United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400

PERSONAL AND ~~CONFIDENTIAL~~

September 2, 1993

Mrs. Hillary Rodham Clinton
Chairperson
President's Task Force on Health
Care Reform
The White House
Washington, D.C. 20500

Dear Hillary:

I am writing to let you know that, shortly after returning from the August recess, I would like to challenge pharmaceutical manufacturers to sign a short-term, "voluntary" price restraint commitment with the Secretary of Health and Human Services (HHS).

Under this commitment, drug manufacturers would limit the average annual increase in their weighted average manufacturer's price to the projected increase in the inflation rate. It would also require manufacturers to limit price increases to the inflation rate on individual product package sizes of drugs normally distributed to the retail class of trade.

I feel strongly about proposing such a commitment at this time for the following reasons. To date, only 17 pharmaceutical manufacturers have publicly stated that they would "voluntarily" limit the price increases on their products to the rate of inflation. Other manufacturers have developed "model" contracts and commitments that they would propose to sign with the Secretary of HHS to achieve the same objective. I commend those manufacturers that took the time to craft their own model "voluntary" restraint commitments because these have served as the basis for the commitment that I am proposing here.

Federal anti-trust laws, however, prohibit the entire industry from developing a uniform pricing restraint proposal of its own. Therefore, I have crafted a commitment which I believe meets the industry's public declaration to "voluntarily" restrain its price increases. This commitment would also standardize a pharmaceutical price restraint approach for all manufacturers in the industry, and provide a mechanism to assure the President, the Congress, and the American public that the manufacturer has met its commitment.

In addition, by signing this commitment, a drug manufacturer would be publicly demonstrating its desire and intent to voluntarily restrain pharmaceutical price increases. This is a goal which has been stated frequently by representatives of the drug manufacturing industry and its member companies.

An important part of this commitment would require that manufacturers limit price increases to the rate of inflation on individual retail pharmaceutical package sizes. This is very important. Data from the first half of 1993 indicate that many individual prescription medications are still increasing in price much faster than the rate of inflation. A table of price increases for over 90 prescription medications for the first half of the year is enclosed. This approach would assure that pricing restraints are meaningful for all Americans, especially the millions of our nation's older Americans, who rely on prescription medicines to maintain life and health.

As you know, for the past four years, the Senate Aging Committee has been carefully following the pricing practices of drug manufacturers. The bottom line is that meaningful restraint on pharmaceutical price increases in the United States is long overdue. Between 1980 and 1992, prescription drug prices increased six times the rate of inflation. As a result, millions of Americans -- especially older Americans -- have had to make the unfortunate choices between buying food or medication. Therefore, to provide relief to older Americans as quickly as possible, I would encourage each brand-name drug manufacturer to sign and return this commitment to the Secretary of HHS by October 15th, 1993.

Your support, and that of the President, for this initiative would be very much appreciated. Because I would like to go public with this commitment next Thursday, September 9, I would appreciate if you would let me know as soon as possible if you have any questions, concerns, or just want to talk about this proposal. Thank you very much.

Sincerely,

David Pryor
Chairman

Enclosures

cc: Ira Magaziner
The Honorable Donna Shalala, Ph.D.

PHARMACEUTICAL PRICE RESTRAINT COMMITMENT

made by

BRAND-NAME PHARMACEUTICAL MANUFACTURERS

to

THE SECRETARY OF HEALTH AND HUMAN SERVICES

September, 1993

proposed by
Senator David Pryor (D-Ark)
Chairman, Special Committee on Aging
United States Senate

NEED FOR PHARMACEUTICAL PRICE INCREASE RESTRAINT

o Between 1980 and 1992, pharmaceutical prices at the manufacturers level increased six times the rate of inflation, making it very difficult for all Americans -- especially millions of older Americans -- to afford prescription medications.

o As a result of this excessive prescription drug price inflation, prescription drug expenses have become the highest out-of-pocket medical cost for 3 of 4 older Americans.

o To date, 17 pharmaceutical manufacturers indicate that they are "voluntarily" limiting price increases on their products to the rate of inflation in one way or another. However, dozens of other drug manufacturers of essential medications have not made such a commitment to the American public.

o Most of these "voluntary" commitments, however, limit price increases on a "weighted average aggregate basis across a manufacturer's product line" to the rate of inflation. While this is a necessary first step toward pharmaceutical price restraint, it is not totally sufficient for restraint to be meaningful to the average older American.

o In addition, there is no uniformity in approach among the pharmaceutical restraint policies adopted by these manufacturers.

o Finally, data from the first half of 1993 indicate that many individual prescription drug products at the retail level are still increasing much faster than the rate of inflation.

PURPOSE OF PRICE RESTRAINT COMMITMENT

o Permit uniformity among pharmaceutical manufacturer price increase restraint approaches.

o Assure that all drug manufacturers are given the opportunity to make a public commitment to restrain price increases.

o Assure that all individual drug product prices at the retail or consumer level do not increase faster than the rate of inflation.

o Provide for an interim measure to contain pharmaceutical prices until the transition to the new health care system is completed.

o Offer a fair and enforceable way to assure that manufacturers meet their commitment to the American public.

PHARMACEUTICAL PRICING RESTRAINT COMMITMENT BY A PHARMACEUTICAL MANUFACTURER TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

This is a commitment made by the pharmaceutical manufacturer identified below (hereinafter referred to as the manufacturer) to the Secretary of Health of Human Services (hereinafter referred to as the Secretary).

1. NATURE OF COMMITMENT

(i) Under this commitment, the pharmaceutical manufacturer agrees to restrain pharmaceutical price increases of all drugs and biologicals sold by the manufacturer in the United States and the District of Columbia which are required to be prescribed under federal law by a physician. In particular, these shall include single source and innovator multiple source pharmaceutical products and biologicals of the manufacturer. The manufacturer agrees not to include non-innovator multiple source pharmaceuticals (generic drugs) as part of this commitment.

(ii) A single source pharmaceutical is defined as a pharmaceutical which is produced or distributed under a new drug application or product licensing application approved by the Food and Drug Administration, including a drug product marketed by cross-licensed producers or distributers operating under the new drug application.

(iii) An innovator multiple source pharmaceutical product is a multiple source drug or biological that was originally marketed under a new drug application or product licensing application approved by the FDA. A multiple source drug has the same definition as found under section 1927(k) of the Social Security Act.

2. TERMS OF COMMITMENT

A. Retroactive Commitment

(i) This commitment by the manufacturer shall be made retroactive to January 1, 1993. The manufacturer will limit the increase in its weighted average manufacturer's inflation index, as described below, to 3.2 percent and its retail pharmaceutical product price index, as described below, to 4.2 percent for 1993.

B. Annual Pharmaceutical Price Increase Restraint:

(i) Beginning in 1994 and for each subsequent calendar year that this commitment is in effect, the manufacturer will limit the increase in its weighted average manufacturer price inflation index and the retail pharmaceutical product price index to the projected rate of increase in the CPI-U (all urban consumers, U.S. average) for the calendar year.

C. Cumulative Pharmaceutical Price Increase Restraint:

(i) Beginning in 1994, and for each subsequent calendar year that this commitment is in effect, the manufacturer will limit the cumulative increase in the weighted average manufacturer's inflation index and the retail pharmaceutical product price index to the projected cumulative increases in the CPI-U from December 31, 1993 through the end of each calendar year.

3. CALCULATION OF THE INDICES

A. Calculation of the Annual Weighted Average Manufacturers' Price Inflation Index:

(i) For a calendar year, the manufacturer will calculate its weighted average manufacturers' price inflation index for all single source and innovator multiple source drugs of the manufacturer by calculating the summation of:

(1) the total net revenue for each dosage form and strength of each such drug distributed to all classes of trade (taking into account any rebates, discounts and free goods) divided by the total net revenue for all such drugs of the manufacturer, multiplied by:

(2) the average manufacturer's price for each dosage form and strength of each such drug distributed to all classes of trade in the current year minus the average manufacturers price for each dosage form and strength of each such drug distributed to all classes of trade for the previous year, divided by the average manufacturers price for each dosage form and strength of each such drug distributed to all classes of trade for the previous year.

