FEDERAL

The federal government, according to Article 74 Paragraph 1 No. 19 GG no power to regulate the production of such drugs, which produces the doctor for use in their own patients.

The production ban in § 1 paragraph 1 of the fresh cells-regulation is void.

Federal Constitutional Court, ruling of 16 2. 2000 - 1 BvR 420 / 97 (Lexetius.com/2000, 3868 [2001/6/68])

1 In the proceedings on the constitutional complaint of Dr. A ..., the wife of Dr. B ..., by Dr. J ..., by Dr. M ... - represented by Felix Busse und Partner, Oxford Street 21, Bonn - v § 1 para 1 and § 2 para 2 of the Regulation on the Prohibition of the use of certain substances for the manufacture of medicinal products (fresh cells-regulation) of 4 March 1997 (Federal Law Gazette I, p. 432), the Federal Constitutional Court - First Senate - composed of the Vice President paper, the Judge Grimm, Kuehling, Judges Jaeger, Haas, the judge Hömig, Steiner and Judges Hohmann Dennhardt for the hearing of 9. November 1999 ruling by rules as follows:

2 § 1 paragraph 1 and § 2, paragraph 2 of the Regulation on the Prohibition of the use of certain substances for the manufacture of medicinal products (fresh cells-regulation) of 4 March 1997 (Federal Law Gazette I, page 432) violate the complainants in their fundamental right under Article 12 Paragraph 1 of the Basic Law. They are void.

3 The Federal Republic of Germany is required to reimburse the complainants the necessary expenses.

4 Reasons: A. The complainants are doctors. Their constitutional depends directly contrary to § 1 para 1 and § 2 para 2 of the Regulation on the Prohibition of the use of certain substances for the manufacture of medicinal products (fresh cells-regulation) of 4 March 1997 (Federal Law Gazette I, p. 432) that "it is prohibited under penalty, in the manufacture of drugs intended for injection or infusion, use of fresh cells. The regulation is the Federal Ministry of Health under § 6 of the Act on the marketing of pharmaceutical products (Medicines Act) in the version published on 19 October 1994 were (BGBl I S. 3018 adopted, 'the AMG). § 6 para 1 AMG is:

5 The Federal Ministry of Health (Ministry is authorized) to prescribe by regulation, with the consent of the Bundesrat, the use of certain substances, preparations or articles from materials in the manufacture of medicines and restrict or prohibit the marketing of medicinal products not manufactured according to these rules are prohibited, where it is necessary to prevent any direct or indirect risk to the health of humans or animals by drugs.

6 The relevant provisions of the fresh cells are Regulation:

7 § 1 Banning the use of fresh cells. (1) It is prohibited in the manufacture of drugs intended for injection or infusion, use of fresh cells. (2) to (5) ...

8 § 2 Penalties and fines. (1) ... (2) According to § 96 No. 1 of the Medicines Act will be punished, whoever used in contravention of § 1 para 1 fresh cells. (3) ...

9 Dispute is whether, on the basis of the Medicines Act physicians can be prohibited to produce fresh cells to the immediate patient use.

10 I. 1 The fresh cells therapy is, in essence, an injection of live animal cells to the patient with the intention of achieving a revitalizing effect. The cells are usually obtained from sheep fetuses. The donor animals originate from - in the female line - closed herds, so will the risk of transmission of certain diseases can be avoided.

11 The fresh cells therapy is one of the so-called alternative healing methods. The therapists are based among other things, that the injected cells to trigger the corresponding organs in the body's own "repair mechanisms" and are therefore effective. Against fresh cells therapy is argued by Western medicine in particular, that a lack of therapeutic benefit might place a high risk, particularly hypersensitivity reactions, autoimmune reactions and transmissibility of infection, are facing.

12 2. The fresh cells-regulation was issued because of the evidence that the Federal Health Office in 1992 and resigned in 1994 in opinion and in the light of previous opinions of the Scientific Committee of the Federal Medical Council. The ban is the danger of fresh cells-based therapy (BRDrucks 38 / 97, p. 4 to 7). In 1987, the federal health department had already ordered the suspension of registration of all medicines for cellular therapy, which were considered to be finished by the transitional arrangements of the Medicines Act or as authorized (see Pharmazeutische Zeitung 1987, p. 1999).

