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The Dismantling of the German Federal Health Agency: A Case of (Failed) Institutional Precaution

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In October 1993, the *Bundesgesundheitsamt* (BGA), the internationally well-reputed German Federal Health Office, was dismantled by the Minister who supervised it. The dismantling of an institution considered among the top public health agencies in the world attracted a great deal of attention worldwide. The case of the BGA, besides highlighting political issues in the field of health and precaution, illustrates the failures that loom in the field of precaution and its institutional implementation. Examination of the circumstances surrounding the failure of the BGA should therefore help us to identify institutional characteristics that might guarantee the successful implementation and safeguarding of precaution. Accordingly, we will outline the facts of the 'scandal of AIDS-contaminated blood' and explore explanations that may account for the institutional disaster. As a conclusion, we will enumerate the lessons for institutions in the field of precaution.

Prologue: Dismantling of a Dysfunctional Agency

Before October 1993, suspicion had been repeatedly raised that AIDS might have been transmitted in HIV-contaminated blood to haemophiliacs and patients undergoing blood transfusions during operations and that the responsible institutions had not guarded against this possibility. Relying on information forwarded by the BGA, the Minister repeatedly declared that no cases of infection through blood products had been reported since the development of an AIDS test and a process to inactivate viruses, i.e., since 1985. In October 1993, the public learned from the press that many cases of AIDS infection had in fact followed treatment with blood products-in the end 373 people had apparently been infected with AIDS in this way since 1985.

Investigations discovered that officials in the BGA, which was responsible for supervising and ensuring the safety of all medicinal products, had been informed of these cases, but that this information never left the relevant agency departments. The President of the BGA, his vice-president, and the competent senior Ministry official had never learned of the spread of AIDS through blood products.

In any case, the scandal of AIDS-contaminated blood was only the last act in a series of incidents that indicated growing inefficiency, laxity and incompetence in this agency that had over its 100-year history contributed to the fame of the German public health sector.

As a consequence, the Minister, presumably eager to avoid his own dismissal, announced the dismantling of the agency in October 1993. A reorganisation in June 1994 broke the BGA down into its component parts.

As a federal superior agency *(Bundesoberbehörde)* the BGA had been organisationally separated from the ministry, but subject to ministerial directives even for the assessment

of technical and medicinal matters. With a president at its helm, the BGA had been composed of an administrative body and seven largely independent scientific institutes, each with its own director.

The reform eliminated the federating and central structures; the components became superior federal agencies on their own, and some functions were merged. Under the new structure, however, the institutes remained as subject to ministerial control and as accountable to the Ministry as the single BGA had been.

Findings of the Inquiry Board

Failures within the Agency

In October 1993, the *Deutsche Bundestag* established an inquiry board to investigate the agency's failures. The board's final report (*BT-Drucksache* 12/8591) accused the agency of years of negligence in its task of protecting the blood supply from AIDS and hepatitis.

The board found (*BT-Drucksache* 12/8591, p. 189-191) that the BGA had continued to approve non-inactivated blood products until 1985, even there had been sufficient reason to consider AIDS to be an infectious disease since 1982. Thus the BGA contravened the German Medical Preparations Act (*Arzneimittelgesetz*, AMG), which requires precautionary measures in case of a "reasonable suspicion of a risk", (§§ 30 sec. 1, 25 sec. 2, No 5 AMG), defined to encompass cases of scientific uncertainties (Rehmann, Wolfgang: *Arzneimittelgesetz*, München 1999, § 5 para. 2).

Moreover, although the BGA had all the relevant facts, it did not provide clear information for patients nor did it recall old products. The board found evidence that such measures had been discussed internally and that at least for certain products the *Stufenplanverfahren*, the administrative process for an action, had begun. However, after a hearing that included public-sector and industry experts as well as representatives of non-commercial blood suppliers, the process stopped and the proposed measures were withdrawn. Moreover, the initial lenient measures that had been taken were also withdrawn in part, on the objection of the pharmaceutical industry and the protests of the non-commercial blood-suppliers (*BT-Drucksache* 12/8591, p. 129-146).