B. Calculation of the Retail Pharmaceutical Product Price Inflation Index:

(i) For a calendar year, the manufacturer commits that the calculation of the retail pharmaceutical product price index for each pharmaceutical product package size of the manufacturer normally distributed to the retail class of trade (as reported by the manufacturer to the Secretary in implementation of section 1927 of the Social Security Act) is equal to the average manufacturer's price as of December 31 of the current year minus the average manufacturer's price as of December 31 of the previous year divided by the average manufacturer's price of December 31 of the previous year.

(ii) For the purposes of the calculation of the retail pharmaceutical product price inflation index, the term "average manufacturer's price" has the same meaning as described under the contract signed by the manufacturer with the Secretary under section 1927 of the Social Security Act.

(iii) For the calculation of the retail pharmaceutical product price inflation index, the manufacturer will adjust the average manufacturers price in the previous calendar year, if necessary, to reflect the price that would have been in effect had the manufacturer not increased its price more than the allowable rate of inflation for that year.

C. Calculation of the Cumulative Weighted Average Manufacturers' Price Inflation Index:

(i) The manufacturer commits that the cumulative increase in the weighted average manufacturers price inflation index through the end of any calendar year during which this commitment is in effect shall be no greater than the cumulative projected increases in the rate of inflation from December 31, 1993 through the end of the current calendar year.

D. Calculation of the Cumulative Retail Pharmaceutical Product Price Inflation Index:

(i) The manufacturer commits that the cumulative increase in the retail pharmaceutical product price index through any calendar year during which this commitment is in effect shall be no greater than the cumulative projected increase in the rate of inflation from December 31, 1993 through the end of the current calendar year.

E. Treatment of New Pharmaceuticals:

(i) For the purposes of calculating the weighted average manufacturers price inflation index, the manufacturer will not include a new package size of a single source or innovator multiple source drug in the calculation of such index until such drug has been marketed in the United States for a period of six months.

F. Determination of Base Period for Pharmaceutical Products Sold or Transferred:

(i) The manufacturer commits that the base date for any single source or innovator multiple source drug product that is sold or transferred to another division or subsidary within the company or to another legally-separate entity or corporation, subsequent to the signing of this commitment is, for the weighted average manufacturer's price inflation index, the average manufacturer's price during the calendar year 1993, and for the retail pharmaceutical price product index, is the average manufacturer's price as of December 31, 1993.

G. Determination of Allowable Increase in Inflation:

(i) The manufacturer will use the December "Blue Chip Indicator" forecast of the next calendar year's Consumer Price Index - all urban consumers (CPI-U) to determine the allowable increase in inflation for the next calendar year.

4. ADJUSTMENT TO MANUFACTURER PRICES FOR EXCESSIVE INFLATION

A. If, after the calendar year, the manufacturer exceeded the allowable rate of inflation in the previous calendar year, the manufacturer will:

(i) pay a sum to the U.S. Treasury through the Secretary of HHS within 60 days of the end of the calendar year which is equal to 200 percent of the difference between the sum of the amounts of excess revenue realized by the manufacturer as a result of price increases for each dosage form and strength of each single source and innovator multiple source drug that increased in price faster than allowable rate of inflation for the calendar year and the sum of the amount of revenue not realized by the manufacturer as a result of price increases for each dosage form and strength of each single source and innovator multple source drug that did not increase in price up to the allowable rate of inflation for the calendar year.

(ii) reduce the average manufacturer's price of the manufacturer's drugs for the new calendar year to the price level which would have resulted in no payment to the U.S. Treasury as specified under subsection (1).

5. PROVISIONS OF INFORMATION TO THE SECRETARY

A. Provision of Price Information:

(i) No later than 60 days after each calendar year, beginning in 1994, the manufacturer will provide the following information to the Secretary for drug products for the calendar year just ended:

(1) detailed description of the calculation of the weighted average manufacturers' price inflation index for all dosage forms and strengths of all single source and innovator multiple source drugs, indicating each specific calculation made in determining this index;

(2) the actual average manufacturers price for each package size of each single source and innovator multiple source drug normally distributed to the retail class of trade, and the average manufacturers price for each package size of each single source and innovator multiple source drug normally distributed to the retail class of trade had the increase in price from the previous year been limited to the allowable increase in inflation;

(3) detailed description of the methodology used to determine any payment that is owed to the Secretary, if any, as a result of the manufacturer's exceeding the allowable rate of inflation.

B. Auditing of the Manufacturers Calculation:

(i) The manufacturer will permit the Secretary to have access, in a confidential manner, to any pricing and sales data of the manufacturer for any calendar year of the manufacturer affected by this commitment, if the Secretary indicates that such an audit is necessary to verify the data that has been submitted to the manufacturer by the Secretary under subsection (A).

6. LENGTH OF COMMITMENT

A. This commitment will remain in effect until December 31, 1996, and then afterward until the National Health Care Board certifies that 80 percent of the population in the United States is covered under a private or public insurance plan that provides coverage for outpatient prescription drugs as required under health care reform legislation enacted by the Congress subsequent to the signing of this commitment.

7. CONFIDENTIALITY OF INFORMATION PROVIDED UNDER THIS COMMITMENT

A. Any information contained in a report submitted to the Secretary by the manufacturer under this commitment shall be confidential and exempt from public disclosure pursuant to applicable provisions of the Freedom of Information Act.

8. TERMINATION OF COMMITMENT

A. The manufacturer commits to provide 180 days written notice to the Secretary if the manufacturer intends to terminate this commitment. In the event of termination, the manufacturer commits to pay the U.S. Treasury through the Secretary the pro-rata amount of any payment due for the calendar year, based on the number of months prior to the effective date of termination.

DATE:_____

Commitment Made:

By the Manufacturer: _____

_____

_____

Acknowledged by:

For the Secretary: _____

_____

_____

PRESCRIPTION DRUG PRICE INCREASES
ON MANY INDIVIDUAL DRUG PRODUCTS TAKEN BY OLDER AMERICANS
STILL EXCEEDING GENERAL INFLATION RATE

January - June 1993

DRUG/MANUFACTURER/USE	PRICE INCREASE PERCENT Jan-June 1993	MULTIPLE OF Jan-June CPI (1.8%)	MULTIPLE OF PROJECTED 1993 CPI (3.2%)
	A	B	C
Betoptic (Alcon) drops [glaucoma]	5.9%	3.3	1.8
Brethine (Geigy) 2.5mg., 100's [asthma]	5.0%	2.8	1.6
Bromfed (Muro) PD Caps, 100's [antihistamine]	7.0%	3.9	2.2
Calan (Searle) 40 mg, 100's [hypertension]	5.5%	3.1	1.7
Calan (Searle) 120 mg, 100's [hypertension]	5.5%	3.1	1.7
Calan-SR (Searle) 180 mg, 100's [hypertension]	5.5%	3.1	1.7
Capoten (Squibb) * 12.5 mg, 100's [hypertension]	4.9%	2.7	1.5
Capoten (Squibb) * 25 mg, 100's [hypertension]	4.9%	2.7	1.5
Capozide (Squibb) * 25 mg, 100's [hypertension]	4.9%	2.7	1.5
Cardizem CD (Marion) * 120 mg, 30's [hypertension]	5.3%	2.9	1.6

Cardizem CD (Marion) * 180 mg, 30's [hypertension]	8.2%	4.6	2.6
Ceftin (Glaxo) * 125 mg, 20's [antibiotic]	5.4%	3.0	1.7
Ceftin (Glaxo) * 125 mg, 60's [antibiotic]	5.4%	3.0	1.7
Colestid (Upjohn) 300 gm [cholesterol]	9.2%	5.1	2.9
Colestid (Upjohn) 500 gm [cholesterol]	9.2%	5.1	2.9
Corgard (Squibb) * 20 mg, 100's [antiarrhythmic]	4.9%	2.7	1.5
Corgard (Squibb) * 40 mg, 100's [antiarrhythmic]	4.9%	2.7	1.5
Corgard (Squibb) * 80 mg, 100's [antiarrhythmic]	4.9%	2.7	1.5
Coumadin (Dupont-Merck) * 1 mg, 100's [blood thinner]	5.1%	2.8	1.6
Coumadin (Dupont-Merck) * 2 mg, 100's [blood thinner]	5.1%	2.8	1.7
Coumadin (Dupont-Merck) * 2.5 mg, 100's [blood thinner]	5.0%	2.8	1.5
Coumadin (Dupont-Merck) * 10 mg, 100's [blood thinner]	5.1%	2.8	1.7
Cytotec (Searle) 100 mcg, 60's [antiulcer]	5.5%	3.1	1.7

