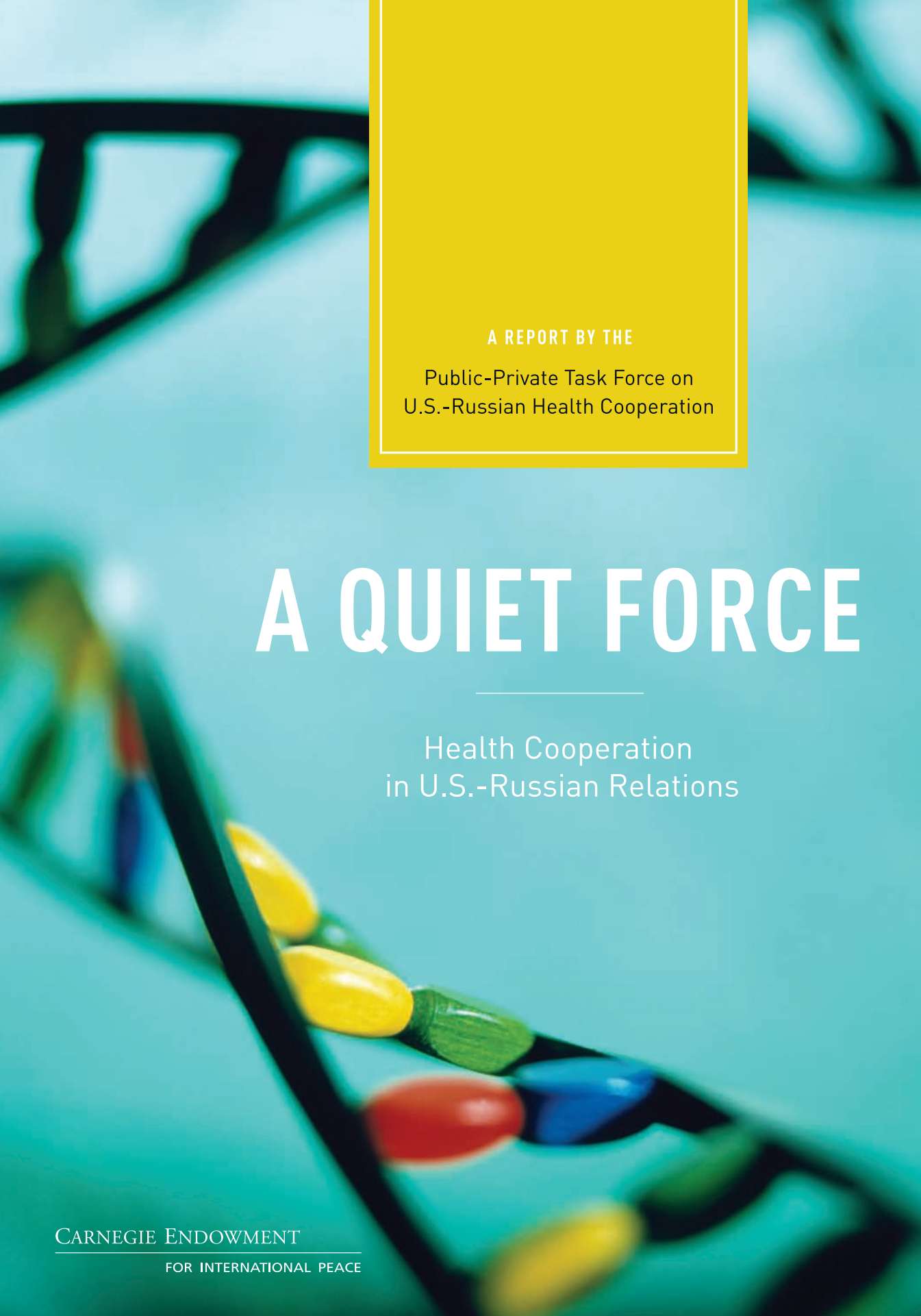

A REPORT BY THE

Public-Private Task Force on
U.S.-Russian Health Cooperation

A QUIET FORCE

Health Cooperation in U.S.-Russian Relations

CARNEGIE ENDOWMENT
FOR INTERNATIONAL PEACE

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SUMMARY

U.S.-RUSSIAN PUBLIC HEALTH COOPERATION has led to extraordinary achievements, from the development and production of the Sabin polio vaccine to the eradication of smallpox. But the full potential of this collaboration has not yet been achieved. Deeper bilateral engagement could drive innovation and economic growth for both countries and the world. Unlocking this latent power requires leadership, resources, know-how, and strong institutional foundations.

THE PUBLIC-PRIVATE TASK FORCE ON U.S.-RUSSIAN HEALTH COOPERATION

- The U.S.-Russia Bilateral Presidential Commission's Working Group on Health can play a central role in deepening U.S.-Russian health engagement.
- To support the commission's work, the Carnegie Endowment established the Public-Private Task Force on U.S.-Russian Health Cooperation.
- Subcommittees on strategic resource allocation, healthy lifestyles, science cooperation and technology transfer, and regulatory convergence and harmonization contributed to the task force's work.
- The task force issued a set of overarching strategic recommendations that cut across these four areas of focus, as well as specific recommendations in each area.

STRATEGIC RECOMMENDATIONS FOR U.S.-RUSSIAN HEALTH COOPERATION

Transform the relationship into one of equal partners. Russia and the United States should move past their post-Soviet donor-recipient relationship and address global health challenges as equal partners.

Find areas where interests align. Focusing on issues that affect multiple stakeholders, such as noncommunicable diseases, will attract the resources and know-how to advance the relationship.

Maintain the momentum of cooperation. Collaboration on a regular basis, not just during times of crisis, will help ensure effective responses at critical times.

Recognize the importance of Track II activities. Facilitating interactions such as peer-to-peer exchanges will build relationships that can produce real outcomes.

Encourage public-private cooperation. Collaboration across sectors will generate the optimal combination of political leadership, technological know-how, and resources.

Take advantage of regional- and state-level strengths. Establishing cooperative relationships at the state level in the United States and the regional level in Russia may help accelerate progress.

INTRODUCTION

COOPERATION ON HEALTHCARE and biomedical sciences has been a feature of U.S.-Russian relations since the early years of the Cold War. Even as tensions prevailed at political levels, scientific collaboration proceeded—leading, in some cases, to impressive results, such as the clinical trial and widespread use of the Sabin polio vaccine and the eradication of smallpox.[1] Over the years, U.S.-Russian health diplomacy has drawn praise for its ability to transcend high politics and unite the two countries around a common cause.

However, the full potential of U.S.-Russian health engagement has not yet been reached. The two countries possess unrivaled scientific resources that, if combined, could drive innovation and economic growth for both. Joint efforts to fight noncommunicable diseases—which include heart disease, diabetes, and cancer and are critical factors of mortality and morbidity in both countries—could improve and prolong the lives of tens of millions of Russian and American citizens. And with their combined population of 450 million, the United States and Russia are well positioned to become leaders in personalized medicine and gene therapies, which require access to large patient-data pools.

Importantly, successful U.S.-Russian health cooperation could have a ripple effect beyond the borders of these two countries—and even beyond health and science. At a time of unprecedented pandemic threats, Washington and Moscow can work together to become a powerful force in alleviating the suffering caused by disease worldwide while contributing to the creation of a more stable and prosperous world.

Unlocking this latent potential requires leadership, resources, know-how, and strong institutional foundations. As the two countries grapple with the crises in their respective

INSIGHTS FROM LEADERS AND PRACTITIONERS

"Health diplomacy is the great leveler which brings countries together in common cause, fighting one of humanity's most ancient and powerful foes: disease."

Dr. Peter I. Hartsock, captain, U.S. Public Health Service, research scientist officer, National Institute on Drug Abuse, National Institutes of Health; member of the task force

healthcare systems, governmental institutions must join forces with private companies, nongovernmental organizations (NGOs), multilateral organizations, and other professional and community resources. Bilateral structures must be strengthened and supported.

Recognizing the unique possibilities inherent in health diplomacy, the Carnegie Endowment for International Peace established a task force to help move this cooperation forward. The task force was created in 2011 specifically to support the work of the Bilateral Presidential Commission (BPC), the coordinating body for bilateral cooperation between the two governments.

The task force, called the Public-Private Task Force on U.S.-Russian Health Cooperation, brought together a broad spectrum of stakeholders from both sides of the Atlantic to examine specific avenues of collaboration in healthcare. Members met for numerous workshops, presentations, and discussions over eighteen months. They set out to examine the two countries' healthcare systems, uncover key areas where the United States and Russia could work collaboratively, and devise specific initiatives to address those areas. (For the full list of participants, please see the Appendix.)

The task force formed four subcommittees to address four areas of focus:

1. Strategic resource allocation
2. Healthy lifestyles (focus on noncommunicable diseases)
3. Science cooperation and technology transfer
4. Regulatory convergence and harmonization

TASK FORCE RECOMMENDATIONS

The task force issued a set of overarching strategic recommendations that cut across all four areas of focus. In addition, the task force issued four sets of recommendations based on the subcommittees' work. (These will be discussed in more detail in the subsequent sections of the report.) The task force's strategic recommendations are:

1. **Transform the relationship into one of equal partners.** In the immediate post-Soviet period, as Russia struggled with the difficulties of transition, the United States' policy toward Russia took the form of economic, financial, and other types of assistance. It is now time for that donor-recipient relationship to give way to a new vision. Russia has signaled that it is ready to assume the role of an equal partner to the United States and a donor vis-à-vis other countries. The United States must acknowledge and honor that. The two countries must work as equal partners in addressing global health challenges.

2. **Find areas where interests align.** Issues such as the rising rates of multidrug-resistant tuberculosis (TB), noncommunicable diseases, and the obesity epidemic can spur multiple stakeholders to take collaborative action. Focusing on these shared interests will attract the resources and the know-how that can help move the overall relationship forward.

3. **Maintain the momentum of cooperation.** The need for cooperation often only becomes apparent in times of crisis, such as global pandemics, and loses urgency at other times. But a crisis is not the time to begin building cooperation. Maintaining the momentum on a regular basis will help ensure effective responses at critical times.

4. **Recognize the importance of Track II activities.** Professional peer-to-peer exchanges have proven to be an important and successful mainstay of U.S.-Russian health cooperation. Continuing to facilitate these interactions will build relationships that can produce palpable outcomes.

5. **Encourage public-private cooperation.** Both sectors must work together to further the collaborative agenda. Only through such cooperation will the two sides generate the optimal combination of political leadership, technological know-how, and resources to move the relevant projects forward.

6. **Take advantage of regional- and state-level strengths.** Much creativity and original thinking in the realm of policymaking begin at the state level in the United States and the regional level in Russia. Establishing cooperative relationships at those levels wherever possible may help accelerate progress.

Top Recommendations for Strategic Resource Allocation

Ensuring the best quality of and access to preventive services, medical care, and prescription medications for diverse groups of populations requires resources. Strategic resource allocation, however, is a challenge for both Russia and the United States. Both countries' systems suffer from inefficiencies in this regard, but the complementary nature of many of these inefficiencies offers an opportunity for the two sides to learn from one another and work together to eliminate them.

The task force made the following priority recommendations in the area of strategic resource allocation:

1. **Build cooperation in the use of health information technology, telemedicine, and electronic medical records.** Health information technology, or the framework for managing and securely exchanging health information across computer systems, can greatly improve the accuracy of diagnostic and therapeutic decisionmaking and support research efforts while improving access to health services and cutting costs. Electronic medical records, which digitize a patient's medical records so they can be easily shared throughout a single organization such as a hospital or a physician's office—and, ideally, across multiple organizations—can help eliminate costly errors. Telemedicine, or the provision of clinical care at a distance with the use of technology, can be particularly helpful in remote areas experiencing shortages of medical facilities and trained personnel. Using technology in this way is relatively new for both sides, and they could benefit from sharing their experience and approaches.