13 Second, the complainants have made to their actual situation, the following information:

14 You are solely focused on a private operating and Frischzellenbehandlungen. For years, they keep closed flocks alone as a source of fresh cells.

15 1. The complainant 1) is general medical practitioner. In 1991 he became a private in the focus since 1977 are carried out Frischzellenbehandlungen. In hospital with 60 beds 53 staff are employed. The turnover is based on more than half of the Frischzellenbehandlung, the number of patients is declining.

16 2. The complainant in this case 2) took over from her father to a sanatorium with 45 beds offering since 1951 Frischzellenbehandlungen. It has 41 employees and earns its profits almost exclusively by Frischzellenbehandlungen. Most patients take it for the umpteenth time to complete.

17 3. The complainant to 3), apply the fresh cells therapy since 1968. He employs four people and as a practicing physician is affiliated with a spa. The number of patients and the profits are falling.

18 4. The complainant to 4) is a specialist in urology. He leads since 1980, a clinic with 42 beds and 29 employees, which specializes in fresh cells therapy and hereby made for more than three quarters of its turnover.

19 III. With her directly contrary to § 1 para 1 and § 2 para 2 of the fresh cells facing a constitutional regulation, the complainants allege a violation of Article 12 Para 1 and Art 14 Para 1 GG.

20 The constitutional complaint is admissible. The complainants were directly affected by the prohibition of criminal penalties in § 1 para 1 of the Regulation itself, and fresh cells. The constitutional complaint is well founded. The Medicines Act empowers the legislature not to interfere in the medical treatment freedom. Article 74 Paragraph 1 No. 19 GG implying a concurrent legislative powers of the Confederation for the marketing of drugs, not for the Pharmaceutical Affairs Law in general. But for the pharmaceutical market of the federal legislature itself should adopt rules and authorize the legislature to do so. Although the traffic involves the entire handling of drugs from production to marketing and consumption. The production could be regulated by the federal government but only for those drugs that were destined for transport. Fresh cells are not a product of this type, since they were not intended marketed. They were manufactured by the doctor and he himself used. In order to lay locally concluded individual operations, which were monitored by means of the health authorities of the countries. The production itself is also harmless and will only be prohibited for physicians, such as the complainants to make it impossible to therapy.

21 Moreover, the ban on live cells and the Frischzellenherstellung therapy is disproportionate. The actual evaluations of the Federal Health Office on the one hand, and the uselessness of the other health hazards were inaccurate and lacked a statistically relevant data base. It would also not considered that the patients were fully informed and expressly declared their consent. For specialized clinics also have a transitional regime must be found.

22 IV At the Constitutional Court, the Federal Ministry of Health on behalf of the Federal Government, the Federal Institute for Drugs and Medical Devices, the Federal Medical and the Association of German Doctors for fresh cells therapy Responses were received.

23 1. The Federal Ministry of Health considers the constitutional complaint as unfounded. The fresh cells-regulation was adopted kompetenzgemäß and substantive constitutional. Article 74 Paragraph 1 No. 19 GG covers the entire handling of drugs from production to consumption in the interest of a comprehensive health protection for patients. For effective prevention it is necessary to recognize at an early stage, ie already in the production of a pharmaceutical product. It is irrelevant whether already emanating from the manufacturing process hazards. A limitation of legislative power, in particular, could not result from the definitions in the Medicines Act. This contains, moreover, for the vet and in connection with narcotics as far-reaching provisions on the production as the challenged regulation.

24 The scheme complies with the proportionality principle. It is necessary to protect patients from serious threats to life and health. Even with direct application of self-made medicines must apply the basic principle of medical self-understanding and ethics laws, to avert possible harm to the patient and treat him the best of our knowledge and belief. When fresh cells therapy would not have noticed the most basic principles of drug production. In the opinion of the Federal Public Health in 1994 described kinds of damage (allergic immediate reactions, incompatibility reactions, autoimmune reactions and infection with scrapie, BSE, rabies and Prokolose) also justified immediate intervention.

