Records

Domestic Policy
Jennifer Klein — 2 copies Recd in ORM 12/16/94
Box 1 -

Drugs
Ethics
Food & Nutrition
Food Stamps
Foster
Nutrition
Public Health
Drug Events
Drug Strategy
Substance Abuse - ONDCP
American Rehabilitation Assn March 13, 1995, Talking Points
Rehab
Smoking
SHIP
Welfare
Welfare
Ackerman
Arney
Barlow
Barca
Barton

ENCLOSURES FILED OVERSIZE ATTACHMENTS 8296
2 copies filed 1/9/97 mm
NARA 5950

Bateman
Baucus
Bentley
Bingaman
Bliley
Boehlert
Bonilla
Bonior
Brewster
Burns
Calvert
Collins
Condit
Conrad
Conyers et al
Conyers
Costello
Domenici
Dunn
Darden
Daschle
DeConcini
Dooley
Fields

Glenn
Greenwood
Harkin
Hatfield
Heflin
Hispanic Caucus
Hochbrueckner
Inouye
Stook
Jacobs
Jeffords
King
Kaptur
Kleczka
Kopetski
La Falce
Lancaster
Lautenberg
Lazio
Leahy
Lewis, John
Lewis, Tom
Lloyd
Mann

Jennifer Klein - Box 1 page 4

Martinez
McConnell
Mental Illness - Kennedy/Wellstone/Dronge/Simon/Domenici/
Simpson
Metzenbaum (and Brooks)
Mineta
Mitchell
Moynihan
Moorhead
Moseley - Braun
Morella
Murray
Myers
Neal
Pelosi
Porter
Poshard
Rahall
Rangell
Robb
Roberts
Ros-Lehtinen
Rowland
Stark

Sanders
Schenk
Schroeder
Simon
Slaughter
Slattery
Snowe
Stokes
Strickland
Specter
Studds
Thurman
Towns
Waters
Wise
Wofford
Young
Conn.
Hicaki - Hawaii
Indiana
Louisiana
Regan - Nevada
Weld - Mass
Oklahoma

Jennifer Klein - Box 1 / page 6

Wyoming
State Legis.
Children's Wrap
Childrens Meeting
Civil justice Project
Contract w/America
WH Organization
Disability
SSI/Disability
AHCPR
Americorps
America's Summit
BC/BC Comparison
Blackmun
Brad
Childen

THE WHITE HOUSE

WASHINGTON

March 28, 1995

MEMORANDUM FOR THE PRESIDENT

FROM: CAROL RASCO

SUBJECT: Families USA Prescription Drug Price Increase Report Analysis and Update

CC: Laura Tyson

You asked for an analysis of the recently released Families USA report on manufacturers' prescription drug price inflation and a more general update on this issue. The following attempts to be responsive to your request and concludes with a brief summary of potential policy options.

Background

As you know, inadequate prescription drug coverage represents one of our most difficult, expensive, and unsolved health policy challenges, particularly as it relates to older Americans. Facts that illustrate this point include:

- **Prescription drug costs remain the highest out-of-pocket health expenditure for three out of four seniors.**

- **Although they represent only 12 percent of the population, older Americans consume 34 percent of all retail prescriptions.**

- **A 1993 Urban Institute study found that 13 percent of seniors are forced to choose between purchasing food or needed medications.**

- **An AARP 1994 study found that fully 46 percent of older Americans (13.8 million) had no prescription drug coverage whatsoever** (no Medicaid, no Medigap, or no private retiree health coverage that covered medications.) Having said this, most of the "influential" elderly, i.e., those that contributed to the repeal of the Medicare Catastrophic Coverage Act, have some type of drug coverage and may not be interested in helping pay for something they already have.

Although not a required benefit, every state covers prescription drugs in their Medicaid programs. It is an expensive benefit, however, and there is little doubt that these **drug coverage programs will be vulnerable to major cuts or total elimination if Medicaid cuts of the magnitude that some Republicans in the Congress are now considering are enacted.** (The problem with this budget-driven strategy is that the short-term savings would be much more than offset by subsequent cost increases in hospitalization and mental health care.)