2. **Focus on evidence-based, prevention-oriented interventions.** Both the United States and Russia should focus on methods that have been shown in well-designed scientific studies to deliver early health benefits and prevent disease.

3. **Collaborate on joint immunization campaigns.** Cooperating on joint vaccination campaigns could allow both countries to strengthen their global leadership positions.

4. **Explore joint projects in personalized medicine.** Personalized medicine is one of the most cutting-edge approaches in medicine. It offers an opportunity for both countries to contribute to a broad impact while leveraging medical and scientific experience and access to large pools of patient data.

5. **Explore jointly how to broaden access to healthcare for underserved populations.** Both the United States and Russia face issues related to access to healthcare coverage. Practitioners in both countries could benefit from professional peer-to-peer conversations on the subject.

6. **Focus on cooperation in the area of emerging pandemic threats.** As the world becomes more integrated, new pandemic threats will inevitably emerge. The United States and Russia have a good track record of working together in this area and should maintain this cooperation.

7. **Emphasize continuing medical education.** Exchanges in the area of continuing or postgraduate medical education have proven to be a successful area of collaboration for the two countries. They will remain important going forward. Today's technology, which provides a broad variety of opportunities for knowledge exchange, while reducing the need to travel, offers many new, cost-effective possibilities to pursue joint efforts in this area.

Top Recommendations for Healthy Lifestyles

Noncommunicable diseases create a tremendous burden on both the U.S. and Russian healthcare systems, reducing lifespans and quality of life for the two countries' citizens. Large scientific studies, published over several decades, consistently show that a healthier diet, increased physical activity, and smoking cessation can prevent a significant number of cases of coronary heart disease, type 2 diabetes, chronic obstructive pulmonary disease, and various types of cancers. Promoting healthy lifestyles is, therefore, imperative for both countries.

The task force made the following priority recommendations in the area of healthy lifestyles:

1. **Focus on prevention and early detection.** Prevention is a central factor in lowering noncommunicable disease rates, yet both the U.S. and Russian systems prioritize managing, rather than preventing, disease. The two healthcare systems are largely oriented toward expensive hospital services and treatment of acute cases, while early-stage disease control has been shown to be more beneficial for the patient and society. One way to promote preventive care is to encourage strong links among the medical community, NGOs, the private sector, community organizations, health policy leaders, and policymakers. Both countries can learn from each other.

2. **Cooperate on a targeted action program designed to reduce the burden of cardiovascular disease and cardiovascular mortality.** Cardiovascular disease and strokes account overwhelmingly for the major causes of premature mortality in both the United States and Russia. The principal risk factors behind this record—cigarette smoking and unrecognized, untreated high blood pressure—are

well understood and amenable to intervention. Both countries could benefit from a well-designed cooperative program to prevent and treat hypertension, especially one that utilizes the successful experience gained in other parts of the industrialized world, while pursuing a parallel strategy to reduce cigarette smoking.

3. **Continue cooperation on tobacco and alcohol control.** Smoking and alcohol consumption levels are particularly troubling in Russia. The United States has had some very important successes in reducing smoking rates and can share its experience with Russia.

4. **Develop joint programs to promote healthy eating, exercise, and healthy lifestyle choices.** The United States has had some success promoting the culture of fitness and healthy lifestyles. But most Russians do a better job of incorporating physical activity into their daily lives than Americans. The two countries can learn from one another in this area.

Top Recommendations for Science Cooperation and Technology Transfer

Deeper engagement in the area of biomedical research and innovation holds tremendous possibilities for both countries.

The task force made the following priority recommendations in the area of science cooperation and technology transfer:

1. **Continue cooperation on multidrug-resistant tuberculosis.** The growth of multidrug-resistant TB worldwide has been one of the most troubling healthcare-related trends in recent decades. Russia suffers from particularly high rates of the disease. Washington and Moscow can benefit from making cooperation in this area a priority.

2. **Increase funding available for scientific research.** Funding opportunities exist for scientific research, both joint and unilateral, on both sides, but they are limited and sometimes not well publicized. Increasing funding and improving information dissemination in the United States and Russia on policies and funding opportunities are essential to moving joint research projects forward.

3. **Facilitate networking among scientists to stimulate collaborative research projects.** Scientific collaboration depends in large measure on scientists designing collaborative projects based on their interests. Networking opportunities and

bilateral meetings can help build relationships among scientists, physicians, grantmakers, government representatives, and other stakeholders.

4. **Develop new bilateral co-funding initiatives and programs.** Washington and Moscow must be equally invested in joint research projects. Joint funding opportunities should be developed through co-funding agreements. Public-private funding support should be tapped as well, relying on both U.S. and Russian philanthropic organizations partnering with pharmaceutical, biotechnology, medical device, and information technology companies.

Top Recommendations for Regulatory Convergence and Harmonization

Regulatory convergence and harmonization, which refers to developing streamlined guidelines across national standards to guarantee the production of safe and effective pharmaceuticals, is pivotal to ensuring the delivery of critically important medicines to patients and the development of new drugs.

The task force made the following priority recommendations in the area of regulatory convergence and harmonization:

1. **Create a platform for ongoing U.S.-Russian regulatory cooperation.** While the U.S. Food and Drug Administration (FDA) and the Russian regulatory agency Roszdravnadzor have formed a collaborative relationship through mutual visits, training, and capacity-building programs, a more solid platform for ongoing dialogue is needed. The example of the European Commission, whose regulatory agencies conduct twice-yearly meetings with their Russian counterparts to ensure that current issues are regularly addressed, may be instructive in this regard and should be studied.

2. **Support the Russian pharmaceutical industry's move to good manufacturing practice standards.** This is a critical precondition for Russia to build up its own competitive pharmaceutical sector. Russia has committed to move to good manufacturing practice standards, but it will require resources and know-how. The U.S. government and private companies have both, and they should become actively engaged in Russia's transition.

3. **Lay the groundwork for mutual recognition of clinical trials conducted in the United States and Russia.** A bilateral agreement on the mutual recognition of clinical trials conducted in the two countries would increase both international pharmaceutical investments in Russia and drug access for Russian citizens.

LOOKING FORWARD

The latent potential of U.S.-Russian engagement on healthcare is significant. Deeper bilateral engagement in this area would benefit not just Moscow and Washington but the world. Reaching this potential will take commitment and political will. The recommendations outlined in this report are meant to help unlock the potential for such cooperation.

U.S.-RUSSIAN PUBLIC HEALTH COOPERATION FROM THE COLD WAR TO TODAY

Healthcare cooperation between the two countries dates back to the 1950s, when the United States and the Soviet Union signed the Lacy-Zarubin agreement "on Exchanges in the Cultural, Technical and Educational Fields." The agreement outlined an exceptionally broad agenda of cooperation, including exchanges in science, technology, medicine, and public health. It proved a success, with hundreds of scholars and graduate students participating in exchanges over the years.[2]

During that time, scientific collaboration between the two countries led to extraordinary achievements in public health. The polio vaccine was developed by American scientist Albert Sabin and first put into mass production and application by Soviet scientist Mikhail Chumakov, paving the way for clinical trials in the United States. And collaboration between the United States and the Soviet Union in 1965–1977, under the umbrella of the World Health Organization, eradicated smallpox.[3]

As the Cold War drew to an end and Russia faced immediate economic and social challenges following the dissolution of the Soviet Union, healthcare cooperation assumed a humanitarian-assistance mode, driven to a considerable extent by the U.S. Agency for International Development (USAID) and the Centers for Disease Control and Prevention

(CDC). USAID allocated a significant portion of the total $2.6 billion disbursed to Russia between 1991 and 2012 to local, regional, and national programs focused on infectious diseases (including HIV/AIDS—over 200 NGOs focusing on HIV/AIDS were funded), reproductive health, family planning, infant and child morbidity and mortality, child welfare, and programs to support orphaned children.[4]

The United States supplied the necessary vaccines and pharmaceuticals, helped restore local production of these materials in Russia, and assisted with addressing serious outbreaks of diphtheria and other infectious diseases.[5] Important hospital partnerships and physician exchanges were launched, helping to send U.S. physicians to Russia and vice versa to facilitate professional exchanges and strengthen local medical facilities. Much work was done in the areas of micronutrient malnutrition, maternal and child health, access to quality healthcare, and mental health.[6]

At the same time, tremendous possibilities opened for the private sector as Russia continued to transition to a market economy. With Russia's $400 billion and the United States' $1.9 trillion import markets, many hoped for an active trade engagement between the two countries. Indeed, U.S.-Russian trade grew steadily, nearly doubling between 2009 and 2011, to reach $43 billion in 2011.[7] U.S. exports to Russia grew from $2.6 billion in 1994 to $8.3 billion in 2011. Russian exports to the United States grew almost tenfold, from $3.2 billion in 1994 to $34.6 billion in 2011.[8] However, that is still relatively small, and there is much left to be accomplished in terms of diversifying the basket of trade.

INSIGHTS FROM LEADERS AND PRACTITIONERS

"As recognized historically as well as proven by our own experience, health sector cooperation is a highly effective instrument for engagement generally. To realize this goal requires a truly cooperative exercise engaging professionals recognized as peers on both sides and the sharing of experience in both directions. Physician exchanges are a key ingredient."

Eduard Burger, Eurasian Medical Education Program; member of the task force

The healthcare market in particular is viewed as having great potential to help the countries boost and diversify this trade partnership. Russia's private healthcare market, which grows at 16 percent annually, is among the fastest growing in the world. It was estimated to be worth $18 billion at the end of 2011 and is projected to grow to at least $25 billion by 2014.[9] Russia's biopharmaceutical market is estimated at $17.5 billion,[10] making it one of the most attractive global markets for U.S. pharmaceutical companies.

There are some success stories. Medical-instrument manufacturers, for example, have had relative success exporting their products to Russia. Optic and medical instrumentation were among the top export categories from the United States to Russia in 2011, representing $548 million of the $8.3 billion worth of American goods exported to Russia.[11] And Russian state investment funds such as RUSNANO and the Skolkovo Foundation have been making investments in U.S. biotechnology ventures with the goal of bringing their products and facilities to Russia.

Ongoing problems, however, hamper progress in this promising area. Despite the adoption of agreements on pharmaceutical development and sales,[12] critics have asserted that the Russian government's current policies aimed at promoting the development of its domestic pharmaceutical industry are actually counterproductive. They note that Russia should be improving the investment climate, incentivizing competition, and generally creating a positive market environment for all players rather than erecting what they perceive as barriers to entry in the name of supporting local industry.

Until Russia's 2012 accession to the World Trade Organization, other issues included the absence of a basic free-trade-agreement framework. Enforcement of laws, regulations, and guidelines has been inconsistent. Companies have been frustrated by the lack of transparency in regard to the growing list of products set aside for local manufacturing—the so-called dry list, which favors domestically produced medicines over imported ones.[13] The absence of good manufacturing practices (GMP) and good clinical practices (GCP) harmonization standards to ensure safe, effective, high-quality pharmaceuticals as well as persistent obstacles to long-term mutual research with Russian pharmaceutical companies have further retarded growth. The absence of GMP and GCP also preclude Russian companies from entering foreign markets, including the U.S. market.

Potential investors have cited Russia's lack of adequate protection for intellectual property rights, structural problems, and inefficient government regulations and policies, including the complicated and time-consuming customs regulations, as the main reasons for their unwillingness to invest.