Cytotec (Searle) 200 mcg, 60's [antiulcer]	5.5%	3.1	1.7
Danocrine (Sanofi-Winthrop) * 200 mg, 60's [hormome]	5.0%	2.8	1.6
Disalcid (Riker) 500 mg caps, 100's [arthritis]	8.0%	4.4	2.5
Disalcid (3M) 500 mg tabs, 100's [arthritis]	8.0%	4.4	2.5
Disalcid (3M) 750 mg tabs, 100's [arthritis]	8.1%	4.5	2.5
Doral (Wallace) 7.5 mg, 100's [sedative]	9.6%	5.3	3.0
Doral (Wallace) 15 mg, 100's [sedative]	9.6%	5.3	3.0
Eskalith (SmithKline) * 300 mg caps, 100's [antipsychotic]	5.9%	3.3	1.8
Eskalith (SmithKline) * 300 mg tabs, 100's [antipsychotic]	5.9%	3.3	1.8
Estraderm (Ciba) 0.1 mg, 8's [estrogen]	5.0%	2.8	1.6
K-Dur (Key) 10 mEq, 100's [potassium]	6.5%	3.6	2.0
K-Dur (Key) 20 mEq, 100's [potassium]	4.8%	2.7	1.5

Lanoxin (Burroughs Wellcome) .125 mg, 100's [heart failure]	5.8%	3.3	1.8
Lanoxin (Burroughs Wellcome) .25 mg, 100's [heart failure]	5.8%	3.2	1.8
Lanoxin (Burroughs Wellcome) .5 mg, 100's [heart failure]	5.9%	3.3	1.8
Lopressor (Geigy) 50 mg, 1000's [hypertension]	6.7%	3.7	2.1
Lopressor (Geigy) 100 mg, 1000's [hypertension]	6.7%	3.7	2.1
Lotrimin (Schering) Cr. 1%, 30 gm [antifungal]	6.5%	3.6	2.0
Lotrimin (Schering) Cr. 1%, 60 gm [antifungal]	6.5%	3.6	2.0
Macrodantin (Procter & Gamble) 25 mg, 100's [urinary tract]	9.7%	5.4	3.0
Macrodantin (Procter & Gamble) 50 mg, 100's [urinary tract]	9.7%	5.4	3.0
Macrodantin (Procter & Gamble) 100 mg, 100's [urinary tract]	9.7%	5.4	3.0
Maxair (3M) 200mcg, 25.6 gm [asthma]	8.9%	4.9	2.8
Maxitrol (Alcon) Opth. Oint., 3.5 gm [eye drops]	7.6%	4.2	2.4
Maxitrol (Alcon) Opth. Susp., 5 ml [eye drops]	7.6%	4.2	2.4

Methotrexate (Lederle) 2.5 tabs, 100's [cancer]	5.2%	2.9	1.6
Micronase (Upjohn) 1.25 mg, 100's [diabetes]	6.0%	3.3	1.9
Micronase (Upjohn) 2.5 mg, 100's [diabetes]	6.0%	3.3	1.9
Micronase (Upjohn) 5 mg, 100's [diabetes]	6.0%	3.3	1.9
Minocin (Lederle) * 50 mg, 100's [antibiotic]	5.2%	2.9	1.6
Minocin (Lederle) * 100 mg, 100's [antibiotic]	5.2%	2.9	1.6
Nizoral (Janssen) Cr. 2%, 15 gm [antifungal]	6.0%	3.3	1.9
Nizoral (Janssen) Cr. 2%, 30 gm [antfungal]	6.0%	3.3	1.9
Norgesic (3M) Tabs, 100's [arthritis]	7.0%	3.9	2.2
Norgesic (3M) Forte Tabs, 100's [arthritis]	7.0%	3.9	2.2
Normodyne (Schering) 100mg, 100's [hypertension]	5.0%	2.8	1.6
Norpace CR (Searle) 100 mg caps, 100's [arrhythmias]	5.5%	3.1	1.7
Norpace CR (Searle) 150 mg caps, 100's [arrhythmias]	5.5%	3.1	1.7

Percocet (Dupont-Merck) * 100's [pain killer]	5.1%	2.8	1.6
Peridex (P & G Professional) Oral Rinse [antibacterial]	8.1%	4.5	2.5
Persa-Gel (Ortho) 5% gel, 90 gm [acne]	4.7%	2.6	1.5
Pilocar (Iolab) 0.5%, 15 ml [glaucoma]	8.2%	4.6	2.6
Pilocar (Iolab) 1%, 15 ml [glaucoma]	7.9%	4.4	2.5
Pilocar (Iolab) 4%, 15 ml [glaucoma]	7.9%	4.4	2.5
Questran (Squibb) * 378 gm [cholesterol]	4.8%	2.7	1.5
Questran Light (Squibb) * 210 gm [cholesterol]	4.8%	2.7	1.5
Restoril (Sandoz) 15 mg, 100's [sedative]	5.0%	2.8	1.6
Restoril (Sandoz) 30 mg, 100's [sedative]	5.0%	2.8	1.6
Rythmol (Knoll) 150 mg, 100's [arrythmias]	5.0%	2.8	1.6
Rythmol (Knoll) 300 mg, 100's [arrythmias]	5.0%	2.8	1.6
Symmetrel (Dupont-Merck) * 100 mg, 100's [antiviral]	9.3%	5.2	2.9

Theo-Dur (Key) 100 mg, 100's [asthma]	6.5%	3.6	2.0
Theo-Dur (Key) 200 mg, 100's [asthma]	6.5%	3.6	2.0
Theo-Dur (Key) 300 mg, 100's [asthma]	6.5%	3.6	2.0
Tobradex (Alcon) Opth. Susp, 2.5 ml [antibiotic]	6.1%	3.4	1.9
Tobradex (Alcon) Opth. Oint, 3.5 gm [antibiotic]	5.4%	3.0	1.7
Tobrex (Alcon) Opth. Oint, 3.5 gm [antibacterial]	6.5%	3.6	2.0
Tolectin (McNeil) DS Caps, 400 mg, 100's [arthritis]	6.4%	3.6	2.0
Tolectin (McNeil) 200mg tabs, 100's [arthritis]	6.0%	3.3	1.9
Tolectin (McNeil) 600 mg tabs, 100's [arthritis]	6.4%	3.6	2.0
Trandate (Glaxo) * 100 mg, 100's [hypertension]	5.0%	2.8	1.6
Vascor Filmtabs (Ortho) 200 mg, 30's [hypertension]	6.0%	3.3	1.9
Vascor Filmtabs (Ortho) 300 mg, 30's [hypertension]	6.0%	3.3	1.9
Voltaren (Geigy) 25 mg, 60's [arthritis]	5.0%	2.8	1.6

Voltaren (Geigy) 50 mg, 60's [arthritis]	5.0%	2.8	1.6
Voltaren (Geigy) 75 mg, 60's [arthritis]	5.0%	2.8	1.6
Zovirax (Burroughs Wellcome) 200 mg, 100's [antiviral]	6.7%	3.7	2.1
Zovirax (Burroughs Wellcome) Oint., 5%, 3 gm [antiviral]	6.7%	3.7	2.1

---

* - Indicates a company that had made a public declaration to hold their price increases, in one way or another, below the increase in the Consumer Price Index.

KEY TO COLUMNS:

A - Indicates the increase in the Average Wholesale Price (AWP) for the drug for the period January - June, 1993 as reported in Medispan Data Base. These prices reflect the average prices at which manufacturers report that pharmaceutuical wholesalers sell their products to buyers, including community pharmacies. AWPs are generally regarded as "sticker prices".

