

**Third party submissions in the proceedings concerning the case of  
*Korobeynikova v. Russia*, application no. 43125/21  
prepared by the Institute for Law and Public Policy**

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Автономная некоммерческая организация  
«Институт права и публичной политики»**

1. By virtue of the Court’s letter of 23 November 2022 the Institute for Law and Public Policy<sup>1</sup> (hereinafter – “the Institute”) was granted leave, under Rule 44 § 3 (a) of the Rules of Court, to make written submissions to the Court in the case of *Korobeynikova v. Russia* (application no. 43125/21).

**Subject matter of the present submissions**

2. As stated in the leave to intervene in the present proceedings (Institute’s letter of 21 July 2022), the Institute shall provide the Court with materials related to the Russian legislation and judicial practice on the issue of provision of patients suffering from spinal muscular atrophy (“SMA”) who are over the age of 18 with the necessary medication free of charge.
3. Being mindful of the Court’s directions as regards the content of the present submissions, the Institute shall focus primarily on the Russian legislation and practices on the matter without commenting on the facts and merits of the case.

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<sup>1</sup> Institute for Law and Public Policy webpage <https://ilpp.ru/eng>

4. Accordingly, the present submissions shall be focused on four main issues.
5. **First**, the overview of the Russian legislation regulating free necessary drug supply to adults suffering from SMA;
6. **Second**, the Practice of refusals of executive authorities on the issue of drug provision adults suffering from SMA;
7. **Finally**, the overview of the existing judicial practice as regards failure to supply adults suffering from SMA with free necessary medication.

#### **Brief overview of situation with SMA**

8. According to statistics from Russia's key non-profit organisation dedicated to helping people with SMA "The SMA Families Foundation", there are 359 patients over the age of 18 suffering from SMA in Russia<sup>2</sup>.
9. It is the duty of the constituent entities of the Russian Federation to finance treatment for citizens over 18 years of age. However, the fiscal capacity of the regions in Russia varies greatly. As of October 2022, the poorest region, the Republic of Dagestan, had an average annual budget expenditure of 45,700.56 roubles per person, while the wealthiest region, the Chukotka Autonomous Area, had an average expenditure of 792,232.12 roubles per person<sup>3</sup>. The difference is more than 17 times.
10. Regional health authorities refuse to meet demands for expensive medicines (including for SMA) in order to save budget money.
11. The state's obligation to provide medication for SMA patients exists for both children and adults. However, measures to simplify the procedure for procuring medication and treatment have only been taken for children: in 2021, on a wave of public outrage at the ineffectiveness of state policy on the treatment of children suffering from SMA, the federal authorities established the "Circle of Kindness" charity fund. However, it does not cover citizens over the age of 18<sup>4</sup>. According to the Circle of Kindness Foundation, all children in Russia diagnosed with SMA receive treatment. More than 100 patients are provided with Zolgensma<sup>5</sup>. The drugs are bought at the expense of the federal budget without any court procedure, so the regional officials do not

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<sup>2</sup> <https://rare-aid.com/news/v-rossii-naschityvaetsya-1266-patsientov-so-spinalnoy-myshechnoy-atrofiyey-fond-semisma/>, data up to 13 July 2022

<sup>3</sup> <https://openbudget.mfnso.ru/novosibirskaya-oblast-i-regioni-rossii/rejtingi-novosibirskoj-oblasti-sredi-regionovrossii/tablitza-rejtingov-sub-ektov-rf> data up to 1 October 2022

<sup>4</sup> <https://www.asi.org.ru/2022/11/17/podozhdem-poka-otnositelno-zdorovyj-chelovek-ne-poluchit-invalidnost/> Presidential Decree No. 16 of January 5, 2021 "On the Creation of a Fund to Support Children with Severe Life-Threatening and Chronic Diseases, Including Rare (Orphan) Diseases, "Circle of Kindness," Russian Government Resolution No. 545 of April 06, 2021. <sup>5</sup> <https://clck.ru/32qQFc>

interfere with the organisation of treatment for children suffering from SMA. The fund is responsible for the patients, removes administrative barriers and deals with legislative changes to speed up the purchase of the drugs and the treatment of patients. However, similar mechanisms do not exist for adult patients.

