' was crossed out and the word 'non-toxic' underlined by hand

Medical and pharmacological knowledge at the time justifies the use of the terminology 'non-toxic' or 'entirely non-toxic'. Expert assessments submitted thus far permit this assumption.

The question remains unanswered whether one should have been more reluctant to determine the non-toxicity of a medication given that the general experience that side- effects of a drug often remain hidden for a long time and do not emerge until it has seen broad application, particularly since thalidomide was a new substance which was not even subject to medical control.

As far as criminal law is concerned, there is little danger that the term 'non-toxic' will lead to accusations of guilt because unequivocally positive results had led the leading gentlemen of our organisation to a strong conviction that we were truly dealing with a non-toxic substance, and it was not humanly possible to anticipate that the drug would later turn out to be toxic.

With a view to civil law, it depends if it is common practice to specifically label a pharmaceutical product 'non-toxic' when it is based on a new substance without considering - in abstract analysis - if significant side-effects may yet emerge despite thorough testing. If this is common practice, the court will have to examine if this practice is in accordance with requirements of due care. We cannot exclude that the answer will be no, if it turns out that such

cases occur relatively frequently. Under civil law there will then be a case of negligence to answer.

Result:

Under criminal law there will probably not be an accusation of guilt.

Under civil law guilt is likely to be assigned on this point (though the risk should probably not be assessed as too high).

In summary of points I. and II., it may be said that accusations which may be made against us for the time up to October 1959, i.e. neglecting to carry out testing (chronic toxicity) and labeling of 'entirely non-toxic' and 'non-toxic' are insufficient grounds for criminal conviction but carry a certain risk with a view to civil law.

III.

Timeframe of October 1959 to September 1960

1. Looking at it from a legal perspective, the time up to 2 October 1959 is irrelevant since there was no indication of neuropathies or other injury following the use of Contergan.

2. On 2 October 1959 Dr Voss advised us that he was treating a 63 year-old man who had been taking Contergan Forte as a sleeping pill for the past one and half years and had started developing polyneuritis over the past six months. He asked if it was possible that Contergan might lead to damage of the peripheral nervous system.

There is nothing legally objectionable about Dr Sievers' reply of 7 October 1959 to this case. In view of impressive positive reports and assessments at the time, this isolated case did not oblige us to undertake a review. It was sufficient to request that the doctor keep us updated.

3. By late December we had become aware of a further five cases (three Dr Voss cases, two Dr Sartorius cases). We confirmed this to Dr Voss per our letter of 17 December 1959.

Grünenthal therefore was advised independently (?) by two doctors that Contergan may lead to nerve damage. Dr Voss certainly voiced the opinion most emphatically that this is so.

When a company is advised independently by different parties that a drug causes certain injuries, this must be taken into consideration as a very real possibility. If such reports are to be taken seriously, and in the case of Dr Voss this is most certainly the case, a pharmaceutical company must do everything in its power that it may reasonably be expected to do.

The company left it at investigating the reported cases as far as possible. To the outside world it looked as though no steps were initiated. Product information leaflets in February 1960 continued to rate the product as 'non-toxic'.

We can be certain that the continued rating of the product as 'non-toxic', despite the cases we had been informed of since late 1959, will be firmly held against us by potential litigants. We must bear in mind that in the interest of public health,

a high level of duty of care is expected of pharmaceutical manufacturers. We therefore cannot rule out that a complete ignoring of nerve dysfunction on account of Contergan will lead to a claim of negligence on our part. The justification for this will be that the labeling of 'non-toxic' of a drug available over the counter is only tenable if the consumer can objectively have no doubt of its correctness.

Result:

No grounds for criminal conviction;

under civil law there is a slightly greater risk of litigation although there is a very real chance that in view of the very minor significance of the cases which had emerged at the time, our conduct will be viewed as justifiable.

4. Up to and including September 1960, Dr von Schrader's records show that five more cases were brought to the attention of the company. In reality, the number will in all likelihood turn out to be higher in the event of litigation as victims will prove that they advised the company during this time. It is also not exactly probable that a total of 10 cases up to September 1960, hardly a significant figure in terms of numbers, would have led to a modification of the product information leaflet (see also external sales memorandum of 17 May 1960).

If we were only talking of a total of five further cases, the modification of the product information leaflet in the autumn of 1960 would adequately address the requirements of a pharmaceutical company in respect of duty of care. In view of the considerable monthly sales figures in the autumn of 1960 which by then had reached 361.7 kg which equate to 3,617,000 daily doses, 10 cases are of no statistical significance.

As mentioned, however, we must seriously count on further cases emerging, particularly as expert medical opinion (leading neurologists, hospitals) leads to judicial enquiries in the context of civil claims. Such cases are not be taken lightly. There were serious neuropathies among the known cases already. Dr Voss found the cases he treated to be refractory to therapy (see Dr Siever's travel report of 7 April 1961). Dr Voss' statement is one of objectivity and moderation. Mrs Dittmann even referred to Mr Voss as a 'Grünenthal-friend' in her report of 1 April 1960. All this portends to taking Dr Voss seriously already at that time.

The fact that we modified the product information leaflet in September 1960 suggests that we seriously took the possibility of nerve damage into consideration. Since product information leaflets are not read regularly by long-term users and also did not filter through to the consumer until months later, this begs the question if this measure was enough. There is a danger that effective education of the consumer or, at the very least the medical profession, will be demanded of us. The fact that the new product information leaflet will not have an effect for months, may be taken as an indicator that we refrained from more effective measures in the interests of turnover.

Result:

From a point of view of civil as well as criminal law, September 1960 is the first truly crucial point in time, particularly in the event that more than 10 cases can be held against us. In any event, justifying our conduct objectively, already appears to be a problem.

IV.

Timeframe of September 1960 to mid-February 1961

The first serious reports of the observation of neuropathies by qualified doctors fall into this time period. Dr Sievers was informed on the occasion of his visit to the Cologne Neurology Teaching Hospital on 11 October 1960 that Professor Wiek had observed six cases of polyneuritis subsequent to Contergan use. It was also mentioned that Professor Laubenthal was supervising 11 cases. Both Dr Frenkel and Professor Laubenthal indicated their intent to publicize this (Raffauf). Professor Arnold of Essen reported numerous 'cases of neuritis' on 21 November and ordered, as we found out from Dr Prinzen, that Contergan Forte was only allowed to be administered in his clinic for short periods. He rejected the idea of long-term medication. Professor Heymer, Director of the Medical Teaching Hospital of Bonn, had also identified polyneuritis as a sequela of exposure to long-term Contergan use. In summary, we became aware of at least 90 new cases in the time leading up to mid-February.

During this entire time we did nothing other than inform ourselves. If the modification of the product information leaflet in September 1960 is to be seen as adequate, we must at least ask ourselves if the advice of leading medical experts becoming known should lead to effective measures concerning the long-term use of Contergan. By late October 1960 so many cases had come to light from so many quarters that we had to be careful and work on the assumption that Contergan may cause neuropathies with long-term use. It is for this reason that an effective policy should have been expected of the company.*

Result:

During the above time frame our measures do not truly measure up to due diligence. A very considerable risk has emerged under civil law. For criminal cases it must be taken into account that the number of cases that have emerged were negligible in relation to sales figures, and we did make an effort to look into cases. Under the circumstances one might subjectively conclude that it was legitimate to analyse what steps to take next.

V.

Timeframe of 15 February to 25 May 1961

Following Dr Voss' presentation, everyone concerned knew that something had to be

* Translator's comment: only partially legible hand-written reference to Dr Oswald

done to stop Contergan causing nerve damage. A number of measures were considered workable:

1.) Applying for prescription requirement together with immediately effective measures.

2.) Advising doctors and pharmacists.

3.) Advising consumers by means of unmissable notes on packaging and/or product information leaflet.

We limited our actions to mail-outs to doctors and pharmacists and renewed modification of the product information leaflet, however. Looking at it objectively, these measures surely were not ideal. The consumer who purchased Contergan over the counter, slipped through the net. It was left to chance whether consumers took potential paraesthesias seriously and consulted a doctor in time. The mail-out to doctors as such was a fairly effective measure but it was lacking in as much as many doctors would have only glanced at such a printed notice.

Result:

The danger that our measures might be deemed inadequate under both civil and criminal law is not insubstantial. It has also become considerably more difficult to resort to subjective excuses for potential neglect on our part.

VI.

Timeframe of 25 May to 19 November 1961

On 25 May 61 we applied for prescription-only listing. This measure did not have any immediate effect. This could only be expected of ministerial statutory orders to this effect which would make Contergan available as a

prescription-only medication. It therefore became necessary objectively to combine the application process with a measure which would take effect immediately. This measure was not taken until 5 September 1961, however (red sticker which read 'on doctor's orders only' – 'sticker project'). In the interest of consistency, this should have been done in connection with the application for prescription-only listing since at the time, a prescription listing in all states was not be expected in the short term. In our favour is that such measures were absolutely unheard of, and prescription-only listing is almost never applied for by a manufacturer. Most probably, however, such arguments will fall on deaf ears. It was a matter of effectively averting the dangers of Contergan use. The mere application for prescription-listing did not represent an effective counter-measure against the dangers.*

* Translator's comment: hand-written reference says: Pharmaceutical Commission

Result:

Both with a view to civil and criminal law, there is the risk that the application for prescription-listing in itself will not be recognized as an adequate measure.

VII.

Malformations/Deformities

As it stands, we do not expect to pay damages on account of malformations or deformities as a result of Contergan use. Aetiology remains open. The question of guilt can clearly only be answered with a 'no'.

This does not mean, however, that trials on account of malformations or deformities are without any risk. Theoretically the danger of being found guilty might come from animal trials with Contergan resulting in malformations/deformities. The judgment of impartial experts will determine whether testing for teratogenesis was necessary before launching the product. If, despite our current expectations to the contrary, this question is answered in the affirmative, then it might only be a small step to being found guilty in a civil trial. Therefore, it is very important for us to prove that testing of Contergan for teratogenic properties, according to scientific knowledge at the time, was not necessary.

The above deliberations obviously do not represent a definitive legal opinion but are intended to roughly highlight the risk of legal proceedings based on the question what

measures could have been expected and required of Grünenthal at various stages.

RT.0001.00063.0238 4 April 1962 Note – 'Re Contergan Situation' by Grt legal epartment

Re Contergan situation

In dealing with the question whether specific measures should be taken at the current point in time, and if so, which ones, one must take into consideration the risk of litigation as well as the issue of what needs to be done to maintain the reputation of the organisation as a pharmaceutical company.

As indicated in the Note of 27 March 1962, very considerable risks of civil law suits arise from September/October 1960. The Note highlighted a number of issues associated with risks which cannot be assessed for their ultimate verdict by the judge at this stage.

It is to be expected, however, that in civil cases the facts of the matter will largely be resolved through the involvement of 'solidarity groups of Contergan victims' and other lobbies. It will hardly be possible for us to restrict the material under review in proceedings, especially since it is to be expected that we will have to respond to detailed presentations from the opposite bench.

Under these circumstances, it is not to be expected that our conduct will be objectively viewed as justified on all counts. Should the court determine, however, that Grünenthal did not exercise reasonable care in the measures it could have been expected to take, possibly in several areas, then it will not take much to establish the guilt required to arrive at a guilty verdict in a civil case. It is well known that the degree of guilt is irrelevant in such a case. Proof of minor negligence is sufficient.

If guilt is established at all, it will almost certainly fall into the timeframe of the first months of 1961 at the latest. Since Contergan use of individual victims went on until about mid-1961 in most cases, this, as a rule, would point to guilt of causing at least part of the injuries in individual cases.

And so we should draw the conclusion that in all probability we can expect to lose most civil suits brought against us.

The outcome of pending criminal proceedings is impossible to predict at the present time. It may be said, however, that chances of success are considerably better than in the case of civil proceedings. Nevertheless, the risk of individual parties involved being convicted is not exactly small either.

Under these circumstances, it appears appropriate to err on the side of caution and be prepared for a negative outcome of legal proceedings in the Contergan matter.

This means that the position of the company must be strengthened so that it can absorb the heavy blow that a defeat in the case would bring about. A strengthening of the position of the company can only be achieved by means of an improvement in its reputation.

The reputation of the company will surely suffer most, indeed it may even receive a fatal blow, if we are convicted in civil and criminal cases and publicly charged with stringing Contergan victims along without having offered them any practical help.

It may be said with some certainty that in such a case we will be presumed guilty from the outset and condemned sharply and publicly for our lack of willingness to carry the damage which has been done.

We must consider too that the standing of the company may possibly be weighed down by the evidence that Contergan causes deformities even if we are absolutely not guilty.

All this has the potential to threaten the existence of Grünenthal. We must therefore do all we can to avoid being caught unawares. Precautionary measures must actively promote the reputation of the organisation. Large parts of public opinion have it that the financial interests of the company take precedence over other concerns in ways that can no longer be justified, especially when it comes to the needs of public health. It will no doubt take a great deal of effort to effectively deal with such accusations.

A potentially explosive situation could be diffused if Contergan injuries (neuropathies) were to be settled. Where settlements are not possible due to legal considerations, one should at least deal in-depth with the medical care of cases. This means that we ought to have thorough medical treatment undertaken at our expense. In the event of court proceedings it would be particularly detrimental to the reputation of the company if we were to be accused of not even having rectified injuries.

Also, general business policy must take the Contergan situation into account to a much higher degree than before to avoid even a semblance of inappropriate conduct. We must allow for a possible blowing up of inappropriate conduct by the public which overall at least has the potential to more or less put a seal of disrepute on Grünenthal as a company. This particular point takes on a very special meaning. A satisfactory solution would also block the main wellspring of staffing difficulties.

Measures taken on behalf of Contergan victims must be accompanied by intensive but very carefully and tactfully managed public relations efforts which must undemonstratively put the conduct of Grünenthal into perspective with the medical and general press.

Therefore the issue of settlements is only part of the problem.

The following speaks in favour of settlements:

A mitigating effect in the case of criminal conviction and a possible disinterest of parties filing for criminal suits once civil claims have been met. This in turn would increase chances of achieving a ceasing of criminal proceedings.

Overall, settlements represent the cheaper solution: it is to be expected that a number of 'victims' would receive settlements whose claims would not have been successful in court. On the other hand, substantial savings could be made by means of lower settlement fees, eliminating legal and court costs as well as substantial cuts of organisational staffing fees. Last, not least, loss must be allowed for that is incurred on account of efforts going into the Contergan matter which cannot be put into productive tasks for the company.Settlements should be carried out as expeditiously as possible. The

lower claims should be dealt with first. Higher claims should proceed to the final stages of settlement only after dealing with the bulk of the smaller claims. Negotiations should not be conducted in a spirit of petty mindedness on our part. Rather, we should aim for a solution seen to be appropriate. Where a settlement cannot be reached, we will have to let such cases go to court. It stands to reason that in most cases appropriate settlements should be achieved with the help of the court. In such cases, one should continue with legal disputes to establish a precedent. If need be, one will have to match the claim as closely as is necessary to avoid conviction. In this manner, it should be possible to avoid a civil conviction in practically all cases.

To the outside world we would present an image of maintaining the upper hand in the malformation suits and were not convicted in civil suits for nerve-related issues either. It would be a significant advantage if the extent of guilt was not established in a court of law. This would allow us to take the firm stance that we entered into settlements because the risks involved in going to court appear too great given that even the slightest degree of guilt suffices to lead to a conviction.

Cases where Contergan does not sufficiently explain the aetiology of the alleged injuries, we should also deal with in court. Only if court proceedings find that causality can be established beyond a reasonable doubt, these cases should be settled in court.

If a criminal case were to lead to a conviction, then clearly the above-mentioned settlement solution would represent the best option. If criminal proceedings were to be dropped or the parties involved are cleared, this does not necessarily say anything of note about the chances of success in civil cases. Even if criminal cases take a positive end, these may well deliver fertile grounds for fighting us in civil suits.

This is because we would probably owe a positive outcome to the establishment of inappropriate conduct assessed in all objectivity on the one hand, but the parties involved being deemed not guilty. Equally, it could become apparent that negligence under civil law may be viewed favourably.

