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FEDERAL DRUG PRICES

**Effects of Opening the
Pharmaceutical Schedule
Are Uncertain**

Statement of Bernice Steinhardt, Director
Health Services Quality and Public Health Issues
Health, Education, and Human Services Division



Federal Drug Prices: Effects of Opening the Pharmaceutical Schedule Are Uncertain

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss our recent report on the potential implications for the Department of Veterans Affairs (VA) and other government purchasers of opening the federal supply schedule (FSS) for pharmaceuticals to state and local governments.¹ During fiscal year 1996, the federal government purchased almost \$1.3 billion worth of pharmaceuticals from this catalog of drug prices. As you know, schedule prices are often substantially lower than retail prices and are available primarily to federal purchasers. VA used this schedule to purchase about \$922 million in pharmaceuticals—about 71 percent of the government's total purchases from the schedule.

In 1994, the Congress authorized the General Services Administration (GSA) to administer a cooperative purchasing program that would allow state, local, and Indian tribal governments, as well as the Commonwealth of Puerto Rico, to purchase pharmaceuticals and other goods and services from federal supply schedules.² VA, to which GSA has delegated administration of the pharmaceutical schedule, expressed concern that prices on the schedule could increase if it was opened to a larger group of purchasers. As a result, GSA proposed that the pharmaceutical schedule be excluded from the cooperative purchasing program because GSA did not plan to open any schedule to nonfederal entities if higher schedule prices would result.

Because of concerns about the potential effects of opening more than 140 federal supply schedules, the Congress directed GSA to delay opening any schedule pending completion of our assessment of the potential impact.³ GSA is currently developing its final implementation plan for opening the schedules.

Today I would like to discuss the factors that could affect schedule price negotiations between VA and drug manufacturers if the pharmaceutical schedule was opened, as well as the opening's potential effects on the

¹Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain (GAO/HEHS-97-60, June 11, 1997).

²See the Federal Acquisition Streamlining Act of 1994, P.L. 103-355, sec. 1555 (1994).

³See the National Defense Authorization Act for Fiscal Year 1996, P.L. 104-106, sec. 4309 (1996) and accompanying conference report, H.R. Conf. Rep. No. 104-450, at 970 (1996). The implications of opening other schedules are discussed in Cooperative Purchasing: Effects Are Likely to Vary Among Governments and Businesses (GAO/GGD-97-33, Feb. 10, 1997).

schedule prices that would be available to federal, state, and local government purchasers.

To assess the potential impact of opening the schedule, we contacted VA, other federal agencies, and the Congressional Budget Office (CBO). We also contacted the Public Hospital Pharmacy Coalition,⁴ the Health Industry Group Purchasing Association (HIGPA),⁵ the National Association of Chain Drug Stores, the Pharmaceutical Research and Manufacturers of America (PhRMA), and several drug manufacturers.⁶ In addition, we analyzed schedule prices and reviewed assessments made by VA, HIGPA, and the Coalition concerning how opening the schedule could affect schedule and other drug prices.

In summary, the effects of opening the pharmaceutical schedule on schedule prices ultimately depend on the outcome of negotiations between VA and drug manufacturers. Because of many uncertainties related to these negotiations, it is not possible to predict how the schedule's prices would change or what the ultimate impact on VA and other government purchasers would be.

Although many factors would influence the negotiations between VA and drug manufacturers, two primary ones are VA's negotiating ability and manufacturers' pricing strategies. Both of these factors would be influenced by the size of the market represented by combined federal, state, and local purchasers that would have access to schedule prices. Moreover, the size of this market could affect the size of any resulting price changes. The larger the market, the greater the economic incentive would be for a manufacturer to raise schedule prices to limit the impact of giving low prices to more purchasers.

At present, federal purchases from the schedule represent about 1.5 percent of the total dollar value of domestic pharmaceutical sales. Estimates of the size of a combined federal, state, and local market, however, vary widely because of uncertainty about which state and local entities would be eligible for schedule prices. If eligibility is not narrowed, VA, PhRMA, drug manufacturers, and the Public Hospital Pharmacy Coalition

⁴The Coalition represents 70 public hospitals that are owned or controlled by state and local governments and serve a disproportionate share of Medicaid and indigent patients.