### **Issue 1 – the Russian legislation concerning adult patients with SMA**

12. Articles 2 and 20 (1) of the Russian Constitution proclaim the right to life as one of supreme constitutional values. The right to health guaranteed by Article 41(1) of the Russian Constitution is also of fundamental value, without which all other values may lose their sense (The Constitutional Court, Decision, No. 816-O-O, 19 May 2009).
13. The Constitutional Court in rulings Nos. 462-O dated 1 December 2005, 56-O dated 2 February 2006, 353-O dated 11 July 2006, 322-O-P dated 8 February 2007, 129-O-P dated 1 March 2007, 965-O-P dated 4 December 2007 and 13-O-O-O dated 19 January 2010 has explained that the State has positive obligations to guarantee the right to life, including by providing medical care. The nature of the social state, which is the Russian Federation, implies that responsibility for social functions, including health care, falls on both the Russian Federation and each of its constituent entities.
14. Per Article 7(1) of the Constitution, the Russian Federation is a welfare state, the policy of which aims at creating the conditions for life with dignity and unhindered development. Per Article 7(2), the Russian Federation supports childhood and disabled persons. Article 41(1) guarantees free medical treatment in state hospitals for Russian citizens.
15. In accordance with paragraph 40 of the List of diseases, defects, irreversible morphological changes, disorders of the functions of organs and body systems, as well as indications and conditions for the establishment of a disability group and the category of 'disabled child' (Russian Federation Government Decree No. 588 of 5 April 2022), hereditary progressive neuromuscular diseases are among the diseases for which a disability group is established. SMA is one of these diseases, which is why adult patients suffering from SMA are assigned disability group I.
16. Under article 6.1, par. 8, and article 6.2, par. 1, subpar. 1, of Federal Law No. 178 of 17 July 1999 “On State social assistance”; article 37, par. 1, subpar. 4 of Federal Law No. 323 of 21 November 2011 “On the basic health-care system in the Russian Federation”, disabled persons are entitled to free medication as required by the standards of medical care.
17. Decree No. 890 of the Government of the Russian Federation of 30 July 1994 “On State support for the development of the medical industry and improvement of the supply of

medicines and medical products for the population and health-care facilities”, and section V of the

“Programme of State guarantees of free medical care for citizens for 2021 and the planning period 2022 and 2023”, approved by Decree No. 2299 of the Government of the Russian Federation of 28 December 2020, stipulate that the obligation to provide free medical care to citizens of the Russian Federation is imposed on the executive authorities of the constituent entities of the Russian Federation.

18. The same decree approved a list of population groups and categories of diseases for whose outpatient treatment medicines and medical products are available free of charge on prescription. According to the list, persons with disabilities of the first group are entitled to receive all medicines prescribed by doctors free of charge.

19. According to part 15 of article 37 of the Law on the Fundamentals of Health Care, the prescription and use of drugs not included in the standard of medical care is allowed in case of medical indications by the decision of the medical commission. The standards of medical care are defined as methods of treatment of specific diseases approved by the Ministry of Health.

20. At the same time, there is a standard of medical care for SMA only for minors. The Ministry of Health has not developed such a standard of care for adult patients.

21. Therefore, in order for a SMA patient to receive a drug, a physician's committee must be held, the conclusion of which will indicate what drug and in what amount can help the patient.

22. Thus, the provision of medications to SMA patients must be funded from regional budgets, based on the decisions of the medical committee.

23. The Constitutional Court confirmed the admissibility of attributing to the competence of the subjects of the Russian Federation obligations to provide medicines (Ruling No. 1053-O of June 2, 2013). But the Constitutional Court also emphasized that the federal legislature must, in any event, strive to ensure that the legal mechanisms it introduces provide citizens with the best possible guarantees of protection of their rights, especially when it comes to taking action in connection with life-threatening illnesses (Ruling of July 2, 2013, No. 1054-O).

24. In addition, as the Constitutional Court has repeatedly pointed out, assigning the powers of the social state to the state authorities of the subjects of the Russian Federation does not mean that the federal authorities cease to be responsible for this state of affairs. If their own resources are insufficient to cover the costs of providing medicines, the subjects have the right to count on Russia to provide them with some form of targeted financial assistance (Decision No. 12-P of June 17,

2004; Ruling No. 502-O of December 27, 2005; No. 508-O of November 16, 2006; No. 1054-O of July 2, 2013).

## **Issue 2 – The practice of refusals of executive authorities on the issue of drug provision adults suffering from SMA**

25. Despite the provisions of the Constitution, the positions of the Constitutional Court, and the provisions of current legislation outlined in Issue 1, the state authorities in every way hinder treatment of patients with SMA due to the high cost of medications and the need to spend money on them from the budget of the Russian Federation.

