

PRESS DOSSIER

50 YEARS of Contergan Trial



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The Contergan* tragedy is and remains a significant part of our corporate history. The owner family and the company as a whole deeply regret the consequences of this tragedy. That is why our engagement for people affected by Contergan in order to improve their individual life situations is important to us. We started our particular offering of support in the year 2011 as “Hardship Foundation” and are continuing our work today within the “Grünenthal Foundation for the Support of Individuals Affected by Thalidomide”. Together with the affected persons, we define projects that represent needs-oriented and concrete assistance. To do so, we engage with them in a constant dialogue about the needs of today and tomorrow, in order to align the support of our foundation accordingly.

We are convinced that it is in the interest of everyone that the trial and the corresponding background be portrayed correctly and put in the context of the time. In the following, therefore, we present some of the facts regarding the criminal trial and the situation of affected persons and also how Grünenthal is living up to its responsibility.

* The drug known under the German brand name Contergan contains the substance thalidomide. Since brand names differed internationally, we will use the agent's name thalidomide in the further course of this document. When it comes to the trial, the German name is still used, since “the Contergan trial” is to be considered as an established term.



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Background

The so-called “Contergan trial” refers to criminal proceedings against nine senior employees of Grünenthal, which began on May 27, 1968 in Alsdorf near Aachen and were terminated by the court two and a half years later on December 18, 1970 with the consent of the public prosecutor.

The criminal trial is still considered one of the most complex and costly proceedings in German legal history. The legal and medical questions concerning the thalidomide tragedy were complex and difficult to answer. The prosecutor needed nearly six and a half years to decide about and prepare for indictment. The 283 days in court took more than another two and a half years.

The criminal trial had already lasted two and a half years, without any end in sight. Since the start of the trial, one accused and the presiding judge had died; other accused were dropped from the trial due to illness. The court expected that the trial would go on for years more. Whether the court would then convict or acquit the accused was not certain. However, those experts already heard by the court by that time had said that, based on the state of science at the time, the teratogenic effects could not have been anticipated.

“All the scientists heard so far have more or less clearly denied the predictability of the deformities.”

Termination decision of the First Main Criminal Chamber Aachen.

Type of procedure and verdict

Criminal versus civil proceedings

The trial examined a possibly negligent behavior by the nine leading Grünenthal employees who were accused. It was not about claims for damages by the affected families. The families would have had to press such claims in subsequent, separate civil proceedings – which would presumably have lasted years.

Although the court heard numerous witnesses and experts for two and a half years, and analysed more than 600,000 pages of documents, a verdict was still not in sight. On December 18, 1970, the court finally terminated the criminal trial with the consent of the prosecutor.

“Minor culpability”

Five independent judges justified the decision to terminate in detail in a nearly 100-page document. The prerequisite for terminating the trial was that for a later conviction, a determination of at least “minor culpability” of the individual accused would have been required.¹ The search for a guilty individual and a conviction were no longer considered appropriate in the sense of a reasonable duration of the trial.

Under these circumstances, the judges did not consider continuation of the proceedings to be justified. This decision was supported by the general public, especially since a solution to the most urgent problem had already found in the settlement reached between the families and Grünenthal in April 1970: the financial security of the affected families. All those involved saw it as a good solution for affected persons; and the media also agreed.²

Legal questions

Clinical trials

By examining the question of guilt in the course of the trial, the parties involved attempted to determine whether responsible persons at Grünenthal could be faulted for failing to do testing or for doing inadequate testing of the active substance. The judges found that this was not the case. Only special laboratories and scientists dealt with questions such as teratogenicity and restricted themselves to examining the specific effect of substances known to be or suspected of being teratogenic. Teratogenicity tests in animals were not the usual practice in the development of medications.

¹ See also Termination decision of the First Main Criminal Chamber of the Aachen District Court [Einstellungsbeschluss der Ersten Großen Strafkammer des Landgerichts Aachen].

² See also DER SPIEGEL, No. 50/1970, Weder Sieger noch Besiegte [Neither Winners nor Losers]. Available at: <http://www.spiegel.de/spiegel/print/d-43822740.html>.

“The whole thing is something completely new. [...] I would like to say that, at the time, I simply did not think of a teratogenic effect. And not only did I not think of it – no one at Chemie Grünenthal, no one in the entire pharmaceutical industry thought of it.”

