Assessment of the Volume of State Funding for the Development of Biomedicine in Russia and in the USA

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ABSTARCT **This article demonstrates that Russia's funding for research and development is less than 2.5 % of global funding, whereas the amount of financing of just three countries, the USA, China, and Japan amounts to 50%. It is argued that the inadequacy of Russia's domestic financing for the development of the science sector vis a vis that of developed countries allows the country to prioritize only a limited number of research fields in its scientific and technological development. We have compared and contrasted expenditures on research and development in biomedicine in the USA and Russia. It has been demonstrated that in 2014, basic funding for 27 research centers included in the US National Health Institutes' network exceeded the amount of financing for 104 Russian medical scientific and research institutes subordinated to the Russian Ministry of Health and Federal Agency of Scientific Organizations by 173 times. We have concluded that a substantial increase in state funding for fundamental, exploratory, and applied research in the field of biomedicine is required if life sciences are to be preserved as one of the priorities in the scientific-technological and social development of Russia. It is also necessary to eliminate all administrative and tax barriers that prevent active participation of domestic industrial entities in the co-financing of the development of Russian drugs and medical equipment.**

KEYWORDS **Biomedical scientific research and development, government funding, priority areas, scientific and technological development, Russia, choice criteria.**

In 2014, basic funding for 27 research centers of the National Institute of Health of the USA amounted to 173 times the amount of funding for 104 medical research institutions subordinated to the Ministry of Health of the Russian Federation and the Federal Agency for Scientific Organizations (FANO). The contribution of the U.S. private sector to the development of technologies and products for the health care market was estimated at 92.6 billion dollars in 2014. In Russia, almost half (45%) of the budget of the Federal Target Program (FTP) "Pharma 2020" was allocated to the development of corporate sector R&D. The President of the Russian Federation has called for "full support" of the development of cutting-edge medical technologies.

HOW MUCH FUNDING DOES ONE NEED FOR IT? THIS ARTICLE OFFERS AN ANSWER TO THIS QUESTION

Current science and technology policy focuses on a radical increase in the efficiency of federal budget funding for civilian science and, above all, for the development of its priorities. For example, on June 25, 2015, at a meeting of the Council for Science and Education the President of the Russian Federation said that the current system of budget planning in the field of science and research was "*highly opaque in the absence of any clear criteria for efficiency in the use of resources.*"

Simultaneously, the President set the goal of selecting several priority areas "*to ensure their funding to the fullest extent,*" and named "*cutting-edge medical technologies*" as one of the key priorities [1].

The purpose of this study was to evaluate the volume of state support for the development of biomedical technologies within the "Life sciences" priorities in the Russian Federation and to compare it with what is being done in other countries.

ASSESSMENT OF THE SHARE OF RF DOMESTIC EXPENDITURE IN THE GLOBAL BUDGET FOR RESEARCH AND DEVELOPMENT

In 2014, the total global budget for research and development (R&D) was estimated at 1.6 trillion dollars [2]. The countries with the biggest R&D expenditures were the USA (31.1% of the global R&D budget), China (17.5%), Japan (10.2%), and the EU countries (21.7%), of which Germany alone contributed an estimated 5.7%. The share of these countries accounted for 78% of the global budget in 2014.

The same year, the share of Russian domestic R&D expenditure

was 2.5% of the global budget (40 out of 1,618 billion USD) [3]. According to the federal law "on the federal budget for 2015, and the planning period of 2016, and 2017" [4], 315.08 billion rubles will be allocated for R&D in the year 2016, which at the current exchange rate (60 rubles per US dollar) amounts to an estimate of a maximum of 5.3 billion USD of state budget funding for the domestic R&D sector in 2016.