In recent years, progress has also slowed in other aspects of cooperation. The number of professionals participating in peer-to-peer exchanges has declined. The National Institutes of Health (NIH) made a range of biomedical research grants available for Russian

scientists, but these generated a relatively low number of applications as a result of social, economic, and political factors. In 2012, USAID was asked to leave Russia under pressure from Russia's Foreign Ministry, and some of the programs and the NGOs it funded began to close, leaving future progress in doubt.[14]

BILATERAL PRESIDENTIAL COMMISSION AS A TOOL FOR COOPERATION

In the Soviet era, the overall relationship between the two countries was managed through a complex set of mechanisms, including high-level official summits and ministerial meetings. These had developed over decades and were a reflection of the times, which demanded a careful balancing of political and ideological tensions with productive cooperation.

With the dissolution of the Soviet Union and the end of the Cold War, that system became obsolete. A new mechanism for government-to-government dialogue needed to be created.

THE GORE-CHERNOMYRDIN COMMISSION

Responding to that need, in 1993 Russian President Boris Yeltsin and U.S. President Bill Clinton established a comprehensive bilateral commission designed to keep officials on both sides engaged with one another on an ongoing basis in the areas of the economy, energy, space, and science and technology, among others. The commission, which eventually came to be known as the Gore-Chernomyrdin Commission after U.S. Vice President Al Gore and Russian Prime Minister Viktor Chernomyrdin, served as an important tool for shaping cooperation in the new era.[15]

One of the commission's early successes in the area of health cooperation was the signing, in 1994, of the Bilateral Agreement between the Government of the U.S. and the Government of the Russian Federation on Cooperation in the Field of Health and Biomedical Research. The agreement served as a "legal foundation in the development of new U.S.-Russian collaboration on health and biomedical research." When the accord was later renewed through January 2004, it was viewed as "evidence of the willingness of both countries to deepen their commitment to achieve practical benefits for the improvement and protection of the health of their populations."[16]

The Gore-Chernomyrdin Commission continued its work throughout the two Clinton terms. In the area of healthcare, it focused on the control of infectious diseases, including TB, HIV/AIDS, and sexually transmitted infections; access to quality care, including primary healthcare, preventive medicine, and particularly treatments for depression, substance abuse, alcoholism, diabetes, cardiovascular diseases, and hypertension at the primary healthcare level; and maternal and child health, including micronutrient malnutrition, reproductive health, and environmental health.[17]

As the United States went through the trauma of the September 11, 2001, terrorist attacks and became enmeshed in wars in Afghanistan and Iraq, the relationship between Washington and Moscow lost some momentum.[18] However, even during this period, strong and productive cooperation in healthcare continued, anchored by USAID, the CDC, the NIH, and various agencies in the Department of Health and Human Services in the United States and by the corresponding ministries in Russia.

THE BILATERAL PRESIDENTIAL COMMISSION

In July 2009, the Bilateral Presidential Commission was created by Russia and the United States as a working body tasked with improving coordination, addressing the challenges of an ongoing dialogue, and supporting cooperation in multiple areas. The establishment of the BPC was broadly viewed as a re-creation of an institutional foundation for the regularized and systematic contacts that had characterized the U.S.-Russian relationship for nearly half a century.[19] Many saw in it an opportunity for U.S.-Russian relations to move beyond personalities and become grounded in institutions that would last beyond the specific administrations that created them.

In establishing the commission, U.S. President Barack Obama and Russian President Dmitry Medvedev called for more regular, institutionalized contacts that would help develop the relationship between the two governments "in a more structured and regular way."[20] At a 2009 summit, the two signed a Memorandum of Understanding on Cooperation in the Field of Public Health and Medical Sciences.[21]

The BPC has emerged as a valuable, albeit less than perfect, structure for managing U.S.-Russian cooperation across multiple areas. In keeping with the original vision, the commission focuses on deliverables. It enabled effective cooperation on a broad bilateral agenda, including nuclear security, arms control, missile defense, counterterrorism, and counternarcotics. It is viewed as having contributed to securing the invitation for Russia to join the World Trade Organization in the summer of 2012, implementing the New START Treaty, facilitating agreement on a number of amendments to the Plutonium Management and Disposition Agreement (the 123 Agreement), and deepening military cooperation, including in Afghanistan.[22]

THE BPC WORKING GROUP ON HEALTH

The BPC Working Group on Health was originally co-chaired by U.S. Health and Human Services Secretary Kathleen Sebelius and the head of Russia's Ministry of Health and Social Development Tatyana Golikova. When Russia's ministry was restructured in the summer of 2012 into the Ministry of Social Development and the Ministry of Health, Dr. Veronika Skvortsova, formerly Golikova's deputy minister, took the reins as the new health minister and became Sebelius's co-chair.

The group promotes bilateral cooperation in four key areas: scientific collaboration, maternal and child health, healthy lifestyles, and global health. Among its specific achievements to date are a signed Protocol of Intent on Cooperation for the Global Eradication of Polio; a new memorandum of understanding between the NIH and the Russian Foundation for Basic Research, which has already generated the first joint U.S.-Russian grant competition on HIV/AIDS prevention science; and the establishment of Text4Baby, a project that delivers health information to mothers by mobile device to improve maternal and infant care in Russia. (Dr. Jill Biden, the wife of the U.S. Vice President Joseph Biden, showed her support for the latter by helping to announce the Text4Baby project in March 2011.[23])

Signing the Protocol of Intent on Malaria Control was an important milestone. The protocol represents a commitment by both countries to work together to end preventable child deaths from malaria. Cooperation will entail training and capacity building, evaluation, operational research, and collaboration with other partners on global malaria control. The protocol is important as a signal that both countries are ready to transcend the donor-recipient paradigm that has prevailed throughout the post-Soviet period, which saw Russia primarily as the recipient of aid disbursed by the United States, and work as equal partners to resolve one of the key global public health issues.[24] The recent USAID departure from Russia, however, has created uncertainty about the future of these malaria-control initiatives, as new sources of funding will now be required.

In addition, the working group has reported facilitating cooperation on a range of bilateral tobacco-reduction programs, including QuitNowText, a mobile text-messaging program that delivers motivational tips to smokers planning to quit. It has also established joint biomedical research programs; maternal and child mortality programs, including use of innovative technologies in the care of premature babies; and programs related to health outcomes of babies born as a result of assisted reproductive technologies. Joint projects are also under way to study the epidemiology of obesity and reduce the incidence of alcoholism.[25]

While the BPC Working Group on Health has several important achievements under its belt, some of its other key initiatives have hardly moved past the initial stage. In 2012 in particular, active engagement by the two sides in education, exploration of key issues, as well as tangible policy implementation, lost momentum. As USAID departed from Russia, concern grew in the United States that healthcare cooperation with Russia would stall.

Relations between Russia and the United States entered a new stage following the 2012 elections in both countries. This shift presents a unique opportunity for the BPC to strengthen its position in the U.S.-Russian dialogue and reengage both sides to move its agenda forward. Its record of achievements to date suggests that it is capable of providing a solid-enough foundation to support the hoped-for continuity and progress in the dialogue, even at times of political change. The Working Group on Health, in particular, has much to offer in terms of advancing cooperation.

INSIGHTS FROM LEADERS AND PRACTITIONERS

"The more we work together, the faster we will be able to test new strategies, learn what works, and implement them in our own communities."

Secretary of Health and Human Services Kathleen Sebelius[26]

TWO HEALTHCARE SYSTEMS IN TRANSITION

While the Russian and U.S. healthcare systems have their own sets of challenges, some of the social and public health issues that the two societies must confront are similar. Both face a growing aging and dependent population that suffers from a high incidence of chronic illness caused by a variety of social and lifestyle factors. Both are challenged by fragmentation and inefficiencies that increase the cost burden on their respective economies and create disparities in access to quality care. And both must reeducate their populations and incentivize providers to focus on prevention and wellness.

Equal access to quality care is an acute problem for both systems, although the underlying reasons are different. Many Russians lack access to care either because they live in a rural area or because they cannot afford prescription medication, which the state-funded programs do not cover. Some 48 million Americans lack access to care because they cannot afford to buy insurance.

At the same time, Russia in particular faces some unique challenges. In the past twenty years, it has had to redesign its entire healthcare system from a highly centralized one, where the state controlled every aspect of healthcare, to a more decentralized system that has to respond to market forces and incorporate private actors. As Russia continues with this process, it has the advantage of learning from the world's best practices and worst mistakes. Rather than adopting methods and policies that may have proven only marginally effective elsewhere, the country can think outside the established paradigms and develop more advanced and, potentially, more effective solutions.

THE RUSSIAN HEALTHCARE SYSTEM

Over the past twenty years, the Russian healthcare system has grappled with the country's transition to a market economy just as the Russian population's health profile shifted dramatically in response to social, economic, and lifestyle changes. Russia's health statistics are among the worst of all countries in the Organization for Economic Cooperation and Development (OECD). Russia lags behind the other OECD countries in life expectancy

by nearly ten years. In OECD countries with similar levels of income per capita, such as Chile and Poland, life expectancy is seven years higher than it is in Russia.[27]

Noncommunicable diseases account for 90 percent of all deaths in Russia.[28] In 2008, cardiovascular disease caused 57 percent of Russian deaths (compared to 35 percent for all OECD countries), while cancer caused 14 percent. Digestive and respiratory diseases followed at 4.3 and 3.8 percent, respectively. So-called external factors, such as acute alcohol poisoning, traffic accidents, suicides, and violent crimes, caused 11.8 percent of Russian deaths.[29]

The Soviet healthcare system was built on the so-called Semashko model, which featured a hierarchical and centralized structure that prioritized fighting infectious disease. The model proved effective for some time, excelling at infectious-disease prevention through population-wide vaccination campaigns. It also offered access to a basic level of care for all citizens. However, as the Soviet system entered a period of stagnation, the healthcare system also inevitably began to decline. Resulting underinvestment led to a precipitous decline in the quality of care, as hospitals grappled with shortages of drugs, medical equipment, and even hot running water.[30]

With the fall of the Soviet Union, the healthcare system became increasingly decentralized, and responsibility for the provision of healthcare was delegated to the regions. The issue of healthcare financing came to the fore. Moscow passed legislation establishing a national compulsory health insurance mechanism and provisions for private insurance.

At the same time, Russia remained committed to the government guarantee of free basic healthcare—a commitment that was enshrined in article 41 of the Russian constitution adopted in 1993. It stated that every Russian citizen "shall have the right to health protection and medical aid" and that this aid shall be rendered gratis in state and municipal establishments. The article also described how the government was to meet this obligation:

> In the Russian Federation federal programmes of protecting and strengthening the health of the population shall be financed by the State; measures shall be adopted to develop state, municipal and private health services; activities shall be promoted which facilitate the strengthening of health, the development of physical culture and sport, ecological and sanitary-epidemiological well-being.[31]

Today, there is a sense that public sector financing may be adequate to cover the guarantee at its most basic level. Private insurance options exist, albeit in a rudimentary form. One of the biggest challenges now is how to allocate the resources efficiently. The system needs to be restructured to effect a shift toward primary care and prevention—a top priority for the government. It is hoped that this will reduce traditional reliance on lengthy

hospital stays. (In 2007, 60 percent of Russia's total healthcare spending went to inpatient care—almost twice the OECD average of 34.2 percent.)

State-run medical facilities, which comprise 95 percent of all such facilities in Russia,[32] are underfinanced and lack key resources, including medical and technical equipment and supplies, making them uncompetitive in terms of care compared to new, private market entrants. Meanwhile, the majority of the population cannot afford private care and the high out-of-pocket payments that are often required even at state-run institutions to access better equipment, purchase medications not covered by government guarantee, and make informal payments to bypass typically long wait lists and gain faster access to a consultation. Complicating the situation is the vast size of the country and the geographic unevenness in the availability and quality of medical services.

