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# USSR: Upgrading the Pharmaceutical Industry



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A Research Paper

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# USSR: Upgrading the Pharmaceutical Industry

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**A Research Paper**

This paper was prepared by [Redacted] Office of  
Soviet Analysis, with contributions from [Redacted]  
[Redacted] the Office of Scientific and Weapons Research  
and [Redacted] the Office of Leadership  
Analysis. [Redacted]

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Comments and queries are welcome and may be  
directed to the Chief, Economic Performance  
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**USSR: Upgrading the  
Pharmaceutical Industry**


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**Summary**


*Information available  
as of 1 April 1988  
was used in this report.*

Increased availability of pharmaceuticals and vaccines could substantially improve the health and morale of the Soviet people. Insufficient supplies of pharmaceuticals have resulted in increases in the infant and child death rate, poor nutrition, a high death rate from strokes and heart attacks, and extended recovery periods from illness. The Soviets report that each year the 3.5 million people absent from work because of illness cost the economy 12-20 billion rubles in lost production. 


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The leadership has begun to recognize the economic cost of poor health care and the vital role that pharmaceuticals play in the prevention and treatment of illness. According to one Soviet medical official, "use of modern treatment methods including new pharmaceuticals could save 2-3 billion rubles paid for sick leave" over a five-year period. 

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The pharmaceutical industry is a microcosm of Soviet industry, displaying many of the problems that the leadership is trying to address in restructuring the economy. Output of the pharmaceutical industry has grown rapidly, but the industry is plagued by shortages and erratic supplies of raw materials and a relatively low technological base. Like other Soviet industries producing consumer goods, it has had neither the capital nor the incentives needed for technological innovation. As a result, most of its enterprises are equipped with machinery and processing facilities that Western companies would consider obsolete, uneconomical, and unhygienic. Other deficiencies include excessively long research-to-production cycles, poor planning and management, an undisciplined work force, and inadequate quality control. Furthermore, pharmaceutical prices, which are set by the state, often are not high enough to compensate enterprises for the costs of modernizing. 

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An ineffective distribution system compounds the effects of production problems. Although the number of pharmacies and pharmacy personnel has grown over the last 15 years, the system is hampered by shortages of pharmaceuticals and storage facilities, poor management and training, insufficient automation, lack of incentives, theft, and black-market activities. And, because there is no organized mechanism for systematically providing information about drugs to physicians and the public, some patients do not receive available medications. 

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To improve supplies of pharmaceuticals to the Soviet consumer, Gorbachev has:

- Merged the Ministry of the Medical Industry with the Main Administration of the Microbiological Industry and replaced ineffective leaders.
- Accelerated technological progress in medical and biomedical research and development.
- Improved labor discipline and cracked down on the black market.
- Set plans to triple investment allocations for the Ministry of the Medical and Microbiological Industry (MMMI)—which produces the bulk of the country's pharmaceuticals—in 1986-90.
- Expanded the network of pharmacies to improve distribution and increased the funds health-care institutions can spend for medications.

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Ongoing changes will marginally improve availability of medicines in the next five years, but sufficient amounts of many types of pharmaceutical products will still be lacking, especially in rural areas. Unless the problem becomes more important in the eyes of the populace, leadership attention will remain focused on those sectors critical to industrial modernization and on those that will have an impact on popular perceptions of improvements in living standards. If Moscow does not follow through with the resources and incentives to signal a real change in priority, the Soviet consumer will continue to be shortchanged in supplies of new antibiotics, vitamins, and anticancer and cardiovascular drugs. [redacted]

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Moscow could alleviate domestic shortages of medicines by increasing imports. Most of any increase will come from East European countries—the major suppliers today—under intra-CEMA product exchanges, but these countries cannot offer the scale of support needed. Imports of medicines and equipment from the West are also likely to increase, but hard currency constraints probably will limit purchases to high-priority commodities. The Soviets generally purchase from the West only sophisticated medicines not available domestically or from CEMA countries. These are usually bought in relatively small quantities for use in special medical facilities or for laboratory analysis and clinical trials in domestic drug programs. [redacted]

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Opportunities exist for Western sales of production licenses and plants, particularly in the biotechnology area, and the Soviets also are interested in joint ventures with Western firms. They are currently negotiating with US, French, and Japanese companies for jointly operated pharmaceutical plants in the USSR. In addition, Moscow will continue to seek access to Western research programs, chemical and microbiological products, and technology through scientific-technological cooperation agreements with Western companies. [redacted]

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This approach, however, faces long leadtimes and an uncertain future. Meanwhile, a failure to substantially increase the availability of pharmaceuticals—from either domestic or foreign sources—will leave Soviet health care more on a par with that in the Third World than that in the developed West. At present, the Soviet populace seems inured to this situation, but morale could be seriously affected if health problems increase or the labor force becomes more knowledgeable about the relative state of Soviet health care. [redacted]

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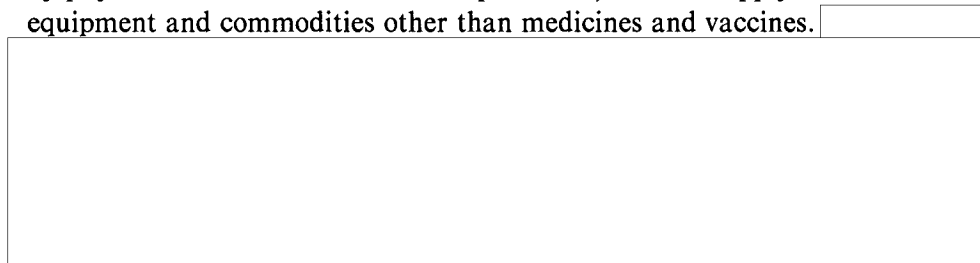


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**Scope Note**

This study examines problems of pharmaceutical production and distribution, steps that have been taken to improve supplies, and prospects for success. It addresses the role pharmaceuticals play in improving the health of the labor force, but does not address other aspects of the Soviet health-care system, such as the adequacy of medical facilities, services provided by physicians and other health-care personnel, and the supply of medical equipment and commodities other than medicines and vaccines.

