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Health, Education and Human Services Division

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The Honorable Henry A. Waxman
Chairman, Subcommittee on Health
and the Environment
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

As the debate over U.S. health care reform continues, prescription drug prices remain the subject of widespread concern. Although the rate of prescription drug price increases (as measured by the consumer price index for prescription drugs) has slowed since 1990, controversy over the high cost of drugs in the United States persists as consumers and policymakers look to other countries where pharmaceuticals may be sold more cheaply.

In light of public and congressional interest in prescription drug pricing, you asked that we examine differences in prescription drug prices in the United States and abroad. In previous reports, we compared factory prices for frequently dispensed prescription drugs in the United States with the prices of the identical drugs sold in Canada or the United Kingdom.¹ For this letter, we reviewed existing studies of the level of drug prices in France.

Several researchers have compared U.S. and French drug prices. Although the magnitude of reported differences varies widely, each of the studies we examined concluded that U.S. prices for prescription drugs were significantly higher than the prices for comparable drugs in France.

¹See Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom (GAO/HEHS-94-29, Jan. 12, 1994), and Prescription Drugs: Companies Typically Charge More in the United States Than in Canada (GAO/HRD-92-110, Sept. 30, 1992).

Some of these studies limited their focus to drugs sold in the undiscounted portion of the U.S. market--that is, drugs sold through wholesalers who are not generally in a position to negotiate manufacturers' discounts.² Although one study focused on brand-name drugs, two studies included generic drugs as well. While including generic drugs and manufacturers' discounts is unlikely to alter the qualitative conclusion that U.S. drug prices are higher than those in France, the reported differentials will be smaller, other things equal, when these factors are incorporated into the comparison.

Although government regulation has restrained drug prices in France, the desirability of similar intervention in the U.S. pharmaceutical market is unclear. Despite its success in lowering drug prices, the French system of price regulation has been unable to restrain continued rises in pharmaceutical spending. In addition, the French government's intervention in the pharmaceutical market may have adversely affected French pharmaceutical research and development. The debate over the potential effects of pharmaceutical regulation cannot be resolved solely by referring to foreign drug prices, and these larger issues are beyond the scope of this letter.

BACKGROUND

The current French health care financing system, established in 1945, is part of the Social Security system (Securite Sociale). This system is designed to provide universal access to health care.³ The Social Security system is the principal purchaser of pharmaceuticals, which accounted for approximately 14 percent of the French health care budget in 1991. The system, together with French private and nonprofit insurance funds, provides nearly complete coverage for pharmaceutical products in France.

In conjunction with its regulation of the health insurance system, the French government has imposed a variety of controls on pharmaceutical

²The undiscounted portion of the U.S. market is estimated to include at least 55 percent of all outpatient prescriptions in 1992.

³For a more complete description of the French health care system, see Health Care Costs: The Experience of France, Germany and Japan (GAO/HRD-92-9, Nov. 15, 1991).

prices that apply to participants throughout the pharmaceutical market: drug manufacturers, drug wholesalers and pharmacists, consumers, and physicians. For most drug products, France sets drug prices and controls price increases. In addition to these controls on the manufacturer's price, the French government regulates wholesale and retail margins and provides physicians with prescribing information. In France, consumers are generally responsible for some portion of the cost of each prescription. The government may reimburse 100 percent, 65 percent, 35 percent, or 0 percent of a drug's cost, with the consumer responsible for the remainder.⁴ Certain groups--the chronically ill, the poor, the disabled, and expectant mothers--are exempt from copayments, and most patients purchase supplementary insurance for prescription drugs that pays for most, if not all, of the copayment cost.⁵

About 4,200 different drug products are available on the French market. In contrast to other European countries, France has virtually no generic drug market.⁶ This is attributed to (1) low prices for brand-name drugs and (2) French laws prohibiting pharmacists from substituting a generic drug for a brand-name drug.

EXISTING STUDIES SHOW LARGE
DIFFERENCES BETWEEN U.S.
AND FRENCH DRUG PRICES

We examined three studies that involved direct comparisons of U.S. and French drug prices, and three others that compared drug prices in

⁴The reimbursement rate is set at 100 percent for 128 vital medicines and for all drugs used to treat patients with anyone of over 30 diseases (defined as "long and costly"), such as Parkinson's disease and AIDS. The reimbursement rate declines to 35 percent for drugs used to treat disorders or ailments that are not normally severe (for example, antiseptics and laxatives). Prescription drugs not reimbursed at 35 or 100 percent are reimbursed at 65 percent.

⁵For more information about the French government's pharmaceutical spending control policies, see Prescription Drugs: Spending Controls in Four European Countries, (GAO/HEHS-94-30, May 17, 1994).

⁶In 1991, generic drugs constituted less than 5 percent of total drug sales.