Therefore, even where criminal proceedings take a favourable development, we can not necessarily count on a lower risk in civil cases. Normally, a successful outcome in criminal cases would discourage many a potential claimant to pursue civil claims. In this case we must, however, allow for the activities of interest groups who will presumably study the results of criminal cases in minute detail. The conduct of interest groups will inform the conduct of all victims irrespective of whether or not they directly participate in the activities of the interest group.

The following speaks against settlements:

We might be prejudged as far as guilt is concerned. Looking at it from a legal perspective, the question of guilt remains open in the case of ex gratia settlements. It should not be underestimated, however, that psychologically courts are being pressured into a guilty verdict. This would imply that we

consider a guilty verdict possible, and one tries as hard as possible to find our most vulnerable spot.

In the case of civil law this is not of major significance. If we settle anyway, we do not need to argue about guilt in general or the possibility generally that Contergan causes neuropathies.

The question takes on a more serious meaning, however, when it comes to criminal law. The fact that we are settling all cases, one by one, may lead the prosecutor's office to search more vigilantly for evidence of guilt since the payments would point to a suggestion of guilt on the part of the company. On the other hand, guilt of the company under civil law does not imply guilt under criminal law of the gentlemen involved. Settlements would also more likely lead to a waning of public interest in criminal prosecution even though the prosecutor's office will be obliged to put through proceedings unless a matter resolves itself of its own accord.

Therefore, one should not overestimate the danger that criminal proceedings might be in jeopardy and consider that failure to compensate may have detrimental effects should we lose a criminal case after all.

The question of the effects of settlements in the light of criminal proceedings would require in-depth consultation with the lawyers involved, in particular Professor Dahs.

The fear that settlements are deemed from the outset as an admission of guilt on the part of the outside world and that this suffices to destroy the reputation of the company, is not justified. We must bear in mind that public opinion today is already more or less convinced that Grünenthal is not entirely innocent when it comes to issues surrounding Contergan. Efforts on the part of the company to remedy the damage caused should therefore meet with a positive response.

Should there be strong legal concerns (in particular on the part of Professor Dahs) about the entering into settlements, suitable measures should at least be initiated which would enable victims to recover their health. Proposals to this effect would need to be put forward by medical teams.

10 April 1962 Letter from Dr Weingaertner in Halle-Wittenberg to Dr Michael (Grt)

In the meantime, I have been able to clarify the question of Contergan. It was indeed discussed among the central expert committee here in the spring of 1961 as to whether a preparation corresponding to Contergan should be produced. However, back then already, the committee chaired by Prof. Dr Jung considered the manufacture of the preparation inappropriate due to the existing material about toxic side-effects available to them - (perhaps the remark by Dr Voß at the conference here in Halle). Prof. Jung informed me that he had advised the company making the application against commencing with developmental work in this regard. I hope to have assisted you.

GRT.0001.00063.0283: 16 April 1962 Mueckter internal Grt memo

It is for tactical reasons that I would like to offer the following suggestion:

We should do everything in our power to phase out the use of the trademark Contergan in all our publications, discussions, etc. as soon as possible and instead start using the scientific term thalidomide. This is already being adopted in correspondence with companies abroad and PETERSEN also uses this expression in his recent study.

Maybe this will enable us to somewhat break up the direct connection between Contergan and Grünenthal.

I have already asked Mr Viehöfer about a second issue in connection with this: Isn't it possible to prohibit Dr Frenkel from using our trademark Contergan in association with his interest group for Contergan victims?

GRT.0001.00063.0290: 18 April 1962 Note – General Contergan Situation' prepared by Grt legal department

Re General Contergan situation
The Note about Contergan dated 10 July 1(9)61 - issued by the Legal Department Dr v V/Str - discussed the issue of guilt 'on the part of Grünenthal' as well as the liability the company would face in terms of civil cases. Upon considering the most notable points of the case as they were known to us at the time, we arrived at the conclusion that our prospects of winning a civil case could only be called slim. We therefore proposed to settle individual cases while expressly denying causality and guilt.
This was our modus operandi for the months of August to September. Until the end of September we dealt with 13 cases of liability through settlements totalling DM 12,000.00. (In addition to the [redacted] case worth DM 20,000.00)

Over October through early November a few more cases of similar magnitude arose.

As you are aware, we stopped the settlements immediately as the press launched its deformities campaign. At the time it was necessary to await the reaction of interested parties who might have to be considered and narrow things down to medical investigation. This medical investigation struck difficulties in many instances. This was partly due to patients not responding promptly or inaccurately, doctors taking their time responding to our questions, visits having to be organised and much else besides. Today, about three [3]* months later, medical investigations of most of the approximately 360 cases are virtually concluded. The same goes for the [x]00** cases where we entered into correspondence. Both in terms of cases of claims and correspondence, we now face having to make a decision on how to proceed, especially since Dr Frenkel accused us of delay tactics in his latest circular to the members of the interest group.

From early March until now approximately three to six new claimants have surfaced per week, and of course we have no way of knowing whether these are captured in the 1,000 cases of Dr Frenkel's.

Measures to be considered might be:

1.) Negative reply to claimants in conjunction with renouncing the term of limitation of liability being 31 December 1963***
2.) Introduction of suitable therapy for patients at our expense without acknowledgement of legal obligation
3.) Compensation settlement along the lines of settlements of August and September.

In the event that we go down none of the paths 1.) to 3.), we will very soon have to answer for Contergan polyneuritis in a civil case.

....

V. Timeframe of 15 February to 25 May 1961

Following reports of polyneuropathies subsequent to thalidomide use in England in early January 1961 and the Voss lecture, those involved finally understood that Contergan polyneuritis needed to be taken seriously as leading specialists in internal medicine and neurologists demanded. At least the parties involved realised that the likelihood of Contergan causing nerve damage could not be considered slight. Inevitably, this posed the question how possible damage caused by the product could be prevented. Legally appropriate measures needed to be taken under public safety obligation. In a similar case the Federal Supreme Court has defined liability with respect to public safety obligation in its decree of 10 July 1951 (Insurance Law 1, 60) on page 343 as follows:

Having looked into similar cases, the Senate has already acknowledged for similar cases that "... The manufacturer of a product ... irrespective of contractual basis may be required under aspects of averting danger to ... instruct in safety measures required. The verdict of 5 November 1955 (Insurance Law 55, 765) lists the case of a poisonous pest control product brought on to the market: Manufacturers must examine if the product could possibly be used in a way that ... might harm the user. If such use is possible while taking due care, the onus is on the manufacturer to see to it that consumers are adequately informed of the possible dangers of the product and the scope of its use ...

The legal thought processes of this verdict are applicable to the case now to be decided on. If the use of an adhesive is so dangerous as shown in the case of product X, then general public safety obligations require a manufacturer of a product to clearly make consumers aware of the dangers and educate them about safety measures to take when using the product."

To satisfy requirements of safety obligations, we considered the following measures:

1.) Application for prescription-only status in conjunction with effective urgent measures.
2.) Advising doctors and pharmacists.
3.) Advising consumers by means of unmissable information on packages and/or product information leaflets.

We left it at mail-outs to doctors and pharmacists and further alteration of the product information leaflet, however. Looking at it objectively, these measures surely were not optimal. We did not reach the consumer who bought Contergan without a script. It was left to chance whether the consumer took a possible tingling sensation under the skin/paraesthesias seriously and consulted a doctor soon enough. The mail-out to all doctors itself was a pretty effective measure, but it was an approach full of loopholes since many doctors would have only glanced superficially at such a print-out.

As such, we will be accused of half measures which had limited value in their effectiveness of averting danger. As mentioned in the Note of 10 July 1961, the modification of the product information leaflet at the end of February 1961 represents a step backwards if anything. The easy-to-read section on the back of the product information leaflet which used to say 'Please Note' was dropped. Its message was incorporated into the last paragraph of the section 'Mode of Action and Tolerability'. The likelihood of this warning being read in this place was certainly not great. The fact that there is a recommendation in the introduction of the leaflet 'to take Contergan only when there is a genuine medical indication and upon doctor's order' will hardly exonerate us.

Since Contergan was a medication which was freely available over the counter at the time, we will have to allow for the possibility that consumers may have overlooked the cardinal symptom we pointed out. It is debatable whether every consumer of a medication available over the counter is obliged to study the product information leaflet before taking the product at least when it comes to long term users. It is to be expected that in dealing with previously unknown side effects, courts will demand a clear and unmissable reference in the product information leaflet in order to avert such danger (see red overprint end of August 1961).

As for the mail-outs to doctors, it will be held against us that we did not highlight clearly enough the possible danger of polyneuritis in connection with Contergan.
The most notorious such example, and there are others which could be cited, is our circular to doctors dated 17 April 1961 in which we dealt with the subject of neuropathy following Contergan under the heading 'Very good tolerability'. (This is the circular to doctors which Professor Thiemann returned to us with the comment that this kind of propaganda is unworthy of a reputable company.)

GRT.0001.00063.0304: 19 April 1962 Note – "Re In-principle determination of next steps in dealing with the Contergan matter", by Grt's legal department

I

In dealing with the question whether specific measures should be taken at the current point in time, and if so, which ones, one must take into consideration

the risk of litigation as well as the issue of what needs to be done to maintain the reputation of the organisation as a pharmaceutical company.

As indicated in the Note of 18 April 1962, very considerable risks of civil law suits arise from September/October 1960. The Note highlighted a number of issues associated with risks which cannot be assessed for their ultimate verdict by the judge at this stage.

It is to be expected, however, that in civil cases the facts of the matter will largely be resolved through the involvement of 'solidarity groups of Contergan victims' and other lobbies. It will hardly be possible for us to restrict the material under review in proceedings, especially since it is to be expected that we will have to respond to detailed presentations from the opposite bench.

As Dr Elbel's supplementary appraisal demonstrates, new documentation continues to emerge all the time which shifts the facts of the matter and puts a negative spin on things. Likewise the same applies to all personal statements which show abundantly what sorts of problems we can expect to be dealing with into the future.

Under these circumstances, it is not to be expected that our conduct will be judged objectively as justified on all counts. Should a court find that Grünenthal did not take

due care possibly in several aspects of the measures it should have objectively been expected to take, then it will not take much to establish the guilt required to arrive at a guilty verdict in a civil case. It is well known that the degree of guilt is irrelevant in such a case. Proof of minor negligence is sufficient.

If guilt is established at all, it will almost certainly fall into the timeframe of the first months of 1961 at the latest. Since Contergan use of individual victims went on until about mid-1961 in most cases, this, as a rule, would point to guilt of causing at least part of the injuries in individual cases.

And so we should draw the conclusion that in all probability we can expect to lose most civil suits brought against us.

The outcome of pending criminal proceedings is impossible to predict at the present time. It may be said, however, that chances of success are considerably better than in the case of civil proceedings. Nevertheless, the risk of individual parties involved being convicted is not exactly small either.

Under these circumstances, it appears appropriate to err on the side of caution and be prepared for a negative outcome of legal proceedings in the Contergan matter.

This means that the position of the company must be strengthened so that it can absorb the heavy blow that a defeat in the case would bring about. A strengthening of the position of the company can only be achieved by means of an improvement in its reputation. The reputation of the company will surely

suffer most, indeed it may even receive a fatal blow, if we are convicted in civil and criminal cases and publicly charged with stringing Contergan victims along without having offered them any practical help.

It may be said with some certainty that in such a case we will be presumed guilty from the outset and condemned sharply and publicly for our lack of willingness to carry the damage which has been done.

We must consider too that the standing of the company may possibly be weighed down by the evidence that Contergan causes deformities even if we are absolutely not guilty.

All this has the potential to threaten the existence of Grünenthal. We must therefore do all we can to avoid being caught unawares. Precautionary measures must actively promote the reputation of the organisation. Large parts of public opinion have it that the financial interests of the company take precedence over other concerns in ways that can no longer be justified, especially when it comes to the needs of public health. It will no doubt take a great deal of effort to effectively deal with such accusations.

A potentially explosive situation could be diffused if Contergan injuries (neuropathies) were to be settled. Where settlements are not possible due to legal considerations, one should at least deal in-depth with the medical care of cases. This means that we ought to have thorough medical treatment undertaken at our expense. In the event of court proceedings it would be particularly detrimental to the reputation of the company if we were to be accused of not even having rectified injuries.

Also, general business policy must take the Contergan situation into account to a much higher degree than before to avoid even a semblance of inappropriate conduct. We must allow for a possible blowing up of inappropriate conduct by the public which overall at least has the potential to more or less put a seal of disrepute on Grünenthal as a company. This particular point takes on a very special meaning. A satisfactory solution would also block the main wellspring of staffing difficulties.

Measures taken on behalf of Contergan victims must be accompanied by intensive but very carefully and tactfully managed public relations efforts which must undemonstratively put the conduct of Grünenthal into perspective with the medical and general press.

II

A. Therefore the issue of settlements is only part of the problem.

Since early December 1961 we have worked on the premise that all our efforts must focus first and foremost on achieving a positive outcome in criminal cases. The following consideration speaks against entering into settlements:

We might be prejudged as far as guilt is concerned. Looking at it from a legal perspective, the question of guilt remains open in the case of ex gratia settlements. It should not be underestimated, however, that psychologically courts are being pressured into a guilty verdict. This would imply that we consider a guilty verdict possible, and one tries as hard as possible to find our most vulnerable spot.

Whether or not the above considerations are still valid today, is a question which depends on whether or nor the financial risk which the company runs by following along the above lines, remains below the line of economic feasibility.

It is difficult to comment on this question, in particular because it is not possible at the present time to establish an accurate estimate of the number of potential civil claims and the level of such claims.

In about 90% of all cases seeking redress, claims have been made based only on a cause and not an amount. Medical clarification of these cases carried out in the past months allows for an approximate estimate of the possible amount of claims (implying liability on the part of the company). In any case there is bound to be a large number of unknown cases.

Our experiences with settlements of August/September 1961 give us some indication.

According to this, one might subdivide cases according to the following percentages:

1. 20% mild cases	in the order of	DM 1,000.00 – 2,000.00
2. 70% medium-range cases	in the order of	DM 2,000.00 – 4,000.00
3. 10% severe cases and more	in the order of	DM 4,000.00 –

We currently have 360 cases seeking redress and approximately 900 cases where we have entered into correspondence according to a PNP report without a claim having been made so far.

Dr Frenkel claims that about 1,000 cases of redress have registered a claim, and it is to be assumed that a number of claimants have registered with us as well as Dr Frenkel. Over the past two months approximately three new cases per week seeking redress have surfaced. There have been virtually no new reports coming in from our field staff via PNP.

After repeated severe denunciation through the press, we therefore assume that in addition to the above figure of approximately 2,000 cases (registered with us and Dr Frenkel), we may expect an increase of up to double that figure at the most. Assuming a maximum figure of 4,000 cases, this would have the following financial implications based on the above estimates of percentages:

Approx 800 million	mild cases	(20%) @ DM 1,500.00 = DM 1,2
Approx 2,800 million	medium-range cases	(70%) @ DM 3,000.00 = DM 8,4
Approx 400 million	severe cases	(10%) @ DM 6,000.00 = DM 2,4
Total: million		DM 12

What is significant from an economic point of view is that about 40-50% of this figure is virtually borne by tax when payments are spread out over several years.

So our Sales Management Team under the leadership of Mr Karsch tells us that we have not only no loss of turnover but a steady increase of sales (although Contergan is of course not included in the figures). Our sales have therefore not been affected to date by attacks of the press and the like. Provided that this does not change in the future, it should be possible therefore to finance the Contergan injuries essentially through ongoing business revenue while taking advantage of the tax situation.

It stands to reason that the scenario changes completely when we have to pay solicitors' and court costs in addition to damages. A 50% increase of the above estimate of 12 million DM to 18 million DM would therefore seem entirely feasible.

On the other hand a reduction might be achievable - where we take the risk of entering into civil suits – since presumably some of the 'victims' may refrain from initiating legal proceedings. These are always unsophisticated people who have an innate fear of courts. It is precisely this group of people that, as experience has shown, will settle for relatively small sums. Furthermore, looking at it from a purely legal perspective, some claimants may be put off by pleas of the statute of limitations. Whether we will be successful with this in a court is doubtful however. As far as the press is concerned, this would be to our detriment in a way that we would not recover from. The headlines will proclaim: 'company has its eyes on profit, then resorts to expiry of victims' claims'.

On the other hand, the first negative verdicts in civil and criminal cases would have the effect of increasing costs. Once the guilt of the company (or one of its leading employees) has been established in a court of law in an individual case, every claimant (at least where represented by a lawyer) will attempt to increase their claim.

