SINGLE PRICE WITH EQUAL VOLUME DISCOUNTS

Policy Recommendation

- In the long term (after managed competition is in place), we recommend that all buyers of a product will have the same access to discounts for equal volume. Manufacturers will have to sell each product at a single price for each specific quantity sold of that product, and may discount only on the basis of volume savings to the manufacturer (e.g., reduced shipping or packaging costs).

- In the short-term, we are not recommending any restrictions beyond those contained in the short-term price control paper.

Policy Rationale

Today drug manufacturers typically segment the market for prescription drugs. For the large number of drugs that have therapeutic equivalents, they are willing to give deep discounts to hospitals, HMOs and other organizations that can choose between different, therapeutically equivalent drugs. Manufacturers are not willing to give similar discounts to retail pharmacies that have little choice but to stock every drug which a fee-for-service physician in their area might prescribe. In fact, there is evidence that, in recent years, drug manufacturers have compensated for the losses in revenue associated with discounts that they have been giving to institutions with drug formularies by increasing the prices to the retail sector.

Even under health care reform, this is likely to continue to be a problem, unless specific measures are taken. To the extent that patients are not on a formulary and are paying for drugs out-of-pocket, they will still be at the mercy of the prescribing practices of their physicians, who are far more influenced by aggressive drug company marketing practices than by price considerations. Even when the physician takes price into account, the patient will pay more than patients in programs which can take advantage of formularies, because retial pharmacies acquire drugs at disproportionately higher prices.

There are some innovative methods of applying the formulary concept to fee-for-service insurance plans. Even today, companies are contracting with health care providers to apply the formulary concept to the fee-for-service sector. These organizations often contract with PPOs and other providers and use counter-detailing as a way to influence physician prescribing. They may receive their fees both from the providers and from drug manufacturers, with whom they negotiate discounts. The flexibility that manufacturers have

with respect to discounts creates the possibility that the intermediaries will face a conflict of interest if the "kickbacks" that they receive from drug companies are more lucrative than the fees they receive from the providers for shifting prescribing to more cost-effective therapies.

The single price with volume discounts will protect the weakest segment of the market -- patients who pay for drugs themselves -- from price gouging. It will eliminate kickbacks to intermediaries. Yet the incentives to use formularies will be retained, because there will still be enormous savings to be realized by switching prescribing to less expensive, equivalent therapies (see "Economic Defense of a Single Price" below).

This proposal should only be imposed when the percent of all drugs that are purchased by formularies is high enough to ensure that the competitive pressures of formularies will force price competition among manufacturers. If the proposal were implemented prior to that point in time, then the probability that manufacturers would set the single price at the higher retail price is significantly greater.

Benefits of this Option

- Will eliminate segmentation of the market for prescription drugs leading to much higher prices charged to the weakest segment of the market (currently retail pharmacies).
- Will eliminate unfairness of the current system where patients who pay for prescription drugs out-of-pocket (through deductibles or otherwise) pay the highest prices.
- Will eliminate potential kickbacks to intermediaries who negotiate discounts with manufacturers on prescription drugs.
- Will simplify information about drug pricing, making it much more difficult for manufacturers to "game" the market.
- Formulary purchasers still do not make up the majority of the marketplace. Therefore, movement to a single price before these purchasers grow in number and market share may actually result in prices moving closer to the average price currently charge to the retail class of trade.
- Would encourage the quick transition to the use of formularies by insurers because there will be a window of time during which formulary purchasers would still be allowed exceptionally lower discounts than their retail counterparts receive.

Economic Defense of a Single Price

It is difficult to rationalize why drug prices (for similar volumes purchased) to the retail class of trade should be different from the prices to HMOs, PPOs and other institutions that use formularies. Purchasers that use formularies are able to control which drugs in a therapeutic class physicians prescribe, which guarantees exclusivity and allows them to force manufacturers to compete against similar drugs based on price. Retail pharmacists, on the other hand, have little ability to negotiate lower prices with pharmaceutical manufacturers because they must stock every drug approved by the Food and Drug Administration; manufacturers charge them much higher prices than they charge purchasers with bargaining leverage. The ability to control the prescribing practices of doctors does not, however, directly result in the efficient provision of prescription drugs. Efficient provision may be evaluated by such standards as accessibility, timeliness of provision, and availability of cognitive services. In fact, many would argue that conveniently located retail pharmacists are equally, if not more, efficient providers.

Manufacturers' ability to price discriminate among purchasers and the resulting cost differentials will encourage the use of in-house pharmacies and mail order pharmacies under managed competition, and may lead to the demise of the retail pharmacy market. This situation will arise because cost-conscious AHPs will look for the cheapest way to provide drugs to their customers, and will direct their business away from the high prices charged by retail pharmacies. If one can argue that this scenario is acceptable and rational, then we need no further policy recommendations for the long-term under managed competition. In this case we would have to assume that retail pharmacists, due to their inability to acquire bargaining power, are an inefficient mechanism for providing prescription drugs to consumers. If we want to ensure that retail pharmacies will continue to exist into the future, however, there is a strong case for implementing a system that allows for equal access to discounts based on volume.

One of the more popular arguments against a single price with volume discounts is that it will discourage the use of formularies. This argument ignores the fact that rebates and discounts are only one of the reasons that insurers use formularies to control expenditures for prescription drugs. More importantly, formularies are used to encourage physicians to use cost-effective therapies. The incentive for AHPs to encourage physicians to prescribe the more cost-effective therapy will remain in place even under a situation in which formulary purchasers are required to pay the same prices as retail purchasers, because the relative cost-effectiveness of two drugs is based on their relative prices, not actual price levels. Controlling the prescribing practices of physicians is more cost-saving than rebates and discounts, which

provide only marginally greater savings to the system.

Another popular argument against a single price policy is that such a system is the same as instituting a national formulary. Those who hold this view claim that a single price will create a situation where one drug will become the obvious choice within every therapeutic class for all formularies -- leading to a monopoly for the drug. This argument does not hold up to in-depth analysis, however. Assuming costs of producing existing drugs are minimal, in order to be included on formularies, manufacturers will have to set prices of therapeutically equivalent drugs so that individual purchasers will be <u>indifferent</u> among them. Drugs that have fewer side-effects and are more effective will have higher prices than will drugs that are less effective or have more side-effects, and their relative prices should capture the their differences in quality.

Formularies will be largely influenced by the individual preferences of those choosing the drugs to be included on a formulary -- i.e., some AHPs will want to emphasize quality over cost, others will opt for the least-cost alternative, and the rest will find a balance between cost and quality. This system is actually the more efficient pricing system, because manufacturers will have to set prices competitively across the entire market if they want to be competitive in the formulary market -- and the lack of bidding and counter-bidding will allow AHPs to make rational, informed decisions that accurately reflect their individual preferences.

The advantage of using formularies exists independent of any rebates or discounts. A single price system encourages increased efficiency in the formulary based market by eliminating the ability of manufacturers to game the pricing system. Manufacturers will no longer be able to tie discounts to one product with purchases of other products that they produce ("bundling"), a practice that discourages emphasis on cost-effective prescribing and encourages brand-loyalty. Furthermore, manufacturers will not be able to "seed" teaching hospitals and other institutions with their products in order to encourage brand-loyalty, regardless of cost-effectiveness, on the part of young physicians who have many years of prescribing duties ahead of them. Finally, a system that encourages equal access to discounts based on volume preserves the incentives to form large purchasing groups.

