## 4. Malformations

The issue of the increasing incidence of malformations in the Federal Republic of Germany came up even before the Contergan scandal. Concern with the matter emerged above all in the debate regarding the effects of nuclear weapons tests. Unfortunately, a 1959 survey initiated by the German Federal Government led to the conclusion that there had been no such increase. As a result, physicians and other experts were immunized, so to speak, against recognizing the increase in thalidomide-related malformations that followed immediately. State-appointed physicians responsible for the treatment of physically disabled persons under the so-called Physically Disabled Persons Act of 1957 and medical specialists at major university clinics were the first to recognize the rising incidence of malformations among newborns during the first six months of 1961. That insight, however, applied only to the limited circle of cases with which these medical experts were acquainted. It only gradually became clear that the phenomenon was present all over West Germany. The first relevant publication appeared in September 1961.

Widukind Lenz deserves special recognition for his contribution to awareness of the teratogenic effects of Contergan and its eventual removal from the market. The physician from Hamburg was informed of an increase in rare limb malformations in North Rhine-Westphalia in mid-1961. Lenz pursued the matter further and identified a substantial rise in the number of similar cases in Hamburg. An increasing number of references to Contergan were noted in the course of interviews with parents during the first weeks of November 1961. Lenz first reported his suspicions to Chemie Grünenthal on November 15. The company rejected Lenz's demand that the medication be withdrawn from the market. Lenz discussed his suspicions at a conference of pediatricians in Düsseldorf on November 18, 1961, but did not actually name the medication in question at the time.

Lenz was visited by representatives of the company in Hamburg on November 20, 1961. The health authority in Hamburg had been informed in the meantime, and Lenz presented his findings to company representatives in the presence of city officials that afternoon. Yet since North Rhine-Westphalia had jurisdiction, as the company was registered in the state, a conference was scheduled there. In spite of the substantial grounds for the suspicions in question (which did not justify prohibition of the drug in the eyes of the officials from Hamburg) the company remained unwilling to withdraw the product from the market and sent out more than 66,000 copies of a physician's statement that downplayed the side effects of Contergan that same day.

Lenz met with representatives of the company at the Ministry of the Interior of North Rhine-Westphalia on November 24, 1961. Although he reported his suspicions and demanded that sales be discontinued, the company's representatives succeeded in diverting the discussion to fundamental issues. Ministry officials remained hesitant to take action, as there was no legal basis – scientifically proven facts that would hold up in court – for prohibiting sale of the drug. Instead, the officials tried unsuccessfully to bring about a voluntary withdrawal from the market. Representatives of the company made it clear that they would take legal action against any attempt to prohibit the sale of Contergan and that the burden of proof rested with the Ministry, which would face claims for compensation for damages amounting to millions. The Ministry representatives took note of this and opted to take no further steps. They explained that they would convene an expert commission and notified the relevant federal and state authorities of the date.