Families USA Report

The Families USA report, "Worthless Promises: Drug Companies Keep Boosting Prices," alleges that drug manufacturers have not been living up to their "voluntary" price constraint pledges. It accurately charges that the manufacturers continue to increase prices faster than the rate of general inflation for drugs that are sold to retail community pharmacies; as a result, out-of-pocket drug costs continue to grow even more burdensome, particularly for low income seniors.

The study reports that prices of the top 20 drugs used by all Americans increased in price 4.3 percent in 1993, or 1.6 times the 2.7 percent increase in general inflation (CPI). It also reports that the prices of the top 20 drugs used by older Americans increased by 4.0 percent in 1993, or 1.5 times the increase in general inflation.

The Families USA report also examines the profitability of the drug industry. It reports that from, 1989 through 1993, the median profitability of all industries was 2.9 percent, while drug industry profitability was 15 percent -- 5 times higher.

Analysis of Families USA Report

1. <u>Inflation</u>

The Families USA report chose to focus on inflation increases solely to retail pharmacists because they fill about 85 percent of all out-patient prescriptions. **However, had the Families USA analysis surveyed all purchasers, including HMOs, hospitals, mail order pharmacy, as well as retail pharmacists, it would have reflected price increases roughly equal to that of the general inflation rate.** (In 1994, e.g., the drug manufacturer's inflation rate was 2.6 percent compared with the 2.7 percent general inflation rate.)

The manufacturer's inflation rate drops when one incorporates the non-retail purchasers because the industry gives these purchasers deep discounts and restrains price increases. The manufacturers say they give these deals because the non-retailer purchasers -- unlike the retailers -- move drug product market share, primarily through the use of formularies. The retailers strongly believe they are being victimized by class of trade discrimination and have filed a class action suit alleging Robinson-Patman Act anti-competitive violations.

Regardless of which analytical model is used, there is no question that drug price inflation has significantly moderated since the days in the late 1980s and early 1990s when it frequently tripled the general inflation rate. However, since the vast majority of Americans purchase their prescriptions at retail pharmacies, they rightly perceive that the prices of their medication purchases are continuing to rise above the inflation rate. (This may help explain why the Families USA report has received such a receptive response.)

2. Profitability

The report's findings on drug profitability appear to be generally accurate. As you know, the drug manufacturers have always claimed that their high profits are necessary to attract investment in risky and expensive research. In the face of market pressures (through managed care, which now represents about 35-40 percent of the total outpatient drug market) and political pressures (through the White House, David Pryor, Bill Cohen, the media, etc.) to constrain price increases, the industry has been able to maintain its high profitability for several reasons. They include:

- **Significant mergers,** which have increased efficiency and eliminated duplication;
- **The growth of managed care and the accompanying centralization of drug purchasing,** which has enabled drug manufacturers to reduce the numbers of personnel utilized to sell (or "detail") new drug products; and
- **Aggressive movement into the generic drug marketplace** by the name brand manufacturers, which has enabled them to benefit from recent generic drug sales growth and to compensate for fact that many drugs are coming off patent.

Outstanding Questions

1. Inflation Moderation: Short or Long-Term Trend?

The obvious outstanding question relating to drug inflation is whether the recent positive trends represent a short or long-term phenomenon. Largely because the managed care market is expanding at unprecedented levels, it seems reasonable to assume that a recurrence of the price escalation the nation experienced in the late 1980s and early 1990s is unlikely -- at least for the immediately foreseeable future.

One threat to an inflation moderated era might be an attempt by some in the drug industry to take uncompetitive actions to confront the current competitive pressures. Some allege that the seeds of this problem are already being layed with the recent purchases of Pharmacy Benefit Management (PBM) companies (drug cost/management firms under contract with insurers and HMOs) by drug manufacturers. The purchase of three of the largest of these PBMs by Merck, Eli Lilly and Smith Kline means that manufacturers control 63 percent of the PBM market. The FTC has indicated that it is monitoring this trend very closely.

2. **Retail Pharmacy as a Purchaser: What is their Status and Administration Position?**

In the last Congress, in response to concerns raised by the retail pharmacy community, we incorporated a provision into the Health Security Act that explicitly prohibited class of trade pricing distinctions. Under HSA, as long as the retailers could prove they were providing the same economic benefit to the manufacturers that other purchasers were, the manufacturers would have to provide equal access to discounts. The enforcement stick was that the industry could not participate in our proposed new Medicare program if a violation was found.