The starting point for settlements, and an appropriate limitation of the level of individual claims, currently is at a favourable stage:

a) Criminal proceedings have a long time to run yet – outcome uncertain.

b) The first teratology trial which is currently under way in Berlin allows us to assume that we will have the first positive verdict in the first legal instance in the not too distant future.
c) As far as civil trials are concerned, no verdict against us has been recorded via PNP.

This puts us in a strong position that allows us to tackle the levels of claims in the context of settlement negotiations with some conviction since the matter of entitlement to a claim has by no means been established. This uncertainty is bound to have a bearing on the reduction of a claim.

At the moment the argument of lengthy time periods going by for claimants, who have to wait out their own civil or criminal claims, also speaks for us. At the end of the day the consideration cannot be far from claimants' minds that they run the risk of receiving only a share or maybe nothing at all after years of waiting or trials if the funds of the company have been exhausted by settlements of previous claims.

As such we arrive at the following conclusion:

1. The question whether claims for redress on account of nerve damage are dealt with by means of settlement or via the courts, touches on a threat to the existence of the company.
2. In view of unfavourable prospects in civil suits (see Note of 18 April 1962 re General Contergan situation) the above indicates that the total amount of damage may have to be revised upward by 50% bringing us to the brink of insolvency.
3. Should one or several gentlemen of the company be convicted in a criminal trial, this would be a huge blow to us. In view of everything we know, we assume, however, that it should be possible to at least partially absorb such a blow to the reputation by means of boosting one's efforts, drawing on distinguished scientists and, if we are lucky, introduction of new, important drugs in so far as the means to achieve this remain at our disposal.
4. The conclusion to draw from points one to three is that a favourable outcome of criminal trials (dismissal of claims or not-guilty verdict for <u>all</u> accused) cannot be given priority over the problem of satisfying the claims for redress.

B. Summary of considerations which speak for and against settlements in so far as they have not been dealt with under A.

The following speaks in favour of settlements:

A mitigating effect in the case of criminal conviction and a possible disinterest of parties filing for criminal suits once civil claims have been met. This in turn would increase chances of achieving a ceasing of criminal proceedings.

Overall, settlements represent the cheaper solution: it is to be expected that a number of 'victims' would receive settlements whose claims would not have been successful in court. On the other hand, substantial savings could be made by means of lower settlement fees, eliminating legal and court costs as well as substantial cuts of organisational staffing fees. Last, not least, loss must be allowed for that is incurred on account of efforts going into the Contergan matter which cannot be put into productive tasks for the company.

Settlements should be carried out as expeditiously as possible. The lower claims should be dealt with first. Higher claims should proceed to the final stages of settlement only after dealing with the bulk of the smaller claims. Negotiations should not be conducted in a spirit of petty mindedness on our part. Rather, we should aim for a solution seen to be appropriate. Where a settlement cannot be reached, we will have to let such cases go to court. It stands to reason that in most cases appropriate settlements should be achieved with the help of the court. In such cases, one should continue with legal disputes to establish a precedent. If need be, one will have to match the claim as closely as is necessary to avoid conviction. In this manner, it should be possible to avoid a civil conviction in practically all cases.

To the outside world we would present an image of maintaining the upper hand in the malformation suits and were not convicted in civil suits for nerve-related issues either. It would be a significant advantage if the extent of guilt was not established in a court of law. This would allow us to take the firm stance that we entered into settlements because the risks involved in going to court appear too great given that even the slightest degree of guilt suffices to lead to a conviction.

Cases where Contergan does not sufficiently explain the aetiology of the alleged injuries, we should also deal with in court. Only if court proceedings find that causality can be established beyond a reasonable doubt, these cases should be settled in court.

If a criminal case were to lead to a conviction, then clearly the above-mentioned settlement solution would represent the best option. If criminal proceedings were to be dropped or the parties involved are cleared, this does not necessarily say anything of note about the chances of success in civil cases. Even if criminal cases take a positive end, these may well deliver fertile grounds for fighting us in civil suits.

This is because we would probably owe a positive outcome to the establishment of inappropriate conduct assessed in all objectivity on the one hand, but the parties involved being deemed not guilty. Equally, it could become apparent that negligence under civil law may be viewed favourably.

Therefore, even where criminal proceedings take a favourable development, we can not necessarily count on a lower risk in civil cases. Normally, a successful outcome in criminal cases would discourage many a potential claimant to pursue civil claims. In this case we must, however, allow for the activities of interest groups who will presumably study the results of criminal cases in minute detail. The conduct of interest groups will inform the conduct

of all victims irrespective of whether or not they directly participate in the activities of the interest group.

Without a doubt the first finalised settlements already will become known publicly. The interest group surrounding Dr Frenkel can be counted on to see to this. It is possible that Dr Frenkel will attempt to disrupt the finalisation of settlements by calling on his members in circulars to interest groups not to negotiate directly with us. Presumably a not insubstantial segment will not be dissuaded from entering into settlement negotiations with us however. In the long run more and more interest groups will tend to opt for cash now rather than wait a long time while living with the uncertainty of a trial risk.

There is also a possibility that Dr Frenkel will attempt to enter into a showcase settlement with us as in the case of the Volkswagensparer trial.

Will the number of cases seeking redress jump up once the results of the first settlements become known?

To some extent this may well be the case, but we need to bear in mind that we will certainly not be faced with more claims as a result of such reports than as a result of ongoing press coverage, lost civil trials or criminal trials. In any case we will have to be prepared for claimants who will approach us anew following the first reports in the press of claims we have settled.

Effect of settlements on the attitude of doctors and pharmacists: due to the negative publicity to date, we will have to be prepared for a loss of confidence with doctors and pharmacists. Negative outcomes in criminal trials or the first negative outcome in a civil case would mean further serious losses. Also, we should not assume that settlements would inflict more damage as they offer far less material for the press to get stuck into compared to civil or criminal trials which are reported on by the press on an ongoing basis, presumably over years.

Should doctors and pharmacists accuse us of deliberate delay tactics, as Dr Frenkel claims, our sales representatives can explain that we have needed time to clarify the medical circumstances of individual cases. This is the only way we could hope to arrive at a reasonably clear picture of the type and extent of injuries. Sensible doctors will appreciate that we cannot possibly make instant cash payments to every malingerer without medical assessment of the background of a case.

In the event that we are accused by Dr Frenkel that delays amount to malpractice on the part of the doctors in our employment:

As we explained already in our press release in early January 1962, addressing the interest group of 'Contergan victims', we must solve every single case medically and legally. Technical problems are the main reason why working towards a resolution has taken time. For each case we have had to write to a number of doctors whose workloads have been such that a speedy reply has not been possible. We have also had inaccurate data of patients which has necessitated further enquiries and other issues. Besides, only legal experts can

make a decision as to when medical investigations suffice for a legal assessment, not doctors.

In order to avoid issues arising from civil law, we have so far borne the costs of therapy in emergencies on condition that we may claim these back if it turns out that we are not at fault. This is to avoid accusations that there is a hidden acknowledgement of guilt as the prosecutor or criminal judge would gather if we had entered into a settlement.

Without a doubt, bearing the costs of therapy will be the only means of avoiding civil proceedings in a large number of cases. If we accept the costs of therapy, we must ask ourselves, however, if we will be dealing with the same accusations by prosecuting authorities and judges as in the case of settlements.

Undoubtedly, no one will pay therapy costs whose position is legally sound and incontestable so that the very fact of accepting treatment costs must reveal a certain degree of uncertainty about the outcome of civil or criminal trials. The difference compared to a settlement probably is not great and in the main is more gradual.

This is true particularly for cases where we bear the costs of therapy in a major way, say in the order of a million (which we currently may not be able to avoid if we want to avoid civil claims and continue with not entering into settlements). The prosecuting authorities can be counted on to be informed of this which then will give them all the more reason to go in search of weakness on the part of the guilty. An amount of such an order also would not serve the purpose of legally bringing us any closer to a final solution. Experience has also shown us that in individual cases successful attempts at therapy will awaken a desire for more rather than lead to a decline in demand.

The following speaks against settlements:

Prejudgement of guilt owing to a hidden acknowledgement of guilt (see above).

In terms of civil law, this is not of great significance. If we settle anyway, there is no need to debate the general question of guilt nor the possibility that Contergan causes neuropathies. In terms of criminal law, the question could have more serious implications. The fact that we settle all cases, one by one, could possibly lead the prosecutor's office to make a concerted effort to search for a guilty party since pay-outs would suggest that the company considers itself guilty. On the other hand, guilt under civil law on the part of the company should certainly not be equated with criminal guilt of the gentlemen involved. Settlements would have a better chance of leading to a waning of public interest in criminal prosecution if it is incumbent upon prosecuting authorities to conduct proceedings with no possibility of dropping them.

Therefore, one should not overestimate the danger that criminal proceedings might be in jeopardy and consider that failure to compensate may have detrimental effects should we lose a criminal case after all.

The fear that settlements are deemed from the outset as an admission of guilt on the part of the outside world and that this suffices to destroy the reputation

of the company, is not justified. We must bear in mind that public opinion today is already more or less convinced that Grünenthal is not entirely innocent when it comes to issues surrounding Contergan. Efforts on the part of the company to remedy the damage caused should therefore meet with a positive response.

The question of the effects of settlements in the light of criminal proceedings would require in-depth consultation with the lawyers involved, in particular Professor Dahs.

29 May 1962 Letter from GRT to Dr Lehmann

... we can advise you of the following:

1. Generally Contergan does not affect ovarian function. It was observed in isolated cases where patients who were regularly taking Contergan had menstrual cycle problems that these virtually instantly disappeared once the substance had been discontinued. Since these were extremely rare findings that did not in any way correspond to the animal test results, the patients could not and/or were not subjected to any further gynaecological or endocrine examinations.

2. In animal experiments a certain spasmolytic effect on the uterine muscles was ascertained, however, in the absence of comparative clinical studies, no statement can be made on the relevance of these findings.

3. During the clinical tests Contergan was of course also trialled in gynaecological and obstetrics departments. The resulting experiences were unreservedly good. The substance was administered both pre- and post-surgical procedures and before and after giving birth. At that time no notable side-effects were reported by any of the clinics. Unfortunately, we do not know if any women in the early stages of pregnancy were amongst the several hundred patients treated in this manner, since no such details were contained in the documentation.

GRT.0001.00064.0088: 20 July 1962 Letter from F Heinrich to Dr von Veltheim

Dear Dr. von Veltheim!

Subsequent to our conversation held in Stolberg, I politely take the liberty of sending you two reports written by me on Contergan side effects from 1959 and 1960 annual report I have already pointed out that the real Contergan side effects have been observed, which we must assess with the necessary seriousness.

I will look through my papers further interesting reports are available, send these to you.

GRT.0001.00064.0194 2: October 1962 Letter from Dr Ernst of the Gerolzhofen Hospital to Profesor Kulck (GRT)

I had the honour of being a guest at Grünenthal about five years ago. At the time your Contergan product was still being trialled under the name of K17 or K18. I had the opportunity to observe animal trials and was deeply impressed with their thoroughness. In particular, I remember very well that Contergan was fed to rats with carcinoma. It was reported at the time that Contergan apparently did not promote cancer growth. Since rats with implanted cancerous cells were used primarily, however, the observation was made that rats which had received Contergan previously, did not go on to develop cancer. This means that the implantation did not take. As much as I was deeply impressed with the thorough testing of the substance in laboratory and animal trials, I equally remember the peculiar attribute of Contergan to prevent cancer growth as outlined by Professor Lenz.

Apparently we are dealing with an effectiveness of Contergan on a background of very young cells. In the event that my memory does not serve me correctly, I would appreciate a brief explanation. Perhaps it is possible to develop a similar substance in this manner which not only targets cancer indirectly but directly. Surely then all the sacrifices that the substance may have claimed, will not have been entirely in vain.

GRT 0139 00168 0330: 20 June 1963, Letter from Hoechst to Public Prosecutor

Hoechst responded to an inquiry from the prosecutor and included a list of generation tests (tests on pregnant animals) conducted by or for Hoechst prior to 1961.

GRT.0001.00005.0554: 27 February 1964 Letter by Prof Weicker to Public Prosecutor

Dear Mr Public Prosecutor,

In your letter dated 28.1.1964 you advised me of the names of eight families, which, as dependents of the Chemie Gruenenthal Company, during the years between 1959 until 1961, had had deformed children. Of these eight families, three had been known to me since 1961/62 - Dr. Huebner, Nix and Plittersdorf - and one since the beginning of this year, Schumann. Apart from these I know of two further families, whose addresses you don't have. I will try to obtain the permission of these two families to allow me to send you their addresses , even in both cases it is a matter of relatively difficult situations.

The reason for my letter today is however the following question: Wouldn't it be useful that I could examine the children of Dr. Koerbel, Dr. Loeschner, Greven and Leufgens to determine whether or not the deformities present in

them are unambiguously deformities caused by Thalidomide? The total number of ten affected families in 170 births - this detail is from Dr. Siewers in his discussion contribution during the symposium in Den Haag in September 1963 - is so unusually large that using it from a scientific as well as from a legal point of view would cause sensation. Especially because of this it appears to be important to me that it should be ensured that a child with a cleft palate or a meningomylocele isn't in this group by accident, i.e. with a deformity which can be observed relatively commonly anyway. Should you consider my thoughts to be correct, I request your suggestion as to the form in which such an examination would at best be carried out. Naturally a short one off visit it is enough for the determination, whether or not it is a matter of a typical case of Contergan. For a scientifically as well as legally impeccable documentation on the other hand it would be better if the children were subjected to the same radiographical and electrocardiographical investigations as the children which I have to assess for the expert report for the trial. To strike a balance it could be possible that the four children which are the subjects of debate could be investigated in the Aachen Clinic by Prof. Schoenenberg - following the same guidelines which we have exhibited for investigations here in Bonn. I would be thankful for your point of view.

STATEMENTS

Archive document: undated statement by the Institute for Pharmacology and Toxicology (Berlin, East Germany).

The statement relates to the rejection of thalidomide drugs by East Germany in early 1961 on the basis of safety concerns and other reasons.

Findings

The findings below are the result of thorough scientific consultations by representatives of experimental and clinical pharmacology, especially specialist representatives of these areas in medical faculties in the German Democratic Republic (University of Berlin, University of Leipzig, University of Jena, University of Rostock, University of Greifswald, Medical Academy of Dresden, Medical Academy of Erfurt and Medical Academy of Magdeburg). As such they do not constitute a personal opinion. They were conducted in preparation for Drug Law legislation in this country and are summarised concisely in the guidelines for preparing an evaluation concerning medicines (rules for implementing the law) and are thus legally binding for the GDR. The relevant consultations were held in repeated meetings in 1950 and 1961; they therefore took place before the particular effects of thalidomide were known.

1. Pharmacological and clinical tests of new, potential drugs are not schematic, but are always to be conducted with a view to the specific efficacy or use of the drug.

2. Testing for side effects from drugs which are not intended for a once-off application, but for repeated, periodic or chronic use, needs to be conducted particularly thoroughly and over a long period of time.

3.This applies especially to drugs which are earmarked to be sold over the counter, and are therefore potentially not subject to ongoing or occasional control through a physician.

Additionally:

4.The responsibility for a new drug's harmlessness lies initially with the manufacturer who has to develop all scientific documentation necessary to prove its innocuousness. This responsibility can neither be shifted to a physician who is not specifically trained in medication toxicology, nor, even less, to a layperson buying the drug (accordingly, in the GDR manufacturer have to demonstrate their scientific qualifications; the licensing procedures valid in the GDR since 1949 relieve manufacturers of certain aspects of their responsibility).

I would like to add my own evaluating statements to these findings:

1.A potential drug, which in animal experiments gives rise to suspicion of toxic effects on organs involving the metabolism like liver or kidney,

on bone marrow and especially on the nervous system, cannot be released for clinical tests on humans without intensive, chronic studies over longer periods (at least half the live-span of a small animal) and involving various kinds of animals - the only exception being when its use can be expected to bring decisive advantages in life-threatening situations. In these instances, clinical trials on humans are justifiable.

2.This last stipulation is never given as far as sedatives are concerned. Thalidomide was never, not even when it was introduced, credited with decisive life-saving significance.