Although there are more than 300 private and numerous public insurers in the Russian market, real competition for patients is rare, leaving most patients with little or no effective choice of insurer. (In many places, patients have little choice in healthcare providers as well.) Insurance companies have failed to develop as active, informed purchasers of healthcare services. Most are passive intermediaries, making a profit by simply channeling money from regional funds to healthcare providers.

Over the past decade, the government has consistently named public health among the top items on its agenda. A series of high-level initiatives has been undertaken. In 2006, Russia launched a National Priority Project on health. The program aims to improve the overall performance of Russia's health system, improve the health of Russian citizens,

INSIGHTS FROM LEADERS AND PRACTITIONERS

"We have spoken about some positive trends in the healthcare system and we have something to show for it. Yet the average lifespan in our country is 8–10 years lower than in neighboring European countries, the death rate from cardiovascular diseases is 4–5 times higher.... A quarter of all the medical facilities in the Russian Federation are in need of overhaul."

Vladimir Putin, president of the Russian Federation[33]

increase the availability and quality of health services, develop primary care, reorient the system toward prevention, and increase the role of cutting-edge technologies and information technologies in healthcare. The program prioritizes continuing education of primary care physicians, salary increases for healthcare workers, and the construction of fifteen regional specialized medical centers.[34]

In 2009, the Russian government adopted the Healthcare Development Concept to 2020, a program aimed at improving Russia's longevity figures and reducing Russians' mortality rate. The program zeroed in on noncommunicable diseases as the primary source of Russia's high mortality rates and set specific goals for reducing their incidence.[35]

In 2010, Russia adopted the Federal Target Program "Strategy for the Development of the Pharmaceutical Industry," also known as Pharma-2020. The program was designed to encourage the transition of Russia's pharmaceutical industry to a so-called innovative development model.

The government has also allocated financial reserves to help domestic industry transition to GMP standards. Domestic companies are being incentivized to develop and produce innovative medicines with the goal of creating import substitutes, improving access to the latest therapies for patients, and facilitating the modernization of the Russian healthcare market by providing Russia with next-generation pharmaceuticals, medical devices, and diagnostic products.[36]

Some experts assert, however, that this top-heavy focus creates inefficiencies in the system. The government is pouring more money into this approach, but there are no safeguards to ensure efficient spending, and there are no incentives to ensure quality of care and accountability for outcomes. These realities breed concern that government spending will be less effective than is hoped.

THE U.S. HEALTHCARE SYSTEM

The U.S. healthcare system also faces a series of challenges. An estimated 1 million Americans suffer from chronic conditions such as diabetes, hypertension, and arthritis. Over 30 percent of adults aged eighteen to thirty-four, two-thirds of adults aged forty-five to sixty-four, and nearly 90 percent of the elderly have at least one chronic disease. Chronic disorders account for 75 percent of direct medical care costs in the United States. Of

these, five illnesses—diabetes, congestive heart failure, coronary artery disease, asthma, and depression—account for most of the costs, with two other chronic illnesses, obesity and tobacco addiction, contributing as well.[37]

Researchers predict that by 2020, more than 50 percent of the U.S. adult population will have type 2 diabetes or prediabetes, with annual treatment costs approaching $500 billion. By 2030, total annual economic costs of cardiovascular disease in the United States are predicted to exceed $1 trillion.[38]

The high prevalence of noncommunicable diseases has put a tremendous burden on the U.S. economy. Total health expenditures in the United States have grown steadily for years, from $724 billion in 1990 (12.5 percent of GDP) to an estimated $2.6 trillion in 2010 (17.9 percent of GDP), and they are projected to reach $4.8 trillion (19.8 percent of GDP) in 2020.[39] By contrast, energy consumption—another hotly debated item in the U.S. budget—has risen from $472.5 billion in 1990 to $1.2 trillion yet remained a relatively constant 8.3 percent of GDP.[40] In 2005, the CDC estimated that chronic diseases accounted for 75 percent of total healthcare spending.

The U.S. government is in the process of implementing the Patient Protection and Affordable Care Act, commonly known as Obamacare or the ACA. The ACA expands the coverage of government insurance programs Medicare and Medicaid, prohibits insurance companies from discriminating against applicants with preexisting conditions, and mandates health insurance for all citizens.

However, the reform will do nothing to fix some of the fundamental problems plaguing the American healthcare system. One of these is the fact that the system is built on a fee-per-service basis, which creates a perverse system of incentives—patients pay for services rendered rather than outcomes, financially incentivizing providers to favor expensive procedures instead of simple, inexpensive solutions and prevention-oriented care. And until the problem of the high rate of uninsured is resolved, it will continue to translate into the overuse of emergency rooms and the use of more expensive services as people delay their doctor visits until the illness has progressed to a late stage and requires more aggressive treatment.

Officials struggle with how to encourage providers to keep costs down, help those in lower-income brackets acquire healthcare, deploy electronic medical records to reduce fragmentation and inefficiencies, and allow patients to access information concerning their own personal health records as well as success rates of doctors and hospitals.

THE PUBLIC-PRIVATE TASK FORCE ON U.S.-RUSSIAN HEALTH COOPERATION

With official encouragement from both sides, the Russia and Eurasia Program at the Carnegie Endowment for International Peace gathered a group of decisionmakers from government, senior industry executives, and representatives of the research community to form a public-private task force on U.S.-Russian health cooperation in support of the BPC's Working Group on Health.

The first meeting of the task force took place in May 2011. During the meeting, participants outlined existing challenges and obstacles to effective U.S.-Russian health cooperation and agreed that supplementing the intergovernmental dialogue with participation from NGOs, the private sector, and the expert community could help produce real and quantifiable results and move the dialogue forward. Nikolai Gerasimenko, first deputy chairman of the Russian State Duma Committee for Health, and John Steele, director of International Government Affairs at the global pharmaceutical company Eli Lilly, were appointed task force co-chairs.

The task force included four subcommittees, which were formed with the goal of producing targeted policy recommendations in four key subject areas:

- Strategic resource allocation
- Healthy lifestyles (focused on noncommunicable diseases)
- Science cooperation and technology transfer
- Regulatory convergence and harmonization

The task force held four substantive meetings, one for each area of focus. Numerous additional workshops and discussions also took place, resulting in a series of recommendations for the Russian and U.S. governments, private sectors, NGOs, and scientific and medical communities.

INSIGHTS FROM LEADERS AND PRACTITIONERS

"The goal of the "For Healthy Life" forums is to change the population's perspective on healthcare from orientation to treatment toward prevention and healthy lifestyle."

Nikolai Gerasimenko, founder of the For Healthy Life Forum and co-chairman of the task force[41]

Several task force members also collaborated with Gerasimenko to develop the For Healthy Life program. The program was formally launched at a high-profile forum on noncommunicable diseases held in Kazan in October 2012 and is geared toward preventing and managing noncommunicable diseases, reducing the mortality rate, and increasing life expectancy throughout the Russian Federation. The forums will be conducted in each of the Russian Federation's eight federal districts over the next four years.

Speaking at the Kazan forum, task force chairman Gerasimenko addressed the 600 participants on the prevention of noncommunicable diseases, emphasizing that the goal of the forums was to shift the healthcare paradigm from disease management to prevention and wellness.[42] A number of top-level government officials attended the event, including Minister Skvortsova, Tatarstan President Rustam Minnikhanov, First Deputy Chairman of the State Duma of the Russian Federation Alexander Zhukov, and President of the Russian Academy of Medicine Ivan Dedov. Leading Russian researchers and clinicians presented their views and internationally adopted strategies on prevention of cardiovascular and respiratory diseases, cancer, and diabetes. Representatives of the U.S. Department of Health and Human Services and the U.S. embassy also participated.

STRATEGIC RESOURCE ALLOCATION SUBCOMMITTEE

AREAS OF FOCUS

Both the U.S. and Russian systems suffer from inefficiencies in healthcare resource allocation. Although the inefficiencies show up somewhat differently in each, many are complementary, which offers an opportunity for the two sides to learn from one another. Russia, in particular, has the chance to avoid some of the drawbacks and excesses characteristic of the American system while learning from U.S. best practices.

Fragmentation

Both systems suffer from fragmentation. In Russia, this comes from the historic emphasis on specialization in medical practice and the prevailing belief among the population that primary care physicians offer poor-quality care. Patients, therefore, often self-diagnose and bypass primary care physicians, going straight to a specialist, resulting in a lack of coordination of care. The system is fragmented geographically, with access to and quality of care varying dramatically from region to region. This is a particularly acute problem for rural areas. Regulatory inefficiency contributes to the problem, with responsibility for quality of care poorly divided among federal and regional regulatory bodies.

In the United States, multitudes of providers and insurance options create inefficiency and replication in care and services rendered. The Institute of Medicine, an independent adviser to the U.S. government and the American public that is part of the National Academy of Sciences, reports that 30 cents of every dollar spent on healthcare in the United States is wasted. The 2009 data show that $210 billion was spent on "unnecessary services, like repeated tests, and $130 billion was spent on inefficiently delivered services, like a scan performed in a hospital rather than an outpatient center." On top of that, the system spent "$190 billion on paperwork and unnecessary administrative costs," $75 billion on fraud, and $55 billion on "missed prevention opportunities."[43]

Some in the United States are trying to address this issue by developing the Patient Centered Medical Home model. This model is intended to be both a physical place and a system of organizing patient care. It seeks to centralize and systematize care by ensuring that primary care physicians coordinate patient treatment. The goal is to integrate all of the patient's needs and respond to them in a centralized and efficient manner. There is particular emphasis on ensuring clear and productive communication among the patient, patient's family, and the provider. The system relies on the use of health information technology, electronic medical records, and other means to ensure the best care.[44]

Both countries are attempting to diminish fragmentation by creating standardized, integrated electronic medical record systems. These systems enable a patient to move from provider to provider without having to replicate costly diagnostic procedures, as patients' full records and test results become available to all successive clinicians treating them. However, even as major hospital systems in the United States have begun to implement electronic medical records, each tends to create its own proprietary system that is inaccessible to others. This means that a patient's records in one institution are nontranslatable into another.

Russia is working to implement a nationwide, computerized, universal electronic medical records system for all public health records. Here, Russia's experience with a centralized medical system may give it an advantage over the United States. Implementing a system that encompasses every market player in the United States is an impossible task for the U.S. government.

INSIGHTS FROM LEADERS AND PRACTITIONERS

"If banking were like health care, automated teller machine transactions would take not seconds but perhaps days or longer as a result of unavailable or misplaced records. If homebuilding were like health care, carpenters, electricians and plumbers each would work with different blueprints, with very little coordination."

U.S. Institute of Medicine[45]

Quality Control

Another challenge for the U.S. healthcare system is a lack of access to performance records and statistics for hospitals, clinics, and doctors. Without easy access to this information, patients are unable to make informed decisions about healthcare providers.

The government has sought to address this challenge in the one area where it has control—the Medicare and Medicaid programs. One of the provisions of the ACA seeks to tie provider reimbursements to quality metrics and reductions in total cost of care by creating affordable care organizations. These organizations bring together providers and suppliers of services, and their members are expected to coordinate with one another in an effort to eliminate duplication of efforts and deliver seamless services for the beneficiaries.[46]

Quality control is also a concern for Russia, where multiple new providers have proliferated, while traditional state-run hospitals are often underfinanced and lack necessary equipment. It remains to be seen how the Russian government will tackle this challenge.