The retail pharmacists strongly supported HSA largely because of the "equal access" provision; to their credit, though, they stuck with us (and the employer mandate) even in the worst of times. Predictably, the manufacturers hated this provision and lobbied extremely hard against it. (As a result, even in the last Congress, there was not a great likelihood that the provision would have survived even had some version of health reform passed last year.)

In the environment of a more drug manufacturer-friendly Congress and in a session that is highly unlikely to produce a traditional Medicare prescription drug benefit, the potential for passing an enforceable "equal access" provision appears to be dubious at best. In fact, the retail pharmacists may well decide they prefer their fate to be decided at the State level, in the courts, and through the development of their own competitive alternatives. (They may prefer this track rather than risk a lopsided defeat in the Congress.) On the competitive front, the chain drug stores just recently established their own Pharmacy Benefit Management company. This week we will be meeting with the retail pharmacy representatives (including Charlie West of NARD) to get a sense of their current position on this issue.

3. **Lack of Adequate Prescription Drug Coverage: What are the Options?**

The problem that will not go away is that the millions of low to middle income class Americans who have little or no prescription drug insurance coverage simply cannot afford their medications. The HSA provided for a prescription drug benefit in its basic insurance benefit for all Americans. It also included a Medicare drug benefit for all the elderly and disabled. However, a required standard benefit package and a $50-75 billion 5-year Medicare drug benefit is obviously not a politically or economically viable option at this time.

In response to your interest in this area, we have been working on three alternative drug coverage options. The first would require all Medicare managed care plans to offer a drug benefit. The second would create a Federally-funded drug benefit through the Medicaid program for those who are eligible for the Qualified Medicare Beneficiary (QMB) program. **The third option would provide for a new Federal Matching grant program to encourage States to set up pharmaceutical assistance programs** for low-income beneficiaries. Attached are some selected pros and cons of each. If you have any preferences, please let us know.

Option 1: Require Medicare Managed Care Plans to Offer Drug Benefit

Pros:

- No cost to Federal Government.
- Would increase from 35 percent to 100 percent the number of managed care plans that offer prescription drug benefits.
- Provides additional incentive for enrollment into managed care.

Cons:

- A required offering could be perceived as overly regulatory.
- Could lead to adverse selection of sick people into managed care plans and discourage managed care plans from entering market.
- Could be viewed by some advocates as presenting a Hobson's choice to the elderly: Choosing between keeping access to all doctors and need to have prescription drug coverage.

Option 2: Create a Federally Funded Prescription Drug Benefit through the Medicaid Program for Qualified Medicare Beneficiaries (QMBs).

Pros:

- Would cost substantially less than a full blown Medicare out-patient program (this option would cost about $9 billion over 5 years) and would better target the benefit to those who are most in need.
- Would use the established Medicaid program to expand coverage rather than set up a new funding/administrative mechanism.

Cons:

- Although States would not pay for the new drug coverage, they would likely face increased costs associated with greater use of the rest of the QMB benefit (because the drug coverage would attract more people.)
- Frequent changes in the eligibility status will make it difficult to distinguish between those who get the drug benefit because of their dual eligibility status or their QMB status. (In other words, it could well create administrative hassles and financing disputes with States.)

Option 3: Develop a New Federal Matching Grant Program for State-Run Pharmaceutical Assistance Programs for the Low Income

Pros:

- States would have discretion to determine eligibility and coverage.

Cons:

- Questionable that many States would opt to participate in an optional and potentially expensive new health program.

Chris

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: KLEIN JENNINGS

Draft response for POTUS and forward to CHR by: _____

Draft response for CHR by: 3/24

Please reply directly to the writer (copy to CHR) by: _____

Please advise by: _____

Let's discuss: _____

For your information: _____

Reply using form code: _____

File: _____

Send copy to (original to CHR): _____

Schedule ? : ☐ Accept ☐ Pending ☐ Regret

Designee to attend: _____

Remarks: PLS DRAFT SHORT MEMO FROM CHR TO POTUS IN RESPONSE TO HIS INQUIRY.