Problems with an all-formulary system

It is my understanding that one major reason that the group does not want to move to a single price is that such a change will remove the ability of formularies to be used as bargaining leverage to negotiate prices directly with manufacturers. These purchasers currently use their ability to move market share to access discounts and force manufactures to compete based on price. However, I think that as we move toward a situation in which everyone is covered by a formulary, the above-mentioned advantage of formularies will diminish. If everyone is covered by a formulary, then manufacturers will just cost-shift and price discriminate within the formulary market, and small, localized formularies will face much higher prices. These rural areas just can't win.

Consider a situation in which everyone is covered by a formulary and the number of people covered under a particular formulary may vary greatly among AHPs. Let's assume that because we allowed manufacturers to price discriminate during the transition to managed care, the retail class of trade has been phased out, and pharmacies are directly controlled by AHPs. If these conditions arise, and if institutions negotiate directly with the manufacturers for prices of drugs within different therapeutic classes, manufacturers will give discounts to the larger formulary purchasers and will be reluctant to discount to the small formulary purchaser. This will happen because manufacturers will be trying to maximize their market share and will not worry about small AHPs with minimal volume commitments. Under this scenario, we will likely see prices in rural areas become disproportionately higher than prices to the large urban AHP formularies. Rather than cost-shifting to retail purchasers as they currently do, manufacturers will cost-shift to small formularies. These conditions encourage the formation of large formularies, and discourage the formation of small, localized rural formularies that would be more sensitive to the needs and preferences of individual communities.

If we were to move to a single price system with volume discounts, this situation would not arise. The mere existence of formularies will encourage manufacturers to price their products competitively, because failure to do so will cause them to be excluded from any price-sensitive formulary in the country -- and their products will be left completely out of the market. In other words, formularies will force manufacturers to compete on price without directly negotiating discounts with the manufacturers. Retail pharmacies, who will be able to purchase drugs at competitive prices, will contract with AHPs to enforce their individual formularies. Given that this pricing system allows prices to change with volume commitments, there will still be incentives for retail pharmacies to join large purchasing groups.

Under a single price system will volume discounts, anyone will be able to purchase their drugs at competitive prices. Small,

rural formularies will be able to contract with retail and mail order pharmacies that are in large purchasing groups, much in the same way that large formularies will purchase their prescription drugs (large formularies may also purchase their drugs directly from the manufacturers). The benefit of using a formulary continues to exist under this price system, because the incentives remain for the AHPs to control costs by encouraging the use of the most cost-effective therapies.

If the incentive structure that we create through health care reform encourages the elimination of retail pharmacies, we will lose an important and arguably efficient means through which prescription drugs can be purchased and provided. Furthermore, by allowing price discrimination to continue to take place, we will be encouraging its continuation into the future. The weak purchasers will just have a different name.

THE DANGERS OF PRICE CONTROLS

According to The Washington Post (March 17, 1993), the White House Health Care Task Force will propose three options for short-term price controls to the President: 1) a short-term freeze on prices of health care products and services, retroactive to prevent pre-freeze increases; 2) a cap on annual insurance premium increases; and 3) an extension of Medicare rates for hospitals and doctors to private services. While price controls are tempting because they offer the hope of immediate cost containment, they are politically and economically dangerous. Politically, they could easily backfire and cause health expenditures to rise rather than fall. Economically, they may tigger unanticipated responses that could affect the economy and reduce the quality of health care.

Price controls may backfire: The experience with price controls in the United States has been that they rarely result in permanent reduction in expenditures, and in some cases have even caused costs to rise.

The failure to have a lasting impact can be seen in the experience with wage and price controls during the Nixon Administration. Price controls kept medical services to a 4.9 percent annual inflation rate when other services were growing by 5.2 percent a year, between August 1971 and April 1974. Providers simply deferred price increases, and once controls were removed, medical care prices began rising at an annual rate of 12 percent -- three percentage points above general inflation[1/]. At the same time, health care providers had sought to maintain their revenues under price controls by increasing the volume of services, so that throughout this period from 1970 to 1975 personal health care expenditures grew at the rate of 14 percent a year[2/]. In the years immediately following the end of medical price controls, Medicare spending was growing by 20 to 30 percent a year[3/].

Price controls may also have the perverse effect of increasing total spending. The incentives for providers to increase the number of services or to break apart or "unbundle" services in order to artificially create more service volume may

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1. Paul Starr. The Social Transformation of American Medicine (New York: Basic Books, 1982) p. 406.

2. U.S. House of Representatives, Committee on Ways and Means. Overview of Entitlement Programs: 1992 Green Book. 102nd Congress, 2nd Session (Washington: U.S. Gov't Printing Office, 1992) p. 287.

3. Ibid. p. 189.

cause the rate of growth in total spending to accelerate. Total spending may also increase when price controls first go into effect because rates are initially overstated. This overpricing results from inadequate data to support accurate pricing and the reluctance of regulators to aim too low and damage the industry. For example, Medicare prospective payment rates for hospitals were set more than 14 percent above average costs in the first few years[4], creating hospital profit margins in the mid-1980s that were nearly triple the average profit margins in the 1970s[5]. The same was true when "all-payer" hospital rate-setting was implemented in four states in the mid 1980s -- the initial rates substantially increased hospital profits: Massachussetts hospital profits rose by 39 percent in the first year; New York hospital deficits were reduced by $272 million over four years; and the first 26 New Jersey hospitals under DRGs gained $2.3 million[6].

Price controls may harm the economy: The fundamental problem with price controls is that they create an artificial pricing mechanism that is political rather than market based, sends the wrong signals to the economy, and focuses incentives on beating the system rather than raising the level of efficiency. Were price controls to actually work, then they could do serious harm to the economy.

Prices that are set at an artifically low level increase demand for services while reducing the benefits for providers of supplying those services. The result is a shortage of supply and rationing -- gas lines in the late 1970s when gasoline prices were controlled. In health care, lower returns on investments due to price controls can be expected to divert investment capital to other industries, slowing the rate of innovation in pharmaceuticals, medical procedures and facilities, and leading to shortages in some areas of supply. While some reduction of capacity may be warranted in health care, across-the-board price controls produce broad and arbitrary results. Areas that are currently underserved will be unable to find new practitioners or

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4. Prospective Payment Assessment Commission (ProPAC). Medicare and the American Health Care System: Report to the Congress, June 1991, p. 55.

5. American Hospital Association. AHA Hospital Statistics: A Comprehensive Summary of U.S. Hospitals, 1990-1991, table 1.

6. Linda Bergthold, "Purchasing Power: Business and Health Policy Change in Massachusetts," Journal of Health Politics, Policy and Law (13:3, Fall 1988);
Kenneth Thorpe, "Does All-Payer Rate Setting Work? The Case of the New York Prospective Hospital Reimbursement Methodology," Journal of Health Politics, Policy and Law (12:3, Fall 1987); and
J. Joel May and Jeffrey Wasserman, "Selected Results from an Evaluation of the New Jersey Diagnosis-Related Group System," Health Sciences Research (19:5, December 1984).

expand services, while areas that now have substantial excess capacity will be only slightly affected.

As a further element of irrationality, regulation tends to allocate resources on the basis of political influence rather than economic efficiency. States with experience in hospital regulation in the 1970s and early 1980s discovered that hospitals became adept at the art of "legislative bypass surgery", gaining exceptions from the legislature to improve or add facilities[7]. Labor unions resisted wage controls under the Carter Administration, successfully forcing the Administration to allow wage increases. As a result, the Administration had to abandon its efforts to keep hospitals under wage and price guidelines[8].