Dr. Herbert Keller,
discoverer of thalidomide, as witness in court.

Contrary to what is sometimes claimed, tests for damage to unborn life (teratogenic effects) were not usual at the time. Only fertility tests – whether a substance has an effect on fertility – were done for some drugs at the time. Possible teratogenic effects were not considered at all by the pharmaceutical industry, as described impressively in court by thalidomide discoverer Dr. Keller.³ The teratogenic effect of thalidomide was demonstrated in targeted testing in New Zealand White Rabbits only after the medications containing thalidomide had been recalled from the market. Years later, an expert WHO committee tried for the first time to introduce standards for teratogenic testing.

No conclusions from polyneuritis to thalidomide damage

The court also examined whether Grünenthal should have expected a teratogenic effect of Contergan based on earlier reports of polyneuritis side effects. That was not the case, for which reason the judges found in the termination decision: “In particular, the neurologists declared nearly unanimously that it would not have been possible to expect deformities based on the cases of polyneuritis observed.”⁴

Market recall

The investigation of the teratogenic effect of Contergan and the market recall are inseparably linked to Widukind Lenz. The human geneticist reported his suspicion to Grünenthal for the first time on November 15, 1961. However, he was not able to substantiate his observations. When Grünenthal received information of suspicion facts from another physician in Australia, the company decided to recall the medication from the market on November 27th. It was only twelve days between the information from Lenz and the market recall.

Participants in the trial

Relationship among the judges, prosecutor, and defense attorney

The most important actors in the trial, in addition to the nine accused, were the three prosecutors and five independent judges. For the nine accused, from time to time a total of 20 defense attorneys were involved, who also filled in for one another in the court sessions that were held multiple times a week.⁵

In the past, the media and historians have put the spotlight on the supposed imbalance between the resources of the public prosecutor and the defense and pointed out the deficiencies in the resources of the state. The number of defense attorneys was necessary because Grünenthal had to utilize various legal specialists, considering the highly complex topic.

No political interference

Individual affected persons and observers assess the settlement reached among Grünenthal and the parents, as well as the law that led to the founding of the “Hilfswerk für behinderte Kinder” [Aid Program for Handicapped Children], as interference by the state. This allegedly led to the termination of the criminal trial and stripped affected persons of the option of taking civil action for damages against Grünenthal. The goal of this speculation is to derive claims for additional compensation from the German federal government.

This claim is wrong from multiple perspectives and, considering the separation of powers and the German legal system, is without any basis whatsoever. The responsibility for the termination of the criminal trial rests solely with the court, which is free from any central directives; directives “from above” are impossible even from a purely legal perspective. In their reporting, journalists from the editorial staff of DER SPIEGEL, which covered and reported on the trial intensively, contradicted isolated rumors that had already begun to surface at the time.

³ See also Dagmar and Karl-Heinz Wenzel: Der Contergan-Prozess (II) [The Contergan Trial II], p. 56-75.

⁴ See also Termination decision of the First Main Criminal Chamber of the Aachen District Court, p. 75f.

⁵ For each accused, the current Code of Criminal Procedure provides for up to three defense attorneys in addition to a possible public defender.

“There was no secret agreement between Chemie Grünenthal and the court, the prosecutor, and the representatives of the co-plaintiffs, as has been suspected. The offer of 100 million by Chemie Grünenthal and the contract to which it led, were and are not linked to any assurance [...]. No one can escape punishment through an offer of compensation.”

DER SPIEGEL⁷

In addition, the trial was held before the eyes of the German public – more than 10,000 newspaper articles appeared during the trial.

A research report published by a historian in the year 2016 on behalf of the State of North Rhine-Westphalia confirmed that the circumstances that led to the termination of the criminal proceedings are, even today, consciously portrayed incorrectly and speaks of “conspiracy theory claims without any supportable basis.”⁶

The role of Josef Neuberger

Proponents of the theory of interference like to invoke the role of Josef Neuberger as example. The accusation is that the attorney and SPD deputy in the state assembly agreed to defend one of the accused and was then sworn in a few weeks later as the new Minister of Justice of the State of North Rhine-Westphalia. In this position, he then, according to the conspiracy theorists, used his influence to get the criminal trial terminated. There was no exertion of influence in favor of the Grünenthal employees. In fact, they were not even indicted until Neuberger was already Minister of Justice. The later termination of the trial was then decided by five independent judges, who were not subject to the instructions of any minister.