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## USSR: Upgrading the Pharmaceutical Industry [Redacted]

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### The Impact of Insufficient Pharmaceutical Supply

The USSR suffers from widespread shortages of pharmaceuticals and vaccines. According to a recent *Izvestiya* article, only 80 percent of the population's requirements for medicines are being satisfied and only 60 percent of needs for cardiovascular preparations are met.<sup>1</sup> Major deficiencies include:

- The insufficient quantity and poor quality of vaccines for infectious diseases.<sup>2</sup>
- Shortages of vitamin supplements, particularly vitamins B, C, and D.
- Insufficient drugs to treat cancer and cardiovascular diseases.
- Shortages of new antibiotics to treat infections as bacteria become more resistant to existing medications.
- Lack of sufficient antihypertensive medications.
- Sporadic availability of medications to treat chronic diseases. [Redacted]

As a result, the health of the Soviet populace has been jeopardized. According to data of the Ministry of Health, 3.5 million people are absent from work each year because of claimed illness, resulting in production losses of 12-20 billion rubles.<sup>3</sup> Inadequate supplies of pharmaceuticals and vaccines manifest themselves in several ways:

- The incidence of largely preventable infectious diseases remains relatively high (see table 1). [Redacted] some 30 to 50

[Redacted] such staples of modern medical treatment as Tagamet for ulcer disease, Sinemet for Parkinsonism, beta blockers and calcium channel blockers for angina and hypertension, and antihistamine-decongestant preparations for the relief of common cold symptoms are extremely hard to obtain. [Redacted]

<sup>2</sup> Although vaccines are not technically classed as pharmaceuticals, they have been included in our discussion as preparations produced to prevent disease. [Redacted]

<sup>3</sup> A Soviet medical official recently claimed that annual payments for sick leave exceed 7 billion rubles and that use of modern treatment methods including new pharmaceuticals could reduce the duration of illnesses and save 2-3 billion rubles over a five-year period. [Redacted]

percent of children in their first year of life are not inoculated against diphtheria. The incidence of measles in the USSR is on a par with that of Brazil. A Western study reports that the effectiveness of Soviet-made vaccines is very low compared with Western products, particularly those against influenza, measles, mumps, and typhoid.

- The lack of proper nutrition in the Soviet diet and shortages of vitamin supplements have resulted in widespread vitamin deficiencies. An article in *Izvestiya* in December 1985 reported that the average citizen is getting only 60 to 70 percent of the vitamins needed for proper nutrition. The lack of vitamin supplements affects most severely mothers who are breast-feeding, infants, and other vulnerable groups.

- Infant and child death rates remain high. Surgery on newborns is more precarious than need be because of a lack of good antibiotics. Childhood diseases are frequently fatal because of shortages of medications and vaccines, particularly in rural areas and small towns.

- Hospital death rates are high. Chronic illnesses are rarely treated successfully because of the sporadic availability of medications; thus, recovery periods are prolonged. Staphylococcus infections are rampant in hospitals because of the lack of good antibiotics.

- Death rates from strokes and heart attacks are high. Very few antihypertensive drugs are available to the majority of the population.

- A widespread black market in prescription drugs has evolved because of chronic shortages of medicines and the low wages of pharmacy and medical personnel (see inset). [Redacted]

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**Table 1**  
**Incidence of Selected Infectious Diseases**

*Cases per 100,000 persons*

	1960	1970	1980	1985	1986
<b>Typhoid/paratyphoid</b>					
USSR	22	9	6	6	5
United States	0.45	0.17	0.22	0.16	NA
<b>Scarlet fever</b>					
USSR	313	194	87	100	128
United States <sup>a</sup>	174	211	162	NA	NA
<b>Diphtheria</b>					
USSR	24.8	0.45	0.13	0.55	0.41
United States	0.5	0.21	0.001	0.001	NA
<b>Whooping cough</b>					
USSR	259	16	5	19.4	6.3
United States	8	2	0.7	1.4	NA
<b>Tetanus</b>					
USSR	1.1	0.27	0.11	0.10	0.09
United States	0.2	0.07	0.04	0.03	NA
<b>Acute poliomyelitis</b>					
USSR	3.3	0.11	0.06	0.05	0.06
United States	1.8	0.02	0.01	0.002	NA
<b>Measles</b>					
USSR	972	194	134	98	59
United States	244	23	6	1	NA

<sup>a</sup> Including streptococcal sore throat.

Source: *Narodnoye khozyaystvo SSSR za 70 let* and *Statistical Abstract of the United States*, 1987.



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**Performance of the Industry**

The pharmaceutical industry is a microcosm of problems pervading Soviet industry as a whole and reflects all of the symptoms that the leadership is trying to alleviate in its restructuring program. Output of the industry has increased substantially since 1970, but production still lags behind the growing requirements of the health service, according to the former head of the Ministry of Health's Main Pharmaceutical Administration (GAPU), Mikhail Klyuyev. Moreover,

overall growth rates have been falling in recent years (see table 2).<sup>4</sup>

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<sup>4</sup> The Ministry of the Medical and Microbiological Industry accounts for 90 percent of domestic output of medicines and medical equipment. GAPU controls over 80 factories that use simple technologies to produce medicines from plants. Important raw materials and other medically related commodities such as glucose, menthol, and endocrine preparations are produced by enterprises of the Ministries of Light Industry; the Chemical Industry; the Petroleum Refining and Petrochemical Industry; the Construction Materials Industry; the Timber, Pulp and Paper, and Wood Processing Industry; and the State Agroindustrial Committee.