Most significantly, price controls create an adversarial relationship with the regulated and divert attention and energy from improving efficiency to gaming the system and enforcing the rules. Assuming providers are motivated by the desire to increase revenues, price controls force them to succeed only by learning the system and then discovering ways to beat it. Rather than rewarding providers who become more efficient, price controls reward providers who increase volume, invent new services, shift services outside of regulated areas, and otherwise stay one step ahead of the regulators.

Price controls, particularly price freezes, create incentives to change the product in order to change the price. The result is a reduction in productivity because labor is diverted to raising the price of an existing product rather than producing new goods and services. For example, during the wage and price controls of the 1970s, producers shipped products abroad and reimported them to avoid domestic price controls, or made small changes in products so they could be considered customized or new products no longer subject to the old price[9]. Health care providers often modify diagnoses or "upcode" cases in order to get higher reimbursement.

The result of price controls is thus a combination of inefficiencies in the distribution of resources, lower productivity resulting from the emphasis on gaming the system, and additional bureaucracy focused on enforcing the rules. Regulators cannot selectively target their disincentives to specific investments, so price controls tend to reduce the attractiveness of all investment affected by the controls. As a result, technological breakthroughs and new developments that

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7. Lawrence S. Lewin, "Cost Containment Until Today: Lessons for Tomorrow," paper prepared for the National Leadership Commission on Health Care, May 9, 1988.

8. Steven Mufson, "Price Controls: Past as Health Care Prologue," The Washington Post, March 14, 1993, p. H1.

9. Ibid.

would improve the efficiency of medical care are discouraged along with those that would not.

One significant area where price controls can interfere with the development of cost-effective technology is in pharmaceutical research. By reducing the returns on pharmaceutical investment, price controls encourage more conservative research strategies and discourage the types of high-risk, and potentially high-return experimentation that can lead to breakthroughs. Thus, price controls would greatly reduce the potential to find cost-effective pharmaceutical alternatives to the expensive medical procedures in use today, and to find cures or early treatment for the most expensive chronic and degenerative diseases.

Price controls would also discourage efforts to improve the efficiency of medical care delivery. First, price controls would reduce investments in managed care technology, much of which is aimed at creating financial incentives for providers to reduce the overall cost of care. Price controls would interfere with the ability of managed care to negotiate payment incentives with physicians, and would thus reduce the potential for managed care to encourage physicians to deliver services more efficiently. At the same time, price controls would create incentives for physicians to generate unnecessary services, thereby adding further to the inefficiencies in existing medical practice.

Medical Price Caps Drafted for Clinton

Adviser Has 3 Options for Short Term

Washington Post 3-17-93

By Dana Priest
Washington Post Staff Writer

White House adviser Ira Magaziner has told industry groups that short-term price controls will be needed to restrain health care spending, and Magaziner's staff is drafting three possible ways to impose controls, informed sources said yesterday.

The sources said these three options will be presented to President Clinton's health care task force this weekend and probably will be forwarded to Clinton for a final decision next month. Each would require congressional action. They would:

- Impose a short-term freeze on prices charged by all private and public hospitals, doctors, laboratories, equipment makers, nursing homes and the like. The effective date of the freeze could be made retroactive to counter last-minute price hikes. Some increases would be permitted several months later, and a federal board would be established to rule on providers' requests for exceptions.
- Impose caps on insurance premium increases and prohibit insurers from cutting the benefits they offer. Annual premium increases probably would be linked to growth in the gross domestic product. In addition to reducing premium cost growth, this theoretically would force insurers to pressure health-care providers to hold down prices.
- Extend Medicare's existing payment system—or a similar formula to set regionally adjusted prices for individual procedures—to all medical services performed by private doctors and hospitals. The Health Care Financing Administration would begin establishing payment rates not already set (for pediatric procedures, for example) and could have the system in place nine months after Clinton presents his bill to Congress.

These three options, drawn from

Clinton Adviser Advocates Health Care Price Controls As a Short-Term Measure

CONTROLS, From A1

a longer initial list, are scheduled to be presented this weekend by the working group on short-term cost controls to the health care task force chaired by Hillary Rodham Clinton. The options will be analyzed, but the list will not be shortened further, sources said.

The three options are scheduled to be presented in April to Clinton, who may choose one or more of them to become part of the comprehensive health care revision proposal he hopes to submit to Congress in May.

A separate working group is scheduled to present the task force with its findings on the most effective ways to control drug prices, according to sources. Those methods include: requiring manufacturers to charge Americans the same prices they charge overseas customers; freezing prices; giving the public a toll-free Internal Revenue Service telephone number to report abusers; and setting up a federal board to review pricing policies and establish criteria for increases.

Magaziner first raised the possibility of short-term price controls in a January memorandum to Hillary Clinton. Over the past several weeks he has met privately with officials of the five largest insurance companies, select drug makers, the American Medical Association and the Health Insurance Association of America (HIAA).

Magaziner's message, according to those at the meetings, has been that the administration believes price controls are necessary for two to three years, both to reduce spending and to help finance health coverage for uninsured Americans while comprehensive reforms are put in place.

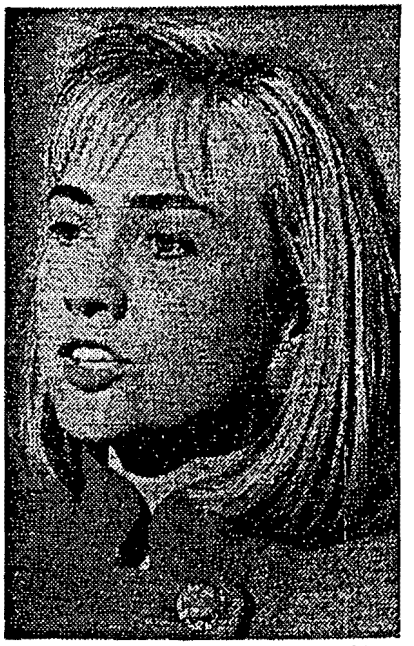
Magaziner, using what one participant described as a "hugs and hammer approach," suggested that if the health industry opposes government-imposed measures, it should come up with enforceable "voluntary" controls.

Reaction to that suggestion has further split already fractious industry coalitions. Some groups, like the HIAA, have hired consultants to develop proposals. The Pharmaceutical Manufacturers Association requested antitrust relief from the Justice Department so it could pursue voluntary price control. Some in the AMA leadership are advocating such radical departures from past policy as limiting fee increases to 3 percent a year.

Equally divided are the insurers. Two weeks ago, Pennsylvania-based U.S. Healthcare, a managed-care insurer, came up with a proposal for limiting insurance premium increases that it circulated in industry circles. It was criticized by some competitors whose business is based on fee-for-service and for whom price controls could spell financial ruin.

"If there is a need for strong cost controls, this is the best way to go," said David Simon, senior vice president of U.S. Healthcare. "But there are many insurance companies who are steadfastly opposed to any type of cost control, especially premium caps."

Opinion polls show that the public favors government-imposed price controls, last instituted in the early 1970s as part of the Nixon administration's overall wage-price controls to fight war-related inflation. For many, however, the controls proved easy to circumvent, and price inflation returned after the controls were lifted.