25 2. The Federal Institute for Drugs and Medical Devices of the opinion that a leave of absence Frischzellenzubereitungen no treatment gap. The documents submitted by the complainants would give no reason to depart from the previously undertaken representation of risk and risk assessment.

26 3. The Federal Medical considers the advice of its Scientific Advisory Board and by the Drug Commission of the German medical profession (technical committee of the Federal Medical), the constitutional complaint as unfounded. Welcome the contents of the regulation was fresh cells. So far, no evidence of efficacy has led to fresh cells will be able to. In the individual case histories if they were not medically sound individual observations. The benefit was not demonstrated, to the stand several times, partly through exposure to lethal virus transmission and hypersensitivity reactions.

27 4. The Federal Association of German Doctors for fresh cells therapy holds the constitutional complaint is admissible and justified. Since 1983 there have been no significant cases of serious side effects. After decades of practical experience one can assume that there was a significant therapeutic benefit was associated with only a small residual risk. Were treated mainly elderly people who sought because of side effects of other drugs and therapies, an alternative treatment.

28 V. Since March 1997 the Federal Constitutional Court has suspended the application of § 1 para 1 of the Ordinance until the fresh cells to the substance of the moment, where the production takes place there called the Medicines for injection or infusion for patients in producing their own doctors.

29 VI. At the hearing, the complainant and the Federal Ministry of Health in their delivery have explained in greater depth.

30 B. The constitutional complaint is admissible.

31 Complainants will be affected by the prohibition on criminal penalties now and immediate. Until the adoption of the regulation, they were authorized to establish for the treatment of their patients required cell therapeutics. You need neither a manufacturing license under the Drugs Act nor were the products themselves to be registered under this Act. Complainants have been made for them is this very important part of professional activity, without the need for an enforcement measure.

32 Against the alleged violation of fundamental rights, the complainants can not otherwise obtain redress before the competent courts. Under the principle of subsidiarity of the constitutional complaint is a reference to such rights, although considered if it is suitable in fact and law to submit the direct effects of a standard judicial examination, the requirements of Article 19 Paragraph 4, sentence 1 GG is sufficient (see BVerfGE 71, 305 [337]).

33 Such protection was not granted by the administrative courts here, however. A standard control procedure of § 47 Paragraph 1 No. 2 APC takes place against the federal regulations do not. Declaratory relief, which were the efficacy of fresh cells-Regulation in respect of the administrative courts deemed inadmissible because they were not sufficiently concrete to be laid on the legal relationship to the drug with government authorities of the case, a standard control for the object (see last sentence of the Federal Administrative Court on 30 . September 1999 -- 3 C 39th 98 -). Attempts by the complainant to obtain before the administrative courts by way of interim relief effective judicial protection, were therefore unsuccessful.

34 C. The constitutional complaint is well founded. The contested ban, which in the Art by 12 Para 1 GG protected freedom of profession, the complainant will intervene, is not kompetenzgemäß adopted. § 1 para 1 and § 2 para 2 of the fresh cells-regulation are unconstitutional and void.

35 I. The regulation, however, surpasses the text of the enabling provision of § 6 para 1 AMG and the scheme of the Act is not drawn under (1.). This standard is, however, taking into account the allocation of competence in Art 74 Paragraph 1 No. interpreted restrictively 19 GG, the federal government is only authorized to manufacture such drugs legal or regulated by regulation and which are intended to be marketed. These drugs do not belong, which manufactures the doctor himself and uses the patient (2.).

36 1. Authorized in its own terms § 6 AMG, the Federal Ministry of Health also to adopt regulations that affect how the challenged regulation alone, the production of pharmaceuticals.