Use of Drugs and Services

Whereas Russia experiences a shortage of lifesaving drugs and a lack of public reimbursement for prescription drugs, there is a growing constituency in the U.S. medical community arguing that Americans overmedicate.[47] Prolonged and intensive drug use frequently results in additional health problems. For example, a recent study found that prolonged insulin therapy was "associated with an increased risk of diabetes-related complications, cancer, and all-cause mortality" in some type 2 diabetes patients.[48] In another study, statins were found to increase the risk of diabetes in post-menopausal women by 48 percent.[49] Overprescription of psychotropic medication for active-duty soldiers and wounded warriors in particular has been scrutinized recently after it was revealed that prescription drugs were involved in one-third of the record 162 suicides by active-duty soldiers in 2009.[50]

In a similar vein, while Russian doctors often lack critically important diagnostic equipment, there are influential voices in the United States that argue the system overuses diagnostic procedures without delivering corresponding benefits to the patient.[51]

Russia is currently investigating how it can make prescription drugs more available to the patients who need them the most while continuing to reorient the population toward making healthy lifestyle choices. To that end, the Ministry of Health is in the process of implementing several drug-reimbursement pilot projects, expected to be carried out in 2015–2016 in select regions.[52]

INSIGHTS FROM LEADERS AND PRACTITIONERS

"Our task, as we go about implementing the pilot projects, is to find the mechanisms that will engage a more responsible attitude to one's health, encourage regular visits to the doctor, support a healthy life style, and move away from bad habits."

Igor Kagramanyan, deputy health minister of the Russian Federation[53]

The U.S. Medicare prescription drug benefit, also known as Medicare Part D, may serve as a model for Russia as it explores different options. Enacted in 2006, the program offers varying levels of drug prescription benefits to Medicare beneficiaries. Generally, not all drugs are covered at the same levels, incentivizing participants to choose certain drugs over others.[54]

While the program has drawn significant criticism, a survey by the AARP, the nonprofit association representing the interests of U.S. retirees, demonstrated that one year after the benefit was introduced, 85 percent of enrollees were satisfied with their drug plan while 78 percent believed that they had made a good choice in selecting their plan.[55]

Care for the Sick Versus Prevention and Wellness

Harvard Business School professor Clayton Christensen points out in his book *The Innovator's Prescription: A Disruptive Solution for Healthcare* that a key contributor to the high cost of chronic illness is the fact that hospitals and physicians' practices are set up to care for the sick rather than to keep patients well:

> There are more than 9,000 billing codes for individual procedures and units of care. But there is not a single billing code for patient adherence or improvement, or for helping patients stay well.[56]

Christensen argues that as long as this business model persists, the costs of healthcare will never be curtailed.

In Russia, too, today's medical system is oriented largely toward costly approaches to disease management. Prolonged hospital stays are typical and are used at a much higher rate than elsewhere. Allocating resources toward prevention and better ways to manage chronic illness, which can help forestall unnecessary hospitalizations and acute care, can become a source of considerable savings.

Medical Personnel

Both countries face an oversupply of some medical personnel and a shortage of others—most importantly, they lack primary care physicians. In the United States, this is due to financial incentives—being a specialist is a far more lucrative occupation. In Russia, the problem is more subtle, having to do with the public's perception that primary care physicians are less competent than specialists. No matter the reason, self-diagnosis and the resulting overuse of specialists in Russia creates massive inefficiencies in the system. It also diminishes the role of primary care physicians, leading to an even greater shortage in both countries.

Medical personnel in the United States enjoy some of the country's highest salaries. In Russia, by contrast, the salaries of medical personnel are 30 percent below the average salary throughout the country.[57] Russian doctors, the vast majority of whom are employed by state-run medical facilities (95 percent of all medical facilities in Russia are in the public sector),[58] also receive lower salaries than their OECD counterparts when compared to the rest of public sector workers. While Russian doctors' salaries are 1.5 times the average wage in the public sector in Russia, in OECD countries, general practitioners are paid 2.5 times and specialists three times the average public employee salary.[59]

Delayed Treatments

In both systems, citizens wait too long to seek medical treatment. In Russia this often has to do with lack of access (particularly in rural areas) and inability to make the extra payments that are often required to supplement the basic services guaranteed by the government, including those for prescription medications, high-tech procedures, and informal payments to providers. Over 80 percent of the Russian population is dissatisfied with the quality of care. As a result, people fail to turn to the healthcare system, often only doing so when hospitalization is needed.[60]

In the United States, the problem is similar in nature: the high rates of uninsured mean that people cannot afford to pay for the services and often delay visiting the doctor until the disease has progressed to a late stage. Overreliance on employer-provided health

insurance exacerbates the problem, particularly during economic downturns. As employers shift an increasing amount of healthcare costs to their employees—or shed workers altogether, leaving them without insurance—people begin to delay medical visits.

TASK FORCE RECOMMENDATIONS

Ensuring strategic resource allocation will require both strategic and tactical approaches. New and creative thinking may be necessary to bypass areas of inefficiency and design new solutions. To create meaningful change, some entrenched modes of thinking and acting may need to be overhauled. This, in turn, will require innovative financing approaches and data management systems.

To that end, the task force made the following priority recommendations in the area of strategic resource allocation:

1. **Build cooperation in the use of health information technology, telemedicine, and electronic medical records.** Health information technology, or the framework for managing and securely exchanging health information across computer systems, can greatly improve the accuracy of diagnostic and therapeutic decision-making and support research efforts while improving access to health services and cutting costs. Electronic medical records, which digitize a patient's medical records so they can be easily shared throughout a single organization such as a hospital or a physician's office—and, ideally, across multiple organizations—can help eliminate costly errors. Telemedicine, or the provision of clinical care at a distance with the use of technology, can be particularly helpful in remote areas experiencing shortages of medical facilities and trained personnel. Using technology in this way is relatively new for both sides, and they could benefit from sharing their experience and approaches.

2. **Focus on evidence-based, prevention-oriented interventions.** Both the United States and Russia should focus on methods that have been shown in well-designed scientific studies to deliver early health benefits and prevent disease.

3. **Collaborate on joint immunization campaigns.** Cooperating on joint vaccination campaigns could allow both countries to strengthen their global leadership positions.

4. **Explore joint projects in personalized medicine.** Personalized medicine is one of the most cutting-edge approaches in medicine. It offers an opportunity for both countries to contribute to a broad impact while leveraging medical and scientific experience and access to large pools of patient data.

5. **Explore jointly how to broaden access to healthcare for underserved populations.** Both the United States and Russia face issues related to access to healthcare coverage. Practitioners in both countries could benefit from professional peer-to-peer conversations on the subject.

6. **Focus on cooperation in the area of emerging pandemic threats.** As the world becomes more integrated, new pandemic threats will inevitably emerge. The United States and Russia have a good track record of working together in this area and should maintain this cooperation.

7. **Emphasize continuing medical education.** Exchanges in the area of continuing or postgraduate medical education have proven to be a successful area of collaboration for the two countries. They will remain important going forward. Today's technology, which provides a broad variety of opportunities for knowledge exchange, while reducing the need to travel, offers many new, cost-effective possibilities to pursue joint efforts in this area.

The task force recommended the following specific initiatives be undertaken collaboratively by a combination of private and public stakeholders in the two countries:

1. Establish a bilateral task force of public and private experts to explore how best to provide universal healthcare by utilizing a mix of public and private financing. Consider conducting a pilot project in a designated region or state.

2. Place more emphasis on disease prevention and the complications of underlying diseases.

3. Improve cost-effectiveness of medical interventions. In Russia, insurance providers currently have no incentive to contain costs. A shift to covering preventive treatment would be an economical measure in the long term as well as the right decision for patients' welfare.

4. Conduct studies on medical mistakes made within the healthcare services of both countries and disseminate the information to educate practitioners.

5. Address the significant regional differences in access to medical services and prescription drugs. These are particularly notable in the economically depressed and rural areas of both countries. This may be achieved in part by reviewing the results of Medicare Part D in the United States and discussing it as a possible model for expanding prescription drug access in Russia.

6. Establish a bilateral task force on aid programs to the developing world to treat rare and communicable diseases and potentially noncommunicable diseases there. Russia has moved in recent years to recapture the position of a global donor and doing so is an important item on Minister Skvortsova's agenda. Global health is also one of the BPC Health Working Group's focus areas. A bilateral task force can help support these goals.

7. Strengthen the role of primary care physicians in patient care. Explore having the primary "district physicians" in Russia achieve greater responsibility and providing economic incentives. Nine to ten Russian regions, including Perm, Samara, Kaliningrad, and Khabarovsk, have already adopted this approach.

8. Explore the applicability of emerging payment policies that bundle payments to all the providers (for example, primary care physicians, specialists, and hospitals) to encourage coordination and quality of care. The U.S. experience with accountable care organizations can be used as a model.

9. Explore coordination and patient compliance incentives, such as "pay for performance" and/or "pay for compliance" approaches as supplementary policies to further encourage quality of care.

10. Provide continuing medical education to primary physicians. Train highly skilled nurses within the primary care system to take on more routine aspects of care to enable physicians to focus on exercising their high-value-added skills, such as medical diagnosis.

11. Study best practices and experience on both sides to draw the best recommendations for developing and deploying telemedicine to rural areas in the most effective way possible—an important cost-saving measure.

12. Improve accessibility and transparency of statistical data on issues such as hospital performance evaluations and the cost of medical services to ensure the best return on investment.

13. Encourage the critical review of medical evidence and the use of that evidence in medical practice to promote more targeted and personalized treatments in both Russia and the United States.

HEALTHY LIFESTYLES SUBCOMMITTEE

AREAS OF FOCUS

The First Global Ministerial Conference on Healthy Lifestyles and Noncommunicable Disease Control, which took place in Moscow on April 28–29, 2011, stated in its official declaration that "a paradigm shift is imperative in dealing with NCD [noncommunicable disease] challenges, as NCDs are caused not only by biomedical factors, but also caused or strongly influenced by behavioral, environmental, social and economic factors."[61] Populations in both the U.S. and Russia are being forced to confront this reality.

Obesity

Obesity is a concern for both countries, although the United States by far outpaces Russia in terms of its obesity epidemic. Obesity has been linked with heart disease, strokes, and type 2 diabetes, among other diseases. More than one-third of U.S. adults (35.7 percent) are overweight or obese. The Centers for Disease Control and Prevention estimated that obesity-related conditions resulted in $147 billion in medical costs in 2008.[62]

The epidemic also affects children, as childhood obesity rates in America have tripled over the past thirty years. Today, nearly one in three American children is overweight or obese and therefore at greater risk for diabetes and other obesity-related health problems such as heart disease, high blood pressure, cancer, and asthma.[63]

Russia, while still nowhere near the United States, nevertheless faces a creeping obesity problem. Among Russians between twenty-five and sixty-four years of age, 47–54 percent of men and 42–60 percent of women are overweight. Of these, 15–20 percent are obese.[64]

Nutrition

Proper nutrition is a critical aspect of both obesity management and disease prevention. The World Health Organization states that about one-third of all cardiovascular disease is caused by improper nutrition. In particular, consumption of fruits and vegetables has been shown to be critical to containing the disease. While Russia's per-capita

consumption of produce grew by 27 percent between 1995 and 2007, it is still much lower than in France and Italy, two countries with low levels of mortality from cardiovascular disease.[65]

American diets are also poor in quality because of a prevalence of high-fat, high-sugar processed foods. Mark Hyman, a physician who has become one of the most prominent critics of American dietary habits, writes: "The average American consumes 24 pounds of French fries, 23 pounds of pizza, 24 pounds of ice cream, 53 gallons of soda (or a gallon each week), 24 pounds of artificial sweeteners, 2.7 pounds of salt, 90,700 milligrams of caffeine annually, and about 2,700 calories a day."[66]

Both populations must confront the reality and consequences of poor nutrition choices.