AWPs usually do not reflect actual transaction prices, but such transaction prices are generally calculated as a percentage of the AWP. For example, a buyer may purchase a drug at AWP minus 10 percent. Therefore, if the AWP increases, the actual transaction price increases as well. Therefore, if a product's AWP is $50 and increases to $53, it is an increase of 6 percent. The original transaction price at AWP minus 10 percent is $45, and the new transaction price is $47.7, which is also a 6 percent increase from the original transaction price of $45. Therefore, the increase in the AWP closely reflects percentage increases in actual transaction prices.

B - Indicates the multiple by which the price increase on the drug for the first six months of 1993 exceeded the increase in the CPI-U for the first six months of 1993, which was 1.8 percent.

C - Indicates the multiple by which the price increase on the drug for the first six months of 1993 exceeds the projected Blue Chip Indicator increase in the CPI-U for the entire calendar year 1993, which was 3.2 percent at the beginning of the year. Therefore, even if the manufacturers do not increase the prices of these drugs any further in 1993, they have already exceeded the projected rate of inflation for 1993 in the first six months of 1993.

Ira /

This is the statement that HRC -- not the President -- wants to send tomorrow on that proposal of David Pryor that calls on the industry (as the President did two weeks ago) to live up to their pledge (voluntarily) to keep their products' prices at or below inflation. Are you OK on this?

DRAFT

STATEMENT ON

SENATOR PRYOR'S PHARMACEUTICAL RESTRAINT AGREEMENTS

Bob B. wanted to be more critical of the industry in the language, but I suggested that you would not think it to be advisable.

First Lady Hillary Rodham Clinton today indicated her support of Senator David Pryor's (D-AK) call for pharmaceutical manufacturers to sign voluntary commitments to restrain prescription drug price increases:

"While we are still evaluating the specifics of Senator Pryor's proposal, we applaud him for his vision, dedication and leadership in doing all he can to help make prescription drugs affordable and accessible for the American public. His challenge to the industry is precisely the type of initiative which must be met by pharmaceutical manufacturers and others in the health care industry if we are going to work together to put the brakes on health care inflation.

"As we understand it, under Senator Pryor's proposal, the makers of prescription drugs would commit to limiting retail price increases to the annual inflation rate. By taking this action, manufacturers would protect the American consumer from escalation of drug prices. This is important because drug price inflation has been particularly significant at the consumer level over the last twelve years.

"Based on the many thousands of letters that the White House has received over the past eight months on health care reform, the cost of prescription medications is among the top concerns of Americans. Senator Pryor's approach appears to provide a realistic way to deal with medication costs during the period of transition to the new system.

"The pharmaceutical industry has repeatedly stated that they are committed to keeping price increases for their products at or below the general inflation rate. Recently the President called on the industry to keep to their pledge. Senator Pryor's proposal represents a golden opportunity for the industry to make good on that pledge to the American public."

#

P.S. This has been approved by HRC Melanne Jeff E Lisa Caputo and Bob B.

DRAFT
STATEMENT ON
SENATOR PRYOR'S PHARMACEUTICAL RESTRAINT AGREEMENTS

First Lady Hillary Rodham Clinton today indicated her support of Senator David Pryor's (D-AK) call for pharmaceutical manufacturers to sign voluntary commitments to restrain prescription drug price increases:

"While we are still evaluating the specifics of Senator Pryor's proposal, we applaud him for his vision, dedication and leadership in doing all he can to help make prescription drugs affordable and accessible for the American public. His challenge to the industry is precisely the type of initiative which must be met by pharmaceutical manufacturers and others in the health care industry if we are going to work together to put the brakes on health care inflation.

"As we understand it, under Senator Pryor's proposal, the makers of prescription drugs would commit to limiting retail price increases to the annual inflation rate. By taking this action, manufacturers would protect the American consumer from escalation of drug prices. This is important because drug price inflation has been particularly significant at the consumer level over the last twelve years.

"Based on the many thousands of letters that the White House has received over the past eight months on health care reform, the cost of prescription medications is among the top concerns of Americans. Senator Pryor's approach appears to provide a realistic way to deal with medication costs during the period of transition to the new system.

"The pharmaceutical industry has repeatedly stated that they are committed to keeping price increases for their products at or below the general inflation rate. Recently the President called on the industry to keep to their pledge. Senator Pryor's proposal represents a golden opportunity for the industry to make good on that pledge to the American public."

#

Pryor & Drugs

The White House

Office of the Press Secretary

For Immediate Release September 15 , 1993

Statement from the White House

SENATOR PRYOR'S PHARMACEUTICAL RESTRAINT AGREEMENTS

The White House today indicated its support of Senator David Pryor's (D-AR) call for pharmaceutical manufacturers to sign voluntary commitments to restrain prescription drug price increases:

"While we are still evaluating the specifics of Senator Pryor's proposal, we applaud him for his vision, dedication and leadership in doing all he can to help make prescription drugs affordable and accessible for the American public. His challenge to the industry is precisely the type of initiative which must be met by pharmaceutical manufacturers and others in the health care industry if we are going to work together to put the brakes on health care inflation.

Under Senator Pryor's proposal, the makers of prescription drugs would commit to limiting retail price increases to the annual inflation rate. By taking this action, manufacturers would protect the American consumer from escalation of drug prices. This is important because drug price inflation has been particularly significant at the consumer level over the last twelve years.

Based on the many thousands of letters that the White House has received over the past eight months on health care reform, the cost of prescription medications is among the top concerns of Americans. Senator Pryor's approach appears to provide a realistic way to deal with medication costs during the period of transition to the new system.

The pharmaceutical industry has repeatedly stated that they are committed to keeping price increases for their products at or below the general inflation rate. Recently the President called on the industry to keep to their pledge. Senator Pryor's proposal represents a golden opportunity for the industry to make good on that pledge to the American public."

###

R-05x

The White House

Office of the Press Secretary

For Immediate Release **September 15 , 1993**

Statement from the White House

SENATOR PRYOR'S PHARMACEUTICAL RESTRAINT AGREEMENTS

The White House today indicated its support of Senator David Pryor's (D-AR) call for pharmaceutical manufacturers to sign voluntary commitments to restrain prescription drug price increases:

"While we are still evaluating the specifics of Senator Pryor's proposal, we applaud him for his vision, dedication and leadership in doing all he can to help make prescription drugs affordable and accessible for the American public. His challenge to the industry is precisely the type of initiative which must be met by pharmaceutical manufacturers and others in the health care industry if we are going to work together to put the brakes on health care inflation.

Under Senator Pryor's proposal, the makers of prescription drugs would commit to limiting retail price increases to the annual inflation rate. By taking this action, manufacturers would protect the American consumer from escalation of drug prices. This is important because drug price inflation has been particularly significant at the consumer level over the last twelve years.

Based on the many thousands of letters that the White House has received over the past eight months on health care reform, the cost of prescription medications is among the top concerns of Americans. Senator Pryor's approach appears to provide a realistic way to deal with medication costs during the period of transition to the new system.

The pharmaceutical industry has repeatedly stated that they are committed to keeping price increases for their products at or below the general inflation rate. Recently the President called on the industry to keep to their pledge. Senator Pryor's proposal represents a golden opportunity for the industry to make good on that pledge to the American public."

###

FOR IMMEDIATE RELEASE
April 26, 1993

Ann Trinca/
Andrea Boldon
202/224-5364

CHAIRMAN PRYOR OFFERS BLUEPRINT FOR PHARMACEUTICAL REFORM
Outlines issues and options in discussion paper to Mrs. Clinton

WASHINGTON, D.C. -- Senator David Pryor (D-AR) today sent a discussion paper to First Lady Hillary Rodham Clinton, Chairperson of the President's Task Force on Health Care Reform, offering his ideas and suggestions on reforming the pharmaceutical marketplace.

"You and the President have indicated a strong interest in assuring that more Americans have better access to pharmaceuticals and vaccines at reasonable prices," Pryor said in an April 26 letter to Mrs. Clinton. "The comprehensive health care reform effort that you are leading gives us a unique opportunity to restructure the pharmaceutical sector of the health care industry."