3. If an intensive examination of chronic toxicity reveals a positive result, the reason for this side effect has to be thoroughly analysed before clinical tests can be conducted on humans. If clinical tests do not result in adverse consequences initially, the substance can be released on the market if clinical specialists evaluate it positively. All conspicuous effects which occur in practice shall be systematically recorded for a period of at least two years. Over the counter dispensing (without medical control or prescription) is therefore not justifiable.

If any kind of side effects are observed, physicians using the medication should be informed of them quickly so that serious consequences can be avoided.

4. These requirements were not met in the case of thalidomide.

Discoveries of thalidomide's neurotoxicity were not brought to the doctors' attention by the manufacturer.

5.The occurrence of specific side effects (neurotoxicity etc.) in humans necessitates renewed testing of the pharmacology of such a substance. At the same time, this substance should be limited in its availability (e.g. only on prescription). These relevant measures were not taken as far as thalidomide is concerned. (Thalidomide was available over the counter in West Germany).

6.Every scientist who is working in the field of toxicology knows that a specific toxic effect observed on an animal does not necessarily mean that it has to appear in a similar fashion in humans or another animal. The occurrence of an embryo-toxic effect as a known neurotoxic connection (animal and human) is therefore not an unforeseeable fact, but has to be considered as a possibility.

7.After it was first reported that embryopathy was suspected by an Australian doctor - especially as it was known that thalidomide occasionally caused damage to the nervous system – a careful examination of this suspicion by the responsible manufacturer would have been necessary. This did not happen.

In 1961, approval of thalidomide as a medical drug in the GDR was the subject of a consultation among experts (clinicians,

pharmacologists and pharmaceutical chemists). At the time they determined the following:

1.Statements about thalidomide found in international scientific literature as well as scientific results published by Grünenthal are insufficient to justify the introduction of a sedative which is meant to be used by a large group of people long-term, especially as thalidomide cannot be classified as a necessary drug (one which is significant because it either saves lives or safeguards the social order).

2.Occasional findings that the product is neurotoxic give rise to the assumption that the compound is not as harmless as the manufacturer claims it to be. In order to introduce the new compound, extensive animal experiments and clinical trials by qualified scientists would be necessary.

3.A very experienced chemists pointed out that the chemical structure of the compound (glutamic acid derivative with possible antimetabolite characteristics) might have unexpected effects when taken long-term. (Prof. Böhm, at the time tenured professor for pharmacy in Leipzig).

In view of the questionable scientific material available, the possible neurotoxicity and especially seeing that the product is essentially clinically dispensable, the expert committee decided to reject the market release of thalidomide – regardless of whether it was produced by themselves or by others. At the time it was also recommended to the state authorities in the GDR to not only prevent an official import, but also to put measures in place to stop private importing of thalidomide. These decisions and recommendations were implemented at a time when the committee was not aware of the embryopathies caused by thalidomide.

ırchive document: 18 February 1963 Letter from Dr Hoff to Prosecutor

Dear Mr Prosecutor,

As instructed I am hereby giving a statement on the travel report by Dr Sievers dated 18 October 1961 (photocopy) that was forwarded to me.

This report contains the remark that at the beginning of the conversation I certainly had proceeded from the notion that Contergan would have to be withdrawn from the market. However, responding to the specific question whether the C preparation should be withdrawn from the market, I [was said to have] said "but perhaps also not", particularly because of the good experiences in psychiatry and paediatrics. Due to this representation, significant points of the conversation conducted between Dr Sievers and me were rendered incorrectly or at least given the incorrect emphasis.

According to my positive recollection that undoubtedly renders the meaning of my comments correctly and probably also renders the actual words used

reasonably accurately, the following was said: Soon after the opening remarks of the conversation, Dr Sievers asked me the question as to whether I thought it was right to withdraw the preparation from the market. I replied that this was of course a very serious decision but that I thought it was necessary to withdraw the preparation from the market. I recall having added too that in this regard he should also explicitly pass on to the owner of the Grünenthal company from me that I personally know this gentleman from the time of my work in Aachen, where I visited his family as a doctor.

Dr Sievers then said that further queries directed at numerous psychiatrists and paediatricians had not resulted in any reports about damage but only in favourable assessments of Contergan. The manufacturing plant was therefore determined not to withdraw Contergan from the market for the time being. I then explained that the injuries, the nerve paralyses, that had already been observed, were nevertheless very disquieting. [I said that] the sleep medications in the barbituric acid series were also capable of causing a number of injuries but that these were known to us and were not as serious overall. [I said that] Contergan belonged to a totally new active group and that the possibility certainly existed that it was interfering with the enzyme processes in the cells in a yet unknown manner, and that further injuries may well transpire. Towards the end of the conversation I believe to have given another reminder as to the fact that I had advocated the withdrawal of Contergan from the market. At any rate, I still added that I would be observing the further conduct of the Rosenthal company with great attention. This last sentence was correctly represented in Dr Siever's report.

Archive document: 15 March 1963 Statement of Pharmacist Koch (who had written to Grt about a malformed baby in November 1960)

The pharmacist Friedrich K o c h, born on 22.7.1899 in Bad Hersfeld, declared at his residence in Lingen/Ems, Emsstrasse 4:

I have just been presented with a photocopy of a letter addressed to me written by Chemie Grünenthal on 2. December 1960. I still remember the events in connection with this letter very well.
I have been a licensed pharmacists since 1926. During all of my employment I took it for granted that I had to be aware and take special care when selling medications to pregnant women. I think I am justified in saying that it is common knowledge that the female organisms is particularly sensitive during pregnancy. This means that during this time a woman cannot tolerate everything she normally would. I was certainly not the only one with this viewpoint, but rather it was definitely shared by a large number of my colleagues. Therefore I believe that the thought that the unborn child could be negatively influenced via the mother through exposure to something – chemicals for instance – has been around for years now. I cannot say whether I had read relevant publications in
technical journals years ago. However, I could not exclude this possibility.

I have naturally also sold Contergan from 1959 onwards at my pharmacy, the Mohren Pharmacy in Lingen/Ems. This product was requested often and was also prescribed frequently. At the time it was seen to be completely harmless and not dangerous even if used continually - according to the directions for use. As a pharmacists I had no reason whatsoever to dissuade a client from using Contergan, even one who was requesting it repeatedly without a prescription, because I trusted the directions for use. I have to emphasize that there is a certain relationship based on trust between a pharmacist and his customers in a town like Lingen/Ems, which might not exist in a large city.

Towards the end of 1960, I cannot remember the exact date, Mrs [redacted], Lingen/Ems, Brunnenstrasse 18, came to me. In October 1960 she had given birth to a child who had internal injuries since birth which had necessitated treatment in a clinic for some weeks. The parents could not account for the injuries. However, her husband had taken it into his head that they might be connected to Contergan. Mrs Schulz had taken Contergan during the pregnancy.

After my discussion with Mrs [redacted] I felt compelled to write a letter to the company Grünenthal on 24. November 1960. In this letter, which I do not have to hand anymore, I enquired whether a child could develop injuries if the mother had taken Contergan regularly during pregnancy.

The thought that a medication might possibly affect a foetus if the mother took the medication during pregnancy did not seem absurd to me at the time, but rather worth investigating. I am sure I would not have thought about this, if the product had been around for a long time with a proven track record and years of experience of using it. However, the circumstances were totally different as far as Contergan was concerned. This was a new product, composed of a completely new chemical structure. Accordingly, the question as I addressed it to the company Grünenthal on 24. November 1960, did not seem unreasonable to me.

- Apart from that, I know from my years of experience that pharmaceutical companies are generally very interested in receiving not only positive, but also negative feedback on new products they are manufacturing. Furthermore, I always took it for granted that the companies would be thankful if they received information or enquiries from practitioners. I have also never doubted that the manufacturer would diligently investigate such information. If this was not the case, the necessary trust between the manufacturer of medications and the pharmacist would no longer exist.

My letter dated 24. November 1960 was answered by the company Chemie Grünenthal with a letter dated 2. December 1960. Based on the content of this letter, I was then able to tell the parents that according to the company, their baby's injuries were not caused by the mother taking Contergan during the pregnancy. Naturally I presumed that the scientists in Stolberg had already looked into the problem of their Contergan breaking through the placental barrier and possibly affecting the foetus or that they would at least look into it after receiving my letter.

Thus reassured by the company, I continued to sell Contergan in my pharmacy. Then a customer told me that he had to go to hospital to be treated for severe constipation which was caused by using Contergan. I will advise the public prosecution in Aachen of this customer's name in writing, provided the gentleman agrees. At about the same time I was also informed by a lady that she had suffered disconcerting symptoms of constipation after taking Contergan. Other customers with whom I subsequently discussed the issue, had not experienced this.

As a pharmacist, you only find out that a company has changed the directions for use (packaging leaflet) if a customer asks you about it or through a special notification by the manufacturer or in the technical press. However, I do have to add that as far as notifications by the manufacturer are concerned, a pharmacists is sent so many letters, brochures etc., that one is not able to read everything. One skims over the correspondence, takes whatever seems particularly important and throws the other stuff in the bin straightaway. There is just no other way to cope with it all. Whether something is of particular interest is usually dependent on how it is labelled. I remember that during my long career, a manufacturer would frequently send out letters which were labelled in such a conspicuous and eye-catching way as to demand the recipient's attention.

I do not remember receiving a letter regarding Contergan by the company Grünenthal which was labelled in such a conspicuous way prior to publications about Contergan's side effects appearing in the technical press. It was therefore only through those three customers which I have mentioned that I was alerted to the fact that Contergan might not be as harmless as it was portrayed in the beginning.

When I heard of the withdrawal of Contergan from the market and the terrible suspicion voiced by Prof. Dr Lenz towards the end of 1961, I asked myself straightaway whether my letter dated 24. November 1960 had failed to prompt the company Grünenthal to investigate the question of a possible effect of Contergan on the foetus and do something decisive in this regard. This would mean that my letter would have been written in vain.

This is all I can say about the Contergan issue. Friedrich Koch

GRT.0001.00029.0160: 2 December 1960 Letter from GRT to Koch (the Grt response to his letter about the malformed baby)

Dear Mr Pharmacist,

We thank you for your kind letter dated 24 November in which you are asking as to whether a child could develop injuries if the mother has been regularly taking Contergan during her pregnancy.

Based on all observations and findings on hand to date, in particular from gynaecological departments, we can negate any causal connection here. Until now not a single indication exists at all to suggest that a human or animal – irrespective of age – could suffer any form of liver damage through Contergan. We therefore like to safely assume that the liver damage

diagnosed shortly after the birth of the baby you are referring to, is not to be connected with the mother's Contergan use.

It would be our pleasure to assist you with any further enquiries.

GRT.0001.001 06.0110: 4 May 1963 Statement by Dr H (Grt has redacted his name in its discovery)

General practitioner Dr [Redacted], domiciled in Munich [Redacted], born on 15 March 1921 in Pfaffenbichel near Rosenheim, when visited in his medical practice declares the following:

My wife was expecting a child in the period around December 1959 to May 1960. The pregnancy ended in a miscarriage. During that time my wife occasionally took Contergan, which, as far as I know, I had come in contact with through brochures of the Grünenthal company. Furthermore, I had also been given the usual doctor's samples.

In autumn 1960, my wife became pregnant again. As far as I recall, her last menstruation was in the first days of October. Because she was suffering from nausea, vomiting and very considerable weakness resulting from sleeplessness, I again gave her Contergan in the time from the beginning of November until December. At that time my wife was in Dr Geisenhofer's care, who runs a private clinic in Munich, Tivolistr. 4, and who treated her and monitored her pregnancy. Dr Geisenhofer also prescribed Contergan to her.

During the pregnancy, she was also given a suprarenal preparation (Cortigarant).

My wife's pregnancy otherwise took its normal course. During the pregnancy, or between the pregnancies, I no longer exactly recall this, I asked a Grünenthal representative, whose name I no longer remember, if I could give my wife Contergan without any concerns. He responded to this question by explaining that Contergan was totally non-dangerous and frequently prescribed especially during pregnancies.

On 14 July 1961, my wife delivered a girl with severe physical injuries. Still on the same day or on the next day, she was transferred to the Schwabing hospital, where she was treated by Dr Amman in the subsequent period of approximately 3 weeks.

When my daughter was around 6 months old, she was treated and x-rayed by Dr Huber at the local orthopaedic clinic at Grünwalderstrasse.

I release all of the afore-mentioned medical practitioners from their obligation to secrecy vis-à-vis the law enforcement agencies. Furthermore, I have no objections for the records of these medical practitioners being reviewed by an expert assigned to do so by the law enforcement agencies.

Immediately after the birth I pointed out the potentially harmful effect of Contergan on the child to Dr Geisenhofer and Dr Ammann. Both rejected such a possibility. I do not recall now as to whether I also pointed out such correlation to a representative of the Grünenthal company. I am being shown

my letter of 28 November 1961 to Dr Lenz in Hamburg. According to that I consider it likely that I raised this with a representative of the Stolberg plant after all. However, I cannot recall details of the names or the actual persons who visited me as medical sales representatives. The reason for this is probably simply the fact that there were long intervals between their appearances here. In addition I am very frequently visited by staff of other companies. I do not know if I would be able to make an identification in a line-up.

My daughter currently lives at my home.

There are no known physical or mental defects in either my or my wife's family. I also state expressly that we wanted our daughter.

GRT.0001.001 06.0107: 4 May 1963 Mrs H Statement

Mrs [Redacted], nee [Redacted], domiciled in Munich, [Redacted], born on 11 March 1922 in Riedering, District Rosenheim, when visited declares the following:

I was pregnant in the time from December 1959 until May 1960. In May 1960 I miscarried. Back then I was hospitalised intermittently at the Clinic Geisenhofer, Munich, Tivolistr., and given Contergan.

After speaking to my husband, Dr Geisenhofer also prescribed Contergan to me after I was discharged.

I had already asked during that pregnancy if I could take the preparation without any concern. Dr Geisenhofer responded to me at the time that according to the manufacturing plant materials, the medication was completely non-dangerous. I know that he is very thorough and went to particular efforts in our case especially.

At the beginning of 1960 I was expecting another child. Conception occurred on October 3rd or 4th. Back then, we wanted a child. Dr Geisenhofer had already told me earlier that I should ensure to be in good physical condition in the event of a new pregnancy. That was in fact the case in October.

In November/December 1960 I suffered from vomiting and sleeplessness. Because I was keen to keep the child in any case and to keep myself calm, I took Contergan during this period, which again had been prescribed by Dr Geisenhofer. which had been prescribed again by Dr Geisenhofer. Moreover, we still had doctor's samples at home. I then went to see Dr Geisenhofer once every month.

It was either during this pregnancy, namely at the beginning, or during my first pregnancy, that we were visited by a representative of the Grünenthal company, whose name or appearance I no longer recall today. I only know that it was a man, probably middle-aged. We asked back then, if I could take Contergan without any concerns. The manufacturer plant's representative explicitly emphasized that Contergan was completely non-dangerous, and particularly suitable for pregnant women. He also said that it was impossible to kill oneself with Contergan. If I had known that Contergan could cause

nerve injury in the form of polyneuritides, I would of course not have taken it. I definitely wanted the child and would have accepted sleeplessness for its benefit. I still recall exactly that I had a bottle of Contergan drops on my night table, and that I read the user instructions again and again.

During my pregnancy I was also given a suprarenal preparation (Cortigarant).

On 14 July 1961 I gave birth to a girl with severe physical damage. Since we wanted the child, I had also still given my consent to a caesarian section, which turned out to be necessary.

The delivery took place at the Clinic Geisenhofer. On the same day, my daughter was transferred to the Schwabing hospital, where she was treated by Dr Ammann.

On the first day after the delivery or on the following day, I overheard fragments of a conversation between my husband and Dr Geisenhofer. My husband mentioned the word Contergan. However, Dr Geisenhofer waved this off.

Later on, my daughter was also treated by Dr Huber at the orthopaedic clinic.

I release all of the afore-mentioned medical practitioners from their obligation to secrecy vis-à-vis the law enforcement agencies. Furthermore, I agree that the records of these medical practitioners are handed over to an expert to be determined by the law enforcement agencies.

To my knowledge, until this date there have been no physical or mental injuries neither in my family nor in my husband's family.

