

## **Summary of the expert report clarifying assumed claims under pharmaceutical liability for thalidomide victims in Germany**

Before 1961, there was no comprehensive and standardised legal framework governing the sale and supply of medicines in Germany. The German Medicines Act did not enter into force until 1 August 1961. However, it did not dictate clinical testing for efficacy and potential risks of medicines prior to release. Consequently, the law was not adequate to prevent medication incidents. In response to the (Contergan) thalidomide incidents, an amended version of the German Medicines Act with the aim to “ensure optimum medication safety” was enacted on 1 January 1978, which, with the exception of a few minor changes, remained in force to this day.

At the time the thalidomide incidents occurred, it would have been difficult to pursue civil action against Grünenthal under product liability. Claims based on tort and violation of protective laws (such as the German Medicines Act) constituted the primary grounds for liability suits. To substantiate a claim, claimants would have had to prove causation and fault in each individual case. Regarding the issue of procedural evidence, it is doubtful if prima facie evidence would have sufficed for the injured party.

With Section 84 AMG (German Medicines Act), the legislature introduced a strict liability law in 1978 that includes development risk. While all other requirements of the regulation are no doubt present, there remains the question of whether general causality is already proved or still needs to be proved and whether there is alleviation of the burden of proof for the injured party. It is also unclear how the competent civil courts and, in particular, the court of appeals would have ruled at the final appeal stage. Nevertheless, if one were to support the requirements of prima facie evidence, it would suggest that the use of thalidomide was generally capable of causing the actual injuries. In terms of establishing causation, i.e. determining the specific cause in each individual case, the reversal of the burden of proof as set out in Section 84 Clause 2 AMG in favour of the injured party should take effect when accepting thalidomide’s overall capability of causing such injuries. Given that the additional requirements of the regulation are also met, a claim pursuant to Section 84 AMG should have been granted, leaving only the question of possible contributory negligence to be investigated.

Pursuant to Sections 86 ff. AMG, in the event of death or injury, a pharmaceutical company has to compensate the surviving family members or the injured person for material damage and personal injury

including the person's financial loss. As set out in Section 87 AMG, material damage includes, but is not limited to, health care costs, financial loss suffered as a consequence of the injury temporarily or permanently preventing or limiting the employment of the injured person as well as any costs incurred due to special needs (disability-related additional costs). The amount of compensation for material damage is determined exclusively on the basis of actual damage suffered by the injured person. In the case of children who are not in gainful employment, it is not possible to determine the loss of income; due to lack of predictability of future development, a declaratory judgment would have to be requested, with the aim to determine a legal basis for a payment of regular benefits or a lump-sum settlement on the merits of the case. Specific claims for benefits can only be asserted when it is possible to substantiate these by stating a particular amount. Disability-related additional costs cannot be calculated in abstract terms, either, but are based solely on the necessities of the individual case, which excludes general statements in this respect as well.

The potential amount of injury claims can be expressed in somewhat more specific terms. According to the medical points table in Attachment No. 2 relating to the guidelines on granting benefits for cases of thalidomide defects, slight to pronounced finger hypoplasia is given a rating of 0.5 points, making it one of the least severe afflictions. For such injury, courts grant about € 9,000, which can be regarded as appropriate for a realistic lower limit of possible injury compensation claims. For the loss of a limb, an average amount of about € 45,000 can be expected. For injuries caused by thalidomide that justify a rating of 80 in the medical point table, compensation of at least € 530,000 to € 560,000 should be expected. The percentage distribution of injuries indicates that 53% of injured persons could file claims for € 30,000 to € 60,000, 25% for about € 45,000, 11% for € 25,000, 5% for € 50,000 to € 80,000, and 2% for more than € 500,000. With some 2,800 thalidomide victims in Germany, a total of at least € 141 million in compensation can be expected for personal injury alone. This yields an average of € 50,000 in monetary compensation for pain and suffering per injured person.

From a realistic point of view, the liability amount that would have to be paid by the responsible party under civil law in compensation for thalidomide defects is therefore at least in the medium to high range of hundreds of millions. Pursuant to Section 88, however, the liability of the responsible party is limited to a specified amount. In the event of death or injury of multiple parties caused by the same medicine, the responsible party is liable to pay up to € 120 million. If the compensation to be paid to multiple injured parties exceeds the stated maximum amount, the individual compensation payments are lowered according to the ratio between their total and the maximum amount. Consequently,

each injured party is only granted a reduced claim the amount of which is lower the more injured parties are involved and the higher their claims are.

When comparing the maximum amount stated in Section 88 AMG with the amount that has so far been paid out by the Contergan Foundation on the basis of the Contergan Foundation Law, it is noticeable that today the latter is already four times greater than the former. As of 31 March 2011, the foundation has paid out a total of € 456.5 million to thalidomide victims, with the average payment per beneficiary being € 202,160.

In order to assert their claims against Grünenthal, the victims would have had to take legal action. According to estimates, the handling of all cases would have incurred costs of approx. DM 50 million. In accordance with the law at the time, the victims were not entitled to legal aid and thus to advance payment of costs and therefore would have had to be willing to face considerable legal risks and years of litigation with an uncertain outcome, while having to cover all injury-related costs themselves until there was a final judgment. Grünenthal was a legal entity in the form of a limited liability company (GmbH) with share capital of DM 4.3 million and wealthy shareholders. The company's financial capacity would have been confronted with the expected claims for damages amounting to a maximum of € 120 million pursuant to Section 88 AMG, i.e. approx. DM 235 million. It can be inferred that Grünenthal would have been unable to pay this amount. The company's inability to pay this debt would have led to bankruptcy in accordance with the law at the time. As a result, the victims would not have been able to pursue their claims against Grünenthal any further and could instead only have made claims for the bankruptcy assets. In that case, the victims and all other creditors each would have received an equal share of the bankruptcy assets based on a specific quota. In view of the corporate value, it is very doubtful whether the payments from the bankruptcy assets would have exceeded the amount that had otherwise been paid by Grünenthal. Given the financial risk of such legal action, the probability of an extremely long litigation process and, in particular, a possible bankruptcy of the debtor, the chances of actually enforcing the claims would not have been good.