HILLARY RODHAM CLINTON
... task force due to get proposals

Especially in the health field, where doctors and hospitals have considerable leeway in deciding what services patients receive, many economists believe that physicians and other providers will offset the controls by simply increasing the volume of their services to make up for lost income.

It was not immediately clear what effect a federal freeze would have on mental health services, which the administration has said it is considering making available to all Americans in a revised system.

Yesterday Hillary Clinton described mental illness and substance abuse as "not only problems in and of themselves, but they are underlying problems that affect the whole [health care] system." The administration, she said, is trying to determine "how much we can do and how soon and how much will it cost and how much of a real change can we make."

Price Controls: Past as Health Care Prologue

Clinton Would Find a History Of Failure, Unintended Effects

By Steven Mufson
Washington Post Staff Writer

By most accounts, the Clinton administration is moving toward a health plan that would begin by imposing price controls on doctors, hospitals and medical suppliers. But if history is a guide, this effort at selective price controls may be doomed from the start.

The reaction to price controls now, as in the past, is likely to be evasion, inflation and confusion, experts say. The resulting distortions could include everything from unnecessary surgery to longer waiting lines, from poorer quality care to strikes over the wages of nurses, technicians and other health care workers.

Though Clinton administration officials stress that price controls in the health sector would be only a temporary measure, economists who were involved in wage and price controls during the 1970s warn that "temporary" controls have a way of lasting unexpectedly long times.

The Nixon administration, for example, slapped wage and price controls on the entire economy in 1971 in an attempt to slow down inflation. The controls were supposed to last 90 days. Instead, they went on for nearly three years.

BY MICHAEL CUSTODE
FOR THE WASHINGTON POST

Throughout that period of wage-price controls, American ingenuity thrived in finding ways around the rules.

Faced with price controls on all the usual cuts of beef, grocers invented new cuts, such as the "watermelon roast," that would be uncontrolled. When companies realized that the prices of imports were exempt, they shipped lumber to Canada and imported it again. Taking advantage of a loophole for customized work, contractors drilled holes in plywood and filled the holes back up to create customized products.

"I was sympathetic to [price controls] all through the 1970s," said Barry Bosworth, a Brookings Institution fellow who was director of President Jimmy Carter's Council of Wage and Price Stability for two years. But "when we actually did it," he said, "you just never would have believed so many things could go wrong."

Nonetheless President Clinton and his health advisers are considering imposing price controls on the health care industry to slow down the 12 percent inflation in that area, a rate roughly four times the rate in the overall economy. Doctors' fees, hospital charges, pharmaceutical prices and other medical services could be hit by government dictates of the sort that have not been used in the United States since the 1970s.

People who implemented wage and price controls during the 1970s warn that the Clinton efforts could be futile.

"As I think back on that period," said Herb Stein, who was chairman of President Richard M. Nixon's Council of Economic Advisers. "We didn't do much good. The trend of prices . . . slowed down, but within a few months after controls were over we were back to the previous trend."

"It would be a mistake to underestimate the ingenuity of people in the private sector to take advantage of discrepancies in a system of price controls," said Marvin Kosters, who was chief economist for Nixon's wage and

See CONTROLS, H6, Col. 4

WASHINGTON POST
MARCH 14, 1993

Health Care and Price Control Perils

CONTROLS, From H1

price control council in the early 1970s and who now is a fellow at the American Enterprise Institute.

The story of Nixon's imposition of wage and price controls shows just how tempting such a policy can become, even for Republican free marketers.

In 1970, inflation had climbed to about 6 percent—modest compared with what was to come later but about twice the average rate during most of the 1960s.

Confident that Nixon was so opposed to wage and price restraints that he would never use them, Congress in August 1970 gave Nixon blanket authority to impose controls in an amendment to the Defense Production Act. The measure was designed to embarrass Nixon by giving him tools he would not use.

Once available, wage and price controls became irresistible.

In February 1971, Nixon used the measure to hold back wage increases in the construction industry. And on August 15, 1971, with inflation running around 5 percent, Nixon imposed a total freeze on wages and prices for a period of 90 days.

Nixon's advisers believed that inflation was "artificial," driven more by expectations than by any real shortages of labor or goods.

"In 1971, we thought we were going to have a one-shot control of the inflation rate," said Stein.

But it didn't work out that way. The controls lasted until 1974; oil and natural gas price controls lasted until 1981. Wage and price guidelines lasted throughout the Ford and Carter years.

And though inflation slowed a little during 1972, it later picked up again, surpassing the 1971 rate.

"We thought we were going to change expectations," Stein said. "But we really just built up expectations that prices would rise when controls went off."

What are the lessons for Clinton administration officials contemplating price controls for health care? There are several:

Beware of the Wrath Of Unions and Employees

When the government freezes or limits price increases for hospitals, doctors or drug companies, it's likely that these health care providers will take tougher stands in wage negotiations with their employees.

Unions then will lobby for exceptions. In 1978, for example, the Teamsters union wanted a wage increase in excess of Carter administration guidelines and the administration backed down. "The administration did not want to face the consequences of a long strike," said Bosworth.

Moreover, he said, "once one group gets in and succeeds in getting an exception, everyone piles on. The notion of fairness is so strong when it comes to wages." If wage increases are granted, then employers demand permission to pass the wage increases through to consumers by raising prices.

The problem is acute in health care, where wage costs make up about a third of hospital costs, Bosworth said. Applying those costs to thousands of different procedures and hospital charges is complicated and sometimes arbitrary, making prices difficult to control.

The Carter administration actually exempted hospitals from wage and price guidelines. "It was just too damn complicated . . . and the labor unions screamed bloody murder," Bosworth said.

Beware of New Technology

A large part of inflation in the health care industry comes from new technology.

"You can't tell me that a 12 percent overall price increase is all because of inefficiencies," Bosworth said. "Some is new technology, new tests that never existed before, new drugs that never existed before. How do you set a price on a new product? You don't."

In addition to breakthroughs in technology, price fixers in health care face the "watermelon roast" problem. People will "create new products trivially different from old products" to circumvent controls, Bosworth said.

Of all the problems Clinton's advisers face in fixing prices for health care, Bosworth said, "the new product problem is most relevant. And they'll be killed by it."

Beware of Increases In Procedures

"If you don't give a surgeon an acceptable price for taking out a kidney, he'll take out two," said Stein, only half in jest.

In fact, said Bosworth, who sits on the board of Blue Cross-Blue Shield of Maryland, when the big insurance company lowered fees on doctors, doctors billed for more work. When Blue Cross in Maryland tried to squeeze charges for hospital stays, the costs of outpatient care shot up. As a result, Maryland hospital care costs less than the national average; Maryland medical care does not.

"Price controls could work for a few months," Bosworth said. "But if you are going to have them in place for a year or more, don't underestimate the ingenuity of people to get around them. Their livelihoods are at stake."

Remember Regional Differences

Just as the cost of living varies in different parts of the country, the cost of health care does too.

But the government will have a tough time explaining why an X-ray or office examination costs more in New York than in Iowa. "You could never explain to doctors in Baltimore why they were getting so much less than doctors in Montgomery County," Bosworth said.

Don't Discourage Investment

One reason for high drug prices is that the government grants temporary monopoly power through the patent system to give companies added incen-

See CONTROLS, H7, Col. 1

Price Controls Revisited: A Failed Experiment

CONTROLS, From H6

tives for research. Research has helped make the pharmaceutical industry into one of the most competitive and innovative—as well as profitable—in the United States.