BOB: TICKLER 3/24

[redacted]

[redacted]

[redacted]

[redacted]

Some Drugs Rise in Price At Fast Pace

Survey Says Top Sellers Exceed Inflation Rate

By MILT FREUDENHEIM

Pharmaceutical companies have increased the pace of price increases on many of their best-selling drugs since the collapse of the Clinton Administration's health care proposal last year.

During the battle over health care, drug companies promised to rein in their price rises, keeping them at or below the increase in the Consumer Price Index. That promise, made in an effort to ward off legislated price controls, has almost been kept over all, with drug prices rising 3 percent last year.

That pledge, however, has not prevented the drug makers from trying to maximize their profits by pushing up the prices of most of their 20 top-selling drugs.

According to health economists who surveyed drug prices for Families USA, a consumer group based in Washington, the prices of the 20 top drugs jumped 3.6 percent in the last 12 months. The price of Zantac, for example, the No. 1 ulcer treatment, rose 3.7 percent.

And this year it appears that the increases might be getting larger. In January, the price of Mevacor, the most commonly used treatment to lower blood cholesterol levels, went up 4.4 percent and Premarin, a big-selling estrogen product used by women after menopause, jumped 6.4 percent.

The Pharmaceutical Research and Manufacturers Association, an industry trade group in Washington, said the list prices that were used in the Families USA survey were misleading because they overstated the price increases by half a percentage point.

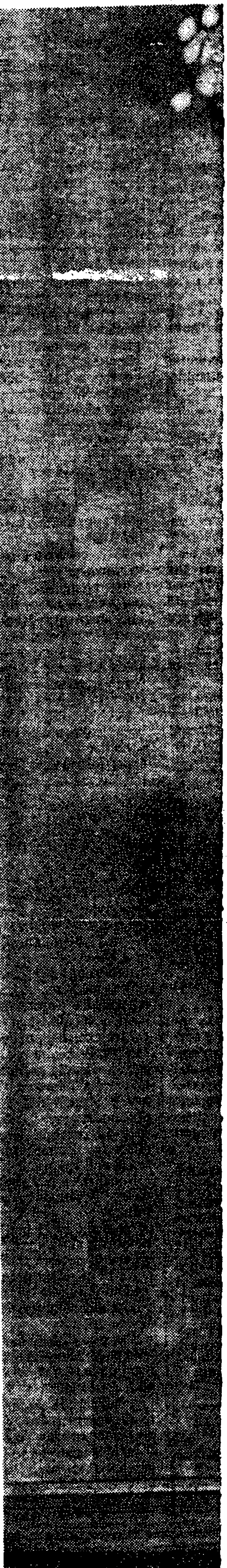
Wall Street analysts have welcomed the price breakthroughs as harbingers of higher profits for the companies. But consumer advocates and their allies in Congress say the increases are painful for millions of low-income people, especially those living on Social Security. The Medicare program for the elderly does not cover retail drug purchases.

It is not clear yet what response there will be in Washington if the price increases continue, in part because the rises still seem low compared with those of recent years; just three years ago, the overall annual increase in drug prices was 6.1 percent.

Still, the change in pricing is getting attention. "Although the increases in drug prices have slowed down over the past year, prices on the drugs older Americans use most continue to rise," said Senator William S. Cohen, Republican of Maine, who is chairman of the Senate Special Committee on Aging.

Representative Ron Wyden, Democrat of Oregon, was blunt. "My sense is," he said, "that some of these big drug companies are saying that the heat's off now.

Continued on Page D6



For Some Drugs, Increases In Prices Outpace Inflation

Continued From First Business Page

They're saying that Congress didn't pass a health care bill last session; they've got a lot of new allies in the Congress, and they can get away with more than they could before."

Joseph P. Riccardo, a drug analyst with Bear, Stearns & Company, said "posted price increases in the U.S. retail market have edged up 4 percent to 5 percent" in the first weeks of 1995. He said worldwide price increases for pharmaceuticals were expected to be at a faster pace this year than in the preceding four years.

Prescription drug prices over all increased 3 percent in 1994, slightly faster than the 2.7 percent general inflation rate, according to the Federal Bureau of Labor Statistics. Through January, the latest available data, overall drug prices and the Consumer Price Index were rising at a 2.8 percent rate.