Furthermore, when Josef Neuberger took on the client, it looked as if the FDP and not the SPD would provide the Minister of Justice. For this reason, he did not see any imminent conflict of interest when he took on the mandate. Above all, however, on the first day in his new office, Neuberger immediately drew a “red line” between his activity as minister and the trial: All members of the ministry were instructed that all documentation and information regarding

the Contergan trial was to be directed to the State Secretary and be withheld from him.

Regarding this, DER SPIEGEL wrote: “Impermissible influence in the Contergan matter cannot be demonstrated for the past.” And: “Whoever expresses suspicion, insults the participating members of the responsible prosecutorial authorities, who would rather have let themselves be chased out of office than be manipulated in the Contergan case.”⁷

Settlement between parents and Grünenthal

About ten years after the tragedy and as the criminal trial concerning Contergan had already been going on for nearly two years, Grünenthal and the representatives of the parents were anxious to find a solution, in order to provide long-term financial support to the affected children and families. Because an end to the Contergan trial was not in sight, and the question of damage claims of the individual children and families would first have had to be clarified afterwards in civil proceedings, which would once again have taken years and caused very high litigation costs for all those involved.

Outside the criminal trial, such a solution was taking shape. On April 10, 1970, Grünenthal reached a settlement with the representatives of the affected children, in which the company would contribute 100 million DM⁸ (about 51.13 million euros) into a foundation. Along with the 100 million DM of the company, another 100 million DM would be provided from federal funds.

Following many rounds of negotiation, the settlement was reached by representatives of the company and the representatives of the affected children independently of the ongoing trial. The judges, in their later decision to terminate the trial, noted that through the settlement, the controversial damage claims of the families “were probably settled much faster and probably more extensively than would have been possible through civil trials.”⁹

⁶ See also Niklas Lenhard-Schramm, Die Haltung des Landes Nordrhein-Westfalen zu Contergan und den Folgen: p. 27 ff.

⁷ DER SPIEGEL, No. 53/1966: Bis zum nächsten Schicksalsschlag [Until the next stroke of fate]. Available at: <http://m.spiegel.de/spiegel/print/d-46415545.html>.

⁸ Based on the costs of living in 2010, that corresponded to the then purchasing power of over 150 million euros.

⁹ Termination decision of the First Main Criminal Chamber of the Aachen District Court, p. 97.

Milestones on the way to the foundation solution

Based on the desire for a rapid solution for affected persons and the problem of the possible demands to be made by the health and nursing care insurance providers in the face of possible damage claims, everyone was searching for a solution.

● **January 1970:** In the Federal Ministry of Justice, there was pressure to find a way to secure financial assistance for the affected children. The following solution was considered: Grüenthal would make any future payments not directly to the damaged individuals but to a fund; the public would be called upon to participate in the aid program through payments to the same fund; the damaged parties would be compensated from this fund, if they would waive any claims against the company.

● **January 1970:** This proposed solution was accelerated further as Grüenthal publicly announced it was willing to make a payment of 100 million DM, if all risks for the company and accused were excluded.

● **February 24, 1970:** Draft law to establish the national foundation “Hilfswerk für behinderte Kinder” [Aid Program for Handicapped Children]

The draft law was sent to the Bundesrat [German Federal Council] on May 4, 1970 and passed by the Bundestag [German Federal Parliament] on November 4, 1971; the Bundesrat gave its consent on December 3, 1971, and the law went into effect on October 31, 1972.

Claims of the social insurance providers

A central challenge for a settlement among the parties resulted from the question of how to handle claims by the health and nursing care insurance providers. To a substantial degree, they had paid the costs resulting from the tragedy. In the normal case, these social insurance providers would have had to demand money back from the affected families that they would receive from Grüenthal in the settlement. In the end the money would thus not have benefited the affected families. In addition, there was also the matter of recourse claims by the social agencies against Grüenthal, which would also have hollowed out the settlement.

