1. Development and testing

The preperidine dione derivative thalidomide, the effective ingredient in Contergan, was developed in the laboratories of the company known as Chemie Grünenthal (now Grünenthal) in the spring of 1954. A product of coincidence, it was discovered in the course of a search for new medications and, in keeping with standard procedure, tested for possible effects. The first pharmacological tests on animals revealed a remarkably acute non-toxicity, as no lethal dosage was identified. Because sleep-inducing effects were believed to have been observed, a long-unfulfilled pharmacologist's dream seemed to have come true: a harmless sleeping medication that could not be misused with suicidal intent. Internal tests conducted by the company were followed by clinical trials of thalidomide in March 1955, both as a stand-alone agent and in combination with other active ingredients. Binding standards for tests of new medications of the kind in force today did not exist in the mid-1950s (ordinarily, no tests of teratogenic effects were performed). The scope and form of such tests were left more or less to the discretion of pharmaceutical producers and physicians. Prior to its introduction to the market in October 1957, the medication was tested by more than 60 physicians, four of whom published their findings. Although isolated cases of side effects (primarily constipation and the so-called hangover effect) were reported, most reports were positive. And although the testing procedures may seem inadequate to contemporary observers, they met the prevailing requirements of the time.

After the first clinical evaluations were submitted to Chemie Grünenthal, the company applied to the Ministry of the Interior of the State of North Rhine-Westphalia for a permit to produce Contergan and Contergan-forte (25 and 100 mg of the effective ingredient per tablet, respectively) on June 11, 1956. Although the first German Medicinal Drugs Law was not enacted until 1961, medications like Contergan were subject to an approval procedure based on an old legal directive from 1943, which was dubious from a legal point of view and was eventually rescinded by the Federal Constitutional Court in 1959. Medications were tested only superficially in accordance with this procedure,

which explains why the approval for Contergan was issued just two months later, on August 9, 1956.

In response to a request by a business partner, the market launch of Contergan was postponed for more than a year. The aggressive marketing strategy developed in the meantime was to have a significant impact on future advertising for Contergan. The medication was advertised as totally harmless and highly tolerable, although isolated indications of side effects had been noted during the testing phase. Because public advertising for sleeping medications was prohibited, marketing efforts were focused initially on physicians and pharmacists. Consumers could also be addressed directly in the package leaflet.

Contergan was introduced to the market in the Federal Republic of Germany in October 1957, and the first advertisements appeared in early 1958. Described in prospectuses, package leaflets and certain publications as “harmless,” “absolutely free of damaging effects” and “totally non-toxic,” the medication was also recommended specifically for sick persons, children and seniors. That was not without impact. The majority of physicians initially expressed satisfaction with the medication. Critical voices were heard only on the sidelines at first. Thus to a certain degree, the company felt confident about the statements made in its advertising through 1958.