Therefore, the BGA did not taken measures that were needed because: firstly, it failed to assess the risk appropriately; secondly, it attributed too much importance to the quantitative aspects of the blood supply; thirdly, it wanted to avoid driving the non-profit suppliers, who could not have inactivated their products, out of the market; and lastly —albeit mentioned rather discreetly by the inquiry board— the BGA may also have overemphasised the economic interests of the industry concerned (cf. *BT-Drucksache* 12/8591, p. 129-146).

Involvement of the Ministry of Health

The inquiry board also found evidence of negligence within the Federal Ministry of Health. The Ministry had failed to recognise the need to develop AIDS expertise within the BGA -although this lack had been pointed out explicitly and repeatedly to officials, even by representatives of the pharmaceutical industry (*BT-Drucksache* 12/8591, p. 233)

Equally fatally, the relevant senior official in the Ministry of Health was obviously in completely over his head in this matter, as illustrated by his production of a memorandum supposed to show that blood-products *had been inactivated* since 1984 —a measure that had never been imposed on suppliers, although it had been discussed internally (*BT-Drucksache* 12/8591, p. 237).

Finally, the Ministry was assumed to be largely responsible for administrative decisions that were and that were not taken in the course of the *Stufenplanverfahren.* The board did not, however, clarify details of the Ministry's involvement in these decisions (*BT-Drucksache* 12/8591, p. 197, cf. p. 129-146).

Structural Deficits

The inquiry board also looked into the institutional structures that led to these inappropriate decisions. The report identified three sets of structural problems that seemed to account for the disaster:

i) weaknesses related to staff,

ii) deficits in the flow of information, and

iii) pressure from political and private interest groups.

The board dealt with five staff issues. First of all, it cited the lack of expertise reflected in the agency's inept risk assessment (*BT-Drucksache* 12/8591, p. 189-191).

Second, the recruitment of top-level scientists and doctors was hampered by the low

level of public salaries and by the repressive atmosphere inside the institution, which treated critical independent voices as trouble-makers rather than supporting them and thereby drove them out (*BT-Drucksache* 12/8591, p. 237-238).

Third, the board named weak leadership as a major precondition for the agency's shortcomings. It found that appointments to the positions of institute directors and president went to people unqualified to fill such positions —an assessment that seemed particularly true with regard to the president of the agency at the time, who had explained to the inquiry board that it was his "philosophy" to rely on to the "responsibility of the pharmaceutical entrepreneurs" because the agency should be only a "moderating spectator" (*BT-Drucksache* 12/8591, p. 234).

Fourth, the board looked at the imbalance of income between officials and private industry employees and concluded that agency officials might feel degraded and psychologically weakened in dealing with counterparts whose salaries were ten- to twenty-fold higher (*BT-Drucksache* 12/8591, p. 237).

Fifth, the board did not find evidence of bribery. Nonetheless, the former BGA president, for example, had spent a considerable amount of his time on well-paid secondary jobs. Over the past ten years, one quarter of all BGA scientists had worked on secondary private contracts, often with the pharmaceutical industry. The board therefore considered whether such practices might not affect the quality of the agency's work and its independence. Given the much higher salaries available in private industry, however, the board concluded that outstanding scientists and physicians could be attracted to leading positions in the public sector only if they were allowed to generate additional income for themselves as private consultants (*BT-Drucksache* 12/8591, p. 234-244).

Problems were identified in the flow of information between the institutes and between the institutes and the president. Outside observers perceived a sense of independence and also rivalry between the institutes. As a consequence, the BGA-institutes, although accountable to BGA-headquarters and to the Minister, often provided inadequate information to both (*BT-Drucksache* 12/8591, p. 234-236).