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**Black-Market Activities**

[redacted] 20 percent of the narcotics used by drug abusers in the USSR come from medical institutions. Drug dealers also obtain narcotics from medical supplies for geological teams going to remote areas and from civil defense kits.<sup>a</sup> [redacted]

A September 1986 article in *Kommunist Tadzhikistana* reported that the republic's pharmacy system is inundated with false inventory reports, embezzlement, and forgery. The author noted that at the central pharmaceutical warehouse in Dushanbe a shortage of 7,000 rubles' worth of drugs was covered up by an accountant to show only a 274-ruble shortage. These drugs undoubtedly found their way onto the black market. In Uzbekistan, special reserves of drugs that are maintained for infants and war veterans ended up in the possession of various pharmacy managers. Inspectors who checked several hundred prescriptions for drugs in very short supply found that almost one-half were forged. [redacted]

<sup>a</sup> Narcotics are often stolen with the cooperation of storekeepers. According to a Soviet emigre, ampules in the civil defense kits containing promedolum, a strong narcotic, are replaced with ones containing water or analgin, a mild painkiller. Storekeepers are paid 1.5 to 2 rubles per ampule; promedolum ampules can fetch 10 rubles on the black market. [redacted]

Some drugs are only available from relatives or friends abroad or on the black market, where the supply is sporadic and the price high. Patients are often encouraged by their physicians to obtain pharmaceuticals that are not available in the USSR from abroad through friends and relatives. Certain drugs used in chemotherapy can cost up to 10 times the official price on the black market. Other medications are available under the counter—for a price—at pharmacies. [redacted]

According to a Soviet emigre, a black market even exists inside hospitals. Patients often have to pay extra for anesthetics and certain medications that are nominally free under the Soviet health system. Diversion of pharmaceuticals intended for patients in hospitals is illustrated by a May 1987 article in *Pravda vostoka* that describes a situation at the Ilyichevsk Central Rayon Hospital in Uzbekistan where one-half of the obstetrical and gynecological patients did not receive many of the drugs prescribed by their physicians. Inspectors found that the head nurse had 107 of these medicines available, but only 20 were being used routinely. Similar situations have been uncovered at other Soviet hospitals. [redacted]

**Production Problems**

The most important problems are shortages and erratic supplies of raw materials and the low technological levels of factories. Inadequate supplies of raw materials from other ministries, particularly the Ministry of the Chemical Industry, have hindered production. Moreover, the Soviets have not adequately developed small-tonnage and high-purity chemicals such as reagents, which are critical to pharmaceutical production. [redacted]

The pharmaceutical industry, like others producing consumer goods, traditionally has had a low priority for resources and has not used its investment funds

efficiently.<sup>5</sup> As a result, many of the industry's enterprises have machinery, equipment, and facilities that are obsolete and uneconomical. Difficulties in obtaining suitable replacement machinery and equipment from other ministries result in low-quality output, above-norm repair expenses, and high operating costs. [redacted]

<sup>5</sup> Capital investment allocated for the medical industry's development in 1981-85 was 1.3 times greater than that in the previous five-year period, and more than 80 new plants started up. However, only 78 percent of capital investment allocated for 1985 was used. [redacted]

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**Table 2** *Average annual percent*  
**USSR: Growth of**  
**Medical Industry Output**

	1971-75	1976-80	1981-85 <sup>a</sup>
<b>Total</b>	<b>11.6</b>	<b>9.6</b>	<b>7.0</b>
Of which:			
Prepared medicines <sup>b</sup>	8.7	8.5	6.7
Antibiotics and organic preparations	11.7	12.6	9.0
Vitamins	19.8	9.9	6.6
Synthetic medical substances	8.0	8.1	7.1

<sup>a</sup> Calculated on the basis of planned 1985 output.

<sup>b</sup> Including processed medicinal plants.

Source: Christopher Davis, "Developments in the Health Sector of the Soviet Economy, 1970-90," in *Gorbachev's Economic Plans*, study papers of the Joint Economic Committee, Congress of the United States, Washington, 1987.

only 35 percent of the demand for equipment needed to manufacture medicines is currently being satisfied. Moreover, the equipment that is available is often of poor quality.

The quality of output also is affected by poor hygienic conditions, below-standard raw materials, and pressure to fulfill ambitious production targets. According to a former Soviet physician, doctors are often wary of using domestically produced injectable penicillin and streptomycin because of poor quality control.<sup>6</sup>

#### Problems of Technological Innovation

In spite of Soviet claims of substantial development of new medicines, Soviet biomedical research and development remains characterized by low technological

<sup>6</sup> Because of the large number of visible crystals in domestically manufactured penicillin solutions and the poor quality of antibiotics in general, Soviet physicians prefer higher quality antibiotics from Poland.

levels, poor-quality research materials, rigid hierarchies in scientific institutions, and isolation from world developments. A July 1986 article in *Meditssinskaya gazeta* assessed the situation:

*Great claims are made by scientific-research and design institutes. But up to now they still do not satisfy the demands for new economic and effective technologies, they know poorly the problems of production, and the quality of their contributions lags behind international standards.*

Research and development institutions themselves are also partly to blame for sluggish technological innovation. They often fail to recognize what is new, engage in irrelevant projects, and frequently cannot produce results after spending excessive amounts. It was noted at the 27th CPSU Congress that the Scientific-Research Institute for Biological Testing had not produced a single medical preparation, after having spent 50 million rubles during a 12-year period.

Another example, according to the head of MIMI, is the All-Union Scientific-Research Institute of Biotechnology, which "in all of the years of its existence, has so far failed to come up with a single significant development that has broad application in the industry."

As with many other civilian industries, the gap between research and production presents another organizational obstacle to innovation. Of the 30 to 35 pharmaceutical products introduced each year, less than one-third are original Soviet formulations. This may be explained in part by the difficulties encountered in getting a Soviet pharmaceutical into production. It takes an average of eight to 12 years in the USSR to create a new pharmaceutical preparation, and research institutes have no real leverage, or incentive, to press factories to put the results of this research into production. An article in *Izvestiya* in

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1985 cited the example of a sorely needed drug for the treatment of alcoholism that was developed over a decade ago. After impressive initial and clinical trials, the drug was recommended for production. The Kazan' Chemical Technology Institute developed and documented a simple, inexpensive method of production. The task of making the drug was presented to the Ministry of the Chemical Industry, which had the facilities for the production of trial batches, but after several years none of the drug had been produced. According to the head of the pharmacology faculty at Kazan', a number of other products have had a similar fate. Even in cases where institutes and enterprises have been linked and experimental factories have been established to expedite production of laboratory discoveries, the industrial enterprises frequently have tasked those facilities to mass-produce existing goods in short supply rather than to manufacture new products. [redacted]

Another problem is the dispersion of biomedical research and development facilities throughout the Soviet bureaucracy. Drug development involves basic research, applied research, prototype development, laboratory testing, animal testing, clinical trials, registration, trial production, quality control testing, and mass production. The entire development process may involve the Academy of Sciences, the Academy of Medical Sciences, the Ministry of Health, MMTI, the State Committee for Science and Technology, and various other ministries and organizations that produce needed equipment and chemicals. Coordinating such operations is extremely difficult; as a result, only a small share of laboratory discoveries ends up as medicines for the public.<sup>7</sup> [redacted]