Smoking and Alcohol

Smoking and alcohol abuse are a concern in both countries, but in Russia the problem is particularly acute. Smoking has significantly declined in the United States and Europe over the last few decades, but it increased by 87 percent in Russia between 1985 and 2006. Almost twice as many Russian adults smoke as in OECD countries on average.[67] Sixty-three percent of Russian men, 30 percent of women, 40 percent of teenage boys, and 7 percent of teenage girls smoke. The OECD estimates that tobacco kills between 300,000 and 500,000 Russians per year.[68]

Alcohol consumption is estimated to kill, either directly or indirectly, half a million Russians per year.[69] It is particularly troubling that drinking and smoking habits take root in Russian society at a very early age.

But there is progress being made. Russian authorities are beginning to put in place new policies to reduce tobacco smoking and alcohol abuse.[70] The Ministry of Health has adopted the promotion of a healthy lifestyle as one of its main priorities. As of July 2012, advertising of alcohol and tobacco was banned in all media in Russia, including on the Internet, public transportation, and billboards.[71] In addition, President Putin has signed into law a ban on smoking in some public places, including schools and subways, and, at a later stage, in restaurants and cafes. It will also severely restrict cigarette sales.[72]

The Campaign for Tobacco-Free Kids has had success working with representatives of the Russian private sector and advocating that employers ban smoking at workplaces. Companies like the Russian airline Aeroflot and the Moscow Metro rapid transit system signed a document signaling their support.[73]

The Russian government has begun to impose an excise tax on alcoholic beverages with the goal of reducing alcohol consumption. At the beginning of 2012, Russia increased its beer tax by 20 percent. It plans to raise the tax by 25 percent in 2013 and an additional 20 percent in 2014.[74] In July 2012, the new excise tax raised the price of vodka by 30 percent.[75] And in August 2012, Deputy Prime Minister Arkady Dvorkovich urged faster growth in the excise taxes.[76]

Exercise

The myriad benefits of exercise include helping control weight; reducing the risk of cardiovascular disease, type 2 diabetes, and some cancers; and improving one's mental health and mood.[77] In recent years, high-profile government initiatives in both Russia and the United States have drawn attention to the importance of exercise.

In the United States, First Lady Michelle Obama launched the Let's Move! initiative in 2010 with the aim of reducing childhood obesity within a generation. In launching the initiative, Mrs. Obama stated that "the physical and emotional health of an entire generation and the economic health and security of our nation is at stake."

In the same vein, the National Football League's Play 60 initiative also targets the childhood obesity epidemic. Play 60 is a national youth campaign that draws on the power of celebrity football players to influence the behavior of their youngest fans. The players challenge kids to stay active for at least sixty minutes a day. The campaign builds alliances with in-school and after-school programs, thus affecting change at the grassroots level.[78]

In Russia, the Health and Development Foundation, formerly known as Healthy Russia, was created some ten years ago with the support of the Russian Ministry of Health, the Ministry of Education and Science, and the Ministry of Sport, Tourism, and Youth Policy. Formed as an NGO, the foundation works in partnership with universities and the private sector, including the pharmaceutical companies Johnson & Johnson, Merck Pharmaceuticals, and GlaxoSmithKline, to conduct educational and outreach programs to improve the health and healthy life skills of the Russian population.[79]

Organizations such as the Health and Development Foundation, however, face an uphill battle in Russia, where the long-standing popularity of sports and athletics has not translated into a grassroots fitness and wellness culture. For real change to take place, stakeholders need to work together to help create a cultural shift that makes wellness, including physical fitness, a value and priority for Russian citizens.

Role of Private Companies

In recent years, employers in the United States have started to heed recommendations to support their employees' wellness and prevention efforts. This, in part, has to do with the fact that employers are typically the ones providing health insurance to employees and are therefore more acutely aware of the cost-effectiveness of prevention.

In recent years, companies have started sponsoring weight-loss and fitness competitions among their employees, replacing junk food snacks with healthier options, offering free disease screening, and supporting their employees' efforts to quit smoking. Some companies provide access to exercise equipment or offer free gym memberships as well.

Private companies, including pharmaceuticals, also have a history of supporting broader initiatives geared at preventing and reducing chronic illness. A number of companies, for instance, sponsored the For Healthy Life forum in Kazan last October. They also participate in ongoing, long-term initiatives, including the Partnership to Fight Chronic Disease, a coalition of patients, providers, health policy experts, and community, business, and labor groups committed to fighting chronic disease,[80] and the Campaign to End Obesity, sponsored by Johnson & Johnson, Pfizer, and Humana, among others.[81]

TASK FORCE RECOMMENDATIONS

Promoting healthy lifestyles in both countries is critically important and will directly impact health and healthcare costs. The task force made the following priority recommendations in the area of healthy lifestyles:

1. **Focus on prevention and early detection.** Prevention is a central factor in lowering noncommunicable disease rates, yet both the U.S. and Russian systems prioritize managing, rather than preventing, disease. The two healthcare systems are largely oriented toward expensive hospital services and treatment of acute cases, while early-stage disease control has been shown to be more beneficial for the patient and society. One way to promote preventive care is to encourage strong links among the medical community, NGOs, the private sector, community organizations, health policy leaders, and policymakers. Both countries can learn from each other.

2. **Cooperate on a targeted action program designed to reduce the burden of cardiovascular disease and cardiovascular mortality.** Cardiovascular disease and strokes account overwhelmingly for the major causes of premature mortality in both the United States and Russia. The principal risk factors behind this

record—cigarette smoking and unrecognized, untreated high blood pressure—are well understood and amenable to intervention. Both countries could benefit from a well-designed cooperative program to prevent and treat hypertension, especially one that utilizes the successful experience gained in other parts of the industrialized world, while pursuing a parallel strategy to reduce cigarette smoking.

2. **Continue cooperation on tobacco and alcohol control.** Smoking and alcohol consumption levels are particularly troubling in Russia. The United States has had some very important successes in reducing smoking rates and can share its experience with Russia.

3. **Develop joint programs to promote healthy eating, exercise, and healthy lifestyle choices.** The United States has had some success promoting the culture of fitness and healthy lifestyles. But most Russians do a better job of incorporating physical activity into their daily lives than Americans. The two countries can learn from one another in this area.

The task force recommended the following specific initiatives that the two countries could undertake collaboratively by any combination of private and public stakeholders:

1. Support existing initiatives and campaigns in both countries that are geared toward encouraging people to include exercise in their daily routines, such as Michelle Obama's Let's Move! initiative and the Health and Development Foundation.

2. Convene expert groups to discuss proper nutritional recommendations. An increasing amount of evidence points to the power of food to reverse heart disease, diabetes, and cancer and to slow down the aging process. Some studies show that intensive dietary changes can even reverse the progress of advanced type 2 diabetes in only twelve weeks.[82]

3. Encourage legislative initiatives that discourage the use of alcohol and tobacco through increased excise taxes. Russia is in the process of implementing such policies, and the United States has had them in place for some time. Work with officials to introduce legislation at the regional level and provide enforcement incentives to police officers.

4. Initiate awareness campaigns about the harmful effects of tobacco at all levels of Russian society, including in the entertainment industry and with the help of public education campaigns. Existing efforts in Russia can be bolstered by U.S. knowledge of the most successful efforts in this regard.

5. Foster local and regional attempts to combat smoking and alcohol abuse. Russia's healthcare system is becoming increasingly decentralized, with key decisions being devolved to the local and regional levels. It is important to support local stakeholders who will bolster these efforts at the grassroots levels.

6. Conduct regional or state-based forums on the basis of regional best practices for preventing and slowing the progression of noncommunicable diseases with a focus on cardiovascular disease, respiratory disease, diabetes, and cancer.

7. Develop anti-alcohol and anti-smoking programming geared toward youth. Encourage young Russians to initiate their own grassroots smoking and alcoholism prevention campaigns, including through the use of social media.

8. Involve pharmaceutical companies, healthcare providers, and the private sector generally to support and promote healthy lifestyles. Investigate known successes and failures of such engagement and use their best practices to form joint initiatives in both countries.

9. Enlist prominent international medical professionals to support a shift in Russia's focus from high-tech medical equipment and costly treatment procedures to healthy lifestyle promotion.

10. Engage private sector companies and NGOs in all government efforts geared toward promoting healthy lifestyles. This facilitates the building of communities and horizontal relationships, which will in turn ground the initiatives in grassroots efforts.

11. Create opportunities for impactful pilot projects that offer a comprehensive approach to addressing noncommunicable diseases with the highest prevalence and burden throughout the Russian Federation. The projects may have the following components:

    - A focused district- or regional-level approach, taking into account local needs
    - A half-day public advocacy event
    - One-day scientific and clinical site visits
    - Population studies to gather more precise relevant data
    - A three-day healthy lifestyles forum.

SCIENCE COOPERATION AND TECHNOLOGY TRANSFER SUBCOMMITTEE

AREAS OF FOCUS

U.S. research and development institutions have long enjoyed strong links with the commercial sector. This is most evident in Silicon Valley—the onetime agricultural area in the Santa Clara Valley south of San Francisco. It has become the global technological hub and is home to many U.S. technology giants.

There, the tight integration of Stanford University, established technology giants, and numerous venture capital firms, combined with a large pool of skilled labor, an ethos of free-wheeling enterprise, and government funding, has generated a unique culture of innovation that many governments around the world are now trying to replicate. Since the 1940s and 1950s, when high-tech firms such as Hewlett Packard and Varian Associates made the area around Stanford University their home, Silicon Valley has become an engine of industrial innovation and economic growth not just for California but for the entire United States. In the first quarter of 2009, fourth quarter of 2009, and first quarter of 2010, Silicon Valley received one-third of the total $4.7 billion in venture capital invested in U.S.-based companies.[83] In 2010, as the U.S. economy experienced one of the worst economic recessions in decades, Silicon Valley's GDP grew by 13.4 percent. (By contrast, the U.S. GDP grew by 2.6 percent, while the GDP of the nearby cities of San Francisco and Oakland registered a bare 0.5 percent growth.)[84]

Russia, for its part, has a formidable history of scientific advances, and U.S. venture capitalists and portfolio managers have long sought to commercialize these and bring them to market.[85] However, many in the Russian community have found the notion of scientific freedom incompatible with market demands. A certain fear persists that is a holdout from the past when scientific findings were held close to the chest and collaboration with foreign scientists was prohibited.

Scientific collaboration and technology transfer, however, is now a central goal of the Russian government. The Pharma-2020 program makes clear that modernization and innovation are Russia's strategic priorities. The latter are closely tied to the government's stated goal of turning science and technology into the new engines of economic growth.

In fact, a number of Russian government agencies are now empowered to fund research and technology-transfer initiatives. These include the Russian Foundation for Basic Research, RUSNANO, the Skolkovo Foundation, the Ministry of Health, the Ministry of Education and Science, and the Ministry of Industry and Trade.

Skolkovo

Over the last decade, Russia, along with many other countries, has closely studied the example of Silicon Valley in the United States. The Russian government is seeking to foster the culture of innovation that has made Silicon Valley famous throughout the world at the Skolkovo Innovation Center, which is being built on the outskirts of Moscow.