This challenge shaped the entire settlement agreement, and a wide variety of individual persons and institutions in Germany worked on possible solutions.

On the way to the foundation solution

In the Federal Ministry of Justice, starting in mid-January 1970, there was pressure to find a way to secure financial assistance for the affected children. For State Secretary Maassen and Federal President Heinemann, it was clear that “it could not be expected” that the parents of the children “would be able to win their claims against Chemie Grüenthal in the foreseeable future.” After all, the criminal trial alone had already been going on for more than two years, without any prospect of ending soon. However, to ensure that “all help did not come too late”, the “only way out” was to reach a conclusion soon in the ongoing settlement negotiations. The company, too, “was neither willing nor able [...] to provide adequate compensation for all the damage.” In addition, the compensation claims of affected persons had been passed to a considerable degree to the social insurance providers, some of which had already declared that they would immediately press their right to transfer of the claims, if Chemie Grüenthal were to make payments to those damaged. In order to eliminate the “recourse right of the social insurance providers”, in the perspective of the time, the foundation was the best solution. Therefore, a corresponding foundation law had to be passed.

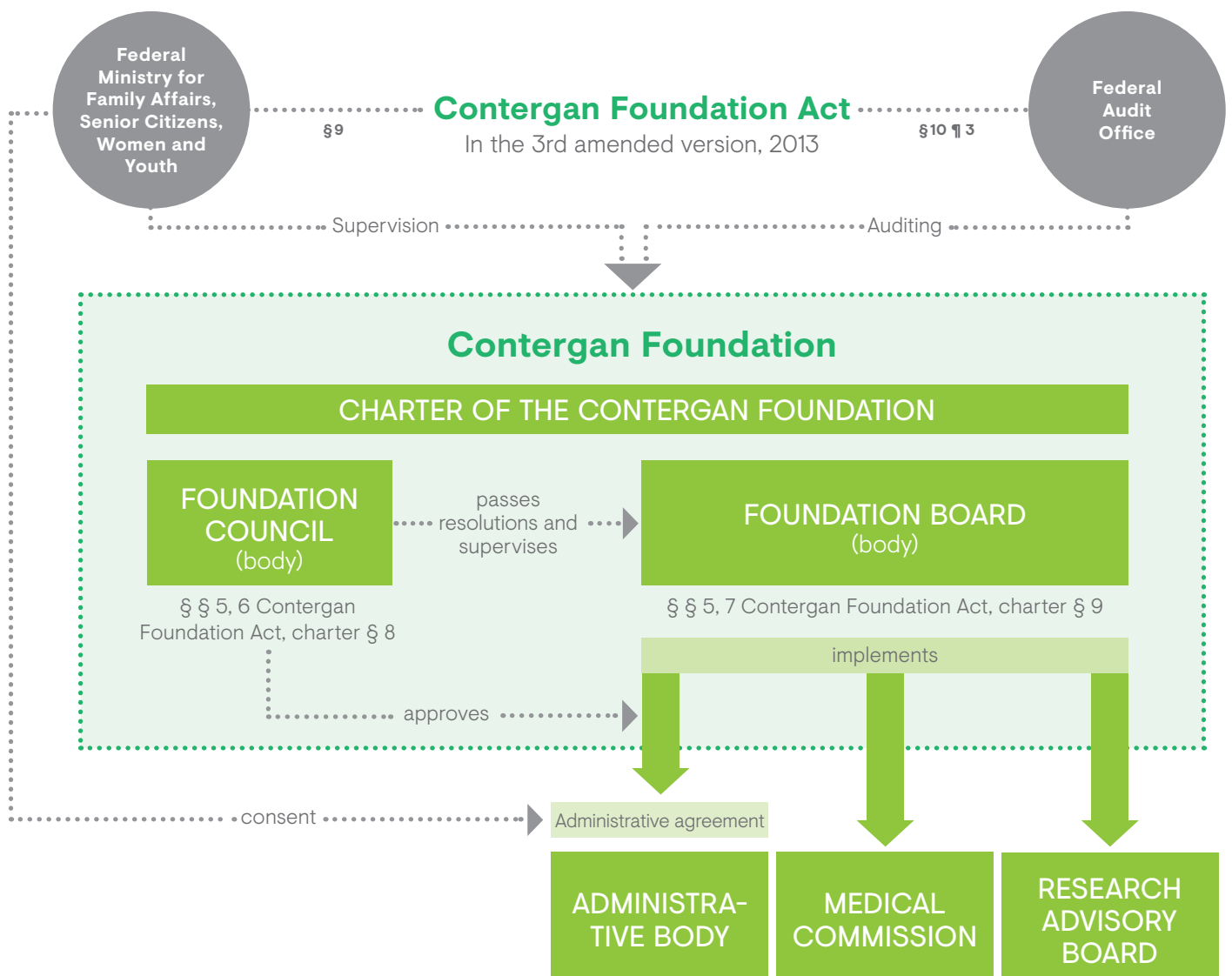
Aid Program for Handicapped Children

In December 1971, the German Bundestag passed a bill founding a foundation under public law, which then came into being on October 31, 1972 under the name “Hilfswerk für behinderte Kinder”. When the Conterganstiftungsgesetz [Contergan Foundation Law] (ContStifG) went into force on October 19, 2005, the foundation was given its current name (Contergan Foundation).

The sum of 100 million DM agreed to with the parents in April 1970 was transferred to the newly created foundation with the consent of the

parents. This was supplemented by another 100 million DM from federal funds. The purpose of the foundation is to provide financial support for persons affected by thalidomide and, by promoting/conducting research projects, to ensure that they can participate in the life of the society and to mitigate impairments due to long-term consequences.

Since then, even after half a century, this combination of long-term state support and the contribution of Grünenthal still represents a life-long, reliable system of financial support for all the affected persons in the country and abroad who were harmed by a Grünenthal product that contained thalidomide.



No representative of Grünenthal in the Contergan Foundation