In February 2015, during the discussion of the R&D budget for 2016, in response to an increase in Asian countries R&D budgets over the past 5 years, which has exceeded the corresponding rate in the U.S., the President of the United States proposed "putting an end to budget austerity" and planning a 6% increase in federal R&D funding for 2016 [5]. Therefore, the expected volume of U.S. state budget funding, allocated for the development of the civilian R&D sector, will exceed 62 billion USD (i.e. almost 12 times the corresponding expenditure in the budget of the Russian Federation.) It should be noted that the share of the federal budget allocated for civil R&D in 2015 is 1.7% in the U.S. and 2% in Russia.

Let us examine how much funding is considered to be sufficient for the development of medical technologies within the framework of such a priority as life sciences, according to federal budget managers in the United States and Russia.

THE AMOUNT OF FUNDING FOR BIOMEDICAL RESEARCH AND ITS INDIVIDUAL KEY AREAS IN RUSSIA AND THE USA

Our analysis of the planned amount of funding shows that biomedical research programs are given priority in the United States. Overall, the already substantial funding of the National Institute of Health ("NIH") in the U.S. (which consists of 27 research centers) to 30.2 billion USD in 2015 will be increased by 1 billion USD in 2016. In addition, the National Science Foundation, whose budget will also be increased to 7.72 billion USD (a 5.2% increase compared to 2015), will increase its funding for the "Understanding the Brain" program (one of the sub-projects of the BRAIN Initiative) by 35.2% compared to 2015.

The analogue of the NIH in the Russian Federation is a cluster of medical institutions, of which 50 belong to the FANO (the former Russian Academy of Medical Sciences) and 54 are within the jurisdiction of the Russian Ministry of Health. The consolidated budget for basic and project financing at these organizations is defined in the State Program for the Development of Health Care in the Russian Federation (sub-program 3) [6], and in 2015, it is set to 11.8 billion rubles, which at the current exchange rate of 60 rubles per U.S. dollar is equivalent to 200 million USD.

In 2016, the gap in funding for the two reference groups of institutions with a similar scope of research will only grow as the USA plans to increase funding for the National Institutes of Health, whereas the Russian Federation will cut funding for the civilian R&D sector in general and biomedical research in particular.

The gap in funding for certain key areas of biomedical research in the United States and Russia is equally huge.

For example, in 2016, the United States plans to increase funding for studies of the mechanisms of antibiotic resistance to 1.2 billion USD, which is an almost twofold increase for this area of priority in comparison with 2015. Financial support for the "Brain Research through Advancing Innovative Neurotechnologies" initiative will increase more than twofold in 2016, from 64 million USD in 2015 to 136 million USD in 2016. The National Childhood Disease Research Program, which has a 2014-2016 annual budget of 1.2 billion USD, will get additional funding in 2016 (165 million USD) to assess the impact of the environment on children's health [5]. A total of 215 million USD is pledged for the development of personalized medicine within the framework of the new "Precision Medicine Initiative," which includes the development of a joint database of the health and genetic data of millions of volunteers. A total of 699 million USD are allocated to the new research program of natural foci of infections.

In the Russian Federation, competitive and project financing for fundamental, exploratory, and applied biomedical research in 2015 originated from several public funds: the FTP "Research and development in priority areas of science and technology complex of the Russian Federation for 2014-2020" (hereinafter, FTP "R&D") and the FTP "Development of the Pharmaceutical and Medical Industry of the Russian Federation for the period up to 2020 and beyond" (hereinafter, FTP "Pharma-2020").

The following table shows allocated and planned amounts of federal budget support for the development of fundamental, translational, and personalized medicine, as well as support for some priority areas in the field of life sciences in the United States and Russia in 2014-2016. It should be emphasized that the list of key managers of biomedical R&D budgets in the Russian Federation and the United States is not exhaustive due to the lack of data.