But prices of the 20 largest-selling drugs, according to economists with Families USA, rose 3.6 percent last year and 3.6 percent during the 12 months that ended on Feb. 28. The Families USA study monitored changes in the manufacturers' list prices to distributors, which reflect changes paid at retail pharmacists by people who do not have drug coverage in their health insurance. Such buying makes up about 44 percent of all drug purchases, according to Stephen W. Schondelmeyer, a University of Minnesota economist who helped prepare the survey. Most of the rest is sold through hospitals, health insurance plans and state Medicaid programs.

The Pharmaceutical Research and Manufacturers Association said the prices that "pharmacies actually paid" for the 20 top-selling drugs increased only 3.1 percent. That included purchases paid by insurers, which often get discounts from both pharmacies and manufacturers. The Families USA survey was of buyers who do not get discounts.

Max Duink, a retired sheet metal worker in Frewsburg, N.Y., in the western part of the state, said he spent $335 a month for heart, asthma and diabetes medicines for his wife. "A year ago it was about $320," he said. "It's going up faster than our Social Security."

A spokesman for Merck & Company which makes Mevacor, said the price increase when averaged for all of Merck's products was 1 percent, well under the inflation rate. Gary Lachow, the spokesman, said prices of some individual products had been raised by the projected inflation rate plus 1 percent. In raising Mevacor by 4.4 percent, Merck projected that the Consumer Price Index would rise 3.4 percent in 1995.

While the prices of most of the top-selling drugs rose faster than general inflation, prices of many others did not, which kept the overall increase at 3 percent last year. And in the face of market competition, some prices were lowered. For example, the price of Prilosec, an ulcer treatment made by Astra Merck, a joint venture company with the Swedish company Astra A.B., recently went down 21 percent.

Audrey Ashby, a spokeswoman for Wyeth-Ayerst Laboratories, which makes Premarin, said it was a [illegible] low-cost drug, only about [illegible] day. She said the company [illegible] sion of the American [illegible] Corporation, raised [illegible] Premarin received [illegible] al for use as a treat[illegible] rosis as well [illegible] symptoms. She added [illegible] pany had committed [illegible] research [illegible] Premarin.

Nancy [illegible] for Glaxo [illegible] [illegible] were also [illegible] sumer Price Index [illegible]

John [illegible] worked [illegible] [illegible]

Swatchmobile in U.S.

DETROIT, March 15 (AP) — The German auto maker Mercedes-Benz A.G. plans to sell its compact Swatchmobile in the United States. Mercedes has said the tiny two-seat car, to be produced jointly with the Swiss fashion watch maker SMH, will be built in France starting in 1997. "We will bring it to North America," said Michael Bassermann, president of Mercedes-Benz North America Inc., in an interview with Automotive News at the International Motor Show in Geneva.

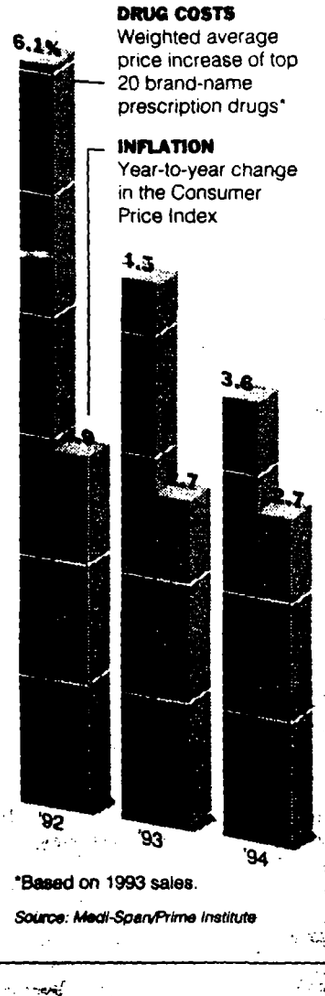
Company News:
Tuesday through Saturday,
Business Day

No I[illegible]

While th[illegible] prescrip[illegible] they co[illegible]

No Price Relief

While the average price increases of the most popular brand-name prescription drugs are not as great as they were two years ago, they continue to outstrip the rate of inflation.



*Based on 1993 sales.