Although the board mentioned this mainly in passing, all these factors need to be considered against a background of two types of extreme political pressure: the electorate's intense response to health and especially AIDS issues, and enormous pressure from interest groups, due to the extraordinary value of the pharmaceutical market (*BT-Drucksache* 12/8591, p. 253-254).

Approaches to an Explanation

There is no single explanation to account for the failure of the BGA. Based on this case, at least four issues may be considered to be crucial for the functioning of an institution in the field of precaution.

Accountability

The Minister's rapid decision to dismantle the agency and subject the institutes to the direct control of his ministry reflected his conclusion that lack of ministerial control and a culture of independence within the institutes explain the BGA's failure. His reform was concerned with enforcing the 'lines of responsibility' between himself and the civil servants and addressed only the information flow problems between the agency and the ministry. It ignored the poor organisation inside the institutes and their weaknesses in relation to the industry.

Regulatory Capture

To a large extent, theories on regulatory capture formulated by Stigler and Peltzmann in the early 1970s (cf. Stigler, George: "The Theory of Economic Regulation", in *Bell Journal of Economics and Management Science* (2) 1971, p. 3-21 and Pelzmann, Sam: "Toward a More General Theory of Regulation", in *Journal of Law and Economics* (1) 1976, p. 211-240) seem to account for the deficits identified. According to this theory, a regulatory agency is 'captured', when it *disregards the common good in favour of the regulated private interest.* To some extent, the agency's informational deficits account for this phenomenon: the regulator depends on information from the regulated enterprises, which may distort it and thus induce inappropriate decisions. The theory's fundamental claim, however, is that capture occurs without the wilful intent of the regulatory agency. The regulator rather becomes gradually entwined with the business of the regulated and tends to be easily influenced by it in the course of normal day-to-day business. Here, capture is the *identification of an agency with its industry.* The regulator feels responsible for the success of the industry. He is therefore prone to defer to the wishes it expresses.

Such 'co-operation' is considered a precondition for smooth regulation and the constant supply of the markets. In extreme cases, the regulator might *identify the economic interest of the regulated with the general public interest.*

Capture is facilitated when agencies lack expertise and leadership, both defects identified in the case of the BGA. These weaknesses, the theory suggests, are produced by 'political appointments' and the limited funding available for public service agencies. The theory holds that even when regulators do not take on secondary jobs that constitute a direct conflict of interest, they may be dominated by the wrong incentives. In particular, the potential of future high-paying jobs with regulated firms may make regulators interested in staying on good terms with them. To these aspects must be added the extraordinary amounts of money that are spent by interest groups on political parties as well as for consultants, lawyers, advertisements, and lobbying to which the individual public servant is constantly exposed and eventually might —even unintentionally— succumb (cf. Balzer-Schnurbus, Sabine: *Ökonomische Theorie der Regulierung unter besonderer Berücksichtigung öffentlicher Unternehmen*, München 1992).

Scientific Independence

The experts invited to a parliamentary hearing to discuss the Minister's reform placed significant importance on the issue of scientific independence and the independence of scientific decisions from ministerial interference. The parliamentary hearing raised the following issues:

In scientific matters the institutes must be entirely free from any political interference. A clear separation of political normative decisions from scientific medicinal assessments is indispensable for consumer protection based strictly on scientific facts.

The experts stressed that finding reputable scientists and dedicated staff depends less on higher funding than on good working conditions. Competent scientists fled the BGA because the Ministry increasingly interfered with scientific decisions. To illustrate this claim, they pointed to the case of salmonellae-contaminated eggs in 1992: the BGA had recommended —based on scientific findings— the cooling of eggs from the 10th day onwards to avoid contamination with salmonellae. For political reasons, however, the ministry favoured a term of 18 days. Despite the refusal of BGA officials to change their advice, the agency was obliged to set the more generous term by directive of the ministry —and to keep the reason for the decision secret. Generally speaking, keeping quiet became the primary obligation within the agency.