I am extremely keen for the investigation of the public prosecutor to be pursued. This is not so much driven by a desire for revenge, although naturally I am not very sympathetic towards the Grünenthal company, but by the fact that my child will later need significant support. It will always need somebody to look after her. However, I am aware that there is no discussion of any damage claim as part of the preliminary investigation and a possible criminal proceeding.

GRT.0001.00180.0145: 6 May 1963 Statement by K ü n z l i (senior Grt employee)

Appearing at the District Court Rosenheim on a summons, Mr Jacques K ü n z l i , Director of the limited liability company Biochemie GmbH in Kundl/Tyrol, domiciled in Stolberg [Redacted] declares the following:

During the time of my employment with the Grünenthal, I regularly attended the BKS [meetings] unless I was absent due to travels. These meetings did not take place periodically but were called when various items to be discussed had come up. Ultimately the BKS were the only opportunity for the sales and research departments to come together and discuss problems concerning both. Back then I personally was very interested to attend the BKS as regularly as possible, and often instigated the meetings.

The contact between research and the commercial side was very loose at the Grünenthal company. When questioned about Dr Mückter, I am convinced that, despite his revenue share, he has remained in the sphere of research and production. However, I have to qualify this by adding that he also contacted the export and licence countries on various occasions to smooth tensions that were occasionally caused by Mr Leufgen's tactlessness. Dr Mückter was the proper man to do so because he enjoyed considerable prestige as a scientist. It was presumably through attending international congresses, possibly also through various holiday trips, that Dr Mückter presumably came in contact with the company's representatives abroad, heard complaints of the company's partners, and was thus able to eliminate certain upheavals. This was probably especially the case in the year 1957, when I joined the company and the various responsibilities had not yet been clearly assigned.

The licence countries were not reporting to my department, so that I cannot say anything about possible negotiations, which Dr Mückter may have conducted with the Distillers and Merrell company. Dr von Schrader – who as I recollect acted as Dr Mückter's deputy until late 1958, and transferred to the licence department after tensions with the latter or with Mr Leufgens – established contact with the Merrell company, and later worked the US market and the other licence markets as scientific staff to the licence department. When the issue of Contergan polyneuritides became acute later on, Dr von Schrader was assigned to work on this.

The turnover of preparations containing thalidomide did not get off to a good start initially. I was responsible to work the South American, African and Asian markets amongst others. The usual doses of 100 mg was apparently too high for consumers there, so that frequent reports of headaches and comparable symptoms were coming in. As far as I remember I suggested producing tablets with 50 mg thalidomide in 1960, and also pushed this through. I am convinced that these pharmaceuticals would have resulted in good business in the areas I worked on in the long run. This is particularly true for the combination preparations, which, labeled non-toxic, were highly suitable to fight pain.

In 1960, towards the end of that year at the latest, I heard of the occurrence of polyneuritides after Contergan use for the first time. This late information was probably due to the fact that the three departments responsible for sales – domestic, license partners and export countries – were kept separate from each other extremely strictly, and that sharing information was not common practice.

I did not receive any such damage notifications from abroad, which amongst other reasons may have been due to the relatively low turnover. Even if individual notifications indicating a connection between Contergan and polyneuritis had been received, given the nontoxicity emphasised by Grünenthal again and again, these surely would not have been taken seriously. In any case, we would have attributed such damage to another substance. The total non-poisonous character of Contergan, which was continuously explicitly emphasised, would simply not have permitted any other

reaction. Even in the year 1960 the research side again and again pointed out the complete harmlessness of Contergan. When I say research, in this context I mean Dr Mückter and his staff.

As far as I recollect, me and my staff for the first time learnt more about nerve damage after Contergan from a report published in the British Medical Journal which we followed back then, but had received from abroad. It was not kept by the company. It may be, however, that at that time those injuries were also discussed within the company, but if so it would have been in a trivialising manner. Anyhow, the sudden occurrence of severe injuries came as a shock to the international department. Back then I was not very familiar with the term polyneuritis so that I first had to make enquiries. Therefore, if I presume that the knowledge gained of the injuries progressed along a [gentle (?); *illegible handwritten insertion*] upward line within the domestic department at first, then the international department was suddenly confronted with a very steeply rising curve. In saying so, however, I would like to stress that we ourselves did not have any injuries abroad.

Through my direct report Dr Eckard, who in my department worked in the same role as Dr Werner in the domestic [department], in essence I heard that a few cases of polyneuritides may have possibly occurred after Contergan use. Even if the injuries were initially irreversible, in terms of their numbers, they were totally disproportionate to the total turnover.

It was not at all the company management or my direct superior Mr Leufgens, who informed me but [I obtained information] via a relatively convoluted path through investigations, which were conducted by Dr Eckard, either in his own initiative or as instructed by me. Up until 15 February 1961 (Düsseldorf presentation by Dr Voss) the situation was such that I had not heard anything at all about nerve damage from the company management, and in the case of any enquiries directed at the person responsible for the preparation, it was distinctly trivialised.

From mid-February until May I was travelling abroad. Dr Bauer, who will appear here to make a deposition tomorrow, will be able to advise the exact dates.

The afore-mentioned dates of my trip were incorrect, as I now remember. To my knowledge I was present in Stolberg from February to April 1961, with the exception of brief trips. Following the presentations about Contergan side-effects given in February and March, Hermann Wirtz personally gave the instruction according to which all company employees were to refrain from making any comments about Contergan outside the company.

As early as at that time, the steps taken by the company in regard to the problem of Contergan side-effects were coordinated. When the compensation claims started, Dr von Veltheim was assigned with their processing, and now had to sort out and record the Contergan injuries together with the actual person responsible for the preparation, Dr Sievers. It was an open secret within the company that Dr von Veltheim enjoyed the full trust of Herman Wirtz. Dr von Veltheim dealt with everything that was of significance to the company's finances. Large transactions, such as export risk guarantees for

instance, were handled by Mr von Veltheim. For example, Mr von Veltheim sometimes spoke to me about taking out an export risk guarantee. Since these were large amounts of money, and I was aware that Hermann Wirtz already shied away from spending significantly lesser amounts, I voiced my concerns in this regard.

But Dr von Veltheim said that if he advised Mr Hermann Wirtz to take out such an insurance, then he would do so. The contract was then indeed concluded.

Dr von Veltheim's work during the course of 1961 increasingly focussed on Contergan damage, so that eventually he exclusively worked on this, and had an office at the Grünenthal headquarters. Roughly at about the same time as von Veltheim, Dr von Schrader was assigned to the Contergan issue. While von Veltheim was initially the dominant personality within the group with Dr Sievers only playing a subordinate role, Dr von Schrader later succeeded in getting the upper hand. Anyhow, this was the impression gained outside. How the internal power relations played out, I cannot say with certainty because the Contergan committee, which as such had indeed already existed since spring, was heavily shielded towards the outside. Around the early autumn of 1961, I had to give up two of my doctors – I no longer remember details of the names – to be assigned to the Contergan committee. I heard absolutely nothing back about the current state of affairs from either of them.

While Chauvistré was charged with sales and human resources within the company, Hermann Wirtz nearly exclusively occupied himself with the financial aspects. Hermann Wirtz also made the decisions. It is my certain opinion that both were fully informed, including about the details, of what was happening in the Contergan committee. I am concluding this from remarks made by Chauvistré at the occasion of the meetings, which preceded the withdrawal of the preparation. Following the withdrawal of Contergan, I presented Hermann Wirtz with the draft of my letter to the international representatives. The conversation at that time also demonstrated that to the greatest extent he was informed about everything to do with Contergan.

The interview is continued at 14:00 hours.

Herr Künzli further states:

In the time after 15 February 1961, and during and after the time the various negative publications appeared, the Contergan side-effects were vigorously discussed within the company – particularly of course within the domestic department and the licence department. However, today I no longer remember any striking opinions. The reason for this may be that I was nearly solely occupied with problems concerning foreign countries, and that we had not received any such communications from abroad. Whether or not Dr Mückter opposed amending the brochures and patient information leaflets, I no longer exactly know today. Anyhow, I cannot remember anything about it.

In my opinion, Mssrs Leufgens and Winandi were fully informed about what was going on in the Contergan committee. This can be concluded from remarks made by both of them at various BKS and other meetings during 1961. Moreover, Winandi was the person immediately concerned because the

daily reports, damage notifications etc. were received by his department. Leufgens was informed of the individual events both by Winandi and Chauvistré, who was heavily protecting him. In the spring of 1961 the issue of the prescription-only requirement for the preparation was discussed at various meetings dealing with Contergan, and which I attended. Essentially two groups formed; Chauvistré, Dr Werner and I argued in favour of having the preparation made prescription-only, while Winandi and Leufgens, for business reasons that were understandable from their perspective, and to my surprise also Dr Mückter, rejected making Contergan prescription-only. While Dr von Veltheim and Dr Sievers only occasionally commented in such meetings or limited themselves to technical issues, von Schrader occasionally changed his view point, so that he could not be associated with either group. Dr von Schrader gave the impression that his joy of discussing clouded the factual approach.

The majority of those participating in the discussion were generally against the prescription-only requirement. At the meetings it was frequently deliberated as to how the classification of Contergan as prescription-only could be delayed. The intention was to be able to give third parties the impression that one had conducted oneself responsibly, without being subjected to such a drastic measure like the prescription-only requirement for as long as possible, however. The general pitch was such that one was endeavouring to be able to present to interested circles an application, which was not to be granted for as long as possible.

While Leufgens, Winandi, probably also Mückter did not seriously deny that Contergan was causing polyneuritides, they nonetheless occasionally took the view that these cases were especially collected by the competition (Bayer, Hoechst etc.) and presented as a targeted attack on Grünenthal. Up until the withdrawal of Contergan from the market, I did not hear that a possible criminal liability was considered or discussed by members of the company.

When asked about the monthly reports by the different departments, I state that the company management, that means Hermann Wirtz, Chauvistré, Mückter, Leufgens, regularly saw these papers. I know from occasional further enquiries by Wirtz, Chauvistré and Mückter that they actually read those reports. Mückter sometimes made suggestions.

I am only scarcely cognisant of circulars, Therapeutical Letters and the Information Service etc.

Brochures and patient information leaflets destined for abroad needed to be authorised by the research department, i.e. by Dr Mückter. I assume that the respective materials for the domestic market required the same authorisation because I recall that at the occasion of a BKS, Dr Mückter corrected a draft and gave it to Dr Werner.

During the summer of 1961 the accusations against Contergan were intensifying. I remember that one day Dr Werner spoke to me in a corridor in the Grünenthal administration building and said that in regard to Contergan, significantly more severe injuries than those already known were to be anticipated in his opinion. He was referring to other injuries than

polyneuritides. In the same period Dr Werner said at the occasion of a BKS [meeting] that one needed to investigate the diaplacental transfer of Contergan by way of an animal test to be able to determine the possibility of damage to the foetus. I still precisely remember this statement. As far as I can recall, Dr Mückter said that one would have to examine this some time. I no longer remember exactly when my conversation with Dr Werner took place, and when the above-mentioned statement within a BKS took place. In September 1961, I went on a business trip which took me to West Africa. The above-mentioned statements by Dr Werner and the response by Dr Mückter were made before this trip. Upon questioning, I declare that I do not know anything about an enquiry from Finland as to whether Contergan was fit to pass through the placenta. Finland was not part of my area of activity. However, certain incoming items were not even presented to me first but directly forwarded to the Contergan committee. This complied with the instruction by Hermann Wirtz, according to which all Contergan enquiries were to be directly handed over to the committee. This arrangement had not only been in place since September 1961 but had been set up as early as after the actual 'founding' of the Contergan 'preliminary committee' in the spring of 1961.

In mid-November 1961, Dr Mückter gave a presentation at a meeting, it was a BKS, on a suspicion uttered by Dr Lenz about a possible connection between Contergan and malformations in newborns. These statements were generally noted with unease, as though one did not really believe them. The events surrounding Contergan had already developed in such a way without this suspicion that, while this further accusation was noted, it no longer had the effect of a sensation. I still remember that several gentlemen from the research department – I can no longer recall individual names – made ironic remarks about Dr Lenz (son of a top Nazi, nothing sensible could be expected from somebody with the first name "Widukind", or similar remarks of this ilk).

It was eventually determined during this meeting that Schrader, and as far as I can recall another member of the Grünenthal company, were to drive to Hamburg to get in contact with Lenz. The further procedures to do with the withdrawal of the preparation are known to the prosecutor. This is why further deliberations on this would be superfluous, especially since I was not involved in the critical meeting which lead to the withdrawal.

When again questioned about the statements made by Dr Werner that one would have to examine as to whether thalidomide was breaking through the placental barrier, I further state that sometime later – but prior to the withdrawal of the preparation from the market – I enquired via Dr Eckard about what happened with the matter. I heard that the trials were under way, but that no determinations had been made in either direction.

Archive document: 11 July 1963 Statement of Brandt (doctor who reported a malformed baby to Grt prior to the cessation of thalidomide sales)

I have been a registered medical practitioner since 1949, and then worked in various hospitals as an assistant physician. I mainly worked in surgery. In 1959 I started my own practice as a general practitioner here in Lübeck.

In March 1961 I was called out to attend to a malformed child. It was the first time that I ever saw such a child. It had severe malformations of the upper extremities. Following a short treatment, which, however, was not in connection with the malformations, I also treated the child on various later occasions.

On 15 September 1961 the father telephoned me and told me that his wife had taken larger doses of Contergan during her pregnancy in Goslar, where the child was also born at the clinic. [He said that] this medication had been very frequently prescribed in Goslar, and that the clinic had told him that several cases of malformations had been observed there in recent times. [He said that] now in retrospect, he realised that a correlation with taking Contergan was probable. I was aware that the parents, who were well situated, had been doing much thinking about their child's malformations. This question was totally new to me and I assured the father that I would discuss this question with the manufacturer at the next opportunity. Approximately 2 – 4 weeks after this conversation with the father, a sales representative of the Grünenthal company made a routine visit to my practice, and I related this case and the suspicion that had been voiced to him. He was unable to tell me about any experiences regarding harmful effects or impacts at all on the unborn child. He promised me that he would discuss this set of questions with his company and notify me, should anything be known about it. I then did not hear anything more in regard to this matter until I happened to read about Lenz' suspicion in the newspaper at the end of November 1961. The father of the child telephoned me one or two days later and said to me that he had already contacted Dr Lenz. I myself then spoke to Dr Lenz on the telephone several times, and also told him that I had already spoken about this question with a sales representative of the company earlier on.

It was about six months later that – as I believe the same sales representative – came to visit me again. The details he gave me on the question of the impact of Contergan on the foetus were still very evasive at that time. He pleaded to the fact that the investigations had yet not been completed. I have just spoken to the father of the child on the telephone. He has agreed to me disclosing his name to the prosecution in Aachen, and he is willing to provide any kind of information.

Archive document: 30 April 1964 Professor Fritz Kemper Statement (a Professor who performed experiments with thalidomide in 1961)

During our visit at the Pharmacological Institute of the University of Munster, the private lecturer Dr Fritz K e m p t e r , residing at Roxel, Schonebeck, declared:

In the spring of 1961 I carried out trials about the effects of psychiatric drugs on the endocrine system. In this context I was also interested in thalidomide and approached Chemie Grünenthal at the end of March 1961, enquiring whether they would let me have some of the pure substance. They complied with my wishes. During the following months, the company sent me a certain amount of thalidomide on request every time.

After experimenting with thalidomide on rats for about 2 ½ months, I used the substance on male chicks. Apart from general questions, I was interested to see whether it was possible to reproduce polyneuritides. At the time, Chemie Grünenthal had no knowledge of the type of experiments I was conducting. However, they always fulfilled my requests immediately.

The trials with male chicks yielded surprising results which were later published in the magazine *Für die gesamte experimentelle Medizin* [For all branches of experimental medicine] 1962, page 454 – 459 (volume 135) as well as in volume 136, page 86-96 of the same magazine. To this extent I am referring to both studies.

In October 1961 Dr Michael from Chemie Grünenthal visited me. I remember that we discussed thalidomide's mechanism of action in connection with the results of the trial involving the male chicks. I had made a short note about our conversation, which reads:

"

13.10.1961

2 pm – 3.30 pm

Visit Dr Michael

(Grünenthal)

"Excerpts of the findings were presented:

1) photos,

2) graphs showing weight,

3) histology, liver and spleen, Fe - colouration.