The main reason that the pharmaceutical industry has been slow to innovate is the absence of effective incentives. Producers face no effective domestic competition, operate in a shortage environment, are protected from foreign competition, and are judged on the basis of fulfillment of quantitative plans rather than consumer satisfaction. As a result, managers

<sup>7</sup> Minister of Health Yevgeniy Chazov noted in a recent speech that, of the 373 preparations approved for clinical use during 1981-85, only 15 to 20 are widely used. [redacted]

prefer to stick to old methods and products rather than risk introducing new technology. A December 1985 Soviet press article commented:

*The reality is that for the enterprise it is more profitable to gradually increase its indicators by traditional "debugged" processes than to get involved with new technology or new preparations. Innovation demands additional investment, the acquisition of equipment, reconstruction of shops or sections, an increase in energy expenditure and much more, which will pay off not tomorrow but in the future. This frightens many directors, all the more because with the existing system of planning and rewards one can be in the vanguard without introduction of new processes or products.*

Furthermore, pharmaceutical prices, which are set by the state, often are not high enough to compensate enterprises for the costs of modernizing, particularly under the new conditions of self-financing and "full economic accountability." [redacted]

#### **Problems in Supplying Pharmaceuticals**

Despite a relative abundance of pharmacies and pharmacists, the system cannot provide an adequate supply of medicines to the population (see inset "The Soviet Pharmacy System"). It experiences chronic difficulties in obtaining sufficient goods from both the domestic medical industry and foreign trade organizations. Planning errors and poor organization exacerbate the situation. [redacted]

**Drug Shortages—Real and Imaginary.** Nationwide, new medications are unavailable from pharmacies or are in such short supply as to make them ineffective in treating chronic illness. Under conditions of limited supply, it is extremely important to get the right medicines to patients promptly. Drugs suffer from the same bottlenecks in distribution as other industrial products, but, in addition, GAPU's errors in estimating drug needs cause both shortages and large stocks of medicines whose expiration dates pass, rendering

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**The Soviet Pharmacy System**

The Ministry of Health controls most pharmacies through GAPU, which operates on a self-financing basis designed to provide profits from sales. Several other ministries are also involved in providing pharmaceuticals. The Ministry of Railways, for example, manages its own system of over 1,000 pharmacies. The Ministry of Defense also maintains an independent pharmaceutical system. [redacted]

From 1971-85 the number of pharmacies increased by nearly 30 percent, to 29,516. During the same period the number of pharmacists increased by 62 percent, to 271,300, compared with 172,000 in the United States in 1985. According to a Western study, sales of medicines by the pharmacy network grew 150 percent between 1970 and 1985 to reach nearly 3.5 billion rubles. [redacted]

Sales to medical facilities such as hospitals and clinics are at wholesale prices, by written order only, and are financed by the state. Medicines administered to patients on the premises are provided free of charge. Soviet consumers can also buy pharmaceutical products directly from pharmacies. Medicines are given free to infants under one year of age, war invalids, and those suffering from specific illnesses. [redacted]

In the USSR, retail prices are relatively low, but the patient very often is unable to obtain necessary prescription and nonprescription drugs. In the United States, in contrast, the pharmaceutical system is relatively expensive at the point of purchase but efficient in supplying US patients and hospitals with precisely what is prescribed when it is needed. [redacted]

them useless. As an example of inefficiency, GAPU has also been criticized for importing medicines that are no more effective than domestic drugs. [redacted]

Widespread shortages of pharmaceuticals stem from a variety of causes other than production problems. These include lack of funds to maintain adequate

inventories, poor stock control, regional supply imbalances, improper use, and hoarding (see inset "Drug Shortages: Guaranteeing Inadequate Health Care"). Pharmacies with adequate stock on their shelves, for example, may not have the funds to buy replacements until their existing stock is sold. Patients often cannot obtain medicines that are in the pharmacy warehouse and sometimes in the pharmacy itself because of negligent pharmacy workers. Even in hospitals, patients frequently do not receive the full course of drug treatment. As a result, a patient's family often has to purchase drugs on its own because of inadequate supplies in hospital pharmacies. [redacted]

Many of the most effective drugs are available only to VIPs.<sup>8</sup> In addition, private hoarding, encouraged by temporary availability and the low prices of certain domestically produced drugs, is widespread. Consumers as well as pharmacies needlessly stockpile medicines to insure against future shortages. Exacerbating these supply problems is the frequent use of unnecessary or nonprescribed drugs for illnesses that should be treated with other drugs or with nondrug therapy. [redacted]

**Infrastructure and Personnel Problems.** Although seemingly adequate on a national basis, the network of pharmacies is still insufficient in Armenia, Azerbaijan, Tajikistan, Kirgizia, Kazakhstan, Turkmenia, the Moldavian SSR, and in a number of oblasts and rayons of the RSFSR. According to a September 1986 article in *Kommunist Tadzhikistana*, for example, the national ratio of pharmacies to population is nearly twice that of Tajikistan. Pharmacy personnel also are unevenly distributed. For example, the number of pharmacists and pharmaceutical technicians per capita in many oblasts in Central Asia and Kazakhstan is only 50 to 75 percent of the national

<sup>8</sup> [redacted] certain Western pharmaceuticals such as lekoverin and prednisone are available in the USSR only for inpatient treatment of VIPs. These drugs were never found in pharmacies, and physicians were not allowed to prescribe them. The Ministry of Internal Affairs and the KGB reportedly routinely stockpile Western pharmaceuticals at the expense of ordinary Soviet citizens. [redacted]

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**Drug Shortages: Guaranteeing Inadequate Health Care**

Stories abound about Soviet hospitals and clinics unable to supply a full course of drug treatment, dentists working without adequate supplies of anesthetics, and chronically sick people living month to month, never sure whether their prescriptions can be refilled. The following examples are typical of the widespread problems in pharmaceutical supply:

- a pamphlet issued by the Pharmaceutical Administration of Novosibirsk. Of 216 primary medications listed for specific illnesses, only 23 were actually available to practicing physicians. Moreover,  secondary and tertiary alternatives on the list were considerably different in pharmacological properties from their counterparts. Furthermore, only one-half of the 216 drugs were even produced domestically.
- A 1986 article in Sovetskaya Rossiya reported that at the central pharmacy in Khabarovsk—which has a reputation for being well supplied—it was impossible to obtain several ordinary drugs such as

analgin or nitroglycerin. In Kalinin Oblast planned supplies of insulin covered only one-half of the known cases of diabetes in the region.