"To the extent we want to invest in the future, we want to encourage more R&D into drugs of the future. Not to do that seems to be opposite to what the Clinton administration seems to be trying to do," said Harvard University economics professor N. Gregory Mankiw. "The tone of the administration is that somehow it's immoral to charge high prices," he said. "Clinton is saying, 'You're taking advantage of that monopoly power we gave you consciously. How horrible!' "

Beware of Unforeseen Consequences

No matter how many Rhodes scholars work on the health care plan, they are bound to overlook some angle.

"The world is interconnected in lot of ways. Once you change prices in one area, it has effects that you can't foresee," said Mankiw. "That is why central planning in the Soviet Union broke down. I don't think Clinton planners will be any better than planners were in the Nixon era or in the Soviet Union."

Remember Gasoline Lines

Price controls on gasoline during the Carter years helped create long lines at the pumps. Price controls on medical care could create waiting periods for medical care, though probably not immediately.

"There is a general lesson," said Kosters. "If you run price controls in a way that avoids shortages, you won't do much to the level of prices. If you have a real price ceiling there can be side effects that become apparent quite quickly."

And so, past price planners have only words of caution.

"We were not trying to set prices," said Bosworth about Carter price guidelines. "We were trying to slow down prices. And even with our far more limited objective, we were not able to do it."

Stein offers two lessons:

"Do not think that we can flirt with controls and not get them."

And, "do not think that the ineffectiveness of controls, which has roots deep in the American economic and political system, can be overcome by sufficiently enthusiastic operators."

A NATIONAL DRUG PRICE REVIEW BOARD

The White House Health Care Task Force is considering a proposal to establish a drug price review board in the United States similar to Canada's Patent Medicine Prices Review Board. The purpose of the Board would be to monitor manufacturers' list prices for prescription drugs, identify prices deemed to be "excessive", and force manufacturers to reduce "excessive" prices. The Board would be established as a quasi-public entity, either independent of other bodies, or accountable to a more-general National Health Board.

Background

Canada's Patent Medicine Prices Review Board was established by the Canadian Government in 1987. The Board was intended to control patented drug prices as an offset to the effects of the 1987 patent law that extended the period of market exclusivity in Canada. The Board has jurisdiction only over patented drugs and has no authority to review prices of generic or "off-patent" drugs.

The Board's function is to force a reduction in prices only for drugs that are found under their guidelines to have "excessive" prices. The Board does not set prices. About 30 percent of new drug prices, and 15 percent of price increases on existing drugs are found to be excessive.

In determining whether prices are excessive, the Board is required to consider: the manufacturer's price for the drug in the last five years, the price of other drugs in the same therapeutic class, the price of the drug in other countries, and the Canadian consumer price index. The Board develops guidelines based on these factors for evaluating the price of new drugs and price increases on existing drugs. Manufacturers are required to submit sales and price data to the Board semiannually.

An initial or launch price for a new drug will generally be considered excessive if the drug's cost per day or per treatment is greater than the cost for therapeutically comparable drugs. If the drug is a breakthrough or is a substantial improvement (in terms of efficacy or side effects) over existing therapies, its price is excessive if it is greater than the median of its price in seven other countries. The price of an existing drug is excessive if its cumulative price increase since introduction or the Board's inception is greater than the CPI increase.

The Board has limited enforcement powers. If a drug price is found to be excessive, the Board can order the manufacturer to lower the price, but has no power to enforce that order. The Board does have the authority, following a public hearing, to

remove the drug's market exclusivity or to remove the market exclusivity of another drug from the same manufacturer or both. The Board is generally effective, though, in gaining compliance due to the threat of negative publicity and loss of market exclusivity.

The Board appears to have been effective in reducing drug prices. From 1987 to 1991, patented drug prices increased at an average rate of 2.9 percent a year -- below the 4.7 percent rate allowed under the guidelines. The General Accounting Office (GAO) in a recent study of the Board found that the differential in drug prices between the U.S. and Canada was one-third greater for drugs under the Board's review than for drugs outside its jurisdiction. Whether this has reduced drug research and development in Canada is difficult to determine, since offsetting positive factors, such as the patent law changes and industry commitments to increase R&D went into effect at the same time.

Issues

Board Review of Prices

Board review of pharmaceutical prices subjects these prices to an arbitrary political standard unrelated to the economics of bringing new chemical entities to market or the therapeutic value to the society and to consumers of that new entity. Because the standards imposed are unrelated to the factors companies consider in the decision to develop a new drug, it is likely that these price standards will have consequences for research and development that are unintended and unanticipated.

For example, pricing by reference to therapeutically-similar drugs reduces the incentive to develop new forms of medication that can have significantly reduced side effects for a small subset of the population. Instead, innovation would have to be justified on the basis either of its substantial therapeutic advancement for a broad cross-section of the population.

Pricing by reference to other countries, particularly for drugs marketed largely in the United States, can result in substantial losses. Manufacturers might be willing to sustain losses on a small portion of their sales as a condition for entering highly-regulated markets, but not across-the-board. Generalizing these losses to their largest market would reduce or eliminate the returns on their R&D investment.

Any simple or arbitrary price standard runs the risk of missing or distorting the economic decisions on bringing new drugs to market. Boards have insufficient data and limited capacity to understand, much less influence the factors that will govern investment decisions.

Comparing List Prices

The Canadian Board reviews only the "ex-factory" or wholesale prices of the manufacturer -- the list prices. This approach seems appropriate for the Canadian market which appears more oriented to list prices and pharmacy distribution than the U.S. market. In the U.S., however, the list price is higher than the actual price for which the product is sold. A substantial portion of the U.S. market involves purchases through HMOs, hospital pharmacies, managed care drug plans, and other intermediaries receiving volume discounts. Focusing on list prices in the U.S. would result in unreasonably large reductions in price.

The same problem would occur in comparing U.S. prices with prices in other countries. Because U.S. prices are significantly higher than actual prices, the differentials between the U.S. and other countries would appear to be larger than they are, and to suggest unreasonably large reductions.

Controlling Launch Prices

One of the most difficult and potentially harmful areas for a Board to attempt to regulate is the launch pricing for new drugs -- particularly new breakthrough drugs. It is noteworthy that the Canadian Board does not attempt to set prices, and second that its guidelines for excessive initial or launch prices refer only to the same drug's price in other countries.

There is a danger in having a Board attempt to set launch prices that the Board will look only at the direct cost of researching and developing the drug. Manufacturers and investors, however, evaluate the risks and potential returns for new chemical entities in determining whether to bring them to market. These factors include the potential that products might not prove marketable in the end, the advantages and potential cost effectiveness of the new therapy relative to existing therapies, and the value that the drug will have for patients and society that can be reflected in the drug's price. If the potential returns substantially outweigh the risks, the development will proceed.

Limiting the price of a drug to its own R&D costs is likely to reduce the returns for high-risk research substantially, to the point of eliminating much of the research that is driven today by the opportunity for a major breakthrough. A Drug Review Board would have little or no capacity to evaluate these factors or to account for this type of decision-making. The result would be to force cost-based pricing, and drug development aimed largely at restructuring market shares for existing drug therapies.