Dr Michael was not familiar with thalidomide's mechanism and metabolism. Grünenthal had carried out trials aimed at Vitamin B (B1, B6). (Pigeons beriberi) without any results.

I was promised the information once the trials were concluded."

I am shown Dr Michael's report on his trip from 24.10.1061. His statements accurately describe the essential content of our discussion.

I cannot remember whether Dr Michael and I elaborated on thalidomide's side effects in human

medicine. I cannot remember in particular whether my visitor announced any figures of reports of side effects received by Chemie Grünenthal. However, I am relatively certain that these questions had not been discussed because they did not touch on our subject.

I recall also a visit by Dr Beckmann - according to my documentation it took place in March 1963 –during which he argued against my vitamin-B-hypothesis; see my publications for further details.

I will shortly send all correspondence with Chemie Grünenthal to the public prosecution in Aachen.

Archive document: 5 June 1964 Deposition Dr Augustin Peter Blasiu

Since the 1.7.1960 I have been in private practice as a specialist for women's diseases. Prior to this I was the assistant medical director in Dr. Roth's private Women's Clinic in Munich (100-200 beds). Apart from Dr. Roth and myself, the clinic is staffed by 10-12 so-called staff doctors. Our patients are as a rule admitted for a period from 14 - 21 days. The pregnant ones are on average in the clinic for 7, at most 10 days.

As to the question of Contergan-issue to our female patients I can say the following: As a sedative, prior to operations, they received for one or two days three times daily one tablet @ 25 mg and after the operation - 3 days later - one tablet @ 100 mg for sleep purposes. With breast-feeding mothers after overexertion during delivery - they suffered from sleeplessness because of this - we dispensed one tablet a 100 mg Contergan-forte after delivery. I wish to point out urgently that patients received Contergan tablets for 8 - 10 days at most. This medication was never given to pregnant women. It is my fundamental outlook never to give mothers-to-be sleep drugs or sedatives. It is an old fact of experience in medicine that, fundamentally, mothers to be are not to be given barbiturates, opiates, sedatives or hypnotics because these substances can affect foetuses. This fact had been known even before the theratogenic effects of Contergan had become known. For this reason I never, - as already mentioned - gave chemical substances to mothers to be. From my publication from 2.5.1958 it is only evident that I gave Contergan to those who had been operated on and to breast feeding mothers. In my publication there is no mention, even with a single word, of issue of the medication to pregnant women.

Prior to my duties in Dr. Roth's Women's Clinic I was working in the First University Women's Clinic in Munich mainly with Prof. Dr. med. Ries in the radiology department. During these duties I constantly checked medications, which was known to the clinic visitor of the Gruenenthal Company, the Chemist Mr. Kaben. That will probably be the reason why he visited me in Dr. Roth's Women's Clinic and why he asked me to test Contergan. At the time, there was no talk of issuing the medication to pregnant women or breast feeding mothers and of testing the affectivity. For me it was out of the question anyway to (sic never) ever issue the medication to pregnant women. After completion of the manuscript it was, via the chemist Kaben - it is also possible, that I had sent it directly to the.company - sent to the company, because it had the greater means of accommodating it in specialist medical publications. My manuscript was returned to me once more by the company with the request that I abbreviate text formulations and omit curve graphs, because these couldn't be accommodated in the specialist medical publication. Changes to the text by the company had not ensued. For my

scientific work I received at a later point in time, without request, a payment of 800.00 DM by the company. I would like to emphasise that no agreements in financial respect had been made. I also never held lectures or readings or conducted research travel at any later point in time which was in any way connected with Contergan. I can only remember once having spoken with Dr. Werner about my research. I have not had any further contact with the company or with executives.

As to the letter by Chemist Kaben to head office on 27.1.1958, which was shown to me in extracts, in which it is noted that
a) casuistry was omitted, to make the publication more dynamic and forceful and to have sent corrections to the publication to Chemist Kaben, and
b) a competitor company wanted to financially support me in opening a practice, if I would delay the "Contergan paper",
I can retort with the following:

As to the first queries listed under a I can really not say anything. I don't know how Chemist Kaben came to such a formulation. As already mentioned, I also wrote my paper completely uninfluenced by the company and I would not have allowed any changes to the text in scientific regard .

As to the text passage about the competitor company or the financial assistance respectively I am lost for words and it is a mystery to me, why Chemist Kaben reported anything like this to the company. Of course several representatives of other pharmaceutical companies knew that I had been testing a preparation called "Contergan" at the time. There had never been any talk about things as Kaben reported them.

At a much later point in time Chemist Mr Kaben approached me with the request of compiling an extended Contergan paper. I very explicitly refused this, especially because I had not prescribed Contergan any more after my first investigation. In our clinic, doctors never prescribed a medication, because patients were issued with what had been purchased in-house. As far as I can recollect, Contergan was not a standard preparation of our clinic that would have been purchased on an ongoing basis. The note by Chemist Kaben from 19.12.1960, whereby I had basically been prepared to write the extended report, is therefore incorrect.

I am being shown a letter from July 1958 (Dr Werner), which had at the time been sent to all independently practicing doctors by the company and which begins with the words "During pregnancy and breast feeding...."

This letter is totally unknown to me and I am seeing it today for the first time. From the contents one would have to assume that I had reported in my paper to have prescribed the sleep drug Contergan during pregnancy and breast feeding, because it harms neither the mother nor the child. As already mentioned, this is not the case and I would have defended myself vigorously against the distribution of any such letter with my name and in reference to my paper.

I regard this letter of the company to the medical profession as unfair, misleading and irresponsible. With my knowledge any such letter with reference to any issue of the medication to pregnant women would not have been sent to the medical profession.
In my own practice I don't have a single case of deformity.
Later on I gave the Gruenenthal Company permission to translate my paper into English and to distribute it.

GRT.0001.00004.0287: 21 October 1964 Deposition Prof Dr Remmer

Via the mediation of Prof. Neuhaus contact to Chemie Gruenenthal developed before the withdrawal of Thalidomide-containing preparations. I had a conversation with one or more representatives of this company without however being able to remember a name. I know however that I had conversations with Dr Sievers several times. Whether or not these conversations specifically with Dr Sievers occurred before the withdrawal of Contergan I can no longer say. On the occasions of the discussions prior to withdrawal I maintained the opinion that Contergan should be placed under prescription only status. I motivated my demand with the scientific experience that all sleep drugs can trigger unforeseeable side effects in the context of acute and chronic toxicity.

Scientific experience tells us that with sleep drugs side effects which are not to be expected often occur. It is for example known of one sleep drug that it had to be withdrawn because it triggered unexpected porphyria. (Sedormide) A sleep drug affects, in order to be able to have effect, the central nervous system, and can therefore result in unexpected side effects due to chronic use and thereby often resulting misuse.

RT.0001.00180.0186: 17 December 1964 Dr Mannheim Testimony (the Grt nployee to whom Dr K reported the malformation of his son and the ispected thalidomide causation in 1959)

I have been informed of the testimony of my colleague, (Redacted) on 13.8.64. I would like to make the following comments regarding this:
I can remember, approximately in the year 1958 or 1959, to have spoken with Dr. (Redacted) about the matter of his having prescribed treatment of one or two pregnant woman with Thalidomide instead of the usual opium drops because of the danger of miscarriage. Dr. (Redacted) reported that this type of treatment had had the same success and that the children of these women were born healthy. I had reported this conversation in an accompanying letter in the Head Office in Stolberg in the corresponding daily report.

I do know that the son (Redacted) of Dr. (Redacted) was born with strabismus (cross-eyed). Of course I discussed this Dr. (Redacted) due to our personal relationship (Translator's note: friendship has been crossed out), which could be the source of this error. I can however not remember having discussed Thalidomide as the possible cause in such a precise form, as is documented in the testimony of Dr. (Redacted). The discussion of possible side effects of

Thalidomide in this context had not caused me to see them as being so probable that I should have reported them.

I can say with absolute certainty that, until November 1961, I had not notified the Main Administration of Chemie Gruenthal of any suspicion in relation to preparations containing Thalidomide possibly having embryo damaging properties, as far as I can remember. Apart from this all reports of mine to Chemie Gruenthal have been made available to the Aachen District Attorney.

Archive document: 14 September 1965 Deposition Dr R S and husband Dr R S

Appearing is

Dr. (R S)...since the 8.2.1954 I have been married to Dr. med. (J S), specialist in internal medicine. From this marriage, two children have resulted...

While the first child was born completely healthy, the child S had the following defects: Underdeveloped nose skeleton with saddle-nose, shortening of the upper lip and paralysis of facial muscles, more on the right than on the left. The absence of both ear shells with the exception of the tragus and the existence of an atresia of both auditory channels. Pronounced underdevelopment of both thumbs. Club hands and club feet development of all four extremities. Cramps had developed during birth and persisted even a short time later. Problems during food intake, which made tube feeding necessary. I must also mention that a naevus flammeus (fonticulus frontalis) of the bridge of the nose existed. Today, this feature has almost disappeared. After the first birth I had an abortion in the autumn of 1958 in the third month after a highly febrile infection. After this incident I had my period regularly. When I had the first day of my last period in connection with the second pregnancy I can today no longer state with certainty. It was probably around the 11./12. April 1959.

The birth date calculated by us would have been the 18.1.1960. Should individual dates be of significant importance, these could, if need be, be requested from Medical Superintendent Dr. Schank's patient files. The course of pregnancy was without peculiarity, if one doesn't consider that I had a very bad feeling during the whole course of pregnancy. I had noticed in particular that child movements in contrast to the first pregnancy had been strangely rhythmic.

The medication Contergan was known to me by name. At the point in time at which the medication was released I was a privately practising doctor in Wiesbaden. I can say with certainty that I myself took the medication Contergan-forte (tablets) after my flu infection in the autumn of 1958 as a sleep drug in the evenings. Taking it was according to need. I can say that we had a pregnancy reaction (toad test) carried out already eight days after non-appearance of the next due period, which ran positively and had thereby been the confirmation of a pregnancy. Because we wanted to have a second child, we were very happy about the confirmation of pregnancy.

After questioning I must declare that I cannot state with absolute certainty today, whether or not I had taken Contergan tablets during the first two months of pregnancy. In this context however I must mention the following incident: After confirmation of the pregnancy I had been visited at a today no longer more accurately statable time in my practice in Wiesbaden by a female doctor's representative of the Chemie Gruenenthal Company. On the occasion of this visit, I asked the doctor's representative whether or not I could take the medication Contergan-forte during pregnancy (early pregnancy) without damage. I asked this because I had been suspicious of any medication during pregnancy, in particular during early pregnancy. I had explained to the doctor's representative, regarding my question, that I was the subject of it. In answer to my question the doctor's representative strongly emphasised the harmlessness of the Contergan-forte medication, so that I had no doubts as to taking it.

After this conversation I regularly took the Contergan-forte medication as a sleep drug in the evenings. Taking it occurred during the entire duration of pregnancy.

The defects of our child made specialist treatments in the Orthopaedic State Clinic Wiesbaden/(Dr. Volk) and prior to this in the Ruesselsheim City Hospital necessary. X-ray images of the child must be located in both hospitals. The child is in our household today.

I relieve the doctors named by me of their duty of confidentiality as well as the expert yet to be chosen by the public prosecutor to allow access to the files. Because of the harm to our child we took up contact with Professor Dr. Lenz in the year 1964. As far as they are in our possession, I release the documents pertaining to this to the files. As a final comment I would also like to mention that neither my husband's family nor in my own family have defects become known, as they have been confirmed in our child S. According to our current knowledge we must assume that the defects of our child were possibly related to taking the Contergan-forte medication.

Dr. med. (JS) ... declares:
I was present during the questioning of my wife (R). I can confirm that my wife occasionally took Contergan-forte-tablets as a sleep drug after a flu infection in the autumn of 1958.

The medication taken was a matter of so-called Doctor's samples. I myself had been working in the Wiesbaden Hospital at this time. In the spring of 1959, when the toad tests had confirmed pregnancy of my wife, we were very happy about this. I was not present during the conversation between my wife and the doctor's representative. My wife however related the contents of this conversation to me on the same evening, which concurs what she has declared today. My wife had been happy that she had, in Contergan-forte, a medication that she could use during pregnancy without harm according to doctors. I can confirm that my wife used Contergan as a sleep drug from this point in time until the end of the pregnancy. I am also of the opinion that the defects of our child S. could possibly be connected with taking the medication

Contergan-forte in the early pregnancy. I agree that our child S. be examined for expert opinion by an expert yet to be named by the Public Prosecutor in Aachen.

GRT.0001.00180.0076: 19 March 1964 Deposition Dr Joachim Heinrich (Grt employee

From 1957 to 1962 I was employed by the Gruenenthal Company as a clinical-scientific employee. It was my responsibility to inform the large government hospitals in Hamburg and Schleswig Holstein of the importance and possible applications of preparations, mainly of the Gruenenthal Company. My scientific documents, which made such information possible, had been received from the management of the medical-scientific department of the company. It follows from this fact that it would have been highly improbable that Dr. Brandt, who had worked as a GP in Luebeck, could have been visited by me. I cannot recollect any such visit.

Under Query: It is possible that Herr Meyer, who at the same time had visited doctors established in the city of Luebeck, had been informed by Dr Brandt in this regard and that he had reported this to me. In any case, it was his duty to inform not me but the scientific management of the Chemie-Gruenenthal Company in relation to this (about deformities or theratogenic properties of Contergan), which had been presumed by Dr Brandt. This notification, had Herr Meyer passed it on to me, was in any case the first possible side effect of this preparation in this direction, which however was based only on conjecture. As far as I can remember, I had related this to the manager of scientific field services in a discussion on the occasion of a scientific evening in Hamburg. Nevertheless, Herr Meyer should have passed on a written report about it the company independently of this, because it was my function to advise local employees, who were not fully qualified medical people, in relation to purely medical-technical questions at their request. Because the above mentioned area of questions had been completely new and unexplained, it could not have resulted in any comment whatsoever from me.

GRT.0001.00180.0237: 19 Feburary 1964 Statement of Meyer (Grt employee to whom Dr Brandt reported the malformed baby)

The company Chemie Grünenthal is the developer and manufacturer of the sleeping aid and sedative Contergan. During my visits to various doctors I recommended this drug, since at the time I was not aware of any harmful effects. My district covered the northern part of Hamburg and the southern part of Schleswig-Holstein. Dr. Hermann Brandt of Lübeck, Ostpreußenring 35, was one of the doctors I visited. I visited him, like the other doctors in my district, about every 6 months. From memory I visited him about 4 or 5 times. During one of these visits, Dr Brandt expressed the suspicion that Contergan may be harmful. He had a patient in his practice who had given birth to a malformed child, where it was certain that she had taken Contergan. I cannot say off the top of my head when this conversation between me and Dr. Brandt took place. It is possible that the conversation took place in

September 1961. However, I would not want to commit myself to it. I could determine the exact time with the help of my logbook which I keep at home.

During our conversation Dr. Brandt asked me if I was aware of any cases where the use of Contergan had caused harmful effects. At the time I truthfully answered this question in the negative. I was indeed not aware of any such case until that time. Dr.Brandt was the first person to express the suspicion that Contergan was responsible for malformations in children. At the time it was only known that Contergan could lead to negative side effects for those who took it, namely neurological pain (Polyneuritis) when taken over longer periods of time. I assured Dr. Brandt during our conversation that I would pass on his suspicion to the company. I subsequently contacted Dr. Heinrich who as the medical sales representative visiting clinics and as the main commercial staff member worked in the areas Hamburg/Schleswig-Holstein and part of Lower Saxony.

Dr. Heinrich lives in Elmshorn. I do not know his address of the top of my head. In the event of complaints of any kind, the medical representatives had to immediately contact either the head office of the company in Stolberg or Dr. Heinrich.The choice was ours. Dr. Heinrich thought at the time that a casual link between the use of Contergan and the malformations of children was impossible. I do not know what Dr.Heinrich in turn arranged at the time. He never mentioned this to me at any time. I did, however, speak to Dr. Brand about the topic about 1 year later . I cannot say either off the top of my head when the conversation between Dr.Heinrich and me took place. I could however find out at home from my documents.