France to those in other European countries.⁷ Each of these studies found that drug prices in France were lower than in other countries. Two independent studies that compared U.S. and French drug prices found that U.S. prices were (on average) 168 percent and 120 percent higher than prices in France.⁸ Another study of U.S. and French drug prices found that, for cardiovascular drugs, estimates of the U.S.-French price differential ranged from 52 percent to 135 percent higher in the United States.⁹ In the other comparisons, one study found Canadian prices to be 105 percent higher than prices in France, and two studies reported U.K. prices that were 95 percent and 45 percent higher than prices in France.¹⁰ An additional study found that U.S. prices were (on average) 154 percent higher than the average price across six major European countries--Belgium, France, Germany, Italy, Switzerland, and the United Kingdom.¹¹ (See table 1.)

⁷An additional study, conducted in 1987 by Farindustria (the Italian pharmaceutical manufacturers' association), reported that U.S. retail drug prices were 357 percent higher than French prices. However, details on this study's methodology were unavailable.

⁸See R. Churnside, "International Comparisons of Pharmaceutical Prices," Department of Health, United Kingdom, 1992; and Association Belge des Consommateurs, Statement Before the Senate Special Committee on Aging, November 16, 1989.

⁹See P. Danzon and J. Kim, "International Price Comparisons for Pharmaceuticals", Wharton School, University of Pennsylvania, unpublished paper, August 1993.

¹⁰See Abteilung für Information und Öffentlichkeitsarbeit der Bundesvereinigung Deutscher Apothekerverbände (ABDA), Apotheken-Report No.42, December 1991, and Esterreichisches Bundesinstitut für Gesundheitswesen, "An International Comparison of Pharmaceutical Prices", Austrian Health Institute, 1993.

¹¹See R. Jordan, "Price Disparity Trends for Pharmaceuticals in the U.S. and Europe," Pfizer, unpublished paper, December 1992.

Table 1: Studies of Prescription Drug Prices in France

Source of study	Countries compared	Date	Number of drugs	Major results
R. Churnside, Department of Health, U.K.	France Germany Italy Netherlands Spain U.K. U.S.	1990	14	In a multinational comparison, U.S. prices were 168% higher than prices in France.
Belgian Consumers' Association, Brussels, Belgium	Greece Spain Portugal France Italy Belgium U.K. Ireland Denmark Germany Netherlands U.S.	1988	25	In a multinational comparison, U.S. prices were 120% higher than prices in France.
R. Jordan	U.S. and a European composite of France, Belgium, Germany, Switzerland, Italy, and U.K.	1990	74	U.S. prices were 154% higher than average prices across the six European countries.

Source of study	Countries compared	Date	Number of drugs	Major results
P. Danzon and J. Kim, University of Pennsylvania	U.S. Canada Germany France Italy Japan Switzerland Sweden U.K.	1992	37-54*	Depending on the methodology for including drugs, U.S. prices were from 52% to 135% higher than prices in France.
Patented Medicines Prices Review Board, Canada	Canada France	1992	107	Canadian prices were 105% higher than prices in France.
Austrian Health Institute	Austria Switzerland Germany Denmark France U.K. Italy Netherlands Sweden	1992	61	U.K. prices were found to be 43% greater than prices in France.
ABDA, German Pharmacist Association	Greece Spain Portugal France Italy Belgium U.K. Ireland Denmark Germany Netherlands	1991	25	Based a multinational comparison, U.K. prices were 95% higher than prices in France.

* The Danzon/Kim study was limited to cardiovascular drugs.

Differences in the study results may have occurred because these studies were conducted over different time periods--for example, the Belgian Consumers' Association study used data from 1988; the Churnside and Jordan studies used data from 1990; and the studies by Danzon and Kim and by the Patented Medicines Prices Review Board (PMPRB) used data from 1992.¹² The studies also differed in the level at which they measured prices--for example, the Belgian Consumers' Association study used retail prices, while the Churnside study used ex-manufacturers' prices (that is, the price that the manufacturer charges to the next purchaser). In addition, the different estimates generated by these studies may be the result of methodological differences.¹³ The Danzon study, for example, produced different estimates depending on whether prices were computed by standard unit or by active ingredient, and also whether drugs were matched by manufacturer or solely by chemical composition.

METHODOLOGICAL DIFFICULTIES
LIMIT THE PRECISION
OF EXISTING STUDIES

Although drug price comparisons seem straightforward at first glance, undertaking such a comparison requires a number of complex methodological decisions. For example, two chemically identical drug products may be manufactured by the same company in the United States and France, but nonetheless may differ in other respects--package size, strength, or form--making comparisons problematic.¹⁴ In addition to

¹²After adjusting for the overall rate of inflation, French drug prices declined between 1985 and 1991. In addition, in 1991 the French government ordered an across-the-board price cut of 2.5 percent for all prescription drugs.

¹³For example, the method used to convert foreign prices to a common currency will affect the size of the reported price differential. The Churnside study uses a purchasing power parity, while the Belgian Consumers' Association, Danzon/Kim, APDA, and PMPRB studies use exchange rates.

¹⁴For a more extensive discussion of the methodological issues in conducting international drug price comparisons, see Prescription Drugs: Companies Typically Charge More in the United States Than in the United

the difficulty in finding precisely comparable products, researchers may face data limitations in dealing with generic products and manufacturers' discounts in the U.S. market. These methodological issues mean less precise estimates of the U.S.-France price differential, although they are unlikely to alter the qualitative conclusion that U.S. prescription drug prices exceed those of France.