The influence of the U.S. pharmaceutical market on the worldwide capacity for pharmaceutical research and development is an important factor to be considered in evaluating the potential effects of a Drug Review Board. Canada's Board has inevitably had some effect on R&D in that country, although it is difficult to measure because of confounding factors. But Canada's influence on worldwide R&D decisions is not significant enough to matter. A major change in U.S. pricing, however, would have repercussions worldwide -- in ways that could not be anticipated by a Board or by the Congress.

VOLUNTARY RESTRAINT AGREEMENTS FOR DRUG PRICES

Many observers believe that a fully implemented system of managed competition would significantly reduce the overall cost of prescription drugs. In the meantime, Members of Congress and some health care task force members are concerned that older Americans will bear the brunt of prices that are rising rapidly for cash-paying purchasers as the scope of discounted purchasing grows.

A number of leading drug manufacturers are proposing binding voluntary restraints on drug price increases in an effort to head off government-imposed price controls. The proposals call for individual companies to execute separate bilateral agreements with the President, under which the companies would agree to:

- limit annual increases in average weighted pharmaceutical product prices to the annual increase in the consumer price index (CPI);
- reduce subsequent year prices if necessary to offset any revenues gained from increases in excess of the CPI; and
- provide annual data on per-unit revenues for each product to the Secretary of HHS.

Legislation authorizing the agreements would give the Secretary the authority to impose monetary penalties on companies violating the agreements.

Political Factors

On balance, the early negotiation of voluntary price restraints would have positive political benefits. They would give the President an early and highly-visible victory in the effort to control health care costs, would raise public confidence in the reform process, and would contribute some momentum to the effort to control other health care sector costs.

Voluntary restraints would also avoid the potential pitfalls of regulating drug prices. Industry leaders warn that drug price controls could have a number of inherent dangers -- they would require the establishment of a separate bureaucracy with the capacity to determine appropriate prices and monitor compliance; they would make the federal government dominant in a marketplace in which its influence is currently slight (unlike the hospital and physician markets where it is a dominant price setter); and they would run the risk of having long term affects on drug

research and development, the profitability of the drug industry, and the positive balance of pharmaceutical trade.

Accepting voluntary restraints would concede to the drug industry on the one critical issue that they would otherwise fight to the end -- price controls -- in exchange for which they might be willing to come to the table, avoid a public showdown, and even provide support for significant aspects of the President's package in the Congress and with the public.

There are potentially negative political consequences to voluntary agreements, however. Drug price controls have a populist political benefit that may be useful in moving the reform package. Price controls would build on the anger that people, particularly older people, feel toward drug manufacturers, and convey a sense of protecting the average American from fatcat lobbyists and corporate tycoons. There is a danger that the public would view voluntary agreements as an early sign of weakness from the Administration -- an unwillingness to take on a major villain and opponent of real reform.

Price controls could also have strategic value in moving the health care reform package. Forcing the drug companies to focus on defeating a price control proposal in the Congress would divert them from other aspects of the package they might otherwise be moved to oppose.

There are also potential political pitfalls with the voluntary agreements themselves, in that they might backfire and embarrass the President: companies might resist negotiating the agreements, or consumers might be betrayed if specific prices continued to increase despite controls on average prices, or if companies raised launch prices to offset the effects of capped increases. To gain support for voluntary agreements within the Administration and on the Hill, there will need to be assurances from the drug industry on all or most of these points.

Enforceability

Voluntary price controls by the drug industry are viewed as less effective than direct price controls in three areas: 1) participation - companies may be unwilling to sign agreements, 2) compliance - they may fail to honor their agreements, and 3) scorability - CBO may not score the agreements as reducing either federal spending or national health expenditures. However, these issues can be largely resolved in the agreements.

Participation -- With voluntary agreements there can be no absolute guarantee that all major drug manufacturers will participate. Individual bilateral agreements are necessary to avoid anti-trust violations for colluding on prices. Government sanctions for non-participation - through tax or other penalties - would be viewed by the industry as

equivalent to mandatory price controls. Nevertheless, companies would have a huge incentive to sign -- both for public relations reasons, and to avoid ceding to competing companies an advantage in negotiating other aspects of the package with the Administration and Congress. Individual drug manufacturers have spent substantial amounts to cultivate a positive public image as good corporate citizens interested in protecting the health of the population -- they will want to avoid being cast as price gougers or greedy profiteers.

Compliance -- The agreements themselves can provide adequate assurance of compliance. The agreement can be enforced under contract law. Industry proponents have also supported provisions in the agreements for external audits of pricing and monetary penalties for violating the agreement. Compliance ought to be the easiest of the problems to deal with.

Scorability -- CBO would most likely be unable to score voluntary restraints with savings until agreements were actually signed. At the same time, CBO could only score savings from the portion of the industry that signed agreements. Nevertheless, if a substantial portion of the industry signed, CBO would be able to score significant savings, depending on the extent to which the agreed-upon growth rate was lower than CBO's baseline projection. A low CBO baseline rate, based on recent growth rates, would yield little savings from either the agreements or price controls.

Controlling Cash Purchases and Discounts

Senator Pryor issued a blistering report last month accusing the drug industry of bad faith in promising last year to voluntarily limit average price increases and then raising prices for cash-paying customers. The problem is that drug manufacturers who provide deep discounts to large volume purchasers -- up to 80 percent in some cases -- can maintain low average increases while raising prices in the cash-purchase market that are offset by losses from discounts. As Senator Cohen characterized it this week, it is the problem of drowning in a pool with an average depth of 3 feet. Senator Pryor's concern is that the elderly (60 percent of whom have no drug benefit) will continue to see large price increases as drug manufacturers are forced to grant discounts to a growing share of the non-elderly maket.

The long-run solution is to extend a managed care drug benefit to the elderly so that they can benefit from volume purchasing as well as other money-saving managed care activities, such as aggressive generic substitution and monitoring of drug utilization for overmedication and negative drug interactions. Since there is no existing Medicare drug benefit for the elderly,

comprehensive reform would provide an opportunity to create a new drug program tied to managed care from the beginning, rather than having to add such a program later that disrupts existing patterns of coverage.

In the short run, some of the manufacturers have indicated a willingness to set voluntary caps on separable parts of the market or on specific products rather than on the manufacturers average weighted price -- although this is still far from an industry position. Nevertheless, it is an item that might be resolved to everyone's satisfaction if the Administration engages the industry to resolve this conflict.

Launch Prices

The one area that causes substantial concern on the Hill is launch prices. Some Members believe that manufacturers would eventually get around voluntary or mandatory caps on the increase in drug prices by introducing new drugs at higher initial or "launch" prices. Setting launch prices, however, would be an almost hopeless regulatory activity and one with serious potential to do unintended damage to the industry.

It is difficult to get a definitive statement on how drugs are priced for introduction in the market. Manufacturers take cost into consideration -- the capital costs as well as the opportunity costs of investment in the R&D for the drug as well as a share of those costs for other drugs not brought to market. The market itself plays a role -- the prevalence and character of the condition to be treated and the cost of alternative treatments -- in short, the value to individuals and to society of effective treatment. A drug that is priced reasonably with regard to these factors will meet the test of cost-effectiveness for inclusion in HMO and hospital formularies and the test of fairness overall in the marketplace.

Public concerns about launch prices tend to focus on important single-source drugs and especially orphan drugs and drugs that come to market with an exclusive license and substantial federal research subsidies. Without alternative drug therapies to choose from, the market has trouble pricing these drugs on the basis of their value - particularly since the price for the majority of consumers is much lower than the list price due to insurance.