"Over the past four years, as Chairman of the Senate Special Committee on Aging, I have been studying the pharmaceutical marketplace in the United States from various perspectives," Pryor said. "In order to assist you in your deliberations about reforming this critical component of our health care system, I have compiled my own perspectives on the current situation regarding prescription drug access and cost containment in this country."

The topics discussed by Chairman Pryor in the paper include:

- the need to provide more information about the cost and value of drugs to health care providers and consumers;
- ideas on how to structure potential prescription drug programs under the "standard" health benefits package and Medicare;
- using Medicare's purchasing power to negotiate with drug manufacturers over prices;
- assuring that any "short-term" pharmaceutical cost containment measures provide relief to the average American from prescription drug price inflation;
- benefits and potential shortcomings of "managed competition" in containing drug prices;
- mechanisms to insure that new drug products -- including drugs developed with federal funds -- are brought to the market at reasonable prices both in the short term and long term.

###

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400

April 26, 1993

Mrs. Hillary Rodham Clinton
Chairperson
The President's Task Force on Health Care Reform
The White House
Washington, D.C. 20500

Dear ~~Madam Chairperson~~ Hillary:

As Chairperson of the President's Task Force on Health Care Reform, you will be dealing with the monumental task of restructuring the nation's health care system. Providing affordable health care to tens of millions of Americans currently without insurance coverage, containing health care costs, and improving the quality of medical care are the challenges that we all face. I look forward to working with you to meet these challenges.

You and the President have indicated a strong interest in assuring that more Americans have better access to pharmaceuticals and vaccines at reasonable prices. These are goals which I share. The issue of pharmaceutical pricing is of significant interest to me because of the impact that rising medication prices have had on our senior citizen population. Because older Americans take more prescription medications than any other population group, and often have inadequate private or public insurance coverage, rising prescription prices have significantly affected the elderly.

The comprehensive health care reform effort that you are leading gives us a unique opportunity to restructure this sector of the health care industry. Over the past four years, as Chairman of the Senate Special Committee on Aging, I have been studying the pharmaceutical marketplace in the United States from various perspectives. The Committee has held many hearings, issued several reports, and I have introduced legislation to contain prescription drug prices.

In order to assist you in your deliberations about reforming this critical component of our health care system, I have compiled my own perspectives on the current situation regarding prescription drug access and cost containment in this country.

The enclosed discussion paper identifies a number of the current problems and issues in the pharmaceutical marketplace. It provides you and the Task Force with some of my own personal reflections on what could be done about pharmaceuticals within the health care reform framework that appears to be emerging from the Task Force's deliberations.

Undoubtedly, the Task Force will receive many ideas on ways to reform the health care system -- including the pharmaceutical segment -- from individuals and groups that have a sincere desire to contribute to the discussion. I just wanted to pass along some of my own ideas about this issue, and want to thank you for your consideration. Once again, I look forward to receiving the Task Force's report and working with you in enacting a plan that truly reforms the nation's health care system.

Sincerely,

David Pryor
Chairman

Enclosure

United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400

PHARMACEUTICAL MARKETPLACE REFORM

submitted to the
President's Task Force on Health Care Reform
by

Senator David Pryor (D-Ark)

Chairman
United States Senate
Special Committee on Aging

April, 1993

SUMMARY

Prescription Drug Access

o If a prescription drug benefit is included in the "standard" benefits package, maximum flexibility should be given to health care plans to structure the benefit within minimum federal standards. These standards should include a "percentage" rather than "flat" dollar prescription cost-sharing provision, and encourage the development of Drug Use Review (DUR) programs. A process should be established to assist health plans in developing and structuring drug formularies and DUR programs.

o It is unlikely that the Medicare program will be immediately integrated into the new "managed competition" health care system. Therefore, Medicare beneficiaries will still have high out-of-pocket drug costs without some initiatives to improve prescription drug insurance coverage for this segment of the population.

o Any Medicare prescription drug program that is developed should include specific pharmaceutical cost containment mechanisms which reflect the tremendous pharmaceutical purchasing power that Medicare will have in the drug market. Any Medicare drug program should also have a comprehensive program of Drug Use Review (DUR).

Pharmaceutical Cost Containment Approaches

o With or without universal coverage for prescription drugs in the "standard" health benefits package, there is a need for prescription drug cost containment mechanisms in the health care reform package. If there is no universal prescription drug coverage, Americans will still pay for most of their drugs out-of-pocket, requiring that pharmaceutical cost containment measures be enacted. With universal coverage, pharmaceutical cost containment measures will make the prescription drug benefit more affordable.

o During the transition period to a health care system based on "managed competition," there is a need to contain the cost of drugs that are currently on the market, as well as new drugs. Without a comprehensive cost containment approach on both classes of drugs, manufacturers may "shift" costs to new drugs, and launch new drugs at much higher prices.

o Voluntary manufacturer pharmaceutical cost containment programs are to be commended, but any national "voluntary" approach should be structured very carefully. Any voluntary approach should require that the price restraint be meaningful for the average American consumer paying for their prescription drugs out-of-pocket, and that these restraints be enforceable and auditable. "Weighted average price increase limits" across a particular product line will have limited impact for the average consumer without cost containment mechanisms on individual drugs.

o In a significant part of the marketplace, managed competition can be effective in containing the cost of drugs that are currently on the market. The drug formulary will be the primary management tool that these health plans will use to provide a quality, cost-effective drug benefit.

o Managed competition may not be as effective at containing the cost of currently-marketed drugs in rural areas. These areas are unlikely -- at least in the early stages of managed competition -- to have the same ability to negotiate lower drug prices with manufacturers as better organized managed care systems. In addition, fee-for-service plans may not have the same ability to contain drug prices as managed care plans.

o Managed competition will only be somewhat effective in containing new drug costs. Assuming that most of the market will use drug formularies, managed competition can contain the cost of new drugs that have therapeutic substitutes or competitors. However, managed competition will probably be ineffective in containing the cost of new drugs that are the first drug or biological in a new class, or drugs that are developed through government-sponsored Cooperative Research and Development Agreements (CRADAs).

Impact of Expanded Prescription Access on Drug Manufacturer Revenue

o Expanded access to pharmaceuticals from enhanced prescription drug insurance coverage may result in significantly increased revenue for drug manufacturers. This will result from the millions of new prescriptions that will be written and dispensed each year. In fact, the PMA recently estimated that 72 million Americans have no or partial drug coverage, and would benefit from prescription drug coverage. The debate over pharmaceutical cost containment mechanisms should be considered with this fact in mind.

o Approximately 60 percent of all generic drugs are made by brand-name drug manufacturers. Therefore, manufacturers will not only benefit from an increase in brand-name drug dispensing, they will also benefit if generic drug dispensing is encouraged in a Medicare drug program or in drug programs for the under 65 population.

THE CURRENT PHARMACEUTICAL MARKETPLACE

There are several problems in the pharmaceutical marketplace that need to be addressed in a comprehensive pharmaceutical access and cost containment package.

Access to Prescription Drugs:

The number of individuals with some type of prescription drug coverage in the United States has been slowly increasing over the past few years, as has been the extent of that coverage. However, more than 50 percent of all Americans under 65 still largely pay for their prescription medications out-of-pocket. This percentage is even higher for the over 65 (Medicare) population, in which about 64 percent pay for drugs out-of-pocket.

The problem of drug coverage is most acute for older Americans who take more prescriptions per year than the average American. The over 65 population is generally unable to afford either Medigap or private drug insurance policies, and Medicare does not have an outpatient prescription drug benefit.

Recent AARP data show that about 8 million older Americans are making choices between buying food and medicine. In addition, the AARP data indicate that the older you are, the more likely you are to take prescription drugs, but the less likely you are to have drug coverage. Medicaid does have an outpatient drug benefit, but it only covers 1.9 million of the 12 million poor or "near poor" elderly in the country. The lack of drug coverage, combined with the expensive cost of drugs, has created a very serious prescription drug access problem for the population group that is between 100 and 200 percent of the poverty level.