These data reveal the absolute incomparability of the amount of funding allocated by the United States and Russia for fundamental, exploratory, and applied research in the biomedical field, as well as for priority support of the most

Funding for biomedical research and selected life sciences priorities in the United States and Russia in 2014-2016

USA	Russian Federation
Federal budget funds allocated for the development of fundamental, translational, and personalized medicine	
2015: Health care services, including the National Institutes of Health (27 research centers) – **30.2 billion USD**[a]	2015: Russian Ministry of Health (54 research centers) – 1.566 billion rubles – *fundamental research*[b] 2015: FANO (50 research centers) – 5.976 billion rubles – *fundamental research*[b] 2015: Russian Ministry of Health (54 research centers) –3.195 billion rubles – *applied research*[b] 2015: Russian Ministry of Health (63 State Medical Academies) – 1.110 billion rubles – *applied research*[b] 2015: Russian Science Foundation, 3.8 billion rubles – *fundamental and exploratory research in biomedicine*[d] 2015: FTP "R&D" – 1.6 billion rubles – *applied research and pilot projects in biomedicine*[d] 2015: Russian Foundations for Basic Research – 1.6 billion rubles – *fundamental research in biomedicine*[d] 2015: Small Enterprise Assistance Fund – 0.65 billion rubles – *applied research and pilot projects in biomedicine*[d] 2015: Decree of the Government of the Russian Federation № 218 of April 9, 2010 – 0.6 billion rubles – *applied research and pilot projects in biomedicine*[d] 2015: Decree of the Government of the Russian Federation № 220 of April 9, 2010 – 0.2 billion rubles –*fundamental research in biomedicine*[d] FTP "PHARMA-2020" – 12.8 billion rubles, including 1.936 billion rubles for funding of pre-clinical trials[d]
Private sector R&D budget for life sciences	
2014: – **92.6 billion USD**[c]	The contribution of industrial enterprises to the consolidated national R&D budget of the Russian Federation did not exceed 12% in 2012-2014[f].
TOTAL 123.7 billion USD	TOTAL 33.1 billion rubles = 600 million USD
Funding for some priority areas of biomedical research	
The study of mechanisms of antibiotic resistance: 2015: **600 million USD** 2016: **1.2 billion USD**	The RSF competition "New approaches to the fight against infectious diseases" 2015: **100 thousand USD/year** (6 million rubles/year)[e]
"Brain Research through Advancing Innovative Neurotechnologies" initiative: 2015: **64 million USD**[c] 2015: **136 million USD**[c] National Program for Childhood Research: **1.2 billion USD** in 2015[c] **+165 million USD** for the study of the impact of the environment on children's health in 2016[c]	2014: A special RAS program "Fundamental research for the development of biomedical technologies" **3.3 million USD/year** (200 million rubles/year, or 1–4 million rubles per project)[f]

Sources:
[a]The 2015 Budget: Science, Technology, and Innovation for Opportunity and Growth [7].
[b]State program of Russian Federation "Development of Healthcare" [6].
[c]2014 Global R&D Funding Forecast [2].
[d] Kazeev K V. Report of the Head of Department of Science and Technology of the Ministry of Education of Russian Federation [8].
[e]Public analytical report "Biomedicine" [9].
[f]Analytical report "Annual monitoring of R&D expenditures (including priority areas of innovation development in Russia)" [3].