Because drugs are for most people still a consumer item purchased at the drug store (unlike hospital and physician care) -- and because most of the elderly still pay the full cost out-of-pocket, high launch prices are viewed as unfair regardless of whether the drug therapy is cheaper than alternative therapy. Also, many expensive drug therapies continue over a long period of time, creating a constant source of irritation for the consumer.

It is much easier and much less disruptive to the economics of drug research and development to regulate annual increases in drug prices than to regulate launch prices. The popular tendency is to want to set launch prices just above the cost of researching and developing the drug. OTA noted, for example, that the average drug recovers revenues that are 4.3 percent above its R&D costs -- this amount could become a standard or the basis for reducing that margin. The problem with this approach is that launch prices are a significant factor in the lifetime financial return from a chemical compound and the decision on whether to invest in developing, testing, and marketing the compound. Significant reductions in launch prices would reduce returns to investors, chase investors away from the drug industry, and discourage company investment in high risk research. The industry also uses launch prices of the most successful drugs to cover low returns on other drugs or losses from drugs not brought to market. Government set launch prices would significantly change the character of drugs brought to market in ways that would be difficult to anticipate.

There is no simple solution to the problem of high launch prices. The authority that the Public Health Service now has to review and approve the pricing of drugs granted an exclusive license could be strengthened. But an attempt at this point to set launch prices would be more potentially harmful and politically disastrous than it would be worth.

Recommendation

Voluntary restraint agreements can have value as an early victory for the Administration and one that would contribute to the growing phenomenon of major interest groups switching positions and throwing their support behind a reform package. There are several reasons why voluntary agreements would be a better political strategy than price controls for the Administration at this point:

- Although there are significant risks that the voluntary agreements might not work, they are no greater than the risks that direct price controls might not work.

- Failure of the voluntary agreements could be characterized as a failure of the drug manufacturers, whereas the failure of price controls would be directly a failure of the Administration.

- Voluntary agreements leave the Administration with price controls as a backup option, while going directly to price controls would leave no backup. Failure of price controls would be an early dead end for the Administration and create a sense that other cost control efforts might fail.

- Voluntary agreements would give the Administration breathing room to learn more about drug pricing. The monitoring of the agreements would disclose valuable baseline data that would make price controls more effective if they later become necessary.

- Voluntary agreements contain an incentive for the drug industry to cooperate and control prices to prove they can work to head off controls. Going directly to controls creates a adversarial relationship with the industry and a strong incentive for the industry to make them fail.

- A loss on price controls would set the industry up to oppose other aspects of reform. A victory on voluntary agreements could be tied to their cooperation and support in getting other features of the Administration package through the Congress.

Concerns about the difficulty in enforcing voluntary agreements, the need to control cash prices, and the need to affect launch prices can be resolve to some extent, although not completely. The industry appears ready to support tight enforcement and is likely to participate broadly, although there can be no guarantees that all companies will participate. It may also be possible to work out separate price restraints below the company's average price in order to prevent substantial increases in cash prices. Though launch prices will remain a concern, they should be dealt with by bringing greater pressure on the industry rather than trying to set launch prices.

INCENTIVES FOR PARTICIPATION IN VRAS

A major concern about voluntary price restraint agreements (VRAs) for pharmaceutical manufacturers is that some manufacturers will decide not to participate in the VRAs and will be free, as a result, to raise drug prices with impunity. This memo reviews some of the options for encouraging companies to participate, and discusses the strengths and weaknesses of each.

Basic Concept

a) Initial Expression of Support

Under the VRA approach, companies would individually communicate to the President their support for legislation that would authorize the President to sign company-by-company agreements. Once a "critical mass" of companies have communicated their support, the legislation would be introduced in the Congress and enacted as quickly as possible.

b) Open Window to Participate

The statute authorizing the VRAs would provide a window of 45 days after enactment when companies could initiate negotiations with the Secretary of HHS, and a window of 120 days after enactment within which an agreement would have to be signed.

c) Protected Signatory Group

Companies initiating contact within 45 days and signing VRAs within the 120 day window would be in the signatory group and protected from any other laws or actions that would regulate drug prices or otherwise have the effect of punishing non-signatory companies.

c) Exposed Non-Signatory Group

Companies that failed to get through the window would be non-signatory companies, and would have no further chance to sign an agreement. They would be subject to any and all federal laws affecting pharmaceutical prices.

Options for Punishing the Non-Signatory Group

Companies will be encouraged to participate by the risk of damaging their public image, fear that signatory companies would influence the reform package to harm their markets, and fear of federal retaliation through price controls. Nonetheless, if these pressures were not deemed sufficient to coerce participation, then there are a few additional options.

Option 1) No Transactions with U.S. Government Vendors

Non-signatory companies would be barred from selling products to Medicaid, the Public Health Service, the Department of Veterans Affairs, the Department of Defense, or other federal agencies.

Pros:

- Can reduce market share and overall revenues for a non-signatory company enough to encourage their participation in the VRAs;
- Federal contracting is a relatively simple factor for the government to influence.

Cons:

- May deprive federal beneficiaries of access to drugs that may be one-of-a-kind or therapeutically significant;

Option 2) Price Controls

Congress would pass price controls on non-signatory companies, limiting increases in their product prices to the CPI.

Pros:

- Would give manufacturers no option but to sign up, since the same result would apply anyway;

Cons:

- Eliminates the distinction between VRAs and price controls and reduces the benefits of the VRA;
- May be a hollow threat -- may be difficult to enact price controls once most companies are participating in VRAs.

Option 3) Limitations in Federal Patents and Licensing

Congress would shorten the patent life for non-signatory companies by 3 years and would limit FDA approval for new generic products. Non-signatory companies would also be barred from qualifying for NIH cooperative agreements or licenses for any Federally-developed drugs.

Pros:

- Coordinates a range of federal functions that drug manufacturers rely upon to encourage companies to sign up.
- Canada can reduce market exclusivity for a company that does not cooperate with the Board in pricing.

Cons:

- Attempts to interfere with patents, new drug approvals, and other federal functions that should be administered fairly may be viewed as unreasonable interference in objective government functions -- likely to be challenged in the courts.

Option 4) Launch Prices

Congress would require all non-signatory companies to seek approval from the Secretary of HHS for initial prices for drugs launched after the enactment date.

Pros:

- This could effectively lower non-signatory company's revenues without VRAs.
- The need to clear launch prices with the government could significantly reduce a company's access to capital markets.

Cons:

- The Secretary of HHS would have no way of establishing appropriate launch prices for one-of-a-kind drugs.
- Non-signatory companies could substantially increase launch prices once drugs were on the market.

VOLUNTARY RESTRAINT AGREEMENTS
FOR PHARMACEUTICAL PRICE INCREASES

This proposal provides a mechanism of Voluntary Restraint Agreements (VRAs) that would be voluntary, yet enforceable and would yield scorable savings for the federal budget and the effort to control health care costs. VRAs would be separate bilateral agreements for each pharmaceutical manufacturing company, signed by the President and the CEO of that company. Under the agreements, companies would agree to hold their annual average pharmaceutical price increases to the rate of increase in the consumer price index (CPI).

Announcement

The President would announce an agreement with the CEOs of major pharmaceutical manufacturers and the Pharmaceutical Manufacturers Association (PMA) to freeze drug price increases for 1993 and subsequent years at the CPI. The President would announce that he is seeking, with the support of the industry, immediate enactment of legislation to authorize a program of Voluntary Restraint Agreements (VRAs) for the drug industry. The announcement would be based on an agreement in principle between the President and each of the companies on a draft VRA.