Archive document: 23 June 1964 Statement of Ernst-Albrecht Josten (the doctor who had published on the effect of medication on the unborn child in 1956 and whom Grt approached for assistance in 1961)

Visited at his home, Dr. med. Ernst-Albrecht Josten, residing in Bonn-Venusberg, Anemonenweg 6, declares:
I am a paediatrician. In the 50's, I worked from time to time at the local University Children's Clinic and at the University Women's Hospital. In 1956, I opened my local practice.

I was given the opportunity to report on my contacts to Chemie Grünenthal in connection with the matter. In 1960 I had a brief exchange of letters with the Stolberg company in connection with Contergan. I submitted a copy of my letter of 23.5.1960 for the records, as well as a letter of Chemie Grünenthal. I cannot recall any details. In the letter of 13 September 1961 the Stolberg company enquired if I was willing to perform tests relating to the question of adverse effect to the foetus through the effect of medication. I cannot remember what my answer was. The matter was possibly handled through verbal discussions with a usual medical representative from Stolberg. In any case, it did not come to any collaboration with the company.

A copy of my paper has been made available to the prosecuting authority. After the paper had been published, the newspaper "Die Welt" ("The World")

published a seminar paper on the subject in line with my tests. I explained on my own accord that the problem was therefore discussed already back hen, and was at least thereby brought to the pharmaceutical industry's attention in general. I was surprised about the withdrawal of the medication containing Thalidomide from the market in
connection with the suspicion indicated by Dr. Lenz. Although I had heard previously Contergan was suspected of causing Polyneuritis. However, since the whole etiology based on the publications seemed unclear to me, and moreover I had no knowledge of the numerically larger extent of the side effects, this problem did not seem very urgent to me. I continued to prescribe Contergan without hesitation, especially since no urgent warning had come from the company's side.

After the allegedly low number of side effects became known, however, I again urgently advised the mothers of the children treated by me to stay in line with the prescription. In answer to the question of malformations itself I can say that about 2 years before the withdrawal of Contergan from the market, an increased rise in malformations in newborns wanted and discussed. It was not, however, a specific type of damage to the foetus but an increase per se. About 9 months before the withdrawal of Contergan, damages as per the Wiedemann Syndrome became the focal point of the medical interest and were increasingly discussed. After Chemie Grünenthal had withdrawn the medication containing Thalidomide from the market, I was perturbed by the, in my opinion, partly unobjective accusations. I considered the company to be respectable with wide testing possibilities. Furthermore I assumed that the company was partially attacked based on professional jealousy. On my own accord I therefore orwarded my publication from 1956 to Chemie Grünenthal, as well as the papers mentioned therein. No discussions with any members of the company's management took place. The contact was maintained either through correspondence or conversations with Dr. Glasmacher. The correspondence should essentially be available to the prosecuting authority. In my opinion no further discussions took place. Even today I do not maintain any connections to the manufacturer which would go beyond the usual extent of what happens between the doctor and the pharmaceutical industry.

As already indicated, I used to be involved in scientific research relating to the effect of medication on the unborn child.

Question:
Would you have considered it essential in the years from 1956 to 1961 for a pharmaceutical company which manufactures and sells thyroid preparations to consider the question of possible foetal damage caused by this medication, and to pursue possible tests in this direction?
Answer:
If a pharmaceutical company at that time had received knowledge, as part of the report of side effects,
of the effect of a medication in its program on thyroids, it would have been the company's duty to examine the relevant literature, to consider any possible foetal damage and to conduct the relevant

tests.

Question:
In the spring of 1961, the working hypothesis was established at Chemie Grünenthal that Contergan
caused a Vitamin B 1 deficiency, which in turn could cause Polyneuritis. Should the research of the
company have considered the question what else could possibly be caused by Vitamin B 1 deficiency,
and should it then have possibly considered any foetal damage and conduct tests in that regard?
Answer:
This question I answer definitely with a yes.
I am of the opinion that from a medical aspect, the company should unquestionably have considered these possible issues.
After the withdrawal of Contergan I was a bit disconcerted that the Stolberg company did not advise the medical profession with the necessary emphasis that the doctors should request their patients to have a look in their medicine cabinet for Contergan and to remove it so that no further misfortunes may occur. Such an instruction seemed to me especially significant at the time, as the company had flooded the doctors and consumers repeatedly with propaganda which emphasised the harmlessness of the preparation.
I expressly declare that I have made the afore-mentioned statements and medical assessments completely independently and to the best of my knowledge. I have neither friendly relations with Chemie Grünenthal or any of its members, nor do I feel hostile towards them. I have closely followed the recording of the questioning.

Archive document: 13 September 1961 Letter from GRT to Josten

Dear Dr. Josten !

We have learned by chance through one of our employees that you used to be involved especially in the
issues of effects of medication on the foetus and the newborn respectively.

We therefore take the liberty today of enquiring whether you still have the ability to perform such tests
or, if this should not be the case, who in your opinion within the Federal Republic would be particularly
capable of carrying out such tests.

We thank you in advance for your assistance and remain,

yours sincerely

CHEMIE GRÜNENTHAL GMBH
Medical and Scientific Department

Archive document: 13 August 1964, Statement of Dr K (who reported to Grt in 1959 his suspicions that thalidomide was responsible for his son's malformations)

When visited in his surgery, the gynaecologist/obstetrician Dr med. (K) ... made the following statement:

On 19.3.1959 my son (S) was born. He had deformed ears and also a visual problem. Naturally, both my wife and I speculated about the cause of these deformities. There were no genetically determined injuries on either side of the family. This prompted me to think that Contergan might be responsible for the deformities. I discussed these thoughts at length with my wife.

I am asked whether I discussed the abovementioned considerations also with a representative of Chemie Grünenthal. Early in the 1950s I was working at the hospital in Leverkusen. It was there that I met Dr Mannheim from Chemie Grünenthal. After I settled here in Dormagen in 1957, he also visited in his capacity as a sales representative. A certain social contact developed quickly, we visited each other with our wives every 3 months or so. Just as frequently, Dr Mannheim visited my surgery in his capacity as a representative of the Stolberg company. I can recall with certainty that I made a possible connection between Contergan and my son's deformities as early as 1959. In the same year, my wife and I had discussed this problem with Dr Mannheim at various times.

As we had our doubts about such a small amount of Contergan – my wife had only taken a few tablets – causing this extent of damage, we felt compelled to discuss this question in great detail with Dr Mannheim. He always explained that he just could not imagine thalidomide causing these type of injuries. I would like to clarify what I mean by 'explained': Dr Mannheim did not offer an official explanation on behalf of his company; these were discussion in which we each stated our opinion openly. In any case, he always maintained that he was sure Contergan could not cause this extent of damage. I established at least a further two malformations during 1959 which I also connected with Contergan. These suspicions were later also confirmed.

After the problem of Contergan and deformities became known to the general public at the end of 1961, I researched both cases – one is a birth which took place on 17.6.1959 and the other one in July 1959. Both women confirmed credibly that they had taken thalidomide during the pregnancy. I cannot remember whether I brought up these two women in connection with Contergan when talking to Dr Mannheim back in 1959. In any case, I can confirm with certainty by way of my documentation – I cannot give any particulars because of medical confidentiality – that I did speak with Dr Mannheim about 'Contergan suspicions' in regard to my son as early as 1959. After checking with my wife just now, I do think these conversations were most probably not held in a social context, but with Dr Mannheim in my surgery. My wife cannot remember such conversations in any case. However, I do know for certain that I had discussed this topic with Dr Mannheim during this particular time period.

I have not seen Dr Mannheim for several years. He now works in Stolberg and does not work in the local area anymore. No factual or personal differences exist or have existed between us.

Archive document: 14 July 1964, statements of Dr K

I was alerted to the content of an excerpt of a daily report dated 26.8.1958 by the pharmaceutical rep Dr Eick, which details, among other things, my observations of problems walking and visual problems in connection with the medication Contergan, especially after long-term use.

I believe the medication Contergan was introduced to me by a pharmaceutical rep of the company Grünenthal shortly after it was brought on the market in September 1957. As far as I remember, I only prescribed the medication very infrequently. On request, I also received doctor's samples from the company.

It is probable that I discussed matters with the pharmaceutical rep visiting doctors, Dr Eick, and told him about the abovementioned observations. I can now no longer recall either this discussion nor the actual person of Dr Eick.

It is probably correct to say that I would have mentioned the problems concerning walking. It is probably unlikely that I informed him about visual problems because, try as I may, I cannot recall this and do not know of any severe cases.

I do remember that my wife took 1 ½ tablets of Contergan-forte half-way through 1958 as a sleeping pill in the evening and that she was quite drowsy the next day. It was conspicuous that she complained about an unexplainable weakness in her knees, which we interpreted at the time as the purely narcotic effect of the drug Contergan-forte. At about the same time I was informed by an acquaintance who had taken the medication Contergan regularly long-term as a soporific that she had observed the same thing herself – weakness in the knees which almost amounted to problems walking. This acquaintance also experienced an unexplained lack of steadiness when walking.

At the time I thought that the medication Contergan would have to be responsible and ensured that my acquaintance discontinued the medication. Some time later my acquaintance told me she was no longer experiencing the same problems since discontinuing Contergan.

I probably used these observation as a basis when talking to the pharmaceutical rep Dr Eick. As far as I remember today, the company never replied to this information in writing. In any case, I never exchanged any correspondence with the company.

Apart from these observation I cannot recall any other cases.

I do not have anything else to add.

GRT.0001.00177.0138: 24 June 1965 Statement of Schuppius (Grt employee)

The specialist Dr med. Arnd S c h u p p i u s, 44 years old, residing at the hospital 'Deisterhort', answered as follows when he was asked during a visit at the hospital 'Deisterhort' in Bad Münder:

"My statement deals with the fact that I had the opportunity during my employment as a doctor in the hospital to work with infections via the placenta and therefore have knowledge which enables me to assess the transfer of orally administered medication on the growing baby.

It was this knowledge of transfer of medications that prompted me to point out during my work at Grünenthal that Contergan should be tested to ascertain whether this substance might possibly be the cause of embryopathies. According to my knowledge, the molecular size would allow for transfer of this substance to the child via the placenta, causing the kind of damage which is already extensively documented in scientific literature.

My advice given in the weekly discussions was received extremely positively by Dr Werner and Dr Oswald, however, in my opinion it was ignored by management, even though I offered to conduct the experiments myself. That is the reason I quit my position there."

In cooperation with various pharmaceutical companies, especially with the company G e i g y (Dr Pulver) I conducted spectrographic examinations to determine the transfer of a medication via the placenta. These studies of mine were published in the technical journal *Medizinische Welt* [Medical World]. I will be making a special reprint available.

I started my university studies in 1939 – however, they were interrupted because of the war – and completed my state examination in the autumn of 1952 and received my PhD at the same time.

In 1958 I was able to receive the accreditation as a specialist gynaecologist/obstetrician after years of working at the women's clinic Hamburg-Altona, Bülowstr. 9, under the supervision of Prof. Willi Schulz. I left Hamburg for family reasons and applied as a researcher with the company Grünenthal, because the area of antibiotics holds a special interest for me. My employment commenced at the beginning of October 1961. As part of the work in the company's medical-scientific department it was my task to work on a specific section of the antibiotic program. This was to be from a gynaecologist's viewpoint.

I was shown a section of the interview with Dr Oswald from 6.12.62 (page 14 – page 175 241 HA.).

The content corresponds to what I know today and I can fully confirm this. My initial statements about testing substances was discussed at Grünenthal at the end of November or beginning of December 1961, after Dr Lenz' accusations were known.

Those discussions mentioned by Dr Oswald could have taken place around October 1961 – definitely not after Dr Lenz' announcement . I can remember these particular discussions; they were received positively by my colleagues (Dr Werner and Dr Oswald) and conveyed to management. The weekly discussions lead by Dr Werner and their results were conveyed to management as far as I know.

The trigger for these talks – scientific discussions – between Dr Werner, Dr Oswald and myself was an enquiry by a foreign doctor – I cannot remember the name and time – who wanted to know whether an infection of the growing child or rather a transfer of medications was possible via the placenta.

I can definitely confirm Dr Oswald's statement regarding the enquiry with Dr Mückter. I felt it necessary to quit my employment with the company Grünenthal because Dr Mückter rejected my suggestion to investigate and because of comments made on the side. There was no personal conversation between Dr Mückter and myself. Dr Werner tried hard to support my efforts, but he was not successful.

I requested, and was granted, the abovementioned dismissal after my insight was confirmed by Dr Lenz and a further suggestion by me to check through conducting tests on a rhesus monkey was ignored once more.
Were embryopathies discussed before Lenz?

My reply is that the topic of embryopathies had already been discussed and the question of a possible influence through medications had been debated. Of special interest here were particularly the type of deformities and the conclusion was reached that this was not something caused by predisposition, however, it might be caused by medication. It was this conclusion which later led to suspecting the soporific Contergan of causing these deformities.

I would like to emphasize again that my insight from the clinic in Hamburg about embryopathies had been discussed in detail with Dr Werner and Dr Oswald when the enquiry by the foreign doctor was received by the company. I am prepared to confirm my statements under oath. I am able to present my own scientific work to the prosecution in the foreseeable future.

GRT.0001.00177.0016: 25 June 1964 Statement of Dr Harald Siebke (to whom Grt wrote in 1957 asking that Contergan be tested in pregnancy)

Visited at the Women's University Hospital in Bonn, Professor Dr Harald Siebke, of Bonn-Venusburg, Women's Hospital, declared the following:
I am the director of the Women's University Hospital in Bonn. In the event that Contergan was prescribed at our hospital, it would have been to a relatively low extent. I personally have certainly not prescribed Contergan more than ten times during my entire life. However, this is not due to a particular aversion to this specific preparation but because I hardly prescribe sleep medications in principle.

I am presented with the copy of a letter by Dr von Schrader dated 05 July 1957, in which I am asked to trial Contergan at my clinic. I commented on this as follows:

I do not recall receiving the letter. An original that would match the copy cannot be found in my records nor in the records of the outpatient department. A carbon copy – as is always produced at our premises – of an answer in which I may have consented to or declined such examinations, could not be located either. In the 29 years during which I have been the head of the Women's University Hospital Bonn, I do not remember ever approving a new preparation declared as a sleep medication for a clinical trial, and I therefore presume that the letter presented to me in form of a copy remained unanswered.

I know Dr von Schrader because his wife gave birth at my clinic. Although I would not recognise him today.

I do not maintain any contacts to members of the Chemie Grünenthal company.

After preparations containing thalidomide had been withdrawn from the market, Dr Glasmacher of Chemie Grünenthal approached my clinic with the request – I correct myself: On 21 May 1962 a Dr Glasmacher of Grünenthal visited me and spoke to me about Contergan cases. I can conclude from my notes that I did not tell her any particulars and [that I] declined giving any significant information.

I do not recall having in any way again spoken to or negotiated with the Grünenthal company or any of their representatives since that visit by Dr Glasmacher. It was only now when I was advised of the visit by Prosecutor Knipfer, that I had someone locate the note dated 21 May 1962 in my diary, and learnt upon questioning my staff that they know Dr Glasmacher from visits to the clinic, which she evidently conducts routinely, just like it is also done on a regular basis by the representatives of other companies of the chemical industry.

Archive document: 5 September 1969, opinion by Professor Dr Dietrich Starck re the generation testing of Thalidomide.

The Senior Public Prosecutor at the District Court Aachen asked me in his letter of 4 June 1969 to prepare a supplementary expert opinion in relation to the question:

"Which results would generational studies with Thalidomide have produced in the years 1954 to 1957 on those animal species, the use of which was already possible at that time".

The reply to the question posed requires initially clarification of the subquestion, which laboratory animals were available already in 1954 to 1957

for routine tests. Of course only mammals are taken into consideration since generational studies are under discussion, hence only viviparous animals with placentation were eligible. For the same reason only animals can be taken into consideration which can be bred in keeping conditions. Therefore, the so-called laboratory animals come into consideration: rat, mouse, rabbit, guinea pig, gold master, pig, goat, monkey.

In addition, the Chinese dwarf hamster (Cricetulus barabensis) and the American cotton rat (Sigmodon hispidus) were newly introduced as laboratory animals. I am not able to determine the exact date of the first use of these two animal species, however I can state with authority that it was before the deadline in question because I already kept and bred Sigmodon in 1956 from such test breedings, and Cricetulus from 1958.