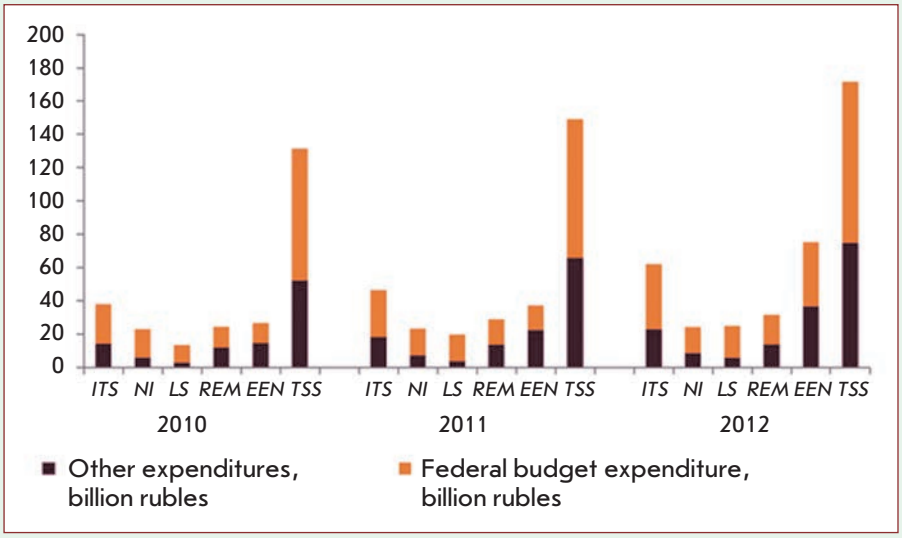

Fig. 1. Structure of Russian domestic expenditures on Research and Development in priority areas of development in science, technology, and engineering *(Source: Science Indicators 2012–2014)*
Abbreviations: ITS, information and telecommunications systems; NI, nano systems industry; LS, life sciences; REM, Rational Environmental Management; EEN, energy efficiency, energy conservation, nuclear power; TSS, transport and space systems

promising and socially important topics.

Another noteworthy topic is the extremely low amount of financing of research activities in medical schools: 63 medical colleges of the Russian Ministry of Health allocate only 1.110 billion rubles or (18.5 million USD) to applied research.

An even more drastic difference is observed in the funding of projects addressing thematically identical issues in life sciences, such as deciphering the mechanisms of antibiotic resistance of pathogenic microorganisms. In the United States, 600 million USD was allocated to finance the program for antibiotic resistance research in 2015, and for 2016, planned federal support for the program has been doubled and will amount to 1.2 billion USD. In Russia, the Russian Science Foundation announced in 2014 an annual competition: "New approaches to the fight against infectious diseases." It has awarded 63 research grants of up to 6 million rubles per year, which is equivalent to about 6.3 million USD in total. Therefore, the difference in the level of funding for similar priorities in the field of biomedicine in the U.S. and Russia is a hundredfold!

THE VOLUME OF PRIVATE SECTOR INVESTMENT IN BIOMEDICAL R&D IN THE U.S. AND RUSSIA

The estimated contribution of national industrial enterprises involved in the development of technologies and products for the health care market to biomedical R&D budgets deserves a separate discussion. The annual R&D budgets of U.S. companies in the field of "life sciences" account for almost half of global corporate budget in this field. In 2014, this figure amounted to 92.6 out of 201.3 billion USD of the global corporate R&D expenditures on the "life sciences industry." Remarkably, this "almost half" contribution by the U.S. biomedical industrial sector has been maintained over the last five years; in 2011, it was estimated to be 84.5 out of 184.2 billion USD of global expenditures (i.e. 46% [2].)

As a result, the ratio of public and private sector contribution in the 2014 U.S. consolidated budget for fundamental and applied research to the biomedical field was *ca.* 3 to 1 (32 billion USD of the health and human services budget, including the National Institutes of Health vs. 92.6 billion USD of corporate contribution to R&D in life sciences) [2].

We have been unable to find information on the volume of Russian industrial companies' investment into the development of drugs and medical equipment in 2014. According to the "Annual monitoring of federal budget R&D expenditures (including priority areas of innovation development of Russia)," the contribution of Russian industrial companies to the consolidated national budget for R&D did not exceed 12% [3].

However, domestic industrial companies actively use public funding, first of all FTP "Pharma-2020", to carry out corporate R&D. For example, in 2015, the FTP funds for scientific research were allocated as follows: 8.64 billion rubles for 312 projects in publicly funded institutions and 7.15 billion rubles for R&D in 215 commercial companies. Thus, almost half (45%) of the FTP "Pharma-2020" budget in 2015 was allocated to the development of corporate sector R&D [10].

These data highlight the fact that the domestic industrial sector not only fails to provide an additional and significant source of research funding for biomedicine, but also creates competition for public funds for R&D in this area.