- An article in Pravda vostoka in May 1987 complained that burn patients in Samarkand Oblast Hospital were not treated with 14 needed drugs that were available in the hospital pharmacy. Although the pharmacy at Khavast Central Rayon Hospital was supplied with a dozen effective antihypertensive agents, only Epsom salts, which is ineffective, was routinely prescribed.
- According to a Soviet emigre, at City Hospital No. 51 in Moscow, only the very basic medicines were routinely available. Antibiotics, narcotics, and effective analgesics were always in short supply. A Soviet acquaintance of a US Embassy official recently told him that, after an appendectomy in a Soviet hospital, her daughter's incision had to be reopened three times because of infection. This was done without anesthesia—a frequent occurrence—because the hospital rewarded doctors and nurses for saving antibiotics and painkillers. In most hospitals, abortions often are performed without effective anesthesia.

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average. The shortage of these specialists lowers the quality of drug services and impedes improved drug supply to the public.

In spite of a 60-percent increase in the area of pharmaceutical warehouses in 1976-84, storage facilities are still inadequate throughout the country, contributing to pharmaceutical shortages and distribution problems. For example, in Tajikistan only 40 percent of the republic's pharmacies have warehouses, and many do not have adequate refrigeration. The lack of refrigeration in some warehouses, where temperatures reach 40° C (104° F) or more in summer, results in deterioration of pharmaceutical products.

The complexity of modern diagnostic and treatment methods demands better training of pharmaceutical specialists. University pharmaceutical science programs were criticized in a report at the June 1985 plenary meeting of the CPSU as being generally obsolete. The report claimed that graduates of pharmaceutical schools are not familiar with the most recently developed medications that are available. To increase the number of trained pharmacists, pharmacy departments have been opened at medical institutes in Kirgizia, Tajikistan, Turkmenia, and in a number of cities in the RSFSR.

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Low average wages and the lack of adequate wage differentials for pharmacy personnel have had an adverse effect on the quality and quantity of labor supply and on work performance.<sup>9</sup> To improve the efficiency of pharmaceutical workers, the former head of GAPU suggested in mid-1986 that they be given material incentives commensurate with their personal contribution.<sup>10</sup> He also recommended that the country's pharmacies incorporate the brigade form of labor, which is designed to improve labor productivity by group pressure and allocation of wages according to each worker's contribution. [redacted]

**Information Deficiencies.** Improvement of drug supplies also depends on an effective system of pharmaceutical information. The lack of a mechanism for systematically providing information about drugs to physicians and the public has led to a situation where some patients do not receive available medications. Current therapeutic practice does not take full advantage of all the drugs available in the pharmacy network, and the absence of advertising means that Soviet doctors are often unaware of what medicines are available. Sometimes doctors prescribe drugs that have long since been withdrawn from the market, while newer drugs go unused. [redacted]

**Imports of Pharmaceuticals**

The Soviets have not traditionally relied on foreign pharmaceutical technology and products from areas other than Eastern Europe, because of a reluctance to become dependent on the West and the low priority of the public health sector for hard currency expenditures. Since 1980, however, annual imports of pharmaceuticals have more than doubled, suggesting an increase in the priority of these commodities. In 1986

<sup>9</sup> Pharmacists normally are paid 110 to 140 rubles per month. The average wage of Soviet workers is 196 rubles. [redacted]

<sup>10</sup> In October 1986 the Soviets adopted a decree "On Raising the Wage Payments of Public Health and Social Security Employees," which included a provision to raise the salaries of pharmaceutical chemists and other pharmaceutical personnel. The new wage payment conditions are to be introduced in stages in 1986-91. In a recent television interview, economic adviser Abel Aganbegyan noted that "health service workers" have received a 30-percent pay increase. We do not know whether this applies to pharmaceutical workers. [redacted]

the Soviets imported 1.2 billion rubles' worth of pharmaceuticals, 93 percent from East European countries (see table 3). India supplied nearly 4 percent, while imports from hard currency countries amounted to only 1.4 percent.<sup>11</sup> [redacted]

The USSR obtains pharmaceuticals from CEMA countries primarily through bilateral exchanges of products. As a general rule, the USSR specializes in the production of bulk pharmaceuticals, while East European countries produce small-tonnage, higher quality products. Poland, the major exporter of medicines to the USSR in 1986, supplied 33 percent of total Soviet pharmaceutical imports. Hungary—which produces several drugs equivalent to those made in the West—ranked second as a source of imported pharmaceuticals, providing 22 percent. The Soviets also obtain Western drugs from Yugoslavia, which has licensing agreements with Western countries. [redacted]

The Soviets generally purchase from the West only sophisticated medicines not available domestically or from CEMA countries. These are usually bought in relatively small quantities for use in special medical facilities or for laboratory analysis and clinical trials in domestic drug programs. Imports include vitamins, hormones, antibiotics, insulin, and anticancer drugs. Finland supplied nearly 2 percent of imported pharmaceuticals in 1986, while France was the leading hard currency exporter. Austria, Switzerland, and West Germany supplied smaller quantities.<sup>12</sup> [redacted]

[redacted]

<sup>12</sup> Soviet imports of Western pharmaceutical technology and equipment have been minimal. The Soviets have purchased three facilities for the manufacture of penicillin- and cephalosporin-based antibiotics from Italian and Swiss firms in recent years, but equipment purchases have generally involved packaging and tablet- and capsule-manufacturing lines, rather than technology for drug production. [redacted]

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**Table 3**  
**USSR: Foreign Trade in Pharmaceuticals**

Million rubles

	Imports			Exports		
	1970	1980	1986	1970	1980	1986
<b>Total</b>	<b>166.2</b>	<b>542.7</b>	<b>1,232.0</b>	<b>31.8</b>	<b>81.4</b>	<b>102.6</b>
Communist countries	156.3	489.5	1,148.6	25.0	65.4	87.2
Eastern Europe <sup>a</sup>	156.3	489.5	1,139.5	18.3	51.9	64.4
Other	0	0	9.1	6.7	13.5	22.8
Non-Communist countries	9.9	53.2	83.4	6.8	16.0	15.4
Hard currency	6.5	33.0	17.4	5.7	14.7	14.7
Soft currency	3.4	20.2	66.0	1.1	1.3	0.7
Of which:						
Finland	0	0	19.7	0	0	0.2
India	3.4	20.2	46.3	0.4	0.8	0.3

<sup>a</sup> Eastern Europe includes Bulgaria, Czechoslovakia, East Germany, Hungary, Poland, Romania, and Yugoslavia.