Differences in French and U.S.
Pharmaceutical Markets Limit
the Number of Comparable Drugs

In the case of France, methodological difficulties are magnified by the idiosyncracies of the French drug market. Many products sold in France are not sold in other countries, limiting the number of drugs for comparison. Some of these research studies, then, are less generalizable because they are based on a small number of drugs. For example, the multinational comparison in the Churnside study is based on 14 products, and the Belgian Consumers' Association study is based on 25 products.

To increase the number of products, some researchers include drugs on the basis of unit of active ingredient, even though the strength or form of the product may differ. For example, the PMPRB study measured prices per unit of active ingredient. While sacrificing some comparability, this method allowed them to include 107 products in their comparison of Canadian and French drug prices. The Danzon/Kim study used two methods of matching--by active ingredient and brand name or manufacturer, or by active ingredient only. While some drugs (in different dosage forms, for example) are less comparable, these methods enabled the researchers to match from 37 to 56 cardiovascular drugs.¹⁵

Exclusion of Generic Drugs
and Manufacturers' Discounts
Can Increase Reported Differentials

In addition to the potentially small number of "matched" products, an additional problem arises in comparing French and U.S. pharmaceutical

Kingdom (GAO/HEHS-94-29, January 12, 1994), pp.42-51.

¹⁵The generalizability of the Danzon/Kim results is limited, however, by their focus on only this one therapeutic category.

products: the use of generic drugs. With the exception of the Danzon/Kim study,¹⁶ the existing comparisons of French and U.S. drug prices have not generally included generic drugs. In France, generic products account for only a small percentage of the market, largely because brand-name prices are set at low levels. By contrast, in the United States generic drugs account for a larger portion of the market. The availability of these lower priced generic drugs could mitigate to some extent the effect of the high prices of brand-name drugs on the U.S. consumer. Although the impact of generic drugs is unlikely to alter the qualitative conclusion of these studies--that U.S. drug prices are higher than prices in France--the exclusion of generic drugs from the comparisons limits their generalizability. While these comparisons are nonetheless valid for brand-name drugs, the estimates from these studies cannot be applied to the entire (brand-name and generic) prescription drug market.¹⁷

In addition, the presence of manufacturers' discounts in the U.S. market may also limit the applicability of existing price comparison studies. In the U.S. pharmaceutical market, certain buyers--such as hospitals, mail-order pharmacies, and some health maintenance organizations--may negotiate price discounts with manufacturers. However, the majority of U.S. outpatient prescriptions represent consumers who are not in a position to benefit from such discounts.¹⁸ This market segment also contains the U.S. consumers who are most vulnerable to relatively high prescription drug prices. In addition, information on manufacturers' discounting practices is generally not publicly available. Therefore, some of the studies we examined used price information for the undiscounted U.S. market segment. Although for this portion of the market this information is an accurate representation of U.S.-French price

¹⁶The Churnside study included 1 generic drug in its sample of 14.

¹⁷For an example of a sensitivity analysis of the effects of including generic drugs, see Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom (GAO/HEHS-94-29, Jan. 12, 1994).

¹⁸The U.S. consumer who buys drugs at a retail pharmacy generally does not benefit from such price discounting, because the wholesalers who serve these pharmacies are not able to negotiate discounts for manufacturers.

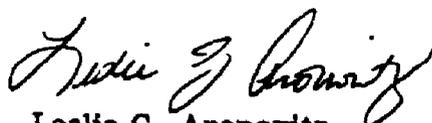
differences, the magnitude of these estimates cannot be generalized to apply to the entire U.S. market. If manufacturers' discounts to other market segments were incorporated into the data, U.S.-French price differences for the U.S. market as a whole would be smaller.¹⁹

IMPLICATIONS OF GOVERNMENT
REGULATION OF U.S. PHARMACEUTICAL
MARKET REMAIN UNCLEAR

France's low drug prices are generally attributed to the regulatory constraints that manufacturers face in selling prescription drugs in the French market. However, the desirability of intervention in pharmaceutical markets remains unclear. Determining the potential impact of a change in U.S. policy is complicated by the many institutional differences between the United States and France, and by the fact that the U.S. pharmaceutical market is appreciably larger than the pharmaceutical market in France. In addition, despite its success in lowering drug prices, the French government has been unable to prevent continued increases in prescription drug spending. The French government's intervention in the pharmaceutical market may also have adversely affected French pharmaceutical research and development. The debate over the potential effects of pharmaceutical regulation cannot be resolved solely by referring to foreign drug prices, and these larger issues are beyond the scope of this letter.

If you or your staff have any questions about this letter, please contact either Scott Smith, Assistant Director, at 202-512-5713 or Sarah Glavin, Senior Economist, at 202-512-7180.

Sincerely yours,



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¹⁹For an example of a study that accounts for some manufacturers' discounts, see Prescription Drugs: Companies Typically Charge More in the United States than in the United Kingdom, (GAO/HEHS-94-29, Jan. 12, 1994).