ASSESSMENT OF THE DYNAMICS OF FEDERAL BUDGET EXPENDITURES IN LIFE SCIENCES IN THE CONTEXT OF R&D FUNDING IN AREAS OF PRIORITY

In 2010, 2011, and 2012, support for the priority areas accounted for 49%, 50%, and 56%, respectively, of

the total volume of federal budget expenditures on R&D. [3]. An analysis of the dynamics of federal budget expenditures on R&D in six priority areas of science, technology, and engineering in the Russian Federation, approved by Presidential Decree № 899 of 07.02.2011 [11], reveals that between 2010-2012 "Life sciences" received the smallest share of the federal budget (Fig. 1) [12].

In contrast, the quotas of public financing in the United States show that life sciences are one of the main scientific and technological priorities of the country. *Figure* 2 outlines the distribution of the U.S. federal budget on R&D between the main recipients in 2012-2014 [2].

The U.S. National Institute of Health received the most significant amount of money compared to all other entities. For example, in 2014 the National Institute of Health received more than half of all the money allocated for the civil sector of U.S. science: 32.0 out of 58.8 billion USD. It is not surprising that more than half of the Nobel Prize laureates in medicine since 2000 are affiliated with U.S. universities [2].

According to the R&D Magazine of the Battelle analytical agency, the U.S. is the global technological leader in the field of biomedicine. The UK ranks second, Germany, third, and Japan fourth with China rounding up the top five (Fig. 3)

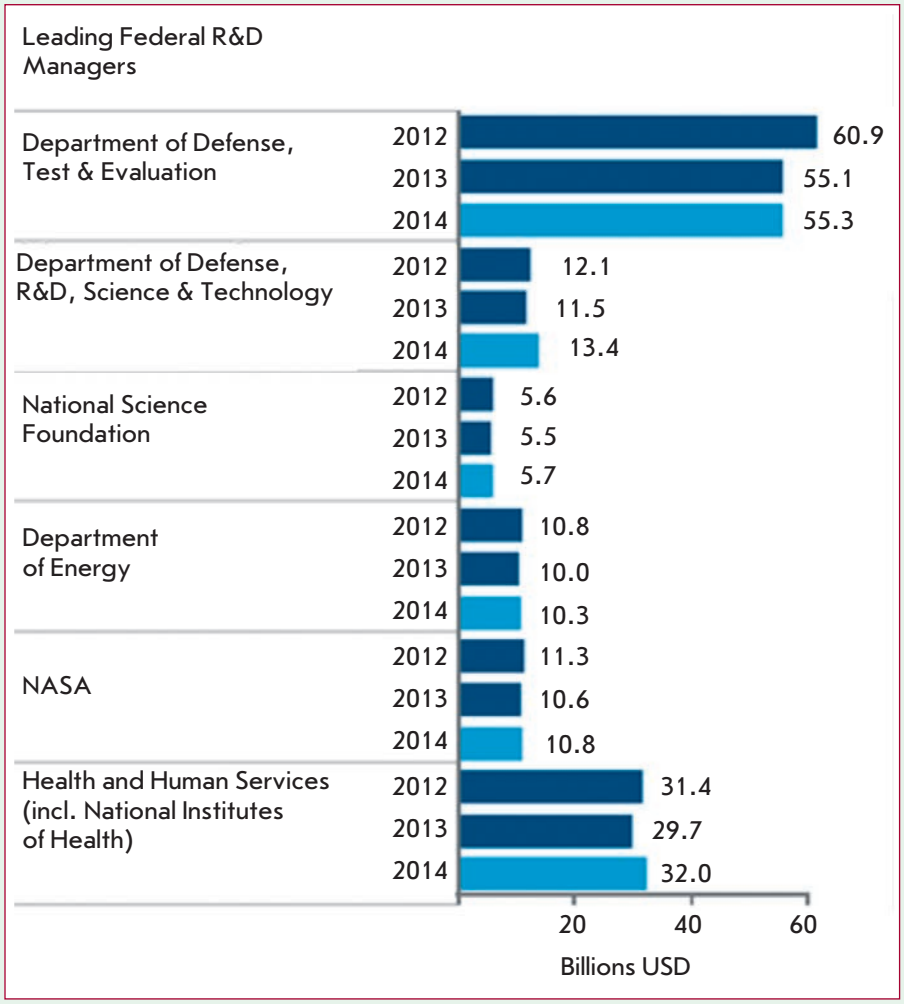

Fig. 2. Distribution of U.S. Federal budget funds between main budget controllers in 2012-2014 *(Source: 2014 Global R&D Funding Forecast)*