Source: *Vneshnyaya torgovla SSSR*, various years.

[REDACTED]

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The Soviets are using science and technology agreements as another means to obtain Western pharmaceutical technology. Although there is often a cooperative element to these agreements and a two-way flow of information, they are part of a planned Soviet technology acquisition effort, and generally the heaviest flow of information is from the West to the USSR. In 1985 the Soviets concluded such an agreement with a US pharmaceutical company for the development and possible licensing of anticancer, anti-infectious, and cardiovascular drugs.<sup>13</sup> [REDACTED]

mid-1987 the USSR and India signed a long-term agreement that includes joint research, development, and production of vaccines for hepatitis and polio and development of immunodiagnostics and antibiotics.

[REDACTED]

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Moscow also has several cooperative agreements with other countries. For example, a 1987 joint research agreement with the Italian firm Pressindustria is designed to develop new antibiotics. [REDACTED]

[REDACTED] Another Soviet-Italian cooperation agreement signed in 1986 provides for joint research in developing new drugs and for exchanges of information and technical personnel. In

#### Upgrading Production and Improving Supply

*There is nothing more valuable to each person and to society as a whole than good health. . . . It is essential to satisfy as quickly as possible the public's need for high-quality therapeutic-preventative and medicinal assistance in all parts of our country. Considerable funds will, of course, be required, and we shall have to find them.*

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*General Secretary Gorbachev*  
*At the 27th CPSU Congress,*  
*February 1986*

<sup>13</sup> This agreement is a renewal of one that expired in the 1970s under which two Soviet anticancer drugs were evaluated for possible licensing in the United States. Clinical trials, however, failed to duplicate Soviet results, and the drugs were never marketed. [REDACTED]

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**Measures To Improve Pharmaceutical Supplies**

The Soviet leadership has taken a number of steps to improve the technological base of the industry and increase supplies of pharmaceuticals.<sup>14</sup> Policies adopted under Gorbachev include those designed to restructure management, improve the quality of products, encourage technological progress, streamline foreign trade, and foster cooperation among CEMA countries:<sup>15</sup>

- Gorbachev's openness campaign has resulted in a substantial increase in the publication of articles critical of all aspects of the health system including the supply of pharmaceuticals.<sup>16</sup>
- In November 1985 the Ministry of the Medical and Microbiological Industry was created by amalgamating the Ministry of the Medical Industry and the Main Administration of the Microbiological Industry (see figure). The merger of the medical ministry with the more technologically advanced microbiological industry was designed to facilitate the development of more advanced medicines.
- The appointment of Valeriy Bykov in December 1985 to head up the new MMMI highlighted a series of management shifts (see inset).<sup>17</sup>
- A Scientific-Technical Council within the MMMI has been created to develop a unified technology policy in the industry. The council will also play a major role in managing contacts with Western companies for licensing deals, sales of technology, joint ventures, and other forms of cooperation.

<sup>14</sup> According to estimates of the Ministry of Health, demand for the most important categories of pharmaceuticals will double by 1990, and by 1995 it will be two and one-half times that of 1985. [redacted]

<sup>15</sup> The state acceptance system, established in January 1987 to upgrade industrial product quality through the use of independent inspectors, may be in force at some pharmaceutical plants, but we cannot confirm this. [redacted]

<sup>16</sup> An article in *Meditinskaya gazeta* in December 1986, for example, was openly critical of problems in the MMMI, such as severe shortages of raw materials and high-quality machinery. [redacted]

<sup>17</sup> Several deputy ministers were removed in the ministerial reorganization. By early 1987, the head of the Main Administration for the Introduction of New Drugs and Medical Equipment, the chief of the Planning-Finance Administration of the Ministry of Health, and the health minister himself had been fired. The head of GAPU was retired in disgrace for the poor performance of the pharmacy system. [redacted]

*Valeriy Alekseyevich Bykov*



*Minister of the Medical and Microbiological Industry*

*An experienced microbiologist, Bykov began his industrial career at the Kirishi Biochemical Plant in Leningrad Oblast in the 1960s. He participated in the plant's planning and construction and also served as its director during 1971-76. In 1976 he became first secretary of the Kirishi city party committee, and in 1979 he moved to Moscow as head of the microbiology section of the Central Committee's Chemical Industry Department. In July 1985, five months before assuming his current post, he became chief of the General Bureau of the Microbiological Industry. In 1987, his close association with the Kirishi plant—which had by then been identified as a source of toxic pollutants—made him the target of protests during which the local populace labeled any illness resulting from the toxic leakage as "Bykov's disease." Bykov holds a candidate of technical sciences degree. He is 49. [redacted]*

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**Structure of the Medical and Microbiological Industry**


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Valeriy Bykov, Minister

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**Collegium of the Ministry**


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*First Deputy Ministers*


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A. G. Sorokin	Lev Telegin
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*Deputy Ministers*


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Nikolay Danilin	Yu. T. Kalinin	V. Ye. Matveyev
Yuriy Shevyakov	M. M. Sobolev	V. F. Romanenko

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**Administrations**


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Cadres and educational institutions