26. However, the absence of a consistent system of legislative regulation of treatment of adult patients with SMA at the expense of the state allows the executive authorities responsible for health policy to interpret the law against the interests of citizens.

27. Legislation contains several lists of rare diseases, which are treated at the expense of the state. SMA is a rare disease, but none of the state lists of rare diseases for adult patients mentions it. According to Article 83(9) of the Federal Law "On the fundamentals of protection of the public health" the federate entities of Russia must only treat those rare (orphan) diseases that are on the list.

28. The legislation does not establish criteria for the formation of lists of diseases. There is a lack of consistency as to why some medications are included in the standard of care and others are not; why standards of treatment for children with SMA have been developed, but treatment for adults is not. This allows us to conclude that the executive branch has unlimited discretion in determining which people will receive a life-saving drug at the expense of the budget.

29. In addition, Paragraph 5, Part 2, Article 81 of the Law on the Fundamentals of Health Protection grants the subjects of the Russian Federation the authority to independently adopt "a territorial program of state guarantees of free medical assistance for citizens". It also prescribes which medications the subject of the Russian Federation will provide to disabled people free of charge. However the territorial programs of the subjects of the Russian Federation do not include medicines for treatment of SMA. Moreover, part 11 of article 83 of the Law on the Fundamentals of Health Protection states that funding for the treatment of illnesses not directly mentioned in the law is provided in accordance with a "territorial program" the content of which depends on the discretion of officials from the regional Ministry of Health.

30. The only option for free receipt of a medicine not included in the "territorial program" and in any of the lists is the prescription of this medicine by a medical commission (as stated in part 15 of article 37 of the Law on the Fundamentals of Health Care). The medical commission is not

bound by legal lists, standards and the "territorial program", is guided by medical criteria and has the authority to prescribe a person any medicine necessary to preserve life.

31. At the same time, in practice, a medical board may not decide to prescribe a drug to a patient suffering from SMA, but to recommend that the patient be treated with that drug. This wording allows the authorities to conclude that the patient's treatment is not mandatory. As a result, no treatment is provided.

32. Moreover, prescribing a drug by a physician's committee does not preclude a repeat physician's committee, which can take a long time, and the result can be the opposite. For these reasons, adult patients suffering from SMA do not receive timely treatment.

33. The opinion of the medical commission on the prescription of the medication and a document confirming disability is sufficient to provide medication for SMA.

34. But despite this, in some cases the medicine is not purchased or such purchase is delayed. This is due to the desire of officials to save budget funds. This is partly based on the fact that untimely treatment will lead to the death of the patient, and the need to purchase expensive drugs will disappear. Therefore, patients are forced to go to court.

35. The lengthy judicial process and subsequent execution of the court decision lead to these mechanisms becoming ineffective, as patients require prompt provision of medications, otherwise the progression of the disease will lead to irreversible consequences. There are regular reports of deaths of adult patients suffering from SMA who have not waited for the court order to provide medication for SMA<sup>5</sup>. At the same time, filing a lawsuit against the regional executive body responsible for implementing health policy is the only way to move things forward.

### **Issue 3 - the overview of the existing judicial practice**

36. **The case of Vitaly Belenkiy about the refusal of treatment because of contrary conclusions of medical reports<sup>67</sup>.** *A man suffering from SMA was denied treatment because one of the three medical commissions determined that it was inappropriate to treat him with Spinraza.*

37. Mr Belenkiy has the status of an invalid from childhood indefinitely, is disabled of the first group, and has been diagnosed with type 2 SMA. He lives in Moscow.

38. Three medical commissions were held for Mr Belenkiy - the first one, held in August 2020, prescribed Spinraza, but he was not given the treatment. Eleven months later, there was a second

<sup>5</sup> <https://www.miloserdie.ru/news/ekspert-nuzhny-srochnye-mery-chtoby-vzroslye-so-sma-ne-umirali-bez-lekarstv/>

<sup>6</sup> <https://cloud.consultant.ru/cloud/cgi/online.cgi?req=doc&ts=SA23mOTuTvZotmzj&cacheid=5FFAF3F11FBF1C9>

<sup>7</sup> <https://cloud.consultant.ru/cloud/cgi/online.cgi?req=doc&ts=SA23mOTuTvZotmzj&cacheid=5FFAF3F11FBF1C9AF0669663A3D4EC1&mode=splus&rnd=RMjVUw&base=KSOJ002&n=85119#wC43mOTqK9fgba0V2>

commission, which did not recommend Spinraza, and a month later, the third commission confirmed the need for Spinraza.