37 a) The Act on the marketing of medicines intended to ensure the interests of a proper supply of medicines for human and animal safety in the transport of medicines, particularly the quality, efficacy and safety of medicines (see § 1). In addition to the statutory commands and prohibitions in § 6 para 1 AMG regulation empowers the Ministry of Health, after the mandatory use of certain substances, preparations or articles from materials in the manufacture of pharmaceutical products may be restricted or prohibited for a direct or indirect risk to human health or animal health posed by drugs. This text therefore allows the regulator to regulate the production of drugs as such.

38 In addition, § 6 para 1 AMG also includes an authorization for such schemes involving the marketing of medicines. The enabling rule differs accordingly - just as the Medicines Act by the way - between the production and marketing of pharmaceuticals. The production is in § 4, paragraph 14 AMG defined as the profits, the making, the preparation, the working or processing, including the siphoning of filling, packing and marking of pharmaceutical products. Contrast, § 4 para 17 AMG defines the market as the holding for sale or for any other tax, offering for sale, display and sale to others.

39 b) The distinction between the production and distribution has as one of the forms of marketing for numerous pharmaceutical regulations importance. What is meant by duty in connection with the manufacturing authorization according to § 13 AMG, which is defined in paragraph 1, sentence 3: A duty to others is when the person who manufactures the drug, which is different from that which it applies .

40 For the pharmaceutical legislation is therefore in law and literature consensus that during the preparation by a physician, the product of his own medicine applied to the patient or use in its immediate sphere of influence through his authority to assistants, or by patients themselves can not supply this meaning is present (see BVerwGE 94, 341; OVG NRW, NJW 1998, p. 847 in an explicit rejection of NJW 1989, p. 792; German, Health Law, 3 Edition, 1997, p. 534 f.; Hoppe, MedR 1996, p. 72 [73]; Kloesel / Cyran, pharmaceutical law, commentary, § 13, n. 11 [cited January 1998]; Pabel, NJW 1989, p. 759 f.; Räpple, The prohibition of drugs of concern, 1991, p. 36 ff; Wolz, drugs of concern 'as a legal term, 1988, p. 40 ff). Doctors therefore need no permission to manufacture, so long as they do not give their manufactured drugs from his hand. If the drug to the patient or other doctors will be reported and thus changes the power to dispose of this medicine, however, is required under the conditions of § 13 AMG a

manufacturing license.

41 This view is consistent with the constitution of 1958 submitted a draft law on the marketing of medicines (see Bundestag document 3 / 654, p. 20). At that time, a uniform legal regime of the total drug traffic, which previously had been partially covered by the Industrial or individual regulations deemed necessary because the population is now easier to gain access to formerly industrially produced medicines have (see Bundestag document cited above, S . 15 left column). The state legislation for supervision of pharmacists, doctors and hospitals but have been taken for granted (Bundestag document cited above), p. 20 left column. In particular, the regulation of freedom of doctors should not be restricted (Bundestag document cited above, p. 16 left column, p. 18 right column, and p. 20 left column). The application (administration, injection) of a drug on the patient during consultation should be explicitly excluded from the tax concept (Bundestag document cited above, p. 20 left column).

42 The statutory definitions of drug law make a distinction between different forms of later medical practice. Doctors who do bring their own medicines on the market, subject to the general rules of drug laws, but also makes the drug law, the freedom of treatment the doctor so far untouched, as the application of medicines to our patients is not understood as a charge within the meaning of the pharmaceutical legislation.

43 c) The challenged regulation provides in § 1 para 1 no regulation, concerns the meaning of the Medicines Act in the marketing of pharmaceutical products or their sale to others. But is limited to a general prohibition on manufacture. But those are not entirely foreign to consistently related to the production rules of the Medicines Act (see § 4, paragraph 14, § 8 para 1 1. alternative to § 54 para 1 sentence 1), let alone from the scheme of the Act derive any objections to the Federal Ministry of Health unused skills.