The Contergan Foundation is exclusively under the supervision of the German Federal Minister for Family, Seniors, Women, and Youths (BMFSFJ). The individual committees are also staffed by civil servants; in addition, persons affected by thalidomide are elected to the Foundation Council.

Committees

The Contergan Foundation is supported by two committees, the Medical Commission and the Research Council.

The Medical Commission is comprised of eleven physicians from various disciplines and a chairperson, who must be a fully qualified lawyer. Examples of the medical disciplines are: otorhinolaryngology (ear-nose-and-throat), neurology, and orthopedics. The responsibilities of the Medical Commission include deciding whether a case of damage exists under the ContStifG law and assessing the extent of the damage. This assessment is done using a detailed point system used to determine the amount of monthly pension payments as well as a one-time capital remuneration payment.

The Research Council is responsible for the promotion and conduct of research on the development of the damage to affected persons and ways to deal with it.

Financial support from Grünenthal

Grünenthal contributed a total of 100 million euros to the Contergan Foundation. The first half was paid when the foundation was founded and the second half in the year 2009. At the request of the then Federal Minister of Justice at the establishment of the Contergan Foundation in the year 1970, the company has since then made yearly payments, in order to cover part of the overall costs for the work of the Medical Commission. For this purpose, Grünenthal issued a statement of indemnity, which is still in effect today.

In creating the Contergan Foundation, the expertise of a Grünenthal employee was also used: The former company attorney Herbert Wartensleben (employed by the company until 1981) was a mem-

ber of the Medical Commission of the Contergan Foundation until 2003. His role in the Commission, however, was of a purely administrative nature: He received applications or, for example, forwarded expert reports to the relevant offices. He himself was never involved in the assessment of possible damage to persons affected by thalidomide.

In addition, he also did not work alone in the Commission: Together with Widukind Lenz, who was the first in Germany to suspect a link between thalidomide and teratogenic damage and was responsible for the expert opinions for the affected children, along with the attorney Schulte-Hillen, who had represented the affected families in the criminal trial as co-plaintiffs, and other members, he took on these duties at the request of the federal government. Measured by current compliance requirements, such a link between an employee of the company and a function within the Contergan Foundation would no longer be possible.

In 2014, documents that, due to the work of Mr. Wartensleben, were incorrectly located in the company archive, were transferred by Grünenthal to the Contergan Foundation.