The experts also urged that leadership positions of the institutes go to high-ranking experts *who are also* strong independent characters. Large institutions need the leadership of an individual who can function not only as a scientist, but also as a manager of such an institution. The challenge of the position is to master the huge quantities of knowledge and information that must remain accessible, be updated, advanced, and brought into co-operative structures such as projects, rather than departments (*Wortprotokoll 90. Sitzung des Ausschusses für Gesundheit*, p. 1-23).

These suggestions are supported by what is seen as the central institutional requirement for precaution in the literature. In his work on administrative decisions and risk assessment, Di Fabio stresses that risk assessment requires public agencies to interact with the outside while inside these agencies, decisions are reached by experts *who are not incorporated into public administration*, that is, either external experts or staff of the agency whose scientific work is not subject to ministerial directives. Di Fabio consequently envisioned the successor of the BGA as an agency at the centre of administrative risk assessment only in terms of organising this assessment and transferring scientific knowledge into the final mandatory decision. The traditional doctrine of political control with clear lines between the minister and the civil servants, he claims, has been rendered obsolete by the risks of modern technology (cf. Di Fabio, Udo: "Das Arzneimittelrecht als Repräsentant der Risikoverwaltung", in *Die Verwaltung* 1994 (27), p. 352-357).

Participation and Pluralistic Bodies

This issue can be reduced to the question of how, in concrete terms, a risk assessment should be carried out and how appropriate results can be ensured.

The law, in general, only provides open legal terms such as "reasonable scientific possibility" or "reasonable scientific probability". However, these terms must be objectified and applied to concrete cases. In international contexts, according to scholars, objectifying the subjective thresholds of the precautionary principle requires the establishment of pluralistic scientific bodies with a high degree of credibility. Precaution requires approaches

of "balanced representation" (cf. Marr, Simon: *The Precautionary Principle in the Law of the Sea*, Kluwer Law International, 2003).

In contrast, the current design of the *Stufenplanverfahren,* the central administrative proceeding required for an intervention under the German Medical Preparations Act, *one-sidedly* provides only for the inclusion of the pharmaceutical industry in written procedures and hearings, but leaves patients and consumers unheard. The independent expert mandated by the inquiry board to review the structures in the BGA consequently supported the idea of participatory approaches, so that stronger representation of patients might possibly counterbalance the pressure currently exerted only by producers (*BT-Drucksache* 12/8591, p. 603).

Lessons to be Learned: Institutional Criteria for Precaution

The purpose of this paper is not to give a full account of the lengthy discussion about the re-organisation of the BGA —a discussion that is still going on- but rather to draw some lessons from this case about institutional characteristics that might guarantee precaution. The following points should be considered:

First: agencies need to be strengthened against regulatory capture through the careful selection of agency staff. In particular directors and senior officials must be both high-ranking scientists and dedicated to consumer protection. 'Political appointments' are likely to stack an agency in terms of capture -while a reputed and dedicated director could protect his agency staff from the inevitable pressures of interest groups.

Second: administrative decisions relating to risk require an independent scientific vote; i.e., risk assessments must be kept clear from any political and hierarchical interference. Scientific independence and the scientific quality of work may also make up for lower salaries and thus strengthen the regulator against capture.

Third: the organisation of risk management requires flat hierarchies to ease the flow of information, to manage huge quantities of administrative transactions efficiently, and to keep the knowledge and information available in the agency accessible and within co-operative structures such as projects, rather than departments. Joint management by a high-ranking scientist and a professional administrator with excellent information skills might be an advisable solution.

The German parliament enacted the legislative proposal of the Ministry of Health as presented. However, it added —quite unconventionally— an "attributive statement" that stated its "assumption" that the act granted scientific institutions independence from political interference, and that the Minister's role was limited to defining priorities and deciding on actions based on the agencies' scientific results. A parliamentary watchdog might also be included in our discussion as an institution that may help to safeguarde independent risk assessment and the implementation of the precautionary principle.