44 2. The federal legislature is in Art 74 Paragraph 1 No. 19 GG However, only the power to regulate the transport of medicines given. This includes, therefore, not have unlimited jurisdiction to regulate all aspects of pharmaceutical legislation. The constitution takes into Art 74 Paragraph 1 No. 19 GG the border where it comes to the marketing of medicinal products in the widest sense. Will fix the federal legislature to optimize the health of the population already in the production of marketable drugs, he keeps so long under those powers, as far as his control drugs that are manufactured for the purpose of marketing.

45 a) Preventive health justifies early control when, with the increasing length of the distribution channel, the effectiveness of state supervision is weakened more and more. Exist in the manufacturing of the product intended to bring this about pharmacies or other outlets in the general circulation, at least a nationwide distribution of the medicine regularly sought. Therefore, there are good reasons why the federal government has so far a power to legislate concurrently.

46 This does not apply to such product manufactured by the physician that are not intended to be issued, and the doctor actually does not add any third party. These herbs are traditionally part of medical therapy that their effects are treated locally on each group of patients is limited. Medical care are held regularly only in a limited sphere of action. They are an essential part of the medical profession and the subject of freedom of medical care and responsibility, with responsibility for the supervision of the countries are.

47 b) The distinction between medical treatment and free medicines to the right has been - as far as can be seen - in law and literature on art 74 Paragraph 1 No. 19 GG has not been explicitly addressed.

48 The scope of the federal government allocated competence was not doubted in the recent jurisprudence of the Constitutional Court. As far as drug law was the subject of proceedings, it was always about buying or selling, and thus to the marketing of medicines (see BVerfGE 9, 73, 17, 269, 20, 283; 75, 166). The literature has traditionally been the concept of traffic broadly (see Maunz, in: Maunz / Dürig, Grundgesetz, vol IV, Article 74 para. 219 [cited 1984]; Kunig, in: v. Münch / Kunig, Grundgesetz-Kommentar, Vol 3, 3rd edition, 1996, Article 74 para. 95; Pestalozza, in: v. Mangoldt / Klein, Das Bonner Grundgesetz, vol 8, 3rd edition, 1996, Article 74 para. 1342 and 1436). On the other hand is generally accepted that Article 74 Paragraph 1 No. 19 GG no global authorization of the federal government for the area of health care is, but that enumerative and specifically some of the fields are set, in which the federal government is normierungsbefugt (see Stettner, in: Dreier, Grundgesetz, 1998, Article 74 para. 89; Degenhart, 74 marginal in: Sachs, Grundgesetz, 2nd edition, 1999, Art. 70). Although it is understood by "marketing of drugs", the entire handling of these funds from production to consumption on the trade, it is not doubted but the other part that the federal government's authority is limited in the doctor's right to certification issues (see Maunz, op cit , para. 215 and 219) and does not extend to the whole medical profession.

49 c) The historical development of competence under Article Title 74 Paragraph 1 No. 19 GG speaks against its use for a power of the legislature to regulate the production of pharmaceuticals, regardless of intended use and meet the marketing requirements for the use of self-manufactured medicines by the doctor.

50 A marketing of pharmaceuticals has evolved since pharmacists determine not produce as assistants of the physician on an individual statement, medicines, and instead finished the market (see the discussion of this development BVerfGE 9, 73 [80 f.]; 94, 372 [374 f.]; Giesbert, the distribution of medicinal products from a legal perspective, 1970, p. 2 ff.) Providing that the framers of the constitution of a traditional division between trade law regimes took over production and distribution of drugs on the one hand and the right doctor on the other. Main Committee and competence committee of the Parliamentary Council affirmed explicitly that it should except the right of admission to the medical profession remain the country doctor right thing (see JöR, NF, Vol 1, 1951, p. 540 to 543).