Legislation

The President would submit and the Congress would enact legislation that would:

- authorize the President to sign separate bilateral agreements with each pharmaceutical manufacturer to hold drug price increases to the CPI;
- limit the duration of the agreements to 3 years with authority to renegotiate subsequent agreements;
- authorize the Secretary of HHS to impose monetary penalties on signatory companies who willfully violate the agreement;
- state the intent of the Congress to consider further action if voluntary action fails to bring drug prices in line with inflation as specified in the agreement;
- clarify that the agreements do not imply regulation of pharmaceutical prices or the implementation of formularies.

Agreements

The bilateral agreements would be negotiated by the Secretary of Health and Human Services and presented for the President's signature within 120 days of enactment of the law. The agreements would provide that:

- the annual increase in the manufacturer's average weighted product prices -- calculated for all of the company's pharmaceutical product prices for all classes of trade -- would not exceed the annual increase in the consumer price index (CPI-U); and the annual increase in average weighted prices for the manufacturer's direct or indirect sales to the retail pharmacy class of trade would not exceed the annual increase in the CPI plus X percent -- beginning with all price increases during the calendar year 1993;

- beginning in 1994, the annual increase in the company's average weighted prices would be reduced below the CPI to the extent necessary to offset the cumulative increase above the CPI, as of the prior year, from the 1993 company baseline in prices;

- the company would provide data annually to the Secretary of HHS on average weighted prices for the company's pharmaceutical products over all classes of trade, and for the retail pharmacy class of trade; and would provide for an annual independent audit of compliance;

- the company and its products would be exempt, during the time the agreement was in effect, from any other federal laws or actions taken after the agreement was signed regulating the prices on the company's pharmaceutical products other than necessary amendments to pre-existing laws.

Companies would have 45 days after the enactment of the law to initiate negotiations with the Secretary. Companies failing to initiate negotiations within 45 days and sign an agreement within 120 days would be subject to all subsequent federal laws and actions taken to regulate pharmaceutical prices.

Enforcement

Individual manufacturers would be under no obligation to enter into VRAs with the Secretary. However, companies would have a substantial incentive to sign, since non-signing companies would risk damaging their public image, would limit their opportunity to participate in developing the health care reform package, and would be subject to future federal acation to regulate or affect drug prices.

Companies that sign and then flagrantly violate the agreements would be subject to monetary penalties imposed by the Secretary of HHS under the terms of the legislation. Penalties could be imposed once the Secretary had made a finding that the company's 3-year cumulative price increases exceeded the CPI-U increase in its 1993 baseline by more than a *de minimus* amount. The legislation would provide an appeals process within HHS for companies to provide evidence that price changes were not in violation of the agreement. Companies would have the right to appeal adverse decisions by HHS to the federal courts.

Preliminary estimates of savings to the federal budget and the reduction in national health expenditures would be developed in conjunction with participating firms after the initial announcement, based on profiles of the companies participating in the announcement. Final estimates of savings would be determined once all agreements were signed.

Price Increases

Companies would be obligated to keep the average weighted price increase of their total line of prescription drugs, calculated for all classes of trade, at or below the CPI, as well as to keep the increase in their average weighted price for direct or indirect sales to retail customers within X percentage points of the CPI.

The measure of total average prices would be the total sales revenues to the manufacturer from all pharamceutical products divided by the number of units of such products sold. This calculation would be adjusted to account for year-to-year changes in sales volume. Prices for retail customers would be based on the total sales revenues from direct or indirect sales to retail pharmacists. The retail calculation would not include revenues from sales to HMOs, hospitals, federal government programs, or mail-order pharmacies.

HHS would be provided with the necessary certified data and audits to determine that total revenues accurately reflected the proceeds from all sales of the companies pharmaceutical products and were not affected by year-to-year changes in accounting practices.

Launch Prices

The initial or launch prices for drugs entering the market while the VRAs are in effect would be established by the manufacturing company. After the first year, the new drugs would be added to the mix of existing drugs for purposes of calculating annual price increases. Competition would effectively control new drug prices, as is increasingly happening in the current environment where new drugs are often priced on the basis of their added value and cost effectiveness relative to alternative therapies. With the emergence of managed competition, all purchasers would benefit from effctive purchasing strategies and active management of the utilization of new drugs.

Advantages

Voluntary Restraint Agreements would provide immediate savings in drug costs without the need to first create a bureaucracy to set prices. While there is some risk that VRAs would not effectively control prices, it is no greater than the risk that government price controls would backfire. While a failure in government price controls would be viewed as a failure for the new administration, failure of the VRAs could be portrayed as bad faith by the drug manufacturers. The advantage of starting with VRAs is that it would leave regulation as a fallback for the government if VRAs fail to manage prices.

Starting with drug price controls immediately thrusts the government into a role for which it is unprepared. The experience with government regulation of hospital and physician services has shown that price controls have not been effective in controlling expenditures. In addition, government has little data, no prior experience, and no proven methods for developing prices for the drug market. Small miscalculations in regulating drug prices could have serious consequences for the drug manufacturers' access to investment capital and ability to invest in research and development.

Voluntary Restraint Agreements provide a way for the industry to act quickly and cooperatively to hold prices down, and avoid the necessity of launching a substantial government bureaucracy and an adversarial relationship with drug manufacturers to regulate prices.

VOLUNTARY PRICE RESTRAINTS: AVERAGE VERSUS DRUG-BY-DRUG

Schering-Plough has proposed that manufacturers voluntarily agree to restrain the annual increase in the average weighted price for pharmaceutical products to the increase in the consumer price index (CPI). To prevent unreasonable increases in the retail market, Schering-Plough has proposed that retail price increases be kept to some function of the CPI increase (e.g. CPI plus 2). Merck has counter-proposed that the annual increase in the price of each drug be kept to the the CPI plus 1 percent. What is the difference?

Average Weighted Prices

Pharmaceutical manufacturers who introduce drugs into highly competitive markets and have their drug prices determined in the marketplace have little control over the average selling price of their drugs. Particularly in markets that are highly segmented, changes in utilization in various segments can have a significant effect on total revenues and thus on average selling prices. Under an average pricing approach, manufacturers can make up for unanticipated gains or losses in their more competitive markets by modifying prices in their less competitive markets. By monitoring aggregate prices, and adjusting prices they can adjust, they can assure they meet their broad inflation targets.

These manufacturers would be unable to meet product-by-product goals for price increases. For some products in heavily negotiated market segments pricing would be out of their hands. If they lose money in these markets, they would be unable to make it up in other markets because of the product-by-product caps. Their loses in the most competitive markets would create general losses.

Individual Drug Prices

Some pharmaceutical manufacturers now encounter fairly homogeneous markets without much competition, and are able to unilaterally price their products. To the extent they determine their price increase, their average selling price can be anticipated, and with a single price and no market segments, changes in volume in different market segments have little effect. Thus their average price increases would look much like their product-by-product price increases. These manufacturers can easily comply with product-by-product price limits because they set these prices and encounter no market resistance when they do.

Under product-by-product limits on increases, the least competitive manufacturers would survive, and would do so by keeping products out of competitive markets. As the more competitive manufacturers experienced losses, the least competitive manufacturers would gain market share. The result over time would be to make the market for pharmaceuticals, and the pricing of drugs in those markets, much less competitive.