⁵HIGPA is a national trade association that represents 84 organizations and vendors that purchase pharmaceutical and other medical products.

⁶The manufacturers we contacted were Eli Lilly and Company; Johnson & Johnson; Merck & Co., Inc.; Pfizer Inc.; and SmithKline Beecham Corporation.

agree that the size of the combined market could be significantly larger than the current federal market. Although the Coalition estimates that limiting eligibility as it suggests could keep state and local purchases from the schedule at between 0.5 and 4.4 percent of domestic pharmaceutical sales, this would result in a combined market about 33 to 300 percent larger than the federal market.

Federal efforts to lower Medicaid drug prices suggest how opening the schedule could put upward pressure on schedule prices. In 1990, the Congress required drug manufacturers to give state Medicaid programs rebates for outpatient drugs based on the lowest prices they charged other purchasers. Because of the size of the Medicaid market, however, many drug manufacturers sought to minimize the impact of the rebates on their business by raising outpatient drug prices to some private sector purchasers.

If the pharmaceutical schedule was opened to state and local governments and drug manufacturers succeeded in raising their schedule prices in response, the impact on different government purchasers would vary. VA, along with the Department of Defense (DOD), the Public Health Service, and the Coast Guard, would be somewhat protected from price increases because the Veterans Health Care Act of 1992⁷ sets maximum prices for these agencies for over one-quarter of the drugs on the schedule. Other federal purchasers would not have that protection. State and local government purchasers, meanwhile, would benefit to the extent that schedule prices were lower than the prices they or their representatives could negotiate with drug manufacturers.

Background

The FSS for pharmaceuticals currently contains almost 23,000 products available to federal agencies and institutions and several other purchasers. The purpose of the pharmaceutical schedule, like other supply schedules, is to provide eligible entities an efficient and economical option for purchasing. These entities can purchase pharmaceuticals, however, through other methods. For example, although VA depends on the FSS for most of its drug purchases, VA has awarded several national contracts on a competitive basis for specific drugs it considered to be therapeutically interchangeable.

Under the Veterans Health Care Act of 1992, drug manufacturers must make their brand-name drugs available through the FSS in order to receive

⁷See P.L. 102-585, sec. 603.

reimbursement for drugs covered by Medicaid.⁸ The act also requires drug manufacturers to sell drugs covered by the act to four agencies—VA, DOD, the Public Health Service, and the Coast Guard—at no more than 76 percent of the nonfederal average manufacturer’s price,⁹ a level referred to as the “federal ceiling price” (FCP). A drug’s FSS price may be higher or lower than its FCP. If it is higher, the protected purchasers pay no more than the FCP.

GSA published in the Federal Register on April 7, 1995, its initial proposed plan for opening the federal supply schedules to state and local governments. The plan proposed excluding from cooperative purchasing the schedule for drugs and pharmaceutical products and one medical equipment and supplies schedule¹⁰ because GSA concluded that opening them would have the unintended effect of increasing costs to federal users of the schedules. The plan also proposed that participation in the cooperative purchasing program be optional for sellers and purchasers.

Impact of Opening the FSS Depends Largely on Price Negotiations

Price negotiations between VA and drug manufacturers will ultimately determine the extent to which opening the pharmaceutical FSS affects the schedule drug prices available to federal, state, and local governments. Opening the schedule could change the dynamics of negotiating FSS prices for both VA and drug manufacturers. Up to now, VA has been able to obtain significant discounts from drug manufacturers by seeking the most-favored customer price. This price represents the same discount off a drug’s list price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions, such as length of contract periods and ordering and delivery practices. Many FSS prices are more than 50 percent below nonfederal average manufacturer prices.¹¹

Representatives of several drug manufacturers explained that their companies have been willing to negotiate low FSS prices because they consider the FSS to be a special, limited category of pricing.