Situation of the affected persons today

Forty years later, the solution worked out in the year 1972 is still the basis of a system of financial support for persons affected by thalidomide in 38 countries, who receive their benefits via the Contergan Foundation. Financial support can be requested by all persons who were harmed by a drug containing thalidomide from Grünenthal or one of its foreign sales partners.

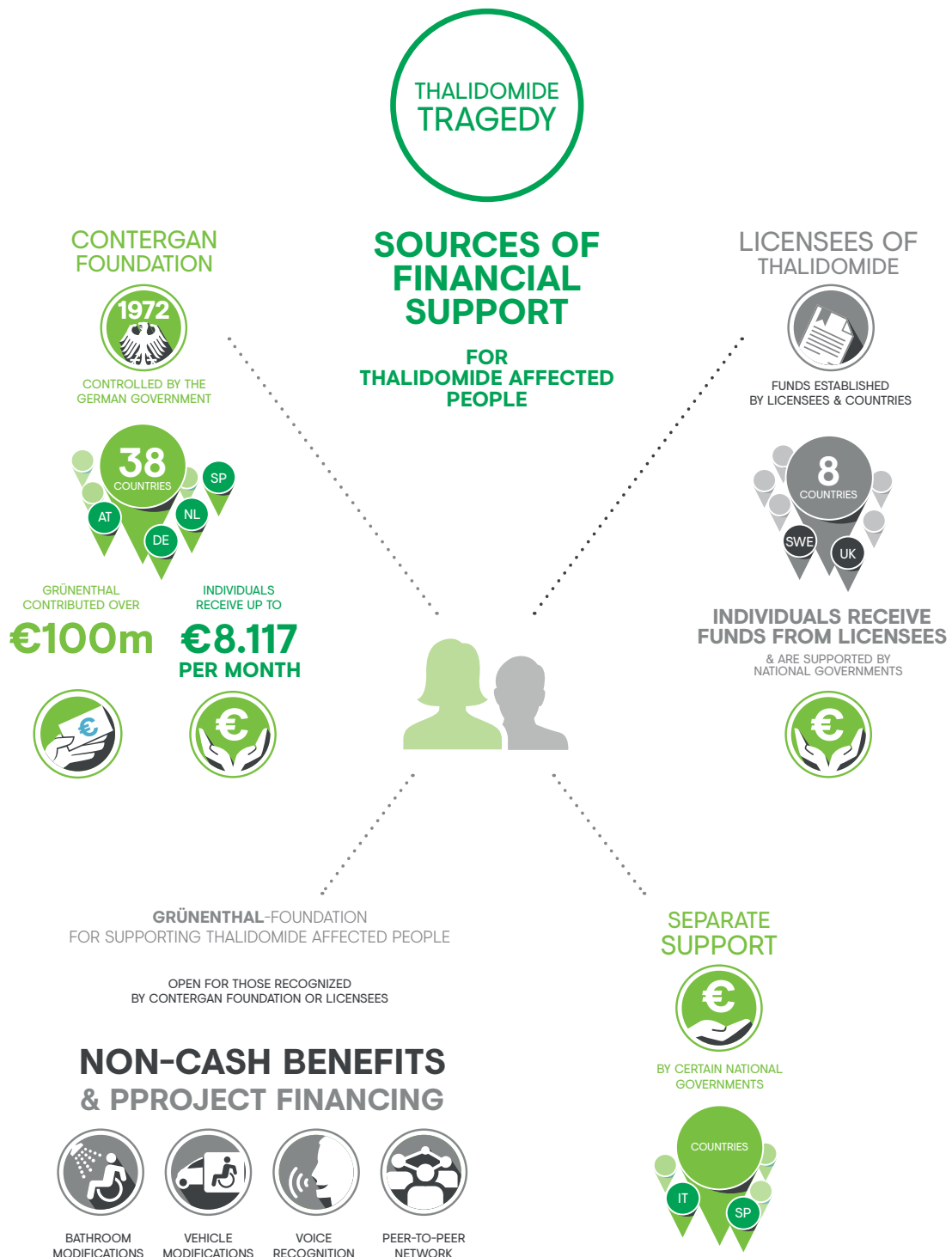
Currently, the Contergan Foundation supports about 2,700 people with an average pension of about 60,000 euros annually; the maximum rate is about 7,900 euros per month. Beyond that, affected persons have received special payments since 2009, financed by Grünenthal's voluntary additional payment in the amount of 50 million euros, and, since 2017, further financial support from the federal government for so-called specific needs.