Source: Medi-Span/Prime Institute

Price change of the top 10 brand-name prescription drugs* between March 1, 1994, and March 1, 1995, and their manufacturer

Zantac Glaxo	3.7%
Procardia Pfizer	4.0
Mevacor Merck	4.4
Vasotec Merck	3.4
Prozac Lilly	3.5
Cardizem MM Dow	4.0
Tagamet Smithkline Beecham	4.0
Premarin Wyeth-Ayrest	4.4
Cipro Miles	3.5
Prilosec Merck	

Economy Shou
Producer Prices

Continued From First Business Page

wondering for months when at least part of this pressure would begin to emerge from the end of the pipeline and affect finished goods — those ready for sale to the final business or individual user.

Today, Janet L. Yellen, a Federal Reserve governor, said she was still somewhat surprised that "we have thus far seen so little pass-through of higher raw and intermediate materials prices into the Consumer Price Index."

The report on consumer prices for February is to be issued on Thursday.

Early in the day, the tentative evidence in the Labor Department report that the pass-through process may be under way unnerved the bond market and pushed interest rates up. But that move was largely offset, later by a contradictory assessment in the Fed's periodic survey of business conditions throughout the country.

"Although commodity prices continued to rise, several districts note that the rate of increase has decelerated," that survey, known as the Beige Book, said. A summary of this anecdotal information from its 12 districts. "There is little evidence [illegible] in labor markets or increases in commodity prices have [illegible] prices of finished goods."

[illegible] the report compiled by the Federal Reserve Bank of New York based on interviews collected through March [illegible] that

Can It Be? Disney Builds Resort Without Mickey

By EDWIN McDOWELL

The Walt Disney Company announced yesterday that it was building its first resort exclusively for adults and families with older children. When the Disney Institute, as the resort is called, opens next February on the grounds of the Disney World Resort near Orlando, Fla., such familiar Disney characters as Mickey, Minnie and Donald Duck will be conspicuous by their absence.

Instead, the 58-acre Disney Institute will allow guests to fashion individual vacations from more than 80 programs as diverse as rock climbing, cooking, animation workshops or golf for hackers and advanced players.

"It is a synthesis of many [illegible]," said Richard Hutton, the Disney [illegible] president in charge of the [illegible], "and by offering new ways for families to get together, we're going to change the way the world [illegible] vacation."

It will provide a sharp contrast to Disney's nearby, Magic [illegible], which was visited by [illegible] 30,000 people a day last [illegible] ing to Amusement Business [illegible] zine. The Disney Institute, [illegible] rooms, will be able to accommodate only about 800 visitors initially and 1,400 in three years.

Rates for three nights, the minimum stay, will range from $587 a person, double occupancy [illegible] meals ($698 with meals), to $[illegible] ($853 with meals). Rates will vary with the type of accommodation, from one-room bungalows to two-room town houses.

At a news conference in New York announcing the Disney Institute, Michael D. Eisner, the company's chief executive, said it was intended to entertain, enlighten and provide guests an intellectual challenge, while adding to Disney's bottom line.

In the 1994 fiscal year ended Sept. 30, theme parks and resorts accounted for almost $3.5 billion of Disney's

The Disney Institute, employing Disney's vast contacting [illegible] already signed dozens of artists and guest speakers to mingle with guests and perform. They include the composers John Williams and [illegible] Bernstein, the [illegible] Franco Harris and Julius J[illegible], at least seven architects, and an [illegible] ment of computer whizzes, financi[illegible] advisers, choreographers and ar[illegible] mators. The National Shakespea[illegible] Guild and the New England Culina[illegible] Institute will also be represented.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
200 Independence Avenue, SW
Washington, D.C. 20201
tel 202-401-7736
fax 202-690-5432

fax transmittal

to: Jennifer Klein

fax #: 456-3878

from:

date:

re:

pages: , including this cover sheet

NOTES:

SCHEDULED MEETING WITH THE ASSISTANT SECRETARY FOR HEALTH

THIS FORM SHOULD ACCOMPANY ALL MATERIALS PREPARED FOR MEETINGS/BRIEFINGS WITH THE ASH.

1. NAME OF PERSON(S) OR ORGANIZATION THAT REQUESTED MEETING	