⁸See P.L. 102-585, sec. 603. The act does not cover generic drugs.

⁹The nonfederal average manufacturer price is the weighted average price of each single form and dosage unit of a drug that is paid by wholesalers in the United States to a manufacturer, taking into account any cash discounts or similar price reductions. Prices paid by the federal government are excluded from this calculation.

¹⁰VA contended that some items on this schedule, which includes in vitro diagnostic substances, reagents, test kits, and sets, could also increase in price if it was opened. The implications of opening this schedule are covered in [GAO/GGD-97-33](#), Feb. 10, 1997.

¹¹The cost of drugs covered by the Veterans Health Care Act that had FSS prices below federal ceiling prices as of Sept. 30, 1996, was, on average, 52 percent below the nonfederal average manufacturer price. See [GAO/HEHS-97-60](#), June 11, 1997.

Representatives of two manufacturers specifically noted that their companies agreed to such prices to help ensure that their drugs were widely used in VA hospitals, where many of the nation's physicians receive part of their training. Some drug manufacturers have indicated an unwillingness, however, to continue to offer such low prices if the FSS is opened to a larger group of purchasers and federal purchasers are combined with other types of government purchasers that the manufacturers have considered to be part of a separate market.

Although VA would be negotiating on behalf of a larger market if the schedule was opened, the increased market share might not in and of itself improve VA's leverage to negotiate lower prices. Drug manufacturers have historically offered different prices for the same product to different purchasers largely on the basis of the purchaser's ability to influence drug utilization (sometimes referred to as the ability to move market share).¹² For this reason, volume of sales, while integral to price negotiations between purchasers and drug manufacturers, is not the only important consideration. A common technique used by large-volume purchasers to influence market share is to establish a formulary. A formulary is a list of drugs that a health plan prefers its physicians to prescribe for patients. Drugs are included on a formulary not only for their medical value but also for their favorable prices. Both inclusion of a drug on a formulary and the drug's cost can affect how much it is prescribed and purchased and, therefore, have an impact on its market share. Because formularies have the potential to significantly affect the sales of drugs, large purchasers that use them have greater leverage in negotiating discounts or rebates with manufacturers who want their drugs listed as preferred drugs. However, because the FSS is a catalog of prices, not a formulary, VA lacks that kind of leverage.

If drug manufacturers are unwilling to extend low FSS prices to state and local purchasers, VA could experience a "showdown" with manufacturers over price increases, which it has not experienced before. Drug manufacturers could respond in several ways. First, they could simply refuse to offer their products to state and local purchasers at FSS prices, an option that is permitted under GSA's current proposal. Representatives of several manufacturers told us, however, that they do not consider this option realistic because some competing manufacturers would be likely to offer FSS prices to state and local purchasers, and no manufacturer would want to concede the potential business. Second, drug manufacturers could

¹²See CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry (Washington, D.C.: CBO, Jan. 1996).

try to increase FSS prices by raising prices to most-favored customers to change the base on which prices are negotiated with VA. Several manufacturers indicated that this option would depend on the size of the market represented by all government purchasers. Third, drug manufacturers could attempt to negotiate higher FSS prices without linking them to most-favored customer prices. This strategy could result in lengthy, difficult negotiations, which VA has not experienced before with manufacturers.

Size of Market Eligible for FSS Prices Would Be Key Factor

The size of the FSS market if the schedule was opened would be a key factor in determining what would happen to drug prices. The larger the market, the greater the incentive would be for manufacturers to raise FSS prices to limit the impact on their business of giving low prices to more purchasers. GSA's proposed implementation plan for opening the schedules included participation by a state and any department, agency, or political subdivision of a state, including local governments. Representatives of VA, PhRMA, drug manufacturers, HIGPA, and the Public Hospital Pharmacy Coalition agree that unless this definition of an eligible entity is narrowed, the FSS market could expand significantly from its current size of about 1.5 percent of domestic pharmaceutical sales.¹³