Prescription drug coverage in the HMO/managed care market is significantly better than the fee-for-service market. A recent "HMO Industry Profile" report found that 97 percent of the best-selling HMO benefit packages cover outpatient prescription drugs.

Escalating Drug Prices:

During the 1980's, brand-name prescription drug prices increased significantly. While the overall inflation rate between 1980 and 1992 was about 22 percent, drug prices at the manufacturers' level increased 128 percent, almost 6 times this amount. In 1992 alone, while the general inflation rate at the manufacturer's level was 1.5 percent, the pharmaceutical manufacturers' level was four times this amount, 6.4 percent. Alternatively, the prices of generic pharmaceuticals stayed below or at the inflation rate during the 1980s because this market is much more price sensitive and competitive than the brand-name drug marketplace.

Data also indicate that citizens of the United States pay much higher drug prices than citizens of other industrialized nations. A recent General Accounting Office study found that Americans pay 32 percent more for prescription drugs than our Canadian neighbors. The fact is the United States subsidizes the rest of the world's pharmaceutical market, with much of this differential going to pay for marketing and advertising campaigns, rather than new drug research and development.

Not only do Americans pay higher drug prices to begin with, but the prescription drug inflation rate in this country is much higher than the rest of the industrialized world. The Administration's goal of bringing American drug prices in line with those of the rest of the industrialized world is laudable.

New Drug Prices:

The prices of new drug products also created a serious problem for patients and the health care system in the 1980s and early 1990s. New drugs were, and continue to be, introduced to the market at very high price tags. Examples include TPA ($3,000 per dose), Foscavir (to treat AIDS, $21,000 per year), Cephalosporin antibiotics ($50-$60 per 10 day supply), EPO ($6,000 per year), Ceredase ($350,000/year), and others. While these new drugs helped to reduce hospital stays, and in many cases avoided more costly medical interventions, there was no indication that the prices for these drugs had any relationship to their costs of production and development, or were priced reasonably.

Mechanisms need to be developed to assure that new drugs are reasonably priced, including those drugs which are developed through federal government Cooperative Research and Development Agreements (also known as CRADAs). These drugs are developed primarily through federal government technology, and then transferred to the private sector. A provision of each CRADA agreement requires that the price of the drug be reasonable. However, it does not appear that the National Institutes of Health (NIH) has an enforceable mechanism in place to assure that these drugs are priced reasonably.

It may not be good public policy to ask NIH to both develop the product, and then assure it is fairly priced. In fact, the NIH suggests that it may not be appropriate for it to make drug pricing decisions. Other experts in the drug pricing arena have suggested that a separate and distinct pricing review board be established. Some have advocated that a royalty system be used to reward the federal government for its contributions to innovation. It is clear, however, that something needs to be done to assure that the American taxpayer receives a fair return from the drugs that they help to discover.

Drug Cost Containment Approaches:

Private and public insurers reacted to the significant drug price inflation in several ways during the 1980s. HMOs adopted the very effective approach used by hospitals to contain drug costs. That is, they established drug formulary systems to negotiate with drug manufacturers over the prices of their drugs. Not only do formulary systems help to reduce costs, they also improve the quality of care provided to patients. Currently, millions of Americans -- including Medicare and Medicaid beneficiaries, and federal employees -- are members of managed care plans which utilize formulary systems to provide drug benefits.

Other outpatient prescription drug programs were not so skillful in containing prescription drug costs, including Medicaid. As a result of the significant cost containment pressures on drugs in the HMO and hospital sectors, drug manufacturers raised prices faster in the outpatient sector -- where most older Americans buy their drugs.

In addition, brand-name drug manufacturers have traditionally refused to bid on drug prices to community pharmacy buying groups. This fact is surprising, since many of these buying groups have drug purchasing volume that is equal to, or greater than, the drug use volume of much smaller purchasers that are able to receive substantial discounts. Third party prescription drug plans have primarily focused on reducing pharmacy reimbursement as a way of containing drug program costs, which is shortsighted at best. This approach does little to deal with the real cause of escalating program costs -- which is the cost of the drug -- not the reimbursement level paid to pharmacists.

Yet, this is the same strategy that was used by the Medicaid rebate program until enactment of the Medicaid prudent pharmaceutical purchasing provisions of OBRA 90. Under this legislation, drug manufacturers have to provide rebates to the Medicaid program, and the price of drugs for Medicaid cannot exceed the rate of inflation.

Lack of "Competitive Forces" in the Drug Marketplace:

Hallmarks of the most competitive markets are information about prices of similar and competing products, and information about the relative value of products compared to similar and competing products. Both aspects are relatively absent from the pharmaceutical marketplace.

o Lack of Drug Price Information: There is very little price elasticity in the outpatient or retail market in the United States. Neither the physician nor the patient has a good idea of the cost of the drug. Many patients do not know what the drug costs until the prescription is filled at the pharmacy, if they pay out-of-pocket. If the drug is covered by insurance, patients are even more insensitive to drug prices.

Insurance plans are getting better at encouraging generic dispensing, but more expensive brand products are used more often than they should be. Buyers of prescription drugs have little information about the price that other buyers are paying, which hampers negotiations between providers.

o Lack of Objective Information about Drugs: More objective and comparative information about drug products needs to be provided to health care professionals so that the best product can be selected at the lowest cost to meet the therapeutic goal. Most of the information provided to physicians about drugs come from drug manufacturer-generated materials. In general, this information tends to be "promotional" rather than "educational" or "comparative."

In addition, physicians are usually not provided with comparative information about drugs in the same therapeutic class. This factor, combined with the fact that there is little price elasticity in the outpatient market, means that traditional market forces have not been working in the drug sector.

o Skewed Incentives for New Drug R&D: The drug manufacturing industry as a whole spends about $11 billion each year on new drug R&D. However, during the 1980's, a significant portion of drug industry R&D was spent on developing drugs that are generally known as "me-too" drugs. These are drugs that represent little or no therapeutic advance over drugs that are already on the market. Drug manufacturers became proficient at making these drugs because of market incentives that rewarded duplication rather than innovation. Policies should be adopted that encourage the more efficient use of the research dollar so that the system produces more "innovative" drugs at prices that are reasonable and fair.

PRESCRIPTION DRUG COVERAGE AND ACCESS

PRESCRIPTION DRUG PROGRAMS IN THE "STANDARD" BENEFITS PACKAGE

Improving prescription drug insurance coverage all Americans is long overdue. Drugs help keep people alive and improve the quality of life. However, because of their high cost and the relative lack of public and private prescription drug insurance coverage, they are out of reach for millions of Americans. If the standard health benefits package includes prescription drug coverage, then maximum flexibility should be given to plans to develop their own prescription drug benefit design.

o Cost Sharing: Except for the poorest Americans, beneficiaries should bear some cost sharing through prescription drug deductibles and co-payments. Serious consideration should be given to requiring that the plans use percentage co-payments rather than flat co-payments for each prescription.

Percentage co-payments, which have become more and more popular in outpatient prescription drug plans, make the consumer more sensitive to the price of the prescription. In addition, percentage co-payments encourage generic drug dispensing. If there are flat dollar co-payments, there should be a perceptible difference between the co-payment for a brand name drug versus a generic drug.

o Drug Use Review (DUR): Each plan should also be encouraged to have a Drug Use Review (DUR) program. Drug use review helps to assure that prescriptions are appropriate, medically necessary, and not likely to result in harm to the patients. The DUR program should include a review of the prescription at the point of dispensing for any potential adverse effects to the patient, such as medication overdoses or drug interactions. The patient should also be counseled on how to use the medication properly, and health professionals should be encouraged to the maximum extent possible to counsel individuals on prescription use.

The DUR programs should also consist of a program of retrospective review to analyze patterns of prescribing and dispensing of drugs, and educational programs for health professionals to assure the optimum in medical outcomes for the patient.

To assist in the development and growth of DUR, a systematic process should be established on the federal level to develop suggested criteria and standards for Drug Use Review programs. This process should include health professionals knowledgeable about the use of drugs in various populations, who can review the current and new medical and scientific literature, and make recommendations on criteria and standards for drug use. These criteria and standards can then be evaluated for potential use by health plans to develop effective DUR programs.