DISCUSSION

According to the list of orders issued on July 14, 2015, following a meeting of the Council for Science and Education [13], the Presidential Administration was charged with defining the principles of establishing priorities in scientific and technological development. It appears that in the current economic situation, it would be prudent to base this choice not only on the assessment of the socio-economic importance of a scientific and technological area for the country, but also on the volume of state budget funding necessary to achieve competitive scientific and technological breakthroughs on the world stage.

The data suggest that the inadequacy of the Russian Federation expenditures on the development of the civil sector of science in comparison with industrialized countries necessitates the selection of a very limited number of research areas as priorities for the scientific and technological development of the country. Only a marked decrease in the number of priorities would "ensure that they are fully funded," as noted by the President of the Russian Federation at the Meeting on Science and Education [1].

When it is declared that priority should be given to technologies that ensure a quality of life and, above all, advanced medical technologies [1], the objectives and expected outcomes of the implementation of these priorities are absolutely clear. However, one should take into account the fact that the development of new medical technologies

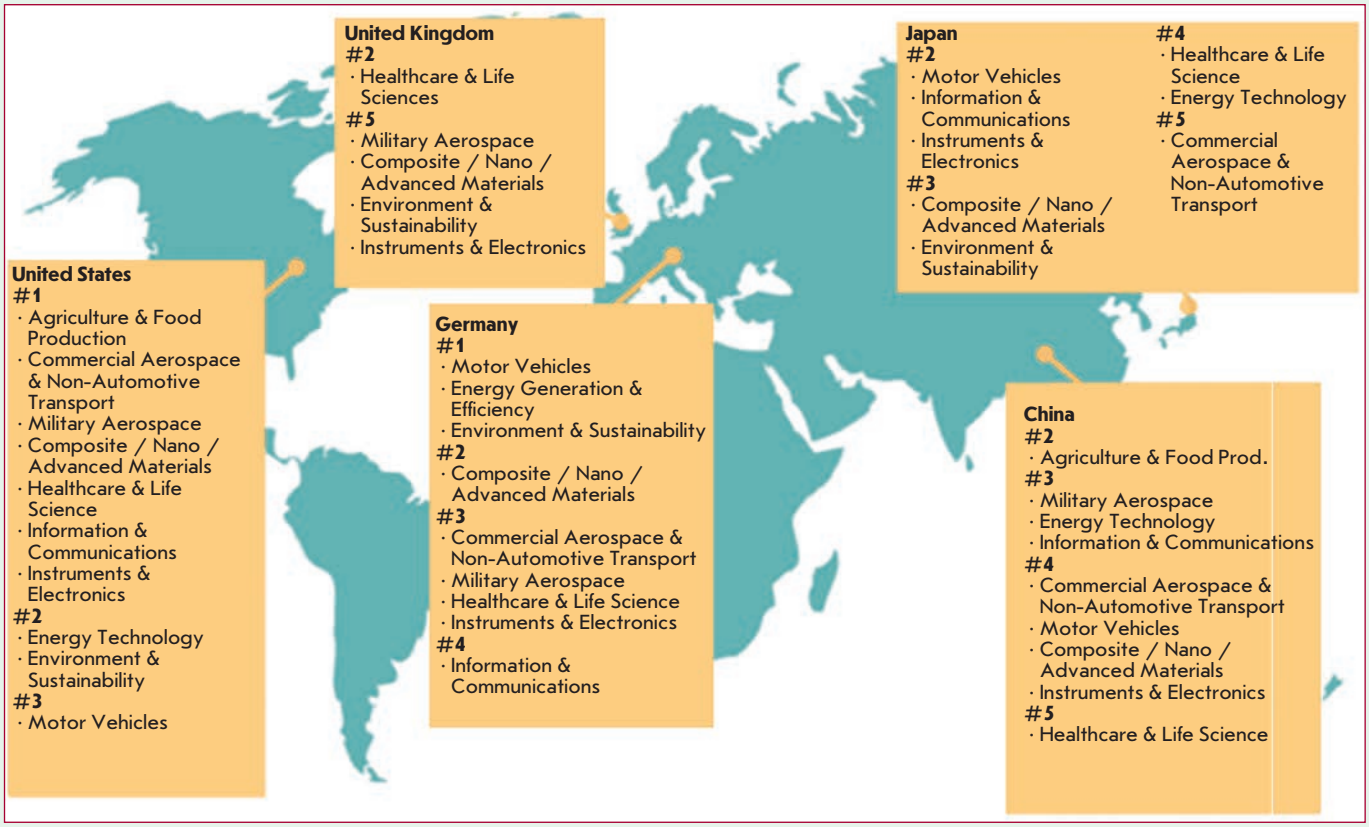

Fig. 3. Five world leading countries in life sciences *(Source: 2014 Global R&D Funding Forecast)*

is one of the most expensive scientific fields in the world, and that countries striving for a position of technological leadership in biomedical fundamental and applied research are pledging budgets which are hundreds of times bigger than funding for biomedical research in the Russian Federation.

An additional factor impeding growth in competitive national biomedical research is the lack of interest on the part of the industrial sector in financing exploratory and applied research aimed at creating new domestic drugs and medical equipment. In the United States, the share of "life sciences" industrial companies' contribution reached 75% of nationwide R&D expenditures in the field of biomedicine in 2014, and in absolute terms their investment in biomedical R&D amounted to 92.6 billion USD, having increased from 84.5 billion dollars back in 2011.

CONCLUSION

Based on the facts outlined above, it seems appropriate to implement the following set of measures aimed at improving the mechanisms of biomedical research funding in Russia.