The strategic vision behind Skolkovo is to bring intellectual capital, startup capital, and potential commercial partners together under one roof, remove bureaucratic obstacles and red tape, and create a propitious legal and fiscal environment to incentivize the conceptualization and commercialization of new technologies. "At Skolkovo, we are assembling an impressive array of people and resources to address the most pressing healthcare issues today," said Dr. Chris Janssen, director for science and education in the biological and medical technologies cluster of the Skolkovo Foundation.[86]

An important part of the Skolkovo mission is developing biomedical technologies. Representatives of Skolkovo's biomedical technologies cluster have been actively searching for successful partnerships in the areas of systems biology, translational medicine, bioinformatics, functional and structural genomics, and drug discovery.[87]

Russian Investments in U.S. Biotechnology

Russia's $9 billion state venture capital fund RUSNANO has made a splash over the last two years with its high-profile partnerships and investments in a series of U.S. biotech startup companies. RUSNANO's mission is to invest 20 percent of its funds in startup life-sciences companies, support technology transfer to Russia, and foster the growth of Russia's biopharmaceutical industry.

In 2011, RUSNANO invested $94.50 million in two U.S.-based companies, BIND Biosciences and Selecta Biosciences, for the development of therapeutic nanoparticles in Russia. RUSNANO is working with BIND Biosciences to address solid tumors and inflammatory and cardiovascular diseases, and it is working with Selecta Biosciences to create a new class of targeted immunotherapies and vaccines for the treatment and prevention of cancer as well as respiratory, infectious, and autoimmune diseases. Both companies will open research and development centers in Russia as part of the deal.[88]

Another beneficiary of RUSNANO's investment is Panacela Laboratories—a joint venture between RUSNANO and Cleveland BioLabs in collaboration with the Roswell Park Cancer Institute, the Children's Cancer Institute of Australia, and the Cleveland Clinic Foundation. It received $25 million for oncology and the development of orphan drugs (pharmaceutical agents developed to treat a rare medical condition).[89] RUSNANO also invested $5 million in BiOptix Diagnostics.[90]

In March 2012, RUSNANO partnered with U.S. venture capital fund Domain Associates to invest $760 million in U.S. healthcare and pharmaceutical firms with the goal of bringing new drugs to the Russian market. The two partners have agreed to invest up to $330 million each in the life-sciences companies in Domain's portfolio. They have also agreed to invest up to $190 million in building a manufacturing facility in Russia for the products created by Domain companies to be sold in Eastern Europe. Under the agreement, roughly twenty existing and potentially new U.S.-based Domain portfolio companies will benefit from the collaboration. The partners can also co-invest in third-party technology.

In July 2012, the companies announced the first beneficiary: Domain's CoDa Therapeutics, a biopharmaceutical company focused on new technology for healing wounds. CoDa is licensing the rights to its technology to a Russia-based pharmaceutical company in exchange for $40 million in financing. As part of the deal, as with all RUSNANO life-sciences investments, CoDa is to establish research and development operations in Russia.[91]

In December 2012, RUSNANO and Domain announced that they would invest $93 million in three additional U.S. firms: Marinus Pharmaceuticals, which is developing a treatment for epilepsy; Lithera, which is working in aesthetic medicine and ophthalmology; and Regado Biosciences, which is working on antithrombotic products.[92]

In December 2012, the widely read *IN VIVO* blog nominated RUSNANO/Domain and CoDa Therapeutics for their Financing Deal of the Year Award. It noted that the deal "turns conventional wisdom on its head" by proving that emerging markets can, in fact, be a source of scientific and commercial innovation in the biopharmaceutical industry, rather than just a way to gain "near-term revenues and cost efficiencies." The blog remarked that, thanks to the deal, U.S. venture capitalists and biopharmaceutical companies are starting to take a closer look at Russia.[93]

Meanwhile, U.S. pharmaceutical companies are moving forward with some of their investments in Russia. Pfizer announced in July 2012 that it was going to use the Russian research and development group ChemRar High-Tech Center to produce Pfizer's type 2 diabetes product.[94] Simultaneously, Illinois-based Abbott Laboratories announced that it would be working with ChemRar's research institute to improve formulations of Abbott's existing drugs while pursuing new joint work on small molecular and viral disease treatments.[95] And at the high-profile 2012 BIO International Convention for Biotechnology in Boston, Merck Pharmaceuticals announced a deal with the Russian pharmaceutical company R-Pharm in which R-Pharm will have rights to develop and commercialize Merck's Hepatitis C inhibitor.[96]

Basic Research

While applied and translational research that translates in-the-lab findings into practical, real-word applications has been getting increasing funding and attention, funding for basic research projects, whose aim is to increase fundamental knowledge rather than offer immediate commercial benefits, has been harder to obtain. Joint U.S.-Russian basic research projects have also been slow to materialize.

Both sides must grapple with a simple lack of awareness of existing opportunities. The NIH reports having had low demand from Russian scientists for its grants. In fact, Russian scholars constituted only 1 percent of visiting scholars in the NIH Intramural Visiting Program in 2010—on par with Hungary, Turkey, and Poland and significantly below China (20 percent), India (13 percent), and Japan (9 percent).[97]

One of the channels of funding for such research is the parallel funding agreement between the NIH and the Russian Foundation for Basic Research. The program awards grants for collaborative research projects in HIV/AIDS prevention sciences. For the most recent funding cycle, the Russian Foundation for Basic Research is contributing $200,000 per project for two years, while NIH's share is $275,000 per project for two years.[98] Thirteen projects were selected through a bilateral peer review process and recommended for funding during the first funding cycle in 2012.[99]

The NIH National Institute on Drug Abuse and the NIH Office for AIDS Research have been particularly active in funding joint research projects in HIV/AIDS and multidrug-resistant tuberculosis. This form of TB is a rising concern worldwide, and the problem is particularly acute in Russia and the former Soviet republics. In 2011, 400,000 new TB cases were registered in fifteen states of the former Soviet Union—40 times the number reported in the United States. Of these, 80,000 were drug resistant. A release from the United Nations stated that "tuberculosis has now gone from probably the most

dangerous infectious disease in the world to definitely the most dangerous infectious disease in the world.[100]

Most recently, recipients of the NIH's National Institute on Drug Abuse grant evaluated the best combination of interventions for reducing the spread of TB in Russian prison populations. Included in the ongoing evaluation work is an assessment of a new TB diagnostic tool that instantly detects TB and its drug-resistant genetic mutations. Researchers predict that, assuming prisoners receive standard treatments, they can cut the prevalence of TB among inmates by 20 percent within four years.[101]

Until its departure from Russia, USAID supported projects aimed at TB prevention as well, sponsoring peer-to-peer exchanges in both countries.[102]

Addressing Legal and Regulatory Challenges

Ongoing regulatory challenges, problems with Internet protocol protection, corruption, and red tape are stalling progress in science collaboration and technology transfer. One key issue is that Russian universities until recently could not own the results of their research.

This is now changing. In 2009, Moscow passed legislation giving Russian universities the right to own and commercialize technologies that result from their research.[103] The United States took this important step in 1980 with the passage of the Bayh-Dole Act. Also known as the Patent and Trademark Law Amendments Act, this legislation granted U.S. universities control over intellectual property arising from federal-government-funded research.[104]

One of the projects built to support Russian universities in commercialization and technology transfer is the Enhancing University Research and Entrepreneurship Capacity project (EURECA). EURECA is a partnership between a select group of American and Russian universities that aims to build "a thriving ecosystem for advanced technology development and commercialization in Russia."[105] EURECA's chief goals are "to support Russian universities in the integration of academic programs, scientific research, and entrepreneurial activities; to strengthen university science commercialization and technology transfer; and to involve universities in collaborations aimed at producing relevant solutions to problems."[106]

Intellectual property rights is another emerging area of cooperation for the two countries. Because innovation is central to its national agenda, Russia is taking an increasingly serious approach to this issue. A new intellectual property rights court is being established at Skolkovo, and in October 2012, Russia held an international anticounterfeiting forum with the participation of Prime Minister Medvedev and other top-level officials.[107] The forum

addressed a wide variety of issues—from law enforcement to intellectual property concerns and the role of technology—as part of its mission to improve state policy in this area.

TASK FORCE RECOMMENDATIONS

Strengthening cooperation in biomedical research and innovation will be mutually beneficial for both countries. It is critical that the two sides find ways to enhance this cooperation. The task force made the following priority recommendations in the area of science cooperation and technology transfer:

1. **Continue cooperation on multidrug-resistant tuberculosis.** The growth of multidrug-resistant TB worldwide has been one of the most important healthcare-related trends in recent decades. Russia suffers from particularly high rates of the disease. Washington and Moscow can benefit from making cooperation in this area a priority.

2. **Increase funding available for scientific research.** Funding opportunities exist for scientific research, both joint and unilateral, on both sides, but they are limited and sometimes not well publicized. Increasing funding and improving information dissemination in the United States and Russia on policies and funding opportunities are essential to moving joint research projects forward.

3. **Facilitate networking among scientists to stimulate collaborative research projects.** Scientific collaboration depends in large measure on scientists designing collaborative projects based on their interests. Networking opportunities and bilateral meetings can help build relationships among scientists, physicians, grantmakers, government representatives, and other stakeholders.

4. **Develop new bilateral co-funding initiatives and programs.** Washington and Moscow must be equally invested in joint research projects. Joint funding opportunities should be developed through co-funding agreements. Public-private funding support should be tapped as well, relying on both U.S. and Russian philanthropic organizations partnering with pharmaceutical, biotechnology, medical device, and information technology companies.

The task force recommended the following specific initiatives within this framework that the two countries could undertake collaboratively:

1. Set up a web portal for principal investigators—the lead scientists or engineers for a particular project—and business to include:

- Information on "business to academia" and "business to nonprofit" public-private models of collaboration
- Links to NIH funding opportunities
- Links to non-NIH funding opportunities
- Links to government of Russia funding opportunities
- Links to venture capital funding opportunities and information.

2. Increase support for education and training programs such as those established by EURECA and others to create more robust bilateral cooperation in scientific research. This may include:
   - Engaging and taking advantage of the services offered by the NIH Office of Intramural Research Training and Education
   - Expanding extramural training opportunities at universities and research centers across the United States to support their Russian colleagues
   - Developing and supporting cross-agency training programs in intellectual property and technology transfer among, for example, the NIH, the FDA, the Department of Commerce, and other agencies
   - Developing and supporting public-private partnerships in clinical research training
3. Pursue funding opportunities from the U.S. government and the government of Russia through co-funding agreements that are based on:
   - Peer-reviewed NIH competitive grants and other U.S. government resources
   - Competitive grants from the Russian Ministry of Science and Education, Ministry of Industry and Trade, Ministry of Health, and the Russian Foundation for Basic Research
   - Public-private funding support for government and business partnerships through U.S. and Russian philanthropic organizations (such as the Foundation for the National Institutes of Health, which raises private funds and creates public-private partnerships to support the mission of NIH) and by partnering with pharmaceutical, biotech, medical device, and information technology companies.

REGULATORY CONVERGENCE AND HARMONIZATION SUBCOMMITTEE

AREAS OF FOCUS

Regulatory harmonization refers to the development of guidelines that are streamlined, or harmonized, across different national standards to ensure the safety, quality, and efficacy of pharmaceuticals circulating on the market. It is widely viewed as beneficial, as it can reduce the time and resources needed for drug development, help avoid the duplication of many time-consuming and expensive test procedures, and help prevent duplication of clinical trials in humans.[108]

Regulatory harmonization is a major challenge for foreign companies attempting to enter the Russian market. The rules governing Russia's import of drugs and medical devices are notoriously nontransparent, making it hard for U.S. companies to deliver much-needed drugs and devices to the Russian market.