The Coalition has suggested that GSA's definition be narrowed to limit access to FSS prices to state and local government entities that purchase drugs for their own use and dispense drugs in their own facilities. The Coalition estimated that defining eligibility this way would result in a state and local FSS market of about 4.4 percent of total dollars in domestic pharmaceutical sales.¹⁴ But the market might actually be considerably smaller, according to the Coalition, because some state and local purchasers are subject to procurement laws or regulations that would restrict their participation in cooperative purchasing. Also, eligible state and local purchasers would not buy all their drugs from the FSS because it is likely that not all FSS prices would be lower than other prices available to them. If these two assumptions were considered, the Coalition estimated that state and local FSS purchases would fall from about 4.4 percent to 0.5 percent of the total drug market. Therefore, the

¹³According to IMS America, a private vendor of pharmaceutical information, in 1996 the U.S. pharmaceutical market totaled about \$85.4 billion in sales, including sales to federal, state, and local government entities. FSS drug sales of about \$1.3 billion for fiscal year 1996 represent about 1.5 percent of U.S. pharmaceutical sales.

¹⁴See PRIME Institute, College of Pharmacy, University of Minnesota, Section 1555 of the Federal Acquisition Streamlining Act: Impact of Cooperative Purchasing on the Pharmaceutical Market, prepared for the Public Hospital Pharmacy Coalition (Washington, D.C.: Jan. 15, 1997).

Coalition's estimates mean that the total FSS market would expand by about 33 to 300 percent if state and local governments are given access to FSS prices.

As for the impact of procurement laws or regulations on state and local participation, 27 of 50 respondents¹⁵ reported in a September 1996 survey we conducted that current state competitive-bidding and other laws would limit their use of federal supply schedules.¹⁶ But most state and local government purchasing officials we contacted indicated that they want the option of purchasing items from the schedules. How many states and localities would change purchasing laws and regulations so that they could participate in the cooperative purchasing program is uncertain. It is also uncertain how many and to what extent eligible state and local entities would choose to buy drugs through the FSS.

Although the size of the combined federal, state, and local market that could have access to FSS prices is unclear, past federal efforts to lower drug prices for a significant market caused many manufacturers to raise prices. Before the Medicaid rebate program was enacted in 1990, state Medicaid programs, which represent about 11 percent of the domestic pharmaceutical market,¹⁷ paid close to retail prices for outpatient drugs. Other purchasers, such as hospitals and health maintenance organizations, paid considerably less. Under the program, the Congress required drug manufacturers to give state Medicaid programs rebates for outpatient drugs on the basis of the lowest prices they charged other purchasers.

After the rebate program's enactment, the prices many large private purchasers paid for outpatient drugs increased substantially.¹⁸ In particular, prices paid by health maintenance organizations rose, on average, more than twice as fast as the year before the program. On the basis of its analysis of these price changes for outpatient drugs, CBO concluded that, because of the size of the market represented by Medicaid, "pharmaceutical manufacturers are much less willing to give large private

¹⁵Respondents represented 48 states and 2 territories.

¹⁶See [GAO/GGD-97-33](#), Feb. 10, 1997.

¹⁷According to IMS America, in 1995 total sales for the U.S. pharmaceutical market were about \$77.1 billion. According to the Health Care Financing Administration, Medicaid drug expenditures for fiscal year 1995 totaled about \$8.4 billion, including rebates.

¹⁸See [Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions \(GAO/HRD-93-43](#), Jan. 15, 1993) and [Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals \(GAO/HEHS-94-194FS](#), Aug. 5, 1994).

purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price.”¹⁹

FSS Price Changes Would Affect Government Purchasers Differently

Although it is uncertain how FSS prices would change if the pharmaceutical FSS is opened, the factors involved in negotiations between VA and drug manufacturers have the potential to produce, in general, an upward pressure on FSS prices.