First of all, given that Russian domestic R&D expenditures in 2016 will amount to no more than 2% of the global budget, we believe that there is no need to include areas of research that are already a topic of major international projects into the list of priorities, since the results of those projects are publicly available and there are no obvious barriers and restrictions to their use in practice in Russian health care. Examples of such projects include the international "Human Proteome" project, the program of study of the mechanisms of antibiotic resistance (USA), the program for the study of the natural foci of infections (USA), etc. That does not mean, of course, that funding for domestic research in these areas should be shut down, but it does not make sense to give them a "priority" status - which implies a concentration of significant financial resources - if those areas can be developed in the Russian Federation through the active use of the results of major international projects.

Secondly, we should eliminate unnecessary duplication of funding of biomedical projects with similar subjects by different managers of the state R&D budgets (both in public funding and in contest-base and targeted financing), and simultaneously achieve a balance be-

tween the amount of funding, numbers of staff at research institutes, and the number of compulsory and competitive research topics.

Thirdly, since the major beneficiary of fundamental and applied research in the biomedical field is the population of the Russian Federation and since the maintenance and restoration of its health is the responsibility of the Russian Ministry of Health, this agency should adjust R&D themes based on the health status of the population, including contests organized by state foundations and institutes for development.

Fourthly, development of biomedical technologies that are relevant to practical aspects of health care in the Russian Federation and making research and industrial production in this area competitive at the global level is impossible without active participation of major industrial companies, both Russian and International. Today, Russian pharmaceutical companies and companies producing medical equipment basically do not invest in the scientific and technological groundwork in the field of biomedicine and do not implement the outcomes of domestic research in production, citing regulatory barriers and lack of guaranteed demand for products from the Russian Ministry of Health. Therefore, it is necessary to strengthen coordination between state entities, scientific organizations, and all other participants involved in the production and consumption of drugs and equipment for medical care in the Russian Federation.

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