39. In reviewing the case, however, the trial court rejected the commissions' two determinations of Spinraza's need and denied Mr Belenky's claim for treatment. The appellate court upheld these findings. It was not until September 2022 that the appellate court found that it was impermissible to reject two of the three commission decisions to provide the patient with Spinraza, reversed the court decisions, and sent the case for a new trial.

40. At present, the case is being re-examined, and the sessions are postponed in order to obtain evidence.

41. Thus, the applicant received the decision of the medical board about the necessity of treatment with Spinraza in August 2020, but until now the treatment has not been provided. More than 2 years and 4 months have passed since the medicine was prescribed. During this time, according to the doctors' prescription, Belenkiy V.Yu. should have had at least 7 injections of Spinraza. Lack of treatment leads to irreparable deterioration of health, can lead to immobilization and death of the patient.

42. The story about patients with SMA being denied treatment in the presence of contradictory conclusions of medical commissions is not unique. **Natalya Shmeleva** was denied treatment based on the opinion of the Moscow medical commission, while the federal commission assigned her Spinraza. However, in her case, the trial and appellate courts denied treatment<sup>8</sup>.

43. **The case of Marina Lisova on the accessibility of treatment depending on the region of residence**<sup>9</sup>. *A person with SMA was denied treatment and justice in Moscow, but after changing his place of residence to the Moscow region, treatment was provided.*

44. Doctors prescribed the drug Risdiplam (Evrildi) for the treatment of SMA. However, Maria could not receive it at her place of residence, even through the courts. The justification for the refusal was also the contradiction in the conclusions of several medical commissions. At the same time, the courts proceeded from the fact that the claims did not contain a justification for prescribing a drug not included in the standard of medical care (for vital signs).

45. Her relatives suggested that Marina change her residential registration to the Moscow region, where several patients with SMA are already receiving treatment. While in Moscow, none of the adult patients at the time of the events were able to procure drugs at government expense.

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<sup>8</sup> <https://novayagazeta.ru/articles/2021/11/03/bol-vnimanii>

<sup>9</sup> <https://novayagazeta.ru/articles/2021/10/15/my-prodolzhim-borotsia-sud-v-moskve-otkazal-v-poluchenii-spinrazyeshche-odnoi-patsientke-so-sma-news>

46. After her registration was changed, Marina went to a neurologist at the outpatient clinic and he prescribed her lifelong treatment with the drug Risidiplam.
47. The day after the consultation, the outpatient clinic sent a request to the Ministry of Health near Moscow. Two weeks later the girl received the necessary medication and began treatment.
48. **Boris Dergachev's case of denial of treatment for bureaucratic reasons<sup>10</sup>.** *He was denied treatment because of mistakes made by the medical committee in compiling the medical records. The courts of appellate and cassation instances sided with the citizen and ordered that he be immediately provided with Spinraza.*
49. Boris Dergachev, a disabled person (group I), lives in the Volgograd region. He has been diagnosed with SMA. The medical commission prescribed him Spinraza. However, the medicine was not actually provided to Dergachev, so he appealed to the court. The first instance court in September 2021 denied the claim. But in February 2022, the court of appeals overturned that decision, issued a new decision on the case, and satisfied Dergachev's claims for Spinraza and the immediate execution of the decision.
50. The Volgograd Oblast Department of Health unsuccessfully tried to challenge the court ruling that Dergachev should be treated. The Court of Cassation noted that the initial reason for the refusal to treat Dergachev was that the medical commission did not properly process the medical records in his case. At the same time, the proper execution of documents is the responsibility of the medical commission, not of the citizen, who should not bear the adverse consequences of not being provided with the necessary medication due to the medical institution's failure to comply with the procedure for executing the appropriate documentation.
51. The court ruling that obligated him to immediately provide Spinraza to Dergachev remained in effect.
52. **Daniil Maksimov's case - about the lack of treatment with Risidiplam after the end of the early access program<sup>11</sup>.** *A private company provided treatment for free, but the state did not. He had to demand the drug by picketing the Ministry of Health.*
53. Nineteen-year-old Daniil Maksimov suffers from SMA and lives in Moscow. Until the end of July 2021, he was a participant in the "Early access" program, which was launched by