For VA and Other Federal Purchasers, Impact of Any FSS Price Increases Would Vary

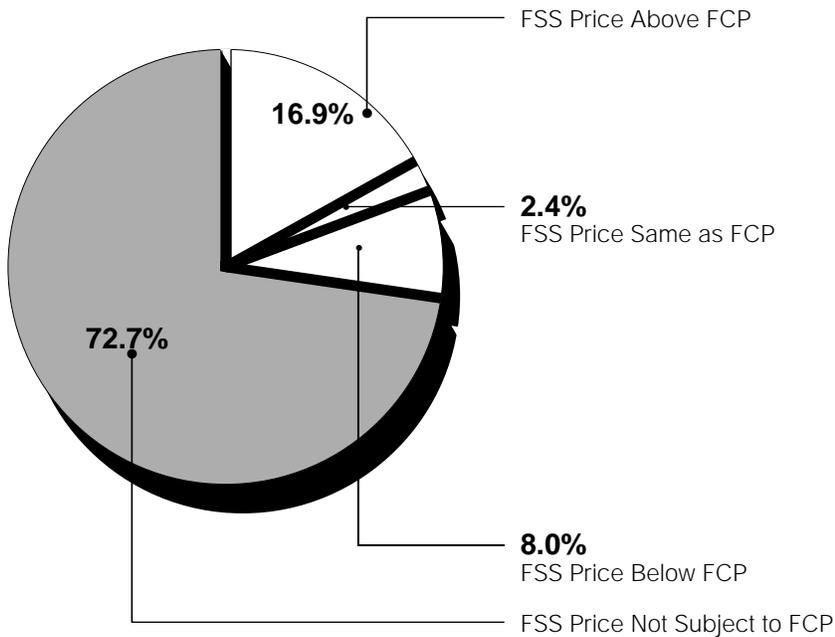
If FSS prices rise after the schedule is opened, all federal purchasers could pay higher FSS prices for many drugs covered and not covered by the Veterans Health Care Act. About 73 percent of the roughly 22,800 drugs on the FSS are not covered by the act.²⁰ However, these drugs represent a smaller portion of federal expenditures because they are primarily generic equivalents of brand-name drugs. A VA official estimated that about three-quarters of VA’s total drug expenditures are for covered drugs. For these drugs, VA and the three other protected federal agencies would not have to pay FSS prices that are higher than the FCPS. But as figure 1 shows, they may have to pay more for the 8 percent of all FSS drugs that currently have FSS prices below their ceiling prices if prices rise to or above the FCPS. The FSS prices for these drugs are, on average, about 28 percent below the FCP.

¹⁹See CBO Papers.

²⁰As of Sept. 30, 1996, the FSS included 22,828 products—6,243 were covered drugs and 16,585 were not covered.

Federal Drug Prices: Effects of Opening the Pharmaceutical Schedule Are Uncertain

Figure 1: FSS Price Relative to the FCP for Schedule Drugs as of September 30, 1996



Not Covered by the Veterans Health Care Act
 Covered by the Veterans Health Care Act

Note: Percentages are based on the number of FSS products, rather than on FSS expenditures.

Source: VA data.

In February 1995, VA presented GSA its analysis of the potential effects of opening the pharmaceutical schedule on FSS prices and VA drug costs, taking into consideration the protection the Veterans Health Care Act provides VA against drug price increases. On the basis of discussions with representatives of numerous drug manufacturers, VA made two key assumptions in its analysis about the potential effects of opening the pharmaceutical FSS: (1) drug manufacturers would eliminate FSS pricing for all drugs not covered by the Veterans Health Care Act, forcing federal purchasers to buy these generic drugs at higher wholesale prices, and (2) FSS prices for all drugs covered by the act would rise to their FCPs.

VA applied those two assumptions to drug purchases it made during the first 6 months of 1994.²¹ According to VA, it spent about \$37.8 million on 4,877 generic drugs not covered by the act. If it had purchased the same drugs at wholesale rather than FSS prices, VA estimated that it would have paid over \$79.7 million, or about 111 percent more. In the same period, VA spent about \$118.3 million on 911 brand-name drugs that were covered by the act and that had FSS prices below their FCPS. Had the manufacturers of those drugs raised the FSS prices to their FCPS, VA estimated that it would have paid over \$152.9 million, or roughly 29 percent more. Thus, VA calculated that, on an annualized basis, the impact of giving state and local governments access to the FSS would have been a \$153.1 million increase in its yearly drug expenditures.