Applying to be included in Russia's national drug list can also prove difficult. The lack of transparency and delays can prevent patients from receiving critical treatments as foreign drug manufacturers try to meet the system's requirements.[109]

Regulatory convergence and harmonization is particularly important for successful cooperation in the pharmaceutical realm. It results in faster and more transparent review and approval processes; reduces the cost burden for pharmaceuticals, as a harmonized format makes for a less expensive documentation-preparation burden; and facilitates the entry of local industry into regional and global pharmaceutical markets. For the public, harmonization results in improved access to necessary medicines and increases trust that those medicines that have been approved meet high quality, safety, and efficacy standards.[110]

Transitioning to International Standards

A key challenge that has prevented successful collaboration among Russian and U.S. pharmaceutical companies is Russia's lack of adherence to international standards known

as good manufacturing practice, a production and testing practice that helps to ensure that a pharmaceutical product meets the standards appropriate to its intended use. GMP has been used to diminish the risks inherent in any pharmaceutical production, in particular cross-contamination with unexpected substances and confusion that may be caused by mislabeling.[111]

Additional best-practice systems that are similar in their philosophy and intention to GMP include good laboratory practice for labs conducting nonclinical studies and good clinical practice for hospitals and clinicians conducting clinical studies on new drugs in humans.[112]

The best-known and most widely followed GMP standards are those developed by the World Health Organization, and GMP rules in the United States and the European Union closely cohere to those standards. One hundred and forty countries participate in the World Health Organization's GMP rules, but Russia has so far failed to meet the complex set of preconditions required for a country to join the system. These include availability of a state pharmaceuticals registration system, regular state inspection of pharmaceutical manufacturing facilities, and compliance of existing manufacturing facilities with the GMP requirements.

Under the Pharma-2020 program, Russia is committed to transitioning to GMP. By January 1, 2014, new GMP rules are expected to come into effect in Russia, enabling it to join the World Health Organization's system.[113] In the meantime, a series of administrative measures is being implemented, including the development of rules and regulations to ensure that the transition takes place.

But the cost of the transition will be high, and the process will likely take longer than anticipated. As of March 2011, only 10 percent of Russia's 1,100 production facilities were equipped in full compliance with GMP standards. Forty percent of facilities partially complied, and 50 percent did not comply at all. Some 10,000 personnel will have to be retrained.[114] Regulatory authorities will have to be trained as well, in accordance with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme, two international bodies that provide active instruction in the GMP field.

The United States is already doing a great deal to support Russia's transition to GMP and GCP. The FDA is collaborating with its Russian counterpart, Roszdravnadzor, through discussions and experience-sharing exercises. The FDA has conducted a multiphase training program in GCP for Roszdravnadzor representatives, Roszdravnadzor's territorial counterparts, and ethics committees at universities and medical schools. In addition, private companies are conducting training sessions and supporting Russian pharmaceutical companies in getting their facilities up to GMP standards.

Clinical Trials

Pharmaceutical companies are also prioritizing the harmonization of industry-sponsored clinical trials. Companies have been expanding their trial sites from traditional locations in North America and Western Europe to other parts of the globe, choosing locations based on the opportunity to reduce costs and accelerate the growth of their market share.[115] Russia has become one of the most rapidly growing non-Western sites for industry-sponsored clinical trials.

One of the reasons behind this is the fact that Russia and the United States do not currently have a mutual clinical trial recognition agreement. Furthermore, in 2010, Russia passed a law mandating that any foreign drug to be marketed in Russia also be tested on Russian citizens. This complicates and raises the costs of market entry. But it also provides access to new groups of patients, which can be beneficial for pharmaceutical companies as they develop new products.

Russian patients have been actively enrolling in clinical trials—in part because participating in the trial is, for some, the only way to receive medical care.[116] The number of clinical trials in Russia increased from 201 in the first six months of 2011 to 448 in the same period in 2012—an increase of 123 percent.[117]

Medical Devices

Medical devices are among the top U.S. exports to Russia, but the quantity exported is still paltry. Regulation is complex and involves a number of different regulatory authorities, including Roszdravnadzor, Gosstandart, and Rospotrebnadzor.

Russia has benefited in this regard from its membership in the Asia-Pacific Economic Cooperation, which helps its member economies develop robust regulatory systems for medical devices.[118] These systems may serve as a model to help U.S. medical-device manufacturers establish productive relationships with their Russian counterparts.

TASK FORCE RECOMMENDATIONS

Regulatory convergence and harmonization across national standards is critical to ensuring that both countries can cooperate effectively in the area of pharmaceutical development. Without harmonized regulatory frameworks, the delivery of critically important medicines to patients and the development of new pharmaceuticals will be delayed.

The task force made the following priority recommendations in the area of regulatory convergence and harmonization:

1. **Create a platform for ongoing U.S.-Russian regulatory cooperation.** While the U.S. Food and Drug Administration and the Russian regulatory agency Roszdravnadzor have formed a collaborative relationship through mutual visits, training, and capacity-building programs, a more solid platform for ongoing dialogue is needed. The example of the European Commission, whose regulatory agencies conduct twice-yearly meetings with their Russian counterparts to ensure that current issues are regularly addressed, may be instructive in this regard and should be studied.

2. **Support the Russian pharmaceutical industry's move to good manufacturing practice standards.** This is a critical precondition for Russia to build up its own competitive pharmaceutical sector. Russia has committed to move to good manufacturing practice standards, but it will require resources and know-how. The U.S. government and private companies have both, and they should become actively engaged in Russia's transition.

3. **Lay the groundwork for mutual recognition of clinical trials conducted in the United States and Russia.** A bilateral agreement on the mutual recognition of clinical trials conducted in the two countries would increase both international pharmaceutical investments in Russia and drug access for Russian citizens.

The task force recommended the following specific initiatives for the two countries to undertake collaboratively:

1. Encourage the private sector and civil society to sustain the momentum of public-private partnership to support harmonization efforts during times that often prove unfavorable for cooperation, such as political transitions.

2. Facilitate exchanges among health professionals and specialists in Russia and the United States through academic symposia, regional site visits, and small-scale pilot projects.

3. Introduce recommendations on pharmaceutical quality, cost structures, and competition.

4. Facilitate transparency with regard to the "dry list" of products set aside for local manufacturing.

5. Form a U.S. expert group to collaborate and advise the Russian government on establishing guidelines for clinical standards. Russia is still developing such standards and can benefit from the United States' significant experience in this area.

6. Ensure that standards for medical care reflect current understandings of the biological basis for disease and peer-reviewed scientific evidence of the effectiveness of treatments. Guidelines should account for the inevitable variability among patients and the idiosyncratic character of treatments and, therefore, permit appropriate flexibility in their application. The United States and Russia should work together to study the role of private, professional organizations alongside government bodies responsible for guideline development.

7. Move toward attaining some level of bilateral regulatory harmonization by encouraging regulatory agencies in Russia and the United States to focus on collaborating to harmonize procedures aimed at the review (including ethical review), approval, registration, and follow-through monitoring of clinical trials.

8. Promote collaboration between regulatory agencies in Russia and the United States to harmonize legislation pertaining to the conduct of clinical research for nonpharmaceutical medical products.

9. Encourage the private sector to contribute expertise in the organization and conduct of clinical trials of medical devices and interventional procedures.

10. Sustain collaboration of the U.S.-Russia Working Group on Rare Diseases that was established under the U.S.-Russia Health Forum.

11. Provide access to lifesaving and life-extending drugs from foreign pharmaceutical companies to the many people in Russia who cannot obtain them because of regulatory barriers. Harmonized regulation and collaboration on orphan drugs could allow these drugs to enter the market.

12. Facilitate rare disease biomedical research and education as well as the creation of an orphan drugs regulatory framework and orphan drug legislation.

13. Develop an agreement on the mutual recognition of clinical research data on orphan drugs.

14. Collaborate on a platform for developing a strong, science-based regulatory pathway for biosimilars—pharmaceutical formulations that are based on licensed biotechnology medicines. Biotechnology medicines are derived from a biological

source, rather than as a product of chemical synthesis. Like generics, biosimilars are cheaper to produce than the original, licensed formulations, which makes them an attractive cost-saving option. However, they are far more complex than generics, and their use raises a host of new issues, including quality and safety, and relevant regulatory and legal issues. Biotechnology medicines and biosimilars are a new phenomenon globally, and all countries where they are used struggle with these concerns. Russia and the European Union are further ahead in this dialogue. The United States and Russia would benefit from creating their own forum for discussing these issues and paving the way for global solutions to these issues. Among the areas they can address are creating unified regulatory guidelines concerning the data required for the approval of biosimilars, including guidelines on quality, nonclinical and clinical issues as well as product-specific guidelines, and agreeing upon safety standards for all biotechnology medicines.

CONCLUSION

The latent potential of U.S.-Russian engagement in public health is significant. From enhanced scientific cooperation to the joint promotion of healthier lifestyles to developing new investment avenues, deeper bilateral engagement in this area would benefit the two countries and the world.

Some aspects of this cooperation are already breaking new ground. RUSNANO's extensive investments in the United States have defied conventional wisdom by demonstrating that Russia can be the one investing in global industry and that it can do so through creative, win-win approaches. And the new multidrug-resistant TB testing device that was developed by NIH-sponsored American scientists working with their Russian colleagues could have a meaningful impact on containing the disease not just in Russia but around the globe.

Reaching the full potential of this collaboration will require ongoing commitment and political will. That is where the BPC Working Group on Health should take the lead. The BPC should be proactive in driving the dialogue forward and making sure the two governments continue to engage with one another, while also inviting the private sector, NGOs, the scientific and professional community, and other stakeholders to the table. Only such

multisectoral engagement can provide all the ingredients—political will, resources, technological know-how, and local knowledge—necessary to move cooperation forward.

The BPC Working Group on Health must continue to focus on outcomes. It is important that it maintain this course unwaveringly, following through on initiatives and turning ideas into action.

Finally, the BPC should not be afraid of bold steps. Many of the problems that have consistently plagued the two countries' healthcare systems may yet be solved by stepping back, taking a big-picture view, and engaging in some truly creative thinking. Ongoing dialogue and sharing of ideas may provide fertile ground for the kinds of insights and creative approaches that could give rise to such solutions. Cooperation between the public and private sectors is critical to achieve that.

The recommendations outlined in this report are meant to help unleash the full potential inherent in U.S.-Russian public health cooperation. The BPC possesses the necessary clout to make this happen. Its Working Group on Health should use it to lead the two countries forward.

ABOUT THE PUBLIC-PRIVATE TASK FORCE ON U.S.-RUSSIAN HEALTH COOPERATION

Critical task force funding came from the Pharmaceutical Research and Manufacturers of America, a trade group representing leading American pharmaceutical research and biotechnology companies, and the Richard Lounsbery Foundation, which aims to enhance national U.S. science and technology capabilities, international scientific cooperation, and science diplomacy.

APPENDIX: TASK FORCE PARTICIPANTS

The following individuals participated in various task force activities:

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3. Joshua Abrams, Campaign for Tobacco-Free Kids
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5. Mateo M. Ayala, U.S. Embassy, Moscow
6. Edward J. Burger, Institute for Health Policy Analysis
7. Cathleen A. Campbell, CRDF Global
8. Bram Caplan, Skolkovo Institute of Science and Technology
9. James Carden, U.S. Department of State
10. James Class, Merck & Co., Inc.
11. Nils Daulaire, U.S. Department of Health and Human Services
12. Elena Dmitrieva, Healthy Russia Foundation
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14. Carly Dougherty, Campaign for Tobacco-Free Kids
15. Jeffrey Ellis, U.S. Department of State

16. Harvey Fineberg, Institute of Medicine
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50. Glenn Schweitzer, National Academy of Sciences
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58. Judyth Twigg, Virginia Commonwealth University
59. Dmitry Yanin, Interrepublican Confederation of Consumer Societies
60. Vladimir Zelensky, Russian Ministry of Health and Social Development

NOTES

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