51 The marketing of medicines has been problematized either conceptually or in content. In that regard, there were more than seventy rich tradition of legal rules that the concept of trafficking in drugs, in adopting the Constitution in an unambiguous meaning documented (see the regulation on the marketing of Apothekerwaaren, dated 25 March 1872 [RGBl p. 85] and the regulation concerning the marketing of pharmaceuticals, January 4, 1875 [RGBl p. 5], the regulation concerning the marketing of medicines, 27 January 1890 [RGBl p. 9] and the subsequent regulation of December 31, 1894 [RGBl 1895, p. 1], dated 25 November 1895 [RGBl p. 455], dated 19 August 1897 [RGBl p. 707], dated 22 October 1901 [RGBl p. 380] and March 31, 1911 [RGBl p. 181], see also the regulation on the marketing of drugs, 4 October 1933 [Imperial Gazette I, p. 721] and the regulation on the production of Arzneifertigwaren February 11, 1943 [Imperial Gazette I, p. 99]) . It was followed by adoption of the Constitution no doubt that the concept of transport involved with drugs, the display and sale of medicines to consumers. Only in this context were also adopted supplementary regulations concerning the manufacture of medicinal products. The manufacture of medicines and their direct application by doctors were never the subject of successful legal regulations on the marketing of drugs have been. Competency Rule of Art 74 Paragraph 1 No. 19 GG was therefore in the Parliamentary Council - Committee on the division of responsibilities - after a long debate about how the division of responsibilities between federal and state governments should take place at the doctor's right to respect of the drug traffic was adopted without any discussion (see Parliamentary Council, Committee on the division of responsibilities [Minutes Word], Part 1, Vol 6 b, Minutes of the 3rd meeting of 23 September 1948, p. 162).

52 d) This corresponds to the colloquial understanding, which are the circulation of goods, pharma and food, commercial as the "sales or distribution of goods" means (cf. Duden, Das große Wörterbuch der deutschen Sprache, vol 8, 2nd edition, 1995, p. 3672 f.; Grimm, Deutsches Wörterbuch, Vol 25, 1956, column, 625). Traffic so far is synonymous with trade in the relevant articles, but said not every generation and Gebrauchmachen.

53 e) The title of the Competence Art 74 Paragraph 1 No. 19 GG then seeks to the control of Arzneifertigwaren (specialties) or otherwise manufactured medicines from. The traditional skills to countries located systems of control over the activities of pharmacists and doctors should not thereby be affected. The concept of drug transport therefore does not address the practice of physicians treating process to apply directly to their patients self-manufactured drugs. In the medical treatment can be indirectly interfered mainly by legislation of the drug traffic, as far as regulations for finished by the doctors in their prescribing should be followed.

54 In conformity with these constitutional provisions § 6 para 1 AMG is interpreted as meaning that the use of certain substances in the manufacture of drugs should be banned only by ordinance of the covenant, if the medicines are manufactured for the purpose of sale to others. Any further legislative delegation violated the law by the Federal Art 74 Paragraph 1 No. 19 GG limits.

55 3. The general prohibition on manufacture in accordance with § 1 para 1 of the fresh cells-regulation and the Criminal reinforcement in § 2 paragraph 2 of Regulation fresh cells are therefore not covered by the authorization of § 6 para 1 AMG. A constitutional interpretation of the challenged provisions is not possible because of § 1 paragraph 2 of the fresh cells for drug regulation, which will be placed on the market, separate stipulations. As the scope of paragraph 1 shall therefore only fresh cells, which are produced by doctors and used immediately. Only this part of the regulation is void for lack of federal regulatory powers, the regulation, moreover, that has not been challenged in the Constitutional Court shall remain unchanged.

56 Whether a ban on the production of fresh cells for immediate application to the patient by the doctor on health grounds are justified, could not be decided here.

57 Article II 14 Para 1 GG does not come into consideration as a basis for review. He is here from Art 12 Paragraph 1 GG as the fundamental sachnäheren displaced. Article 14 Para 1 GG protects the acquired, the results of completed work, art 12 Para 1 GG against the acquisition, the control itself (see BVerfGE 84, 133 [157]). Here, the regulation interferes with the freedom of the individual employment and career opportunities, so the scope of Article 12 Para 1 GG is affected. The limitation of the post who use existing assets, for the protection of Art 14 GG principle is concerned, here is only an indirect result of the challenged action restriction.

58 III. The decision on costs is based on § 34 a Paragraph 2 BVerfGG.