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[http://4kas.sudrf.ru/modules.php?name=sud\\_delo&srv\\_num=1&name\\_op=case&case\\_id=13174683&case\\_uid=94029df4-ac21-4b87-bd8e-e18a7332b4d0&new=2800001&delo\\_id=2800001](http://4kas.sudrf.ru/modules.php?name=sud_delo&srv_num=1&name_op=case&case_id=13174683&case_uid=94029df4-ac21-4b87-bd8e-e18a7332b4d0&new=2800001&delo_id=2800001)

<sup>11</sup> [https://plus-one.ru/society/2021/08/18/lyudi-so-sma-vyydut-na-piket-za-pravo-nalechenie?utm\\_source=web&utm\\_medium=article&utm\\_content=link&utm\\_term=scroll](https://plus-one.ru/society/2021/08/18/lyudi-so-sma-vyydut-na-piket-za-pravo-nalechenie?utm_source=web&utm_medium=article&utm_content=link&utm_term=scroll) <sup>12</sup>[https://plus-one.ru/manual/2021/08/18/lyudi-so-sma-vyydut-na-piket-za-pravo-nalechenie?utm\\_source=web&utm\\_medium=manual&utm\\_content=link&utm\\_term=scroll](https://plus-one.ru/manual/2021/08/18/lyudi-so-sma-vyydut-na-piket-za-pravo-nalechenie?utm_source=web&utm_medium=manual&utm_content=link&utm_term=scroll)



Risdiplam, the manufacturer of the life-saving drug - in Russia it was registered only in 2020, and at first the company decided to provide the drug for free. But the program ended, and the state did not provide the necessary therapy.

54. The Moscow Department of Health cited the lack of clinical guidelines and treatment standards for adult patients with SMA as the reason for refusing treatment.

55. Daniil Maksimov picketed the Ministry of Health of the Russian Federation, thereby drawing public attention to the problem of adult patients with CMA receiving life-saving medications<sup>12</sup>.

## **Conclusions**

56. Adult patients with SMA are not provided the medications on which their lives depend. As of July 2022, less than half of adult patients with SMA are receiving needed treatment<sup>12</sup>. According to current legislation, the necessary treatment must be provided free of charge to every patient suffering from SMA.

57. The situation with the provision of drugs for adult patients with SMA remains critical, and the authorities are not taking steps to improve it. The situation with the provision of necessary medicines to minors was also disastrous and began to improve only in 2021 after the establishment of the state fund "Circle of Kindness". However, this fund helps only minors.

58. A person's place of residence affects the authority's policy on treatment for SMA. For example, in Moscow it is much more difficult than in the Moscow region to get a referral for treatment and a positive court decision in the case of a refusal to issue such a referral. This is due to the fact that the financing of drug coverage for patients with SMA lies in the regional, not the federal, budgets. Not every region is willing to allocate significant sums for the treatment of patients with SMA, despite legal provisions and court decisions.

59. Often medical facilities refuse to treat adult patients with SMA without a court order. However, even if the case is successfully resolved in court, the average person will go at least a year without treatment. The entire legal process, the entry into force of the decision, and the organization of the state purchase of the drug will require additional time, during which time, without treatment, the person suffering from SMA experiences physical pain and his or her health condition irreversibly deteriorates, which can lead to death.

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<sup>12</sup> <https://rare-aid.com/news/v-rossii-naschityvaetsya-1266-patsientov-so-spinalnoy-myshechnoy-atrofiyey-fond-semisma/>

60. Authorities responsible for funding the purchase of expensive SMA drugs use every opportunity to delay or deny treatment to adult patients. This happens at all stages of the struggle for life-saving treatment: medical examination, obtaining an opinion of medical commission on the need for treatment, attempts to obtain medication from medical institutions, correspondence with regional health authorities, litigation, enforcement of court decisions.

61. Because of contradictions and loopholes in the law, inaction by health care authorities, lengthy court proceedings, and the organization of state procurement of drugs, adults suffering from SMA do not live long enough to receive the required and prescribed drug coverage from the state.

62. To conclude, the Institute sincerely hopes that the present submissions will be useful for the Court in the proceedings in the case of *Korobeynikova v. Russia*.

63. The present submissions are sent to the Court within the time-limit fixed in the Court's letter of 23 November 2022.