THE MEDICARE POPULATION

It is unlikely that the Medicare program will, in the short term, be folded into the new system of "managed competition". If this is the case, then the Administration will need to consider the additional benefits that could be provided in the fee-for-service Medicare program to reflect the package of health benefits being provided to the under 65 population. As such, the Administration may be considering the development of a Medicare drug benefit under the current fee-for-service program.

Based on experience with the outpatient prescription drug benefit in the Medicare Catastrophic Coverage Act (MCCA) of 1988, the Task Force should consider the following issues when designing a potential Medicare outpatient prescription drug benefit:

o Deductible: The deductible in MCCA was designed to cover only 17 percent of Medicare beneficiaries each year. However, there are many beneficiaries who have high out-of-pocket drug costs which may not be "catastrophic" as defined by the deductible, but as a percentage of their income. The Task Force should keep this fact in mind.

o Cost Containment: A Medicare outpatient prescription drug program will benefit from any system-wide drug cost containment strategies that may be enacted. However, MCCA was enacted without any specific pharmaceutical cost containment mechanisms for the program. This resulted in rapidly-escalating MCCA drug program costs, even before the first prescription could have been filled under the program.

Because Medicare would become one of the largest prescription drug programs in the nation, it should use its leverage to negotiate lower prices with drug makers. One cost containment option would be to require manufacturers to provide discounts to the Medicare program equal to a certain percentage of the Average Manufacturers' Price (AMP). An additional rebate could be required of the manufacturer if drug prices increase faster than the rate of inflation (CPI). Reimbursement for manufacturers' products under any government program could be contingent on signing an agreement with the Secretary of HHS to provide these rebates to Medicare. There is precedence for this drug cost containment approach in the Medicaid rebate law of OBRA 1990, and in the Veterans Health Care Act of 1992.

o Further Options to Contain Medicare Drug Costs: Any Medicare drug benefit should encourage the dispensing of generic drugs when these drugs are medically appropriate. There is substantially more brand name prescribing throughout the health care system, where generics could be dispensed, especially in the current Medicaid program. Medicare would save hundreds of millions of dollars by encouraging as much generic dispensing as possible.

Reimbursement incentives should be provided under Medicare to encourage the dispensing of generic drugs. In addition, a uniform generic substitution override procedure should be adopted, enforced, and audited by the Health Care Financing Administration (HCFA).

A Medicare drug pricing guide should be provided to physicians and pharmacists about the relative cost of drug regimens for various diseases within therapeutic classes. This approach will make health care providers more sensitive to the cost of various courses of drug therapies for Medicare beneficiaries.

o Drug Use Review: The Medicare drug benefit should include a comprehensive program of drug use review. The DUR language enacted in OBRA 90 for Medicaid recipients could be used as a model. This includes a program of prospective and retrospective review, and educational interventions. Payment for medication management, especially among high-risk Medicare patients, should be explored.

CONTAINING PRESCRIPTION DRUG COSTS

The overall goal of pharmaceutical cost containment should be to contain prices on drugs that are already on the market, assure that new drugs coming to the market are priced reasonably and fairly, minimize the opportunities for cost shifting from one population or provider to another, and use the marketplace and other mechanisms to encourage drug manufacturers to do research on innovative, rather than duplicative, therapies.

The following section discusses the impact of "voluntary restraint agreements," and "managed competition" in containing pharmaceutical prices for the outpatient market for both currently-marketed and new drug products.

VOLUNTARY DRUG PRICE RESTRAINTS

In the interim period during the phase-in to managed competition, there will be a need to develop responsible mechanisms to contain pharmaceutical prices. Cost containment is especially vital and long overdue in the outpatient or retail sector of the pharmaceutical marketplace.

It may be several years before universal coverage for prescription drugs is phased in, both for the under 65 and Medicare populations. For this reason, Americans in the retail marketplace will still pay for prescription drugs primarily out-of-pocket. Therefore, it is especially important that any interim pharmaceutical cost containment measure be meaningful and perceptible to the average American. In addition, these cost containment mechanisms should probably remain in place until a large segment of the market is under "managed competition".

Several drug manufacturers have offered voluntary pharmaceutical cost containment proposals for this interim period. These proposals generally provide that the manufacturer will not increase its "weighted average price across the entire product line" faster than the rate of inflation. These are welcome proposals because they acknowledge that drug prices are too high and have been inflating too rapidly.

But as the February, 1993 report of the U.S. Senate Special Committee on Aging indicated, this approach is by itself not meaningful to the average American. That is because, in making this "weighted average" calculation, the manufacturer would take into account all its price increases and rebates across its entire drug product line, and to all classes of trade -- hospitals, HMOs, nursing homes, government, and the outpatient sector -- when determining whether it increased its weighted price by more than the general rate of inflation.

It would make little sense to only require that manufacturers agree to limit drug price increases to a "weighted average," because the average American may see little or no impact from this limit. Under this approach, most Americans would not pay a "weighted price," they would pay the actual price in the retail or

outpatient market, which is generally higher than the "weighted average price." In fact, as the Aging Committee report showed, some drug manufacturers that had made voluntary pledges were able to increase prices to the average American much faster than inflation, and still maintain that their "weighted average" price increased slower than inflation.

However, before we embrace these approaches that use "weighted averages," more analysis is needed of whether these mechanisms are truly going to have an impact on the prices of pharmaceuticals. There are several other potential issues and concerns with using a "weighted average" when attempting to restrain drug price increases, which are described below:

o Producer Price Index (PPI) vs. Consumer Price Index (CPI): Most of the "voluntary" manufacturer pricing restraint proposals allow pharmaceutical prices to increase no faster than the rate of inflation, as measured by the Consumer Price Index, or CPI. However, a strong argument can be made that drug manufacturer price increases should be pegged to the Producer Price Index for all finished goods, or the PPI. The CPI measures price changes at the retail or consumer level, while the PPI measures price changes at the manufacturer's level. Because drug companies are "manufacturers," it may make more sense to tie their price changes to a manufacturer-based index rather than a retail-based index.

o New Drug Prices: While drug manufacturers may pledge to voluntarily restrain price increases on currently-marketed products, there is absolutely no guarantee that manufacturers will simply not introduce new drug products to market at much higher prices to offset the price constraint on currently-marketed products. In fact, pharmaceutical manufacturers can introduce a new drug to the market at a launch price that will allow it to recoup the revenue that it wants from the sale of the drug, and only increase the price of the product each year by the general inflation rate. New drug product prices, as we have seen over the past few years, can be a serious problem for consumers and health care institutions.

o New Drug Product Prices in the "Mix": Because a new drug product or any new product line item (such as a new package size) is introduced to the market at essentially a "zero" inflation rate, it may have the effect of diluting inflation on the other products when included in the "weighted average" mix. That is, drug manufacturers could increase prices faster than inflation on some products already in the "weighted" mix, but this could be offset by the fact that a new drug product's launch price enters the market at "zero" inflation. This was the exact problem facing Congress when developing the "additional rebate" formula for the Medicaid program. To resolve this, new drug products were excluded from the "weighted calculation," and cannot inflate faster than the CPI on a drug-by-drug basis for Medicaid. This particular problem needs to be further explored before any approach that uses a "weighted average" is considered.

o Weighted Calculations Based on Sales Volume: Some manufacturers are suggesting that these "weighted average" calculations be made based on their total sales volume. That is, the total sales of the manufacturer divided by total units of drugs sold would result in a price that could not increase faster than inflation year after year. However, this method of calculating the weighted average change could result in a manufacturer having a lower weighted average inflation rate than it would have otherwise.