Equipping and outfitting

Sales of medical products

Production

Chief mechanic and chief power engineers

Design and capital construction

Material and technical supply

Finance

Accounting, bookkeeping, and financial control

Foreign relations

Labor organization, wages, and worker cadres

Technical

Economic planning

Economic

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**Production Associations**


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Medical glass and plastics

Supply of medical and microbiological output abroad

Medicinal plants procurement and processing

Medical industry products export

Antibiotics, blood substitutes, and organic preparations

Microbiological substances

Synthetic medical substances

Medical technology

Prepared medical substances manufacturing

Vitamin manufacturing

Medical technical devices manufacturing

Medical instrument building

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- Many institutes of the MMMI have been incorporated into scientific-production associations in the hope of shortening the time required for the introduction of newly discovered medicines.
- Investment for modernizing existing pharmaceutical plants and constructing new facilities—particularly those for producing biotechnological products—in 1986-90 is three times that of the previous five-year plan.
- A campaign to tighten labor discipline to boost productivity and reduce absenteeism has been coupled with an anticorruption campaign against medical and pharmacy personnel who engage in black-market activities.
- The general foreign trade reform of January 1987 allowed MMMI to conduct trade directly with foreign firms. Medeksport, the organization responsible for trade in pharmaceuticals, was subsequently transferred to MMMI.<sup>18</sup>
- Moscow is pushing for greater scientific and technical cooperation with CEMA countries, particularly in expanding output of interferon, insulin, and growth hormones and in developing materials for research in genetic engineering. [redacted]

In August 1987 a resolution on priority measures to improve public health services in 1988-90 was adopted by the Council of Ministers. It called for increased spending on food, medicines, and bandages for hospitals, and expanded eligibility for free and reduced-fee medicines. The Ministry of Finance was instructed to spend an additional 5.4 billion rubles to implement the resolution's goals. In November the CPSU Central Committee and the Council of Ministers

<sup>18</sup> This change is designed to provide the ministry with the administrative expertise necessary to conduct foreign transactions. The new arrangement allows the ministry to retain a large share of any hard currency its enterprises earn. These funds can be used to finance imports of technology and products. MMMI also has increased rights to engage in scientific-technical cooperation and establish joint ventures with Western firms. [redacted]

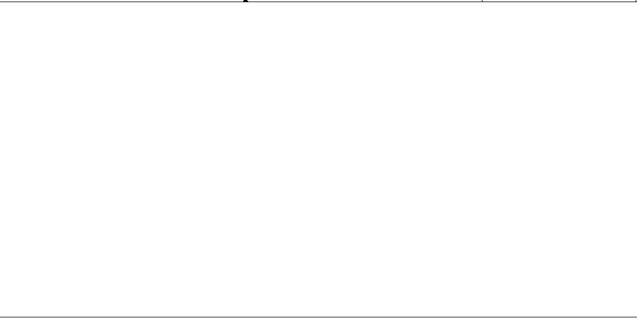
announced a major new program for restructuring the health-care system during 1988-2000. Provisions that are likely to affect the supply of pharmaceuticals include:

- Increasing the output of "modern medications" to completely satisfy needs with Soviet-made products by 1993.
- Raising the quality of pharmaceutical products to world standards.
- Doubling the volume of sales of medicines and medical articles by 1995.
- Reducing production of ineffective drugs, using the resources released to produce new medicines.
- Ensuring an equitable distribution of medicines to various regions of the country.
- Expanding the network of pharmacies by 2,000 and providing the necessary material resources.
- Increasing the money institutions can spend on medications by 80 to 120 percent for hospitals and 100 to 200 percent for polyclinics. [redacted]

**Getting Help From Abroad**

The USSR could alleviate domestic shortages of medicines by increasing imports. Moscow is pressing for increased supplies of pharmaceuticals from Eastern Europe. For example, according to the Soviet press, Soviet-Yugoslav pharmaceutical trade is scheduled to double in 1986-90, and the two countries also will exchange technology for the production of new medical preparations. [redacted]

Moscow is also interested in joint ventures with Western firms in the pharmaceutical area. [redacted]



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Moscow is also looking to the West for help in boosting its capabilities in biotechnology, one of five key technologies that Gorbachev has targeted for improvement.<sup>19</sup> Advances in biotechnology will not do much to alleviate the problems in supplying pharmaceuticals. In fact, Moscow's interest in biotechnology may lie more in its agricultural and military applications than in its medical ones (see inset). [redacted]

The Soviets are seriously committed to boosting their biotechnology capabilities—including the allocation of scarce hard currency—and recently hosted an international exhibition of microbiological technology and equipment. In 1987 an Austrian-led consortium won a \$60 million contract to build research and production facilities at the Shemyakin Biotechnology Institute in Moscow. Laboratories and pilot plants will produce animal and plant growth regulators, peptides, chemical reagents, pure solvents, monoclonal antibodies, proteins, and polymers. Many of these products have valuable diagnostic and therapeutic applications.<sup>20</sup> Last year an Italian firm won a \$23.5 million contract to construct a biotechnology research and production facility at Ufa. [redacted]



[redacted] Other biotechnology projects under negotiation involve complexes at Taroussa and another one at Ufa. All of these new facilities will be able to produce a number of products used in the medical, pharmaceutical, agricultural, veterinary, and energy sectors of the economy, as well as provide the Soviets with the potential capability to produce biological warfare agents. [redacted]

<sup>19</sup> The others are nuclear energy, advanced materials, microelectronics and computers, and machine automation. [redacted]

<sup>20</sup> Monoclonal antibodies can provide better diagnostic agents for human immunodeficiency virus—which causes AIDS—and more effective therapeutic products, particularly anticancer agents. Proteins could include such important products as human growth hormone, insulin, interferon, and hepatitis-B vaccine. [redacted]

### Viability of the Program

The steps that the Soviet leadership has taken probably will provide some improvement in the production and distribution of medicines. But shortages of many types of medicines will still occur, especially in rural areas where, despite plans to increase availability, progress will be slow. [redacted]

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Moscow needs to reduce obstacles that will prevent effective implementation of some of these measures. Foot-dragging and resistance, for example, have characterized ministerial reaction to the decentralization of some production decisions. Moreover, enterprises cannot effectively influence the quality of their output unless they are able to choose their own suppliers. The gradual introduction of a new wholesale trade system this year may help, but, since most pharmaceutical products are likely to fall under the classification of state orders, plant managers may still be faced with the same unreliable suppliers.<sup>21</sup> [redacted]