Of particular significance would be the question since when monkeys have been bred for experimental purposes. First and foremost, macaques (Rhesus Macaca mulatta and long-tail macaques M. fascicularis and a few other species), baboons, squirrel monkeys (Saimiri), marmosets (Callithrix – Hapale) qualify as monkeys for testing and experimental purposes. Long-tailed monkeys (Cercipithecus) have been used and are still being used for testing purposes, however they are not suitable for generational studies due to difficulties in breeding. The rhesus macaque and the long-tail macaque are practically likely to be in the foreground by far, or have been in the 50s. The Saimiris and marmosets which are easy to use and breed, were often used in the USA but initially hardly at all in Europe.

It is difficult to give details of the specific breeding of macaques for experimental purposes or their beginning as the breeding of these monkeys is very easy and has been common in pet shops for a long time, i.e. hasn't caused any problems. Nevertheless, the dates can be narrowed down. In Germany, breeding of long-tail macaques was set up in the 20s under Prof. Harms and Dr. Spiegel in the zoological institutes Tübingen and Jena. This breeding program was in existence from 1927 to 1939, and partly until 1945. This breeding program, which was deliberately kept small, resulted in 90 pregnancies with 72 young animals. The breeding was scientifically exactly monitored and controlled. The results were known to all specialists. They were published:

SPIEGEL, A. Biological observations in long-tail macaques. Birth and development during the first months of life. Zool. Anz. 81, 1929

SPIEGEL, A. Observations of the sexual cycle, the gravidity and the birth in long-tail macaques. Arch Gynaekol. 142, 1930

SPIEGEL, A. Study regarding the reproduction in long-tail macaques. Zbl. Gynaekol. 55, 1931

SPIEGEL, A. Observations and studies on long-tail macaques

Der Zool. Garten (The Zoological Garden) N.F. 20, 1954 Overall report!

HARMS, J.W. "Reproduction biology" and "Pregnancy and birth" in primatology I. 1956

This answers the question as to which laboratory animals were available in the years 1954 to 1957.

It is more difficult to answer the question, which laboratory animals should have been used if substances were to be tested for teratogenic effects and at the same time conclusions were to be drawn in relation to human beings. I can only refer to my statements in my assessment of 5 April 1969 (pages 8 and 9). Translating the results from animal experiments to human beings is only possible with criticism. The experiment on animals not resulting in any teratogenic effects in the offspring does not mean that the substance used is harmless for humans. Due to the big differences in the placenta structure and the permeability of the placenta it is recommended in any case, if the tests with laboratory rodents turn out negative, to perform tests on monkeys. Only monkeys have a structure of a limiting membrane between mother and embryo which is similar to those of humans. If the test on monkeys turns out negative, then it is highly probable that the behaviour in humans is the same. This is then no absolute certainty either. Negative test results for example in rats in my opinion do not alone justify binding conclusions with regard to humans. They should always be supplemented by tests on monkeys. These facts have been generally known to embryologists at least since 1909 (publication of the placenta study by O. GROSSER).

When evaluating such tests, a number of further aspects must be taken into consideration. 1) The embryos must be carefully checked for malformations. An external inspection is not sufficient. It is necessary to dissect the embryos in rows of sections and to expertly examine those. Experiences with examinations of embryos from mothers who had German measles showed that in the beginning, malformations had often been overlooked because the embryos had only been examined superficially.

2) It must be ascertained that the substance to be tested reaches the correct site of action, i.e. the tissue of the embryo. It must, therefore, cross the placenta barrier and must not be broken down in the mother's body beforehand, or excreted from it.

The substance must also not be broken down immediately in the embryo. If the substance is administered per os (orally), it must be ensured that it is absorbed in the intestinal tract.

3) The substance must reach the correct site of action at the right time. As I indicated in my report of 5 May 1969, the fact that different parts of the embryo are sensitive at different times plays a part. These critical or sensitive phases start in various embryonic stages not simultaneously. The conclusion from this is that for generational studies, a series of tests is to be prepared and that the substance to be tested is to be used in various phases of the early pregnancy. The crucial point is that staggered tests are performed at the time of body and organ formation, i.e. in monkeys during the first 4-6 weeks of pregnancy. Later phases of the gravidity are often already insensitive, apart from the sexual organs.

Taking into consideration the factors cited, animal experiments with Thalidomide in the years 1954 to 1957 would not have had any different results than today. The prerequisites stated by me were surely known to embryologists in the years 1954 to 1957. During that time, there would doubtlessly also have been embryological experienced experts available as advisors.

Due to the first incidences of dysmelia in 1958/59 in Western Germany, and since Thalidomide was made responsible in 1961 as the cause for the frequent incidences of malformations of extremities in humans, animal experiments have been performed on the following laboratory animals: Rat (GIROUD-MERCIER, TUCHMANN-DUPLESSIS 1962, SOMERS 1962, FELISATI 1962, KLEIN OBBINK-DALDERUP 1963, 64, DWORNIK a. MOORE 1965, GLOBUS a. GIBSON 1968, SCHUMACHER and others 1967). Mouse and rabbit (GIROUD, MERCIER, TUCHMANN DUPLESSIS). Rabbit (GIROUD and colleagues, SOMERS 1962, SPENCER 1962, SCHUMACHER and colleagues 1967, FOX 1966). Pig, cat, dog 9DELATOUR 1965). Macaques: DELAHUNT and others 1964, WILSON 1964, HENDRICKX, AXELROD, CLAYBORN 1966). Baboon: BARROW, STEPPEK, KING Macaques 1968/69.

The tests on rats were initially negative (GIROUD and others). Later tests on rats show that after giving Thalidomide, increased rates of embryo resorption and ossification anomalies of the sternum and cervical vertebra occur (KLEIN OBBINK-DALDERUP).

These findings on the rat were confirmed (DWORNIK a. MOORE 1965) and histologically and histochemically analysed by GLOBUS and GIBSON 1968.

With regard to the mouse, GIROUD-MERCIER-Parot and TUCHMANN-DUPLESSIS 1962 provided evidence of malformations of the facial development and the eyes following treatment with Thalidomide in pregnant females.

GIROUD and colleagues (1962) found very serious malformations in rabbits after use of Thalidomide in pregnant females. These malformations affected in particular the limbs, the axial skeleton and the central nervous system. The findings on the rabbit were confirmed (SOMMERS 1962, SPENCER 1962). Comparative studies on rat and rabbit were performed by SCHUMACHER, BLAKE, GURIAN and GILETTE (1967). These tests too determined that the teratogenic affect is more pronounced in rabbits than in rats (smaller effective dose, severity of the defects). Furthermore it was discovered that the type of malformations is different for both species (rabbit: particularly malformations of extremities, rat: malformation of the ribcage, the vertebrae and the sternum). Significant differences in the resorbability of Thalidomide through the intestinal wall were proven (much faster absorption in rabbits compared to the rat). Finally, there were indications that the responsiveness towards Thalidomide can be different in different genetic lineages of rabbits. The occurrence of such congenital differences in the responsiveness is not unexpected. The data provided by FOX that Thalidomide does not cause any

malformation in intravenous use in rabbits are disproved by the findings of SCHUMACHER and others that the solutions were hydrolysed.

Malformations following the use of Thalidomide were also found in pigs, cats and dogs (DELATOUR 1965).

From all the laboratory animals, monkeys (rhesus monkey, long-tail macaque, baboon) have proven to be the most sensitive. They already respond to much lower dosages than other laboratory animals. Malformations following the use of Thalidomide were found in Macaca irus philippinensis by DELAHUNT a. LASSEN 1964. HENDRICKX, AXELROD and CLAYBORN 1966 obtained typically malformed fetuses in baboons.

WILSON and GAVAN treated Macaca mulatta and found typical phokomelia of the arms in animals which had been given Thalidomide between the 24th and 27th day. Malformations of the hind legs occurred following Thalidomide treatment on the 30th day of the pregnancy. BARROW-STEFFEL-KING 1968/69 also obtained malformations of the extremities and malformations on the intestinal tract, gall bladder and coronary arteries following the use of Thalidomide on the 27th, 28th and 29th day of the gravidity in Macaca mulatta. I am aware that L SCHMIDT in the USA produced typical malformations due to Thalidomide in macaques. The results have not been published yet.

The question posed to me is answered by these statements. The laboratory animals available in the years 1954 to 1957 have been named. There can be no doubt that generational studies, taking into consideration the stated criteria, would in those years have led to the same results as were achieved in the following years.

Frankfurt / Main, 5 September 1969 Prof. Dr. Dietrich Starck

ENGLISH LANGUAGE DOCUMENTS

GRT.0001.00027.0257: 6 October 1960 Letter from KM Shah & Co (Ceylon) to GRT

We have to bring to your kind notice that we are receiving a lot of complains about Softenon, that it produces bad after effects, drowsiness etc.
Some doctors are now reluctant to try the samples of Softenon.
Please let us know your view on this matter, so we may withdraw this (sec) products immediately, if you're convinced that their complaints are justified, as we feel it may even effect our propaganda campaign on other products.

GRT.0001.00029.0058: 8 November 1960 Letter from Kennedy, DCBL to Muckter, GRT

In the last year we have come to realise that long term thalidomide therapy (3 months or more) may give rise to peripheral neuritis. Seven cases have been reported to us, of these three had definite symptoms and signs attributable to thalidomide which cleared up on withdrawal of the drug.

GRT.0001.00062.0207: 27 December 1961 Letter by GM Khoury Pharmaceuticals)

The object in this dilemma is to let not the Proffesion in Jordan fool that something wrong and mistakable has been sold to them the past time, we will suspend the 'Softenon' Products from sale by claiming that they are out of stock, and after a while, when it has been forgotten by doctors through their stopping to prescribe it, and in the time, when it has been no more in demand, we will collect the supplies that are left on Dealers' shelves unsold, and provide them with credit Notes.

With respect to products that contain Thalidomide in small countries, we have in mind the same steps in tracking the matter, which we believe will be best, solved without affecting the Grunenthal reputation and all those concern are happy.

Although this measure may show as unethical and against scientific rules, but we believe that we should take it, as we wish not to touch the Grunenthal " Wage" which has the highest of esteem among the Medical Professions of the Jordan.

We hope that you will approve our method of tackling this matter by leaving it to us to act alone, and getting out of it, though you may not approve it in principle, as we understand our market circumstance and mentality quite well, we place ourselves as fully responsible towards the aforementioned action which we have decided to take

GRT.0001.00062.0242 4 January 1962 letter by Astra, Argentina, to von Schrader (Grt)

If we follow the drastic recommendations and write off Sotenil in Argentine with one single strike, this company will not only suffer a moral and economic loss, but foresee a very difficult read for Chemie Grunenthal ever to come back to the Argentine market.

Would you please give me your frank and personal opinion on the possible drawbacks of following my suggestions, i. e : to sell out existing stocks and then slowly forget about Softenil. In the meantime, we could warn all the doctors of prescribing it to pregnant women.

GRT.004.01678.0388: 28 February 1962 Letter from Lebanese doctor to Grt

Dear Sir,

I am (Redacted), from Zahle, Lebanon, and have been in practice for ten years. I am married and have a child now two and one half years old. She was born in perfect condition. My wife is American; 22 years old and in perfect health. I am 34 years old now and have been all my life in perfect health. Seven years ago we had a baby girl born with the following deformities:

1. Absence of radius in the left arm with a vestigial thumb on both hands.
2. Both hands are turning in.
3. A short radius in the right arm.
4. The left arm is short and the muscles of the left shoulder are atrophied.

I am sending you x-rays and photographs which were taken at the age of three weeks. Copies of these x-rays and photographs were sent to Canada to Dr. Martin A. Entin M.D., Medical arts building, Montreal. Dr. Martin is a world known specialist in the reconstructive surgery of arm and hand deformities. He has written many articles and given reports on this subject in the North American Journal of Surgery and Joint Surgery. That is why I knew about him and wrote to him asking his advice about our child. I received an answer from him dated October 5, 1961 in which he advises me to take the child to him when she is three years old. The child will need a number of surgical procedures which would take a minimum of three year's time. All the surgical procedures would give some partial use to the hands but the aesthetic appearance will never be satisfactory.

Other photographs and x-rays were sent to the United States to Dr. Henry Kessler Jr. of Kessler Institute, New Jersey, who is also another world known specialist in this field.

Since the birth of our child I have been very interested in investigating the etiology of such deformities. I didn't find any hereditary factors from both sides, the mother's and mine. My wife didn't have any diseases during her pregnancy. Delivery was at full term and the birth normal. I kept searching for the possibility of some drug effect. Since my wife was suffering from insomnia during her first three months of pregnancy and since I was such an admirer of the Gruenthal products among them SOFTENON. So I sometimes have her Softenon tablets and syrup. That was the only drug she took during her pregnancy, for insomnia. I gave her pyridoxine for nausea. I began to suspect Softenon as being the only factor causing this deformity when I saw two other babies born in the same summer of 1961with deformities of their upper arms which were worse than our child. One of them had no arms at all. The hands came straight off the shoulder. The mothers of those two children were patients of mine and I prescribed for nervousness and insomnia your SOFTENON. At that time I was struck by the coincidence of such happening and I kept reading and investigating until I found the same epidemy in West Germany, (Nordrhein-Westfalen.) Investigations were made by doctors and universities on that subject and all their findings pointed to drugs containing Thalidomide.

That is why I am writing to you now to enrich your record of information by my case, the most cherished in my life, which was a sacrifice to your product, Softenon. I wish now I had never been a doctor and had never heard of a drug called Softenon, so I would have had less chances to give it to my wife. Now I have to suffer the consequences every time I see my child with her deformities. I now am willing and mut pay every penny I earn at least in the hope of seeing my child with hands close to normal.

I wonder what will be my reward from your company for prescribing in the past three years;

> Prevethenat, Megacelline, Grunovit, Hormo-Grunevit, Didrosulfon, Didrosulfon with hydrocortisone, and the product which crowned all my knowledge and admiration of your factory; SOFTENON.

Wishing to hear from you soon, I remain

Sincerely yours,

(Redacted)

GRT.0001.00169.0220: 6 March 1962 Letter from Grossman Laboratories to Leufgens, GRT

I am enclosing herewith a photo static copy of an article that appeared in the Medical World News, which is also distributed in Mexico. We frankly cannot continue with Talargan in view of this article, for if we were to continue, our competitors would very definitely show this article to the Medical Profession and we would be condemned for maintaining it in our line to the point of where it may insure us very seriously, and it is my definite decision to discontinue it. I have today issued the necessary orders not only to withdraw dispatching any further orders, but to withdraw everything presently on the market from wholesalers and pharmacies.

I regret that this action had to be taken, especially in view of the fact that we have a substantial amount of money invested in the product, and we shall, of course, expect you to credit us for all new raw material, finished material and literature not used to date, as I believe you were completely wrong in suggesting that we continue with the product as it was still on sale in other countries.

I believe you can understand me taking this action, as I must very definitely protect the reputation of our business, but beyond that, I could not live with myself if it was brought to my attention that one child was born deformed because of a product sold by us.

GRT.0001.00064.0157: 31 August 1962 Letter from Somers, DCBL to Loschner, GRT

I have made no different findings in rats mice and rabbits to those already reported to you. The rabbit experiment I have repeated three times and at the dose level of 150 mg/kg the incidence of malformed litters has been almost 100 per cent. I have also had malformations at lower dose levels namely 30mg/kg and 7mg/kg. A litter at this lowest dose level contained two young which were veritable monsters.

I look forward to having your results shortly, and I hope that you will soon be successful in getting malformations like mine. If you are getting resorptions then you should be able to get malformations providing you get the conditions right. This implies the right dose, the right level of dosing and the right strain of rabbit. Diet may also be most important.

Other Companies who have been trying my technique in this country have been successful (Wyeth, May and Baker, Pfizer), but there hjave been failures reported from two sources. In one of these dosing was started on the 2nd day of pregnancy and all the rabbits showed resorptions.

GRT.0006.04254.0012: November 1967, statement by Lederle Laboratories as to reproduction studies in animals begun prior to 1961 by American Cyanamid personnel.

Effects of American Cyanamid products on reproduction;

(Published papers by American Cyanamid personal on studies begun prior to 1061)

Prepared by the Literature Services Department.

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AFFIRMED AT Melbourne)

In the State of Victoria)

THIS 13th day of July 2012)

Before me:)

PATRICK GORDON
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An Australian Legal Practitioner within the