That is, a manufacturer's sales of a particular drug could fall off, decreasing the percentage of sales that this drug contributed to the manufacturer's total drug sales. A manufacturer could then increase the inflation rate on another product well beyond the rate of inflation to account for the drop in revenue from the other product, and still not increase total pharmaceutical sales by more than the rate of inflation. Unless there was a specific cap on the rate at which any particular drug product could increase, basing weighted increases on sales volume appears to leave too many doors open for manufacturers to increase prices faster than inflation.

o Intracompany transfer or resale of drug products: It may be possible for a manufacturer to "transfer" or "resell" a drug product to another newly-established operating unit within the company. This would permit the company to "relaunch" the product at a higher base price, and avoid paying any inflation penalty. For example, if a company sold a drug at $1.00, and inflation was 5 percent, it would have to pay a penalty if the price increased over $1.05. However, a manufacturer could establish another operating unit within the company, and "relaunch" the product at $1.25. This would establish a new "base period" for the drug, meaning the manufacturer would not only avoid paying the inflation penalty, but could also relaunch the product at a price that would allow it to maintain price increases at the inflation rate.

o Pharmaceutical Price Constraints Must Consider the Impact on Pharmacist Reimbursement: In general, pharmacists are reimbursed by many third party plans, including Medicaid, on the basis of the Average Wholesale Price (AWP) for a particular product. Therefore, the impact of any pharmaceutical pricing restraint on the AWP should be considered before it is developed.

IMPACT OF MANAGED COMPETITION ON DRUG COSTS

Along with the drug industry, many sectors of the health care industry are advocating that "managed competition" be the primary mechanism used to contain health care costs. It is difficult to imagine, however, that managed competition alone can work to contain the prices of drugs throughout the entire system. For example, it is unlikely that managed competition can contain the prices of currently-marketed drugs in certain rural areas, or the prices of certain new drugs.

As managed competition plans are developed, it is likely that the increased use of therapeutic drug formularies will result in more price competition, and presumably lower pharmaceutical prices, for managed competition plans. The use of drug formularies has been, and will continue to be, the most effective mechanism to stimulate competition and hold down overall pharmaceutical costs. Health plans can also use Drug Use Review (DUR), therapeutic interchange, generic substitution, physician counterdetailing, and negotiations with providers to lower total pharmaceutical costs.

However, it is not clear that managed competition will work in some rural areas of the country as quickly as it will work in other parts of the country. While networks of providers will probably form in these areas, these networks may not be of the same size, and hence not have the same bargaining leverage, as do the larger urban/suburban-based managed care plans.

As a result, drug manufacturers may attempt to shift costs to rural areas, meaning higher prices for drugs in these areas because of the relative lack of bargaining clout. Citizens in these areas of the country should not be penalized with paying higher drug prices simply because they live in rural areas. It is also not fair for Medicare beneficiaries -- who may have to pay several hundreds of dollars in drug costs before a Medicare deductible is reached -- to continue to pay for a cost shift to rural areas. For these reasons, there may be some need for a permanent pharmaceutical price cap, at least in these areas of the country, in order to protect rural-based and fee-for-service health plans from cost shifts.

NEW DRUGS AND BIOLOGICALS

Much of the pharmaceutical pricing debate to date, and most of the solutions proposed by the manufacturers, have focused on the prices of drugs that are already on the market. However, while this debate is important, we cannot let it divert our attention from a more serious concern that will have a significant impact on pharmaceutical expenditures in this country over the long term: the prices of new drugs that will be introduced to the marketplace.

Under any scenario, containing the cost of new drugs and biotechnology products coming to the market will be a challenge. Almost every other industrialized nation in the world recognizes the importance of assuring that new drugs are brought to the market at fair prices. The United States should have a policy that assures that Americans are charged reasonable prices as well.

Before the full implementation of "managed competition," and until we achieve universal prescription drug coverage, the average American will still pay for drugs out-of-pocket, including many new drugs. Recent history tells us that the cost of new drugs have the ability to break the financial backs of the average American or the average health care institution. Price restraints on "currently-marketed" drugs will have no practical meaning for the average American buying a new drug.

Under "managed competition", the approach to cost containment on new drugs depends largely on whether or not the new drug coming to the market has a competing therapeutic product. Formularies are effective in containing new drug costs if the new drug is in a therapeutic class with at least a few other competitors. Manufacturers will have to demonstrate that the "new" drug has some advantage over drugs that are already on the formulary before it will be used by the health care plan.

Manufacturers now contend that new drugs in competitive therapeutic classes have come to market in recent years at prices that are lower than the price of the market leader. The industry, however, has NOT produced data which show how price competition exists among drugs for which there are no competitors. This has to be a major concern for the health care system.

Simply put, competition cannot contain new drug prices in cases where competition does not exist. This is the situation that exists with the pioneer or first drug in a therapeutic class (e.g. the first cholesterol-lowering drug, the first calcium channel blocker, AZT, cancer drugs, TPA), orphan drugs (e.g. Ceredase, EPO), or drugs developed with substantial federal involvement or through NIH cooperative research and development agreements (CRADAs) (e.g., Taxol, Levamisol, AZT, DDI, and other AIDS and cancer drugs).

For these drugs, manufacturers can essentially set the launch price, without the health care system having any idea of whether the price is "fair" or even "reasonable." Health plans are almost always required to provide innovative drugs to patients, which further erode their ability to negotiate prices with drug manufacturers. Until therapeutic competitors are introduced to the market -- which can take several years -- the makers of these innovative drugs will be able to set any price and raise it, leaving the managed care plans as "price takers," rather than "price negotiators."

Finally, the issue of drugs developed through federal government technology transfer programs need to be addressed, especially Cooperative Research and Development Agreements (CRADAs). Recent history tells us that the federal government has significant involvement in the development of many new therapeutically-significant drugs. Therefore, the price of these drugs should reflect the government's investment.

However, we know that CRADA agreements represent only a small part of the technology developed with federal government support. Extramural research grants -- to universities and academic centers -- actually comprise the bulk of federal government funded new pharmaceutical research activities. We need to assure taxpayers that all inventions that they help to discover -- both through intramural and extramural grants -- are priced fairly.

Everyone agrees that incentives need to be maintained for the industry to conduct research and development on new drugs. However, it seems to be a wise policy to assure that the health care system is paying reasonable prices for these drugs. While we want to reward those companies that take risks to develop new products, that does not mean -- as a matter of public policy -- that the manufacturer should be able to charge whatever the market will bear. Therefore, it seems only prudent that the Administration develop a reasonable policy on new drug pricing to meet both of these goals.

THE FUTURE PHARMACEUTICAL MARKETPLACE

An important fact being obscured by the debate over pricing is that drug manufacturers may gain significantly from the increase in pharmaceuticals used in the United States as a result of universal prescription drug insurance coverage. While many of the 72 million Americans without prescription drug coverage are still buying their prescriptions out-of-pocket, there are many who are not filling their prescriptions at all or having them refilled. As several studies have shown, millions of older Americans are making choices between buying food and paying for their medications. This situation would most likely correct itself under a reformed health care system.

As a result of this expanded coverage, one estimate is that total prescription drug expenditures in the United States will increase from $73 billion in 1994 to $97 billion in 1998. That is a 33 percent increase in total pharmaceutical expenditures in this country, most of which will flow directly to drug manufacturers. Therefore, the Administration must recognize that any reduction in pharmaceutical prices or price growth from any short term or long term strategies to contain pharmaceutical costs may be more than offset by the increase in revenue to pharmaceutical companies.

Research and development spending on new drugs will be more a function of total revenue of a manufacturer, not a function of whether there are cost containment strategies. On that score, there is no reason to believe that manufacturers will have any less incentive to do R&D. That is because their revenue stream will likely grow, since an increasing patient population base will be able to obtain their drug products with enhanced insurance coverage.

In addition, as drug buyers become larger and larger, manufacturers may also be able to reap a windfall from a decrease in marketing expenditures, since more and more decisions about which drugs to buy may be made by the formulary systems of accountable health plans. Manufacturers will, in the new environment, be marketing to fewer, larger buyers of their products. As we know, drug manufacturers on average spend 25 to 30 percent of their total sales on marketing and advertising, but only 12 to 16 percent on research and development. Reductions in marketing expenses could save drug manufacturers billions of dollars each year.

The Administration should develop policies that foster the development of the pharmaceutical industry and provide incentives to do research and development However, it needs to consider the entire context of the pharmaceutical marketplace when developing these policies. This context includes an expanded prescription drug marketplace, which will generate an increase in total pharmaceutical manufacturer revenue over the long term.