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The substantial increase planned for investment in the MMMI certainly indicates an intent to improve pharmaceutical supplies, but followthrough will prove difficult given the demands on investment resources elsewhere in the economy. Meeting the industry's needs for new equipment, better materials, and properly trained workers from domestic resources alone will be particularly difficult. The machine-building ministries, for example, consider the drug industry's orders for equipment unprofitable—the equipment requested is complex, at times unique, and often only

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<sup>21</sup> A major new decree, adopted in July 1987, on restructuring the USSR's material and technical supply system is designed to eliminate shortages of material resources in the economy by loosening central control over resource allocation and switching to a system of wholesale trade. The decree proposed a four-to-five-year period for the complete changeover. State orders will continue to account for defense-related materials and certain national resources, such as oil, gas, and metals, while a combination of state orders and wholesale trade will apply to enterprises producing other goods. Ultimately, certain sectors, such as consumer goods, are scheduled to change completely to wholesale trade. [redacted]

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### *Applications of Biotechnology*

*New biotechnical methods, such as genetic engineering, make it possible to lower the cost of many drugs and accelerate development of new compounds. In the United States, commercial applications of biotechnology have already resulted in new pharmaceuticals, including products to minimize the effects of heart attacks and to screen blood for antibodies to human immunodeficiency virus. Interferon and interleukins have been successful in treating some cancers, and DNA is used in genetic testing and "fingerprinting."*

*With the express purpose "to introduce the achievements of genetic and cellular engineering," the Soviets established Biogen, an interbranch scientific and technological complex (MNTK), in December 1985.<sup>a</sup> Biogen has been tasked with manufacturing the "newest and latest generations of compounds for medicine and agriculture based on biotechnological methods." During 1986-90 about 250 kinds of new products are scheduled to be developed on the basis of biotechnology. The Soviets recently started an enterprise for the production of biotechnological preparations that they claim to be the first of its kind in Europe. The plant will use flexible manufacturing technology for preparing experimental test batches of drugs. The first biosynthesized products will be dalgargin (used to treat ulcers), urokinaza (which dissolves blood clots), and analgesic compounds.*

<sup>a</sup> MNTKs are complexes of research institutes and industrial organizations that operate across ministerial lines. Each MNTK has an academic or industrial institute as its nucleus and is designed to coordinate all of the work in its field throughout the USSR. Resources are supplied by the State Committee for Material and Technical Supply. When new technologies are approved, the State Planning Committee selects the enterprises to use the technology. Planners believe that this method of organizing intersectoral development is simpler than organizational restructuring.

*Using biotechnology techniques, it is possible both to modify existing chemical and biological warfare agents and to create new ones. Many of the fermentation processes and much of the equipment required to create pharmaceuticals for commercial use are the same as those required for the production of toxins and other chemical/biological warfare agents. Genetic engineering, for example, can be used to:*

- *Selectively modify existing infectious organisms to provide greater infectivity and greater resistance to environmental degradation.*
- *Change the molecular composition of toxins and produce toxins derived from other organisms, such as bacteria, fungi, and plants.*
- *Produce bioregulators, compounds normally present in the human body only in minute quantities. If introduced in higher-than-normal concentrations or if genetic or chemical manipulation has been used to alter their structure or activity, they can produce a wide range of deleterious effects.*

*Biotechnology-derived agents would have many advantages over traditional biological warfare agents. Detection and identification would be more difficult because the variety of potential agents is essentially unlimited, and they would have a much wider range of effects. The effects caused by these potential agents could range from emotional and behavioral changes to physical effects such as extreme pain, rapid induction of sleep, hemorrhage, and death. Properties could conceivably be tailored to specific field requirements for stability, persistence, and rapidity of effect.*

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a few pieces are needed. Furthermore, other sectors of the economy—such as energy—command higher priority for supplies of machinery. The tightening of labor discipline will provide some short-term gains but little sustained benefit. Stiffer sentences for theft and black-market activities should curtail some corruption, but there will always be those willing to take risks to supplement their low wages. [redacted]

Accelerated development of the pharmaceutical industry requires a corresponding development of its raw material base. But many of the problems in securing supplies from other ministries remain unsolved. The Ministry of the Chemical Industry and the Ministry of the Petroleum Refining and Petrochemical Industry, for example, have long delayed expansion of production, and they have few plans to produce certain raw materials such as small-tonnage and high-purity chemicals that are critically needed for the production of several medications. Moreover, shortfalls in the delivery of raw materials from the chemical industry will continue, because chemical plants, having their own ministerial hierarchy, feel that orders for the M MMI have less priority. [redacted]

As a result of the industry's failure to obtain sufficient resources, the system is likely to feel increased pressure for expansion of pharmaceutical imports. Most of any increase in imports will come from East European countries, but these countries cannot offer the scale of support needed. Imports of pharmaceuticals from the West are likely to increase somewhat, and there should be some opportunity for Western sales of production licenses and plants, particularly in the area of biotechnology. Hard currency constraints and a conservative approach to borrowing, however, probably will limit purchases to those of highest priority. At the same time, we can look for growing Soviet interest in establishing additional scientific-technological

cooperation agreements with Western pharmaceutical firms. Through cooperation agreements the Soviets may be able to gain better access to research programs, chemical and microbiological products, and more advanced production technology. [redacted]

The quality and sophistication of pharmaceutical products should improve with the increased role of microbiology enterprises, and anticipated changes in the research and development system should help accelerate the pace of technological progress in the biomedical area. Because of its high profile as a leading-edge technology, biotechnology may receive undue attention while the real problems in supplying the Soviet consumer with necessary medications—such as new antibiotics, vitamins, and anticancer and cardiovascular drugs—get short shrift. [redacted]

Unless the problem of inadequate pharmaceutical supplies becomes a more significant concern to the populace, leadership attention will remain focused on sectors that either are critical to industrial modernization or weigh heavily in consumers' perception of their well-being such as housing and food. Even increased funding and administrative efforts to improve pharmaceutical supply and distribution run the risk of bogging down in the morass of indifference, inefficiency, and lack of quality that has so enmeshed other sectors of the economy not blessed with priority attention of the leadership. [redacted]

Failure to supply adequate pharmaceuticals will leave Soviet health care more on a par with that in the Third World than that in the developed West. At present, the Soviet populace seems inured to this situation, but morale could be seriously affected if health problems increase and the labor force becomes more knowledgeable about the relative state of Soviet health care. [redacted]

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