¹⁰ See also Annual Report of the Contergan Foundation 2016 (p. 18): https://www.contergan-infoportal.de/fileadmin/downloads/NEU-DOWNLOADS/Geschaeftsberichte/Conterganstiftung_Geschaeftsbericht_2016.pdf.

In the countries in which other companies marketed counterfeit drugs independently of Grünenthal, for example in Italy, the affected persons receive support from the respective country. In countries in which licensees marketed their own thalidomide products, these companies provide the financial support together with the government. For example, such arrangements exist in Great Britain and Sweden.

Furthermore, the foundation created by Grünenthal, the “Grünenthal Foundation for the Support of Persons Affected by Thalidomide”, supports individual persons through the financing of non-monetary benefits and projects.

The following graphic illustrates exactly how the support system for persons affected by thalidomide works.



The change in the way
Grünenthal deals with the
tragedy and the people
affected

Today

Since it has existed, the Grünenthal Foundation has provided support in more than 1,000 cases.

2016

The Grünenthal Foundation supports affected persons by providing mobility escorts for them while traveling.

September 2014

The company starts a dialog with the affected persons and their support on the international level.

May 2013

Grünenthal organizes the first roundtable with representatives of the associations of affected persons, in order to discuss suitable projects for the Grünenthal Foundation.

December 2012

The Grünenthal Foundation is established.

August 2012

After more than 50 years, the company officially apologizes for its long silence and for not finding its way to the people.

June 2011

The company establishes the Hardship Initiative to improve the life situation of affected persons. For example, support for modifications to cars and apartments.

October 2009

Grünenthal voluntarily contributes 50 million euros to the Contergan Foundation.

November 2007

Dialog begins with the German Federal Association of Affected Persons as well as politicians.

“For us, the Foundation team, personal communication with the affected persons is the core of our work; that is why we take a lot of time to learn about individual needs, to enable the Foundation to help where it helps the individual person most”.

Tom Hermes



Grünenthal's support for persons affected by thalidomide today

Since 2007, Grünenthal has assumed increasing responsibility for the support of persons affected by the tragedy. This ranges from the establishment of a continuous dialog with representatives of the affected persons, to an apology, to the start of the Hardship Initiative and the creation of the Grünenthal Foundation.

An important step in dealing with individuals affected by thalidomide was the apology by the then Chairman of the Managing Board, Dr. Harald F. Stock on August 31, 2012, which he addressed to the persons affected by thalidomide and their families. In a speech, Dr. Stock expressed the consciousness of the company of the great suffering endured by the affected persons in the tragedy and asked for forgiveness of the long silence.

In the same year, the “Grünenthal Foundation for the Support of Persons Affected by Thalidomide” was established. The purpose of the foundation is the sustained improvement in the life situation of the persons affected. The foundation provides support worldwide for applicants who are recognized by the Contergan Foundation or a similar institution that applies comparable criteria in the recognition of thalidomide damage. Since it has existed, the Foundation has provided support in more than 1,000 cases.

People who are handicapped by shortened arms or legs face great challenges in everyday life. They start with daily personal hygiene and range to the care of their own family: Getting into a commercially available bathtub or cooking in a standard kitchen are hardly possible for the affected persons. For example, electrical equipment is arranged at too high a level or cannot be operated at all with short arms. In these cases, the Grünenthal Foundation provides specific support.

Furthermore, support is also provided for local projects, in order to meet the needs of affected persons. For example, in Belgium there is a patient card. The special needs and requirements of affected persons are often not known to the medical personnel there. They are recorded on the card, so that, in case of emergency, the central special requirements for possible interventions can be called up.

The Grünenthal Foundation is engaged in a continuous dialog with the affected persons, to understand the individual needs of the people and to learn what form of support is needed. Regular

talks with persons affected by thalidomide show again and again the importance of this direct person-to-person communication. In the future, too, the Grünenthal Foundation will maintain contact with the affected persons and adapt support to their changing needs. This will always be done in a dialog with the affected persons and with a focus on the benefit for an improved quality of life.

Additional information:

<http://thalidomide.grunenthal.info>

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