Those federal purchasers that, unlike VA, have no protection from the ceiling prices established by the Veterans Health Care Act would pay full FSS prices on all drugs bought from the schedule. As of November 1996, only 25 of 162 drug manufacturers had FSS prices that were above the FCP. But, manufacturers may offer purchasers not protected by the act prices above the FCP. Representatives of several drug manufacturers told us that their companies would consider this option attractive if the pharmaceutical schedule was opened because it would allow them to offer prices above the FCP to state and local purchasers. Federal purchasers not protected by the ceiling prices would pay the full amount of such price increases.

The potential impact of FSS price increases on different government purchasers when purchasing from the pharmaceutical schedule is summarized in table 1.

²¹According to VA, calculations were based on actual contract purchase prices from VA's prime vendor network from Jan. 1 through June 30, 1994.

Federal Drug Prices: Effects of Opening the Pharmaceutical Schedule Are Uncertain

Table 1: Potential Effects of FSS Price Increases on FSS Prices Paid by Government Purchasers

Purchaser	FSS price paid		Implications
	Before FSS opened	After FSS opened	
VA, DOD, Public Health Service, and Coast Guard	Lower of FSS or FCP for covered drugs; FSS for drugs not covered	Lower of FSS or FCP for covered drugs; FSS for drugs not covered	FSS price for 8% of drugs could increase up to FCP; FSS price could increase for many drugs not covered.
Other federal government entities	FSS	FSS	FSS prices could increase for many drugs covered and not covered.
State and local government entities	Not applicable— negotiated prices	FSS	FSS prices, even if they increase, could be lower than prior negotiated prices; if they are not, purchasers could try to negotiate lower prices.

Note: For the purpose of this table, federal purchasers are considered to be dependent on purchasing many of their drugs from the FSS rather than from alternative sources.

State and Local Purchasers Could Choose Between FSS and Other Drug Prices

Opening the pharmaceutical schedule would give state and local purchasers the choice of buying drugs from the FSS or from other sources. The Public Hospital Pharmacy Coalition contends that state and local purchasers would benefit from having access to the schedule and manufacturers would have little incentive to raise FSS or other drug prices because

- a manufacturer’s participation in the cooperative purchasing program is voluntary, thus allowing a company to opt out of the program if it anticipates any adverse economic consequences;
- if a manufacturer concludes that it must participate in the program for competitive reasons, the same competitive forces will keep prices from rising;
- the potential size of the state and local market will be small, given the Coalition’s proposal for determining eligibility to access FSS drug prices; and
- market size is but one of many factors drug manufacturers consider in developing drug pricing strategies.

Assuming negligible adverse effects on FSS prices if the schedule is opened, the Coalition anticipates considerable financial benefits for many state and local purchasers. For example, a Coalition analysis of the differences between FSS prices and the prices nine public hospitals paid for

the 100 drugs each hospital spends the most on showed that FSS prices, on average, were lower than the hospitals' purchase prices for about 83 percent of the drugs.²² FSS prices were, on average, about 17 percent lower than the prices the hospitals paid.

If the pharmaceutical schedule is opened and FSS prices rise, the extent to which state and local government purchasers could benefit is unclear. The drug prices paid by the hospitals in the Coalition's analysis show that many FSS prices could rise and still be lower than what some state and local purchasers currently pay. If FSS prices remained higher than what state and local purchasers were accustomed to paying, they could try to negotiate better prices for themselves. However, the incentive for a drug manufacturer to negotiate a price below the FSS price would be limited because the negotiated price could become the most-favored customer price and, thus, potentially affect the manufacturer's FSS price negotiations with VA. In any case, VA and other federal purchasers would still face an increase in FSS prices.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or Members of the Subcommittee may have.

²²The analysis was based on FSS and hospital purchase prices as of Oct. 1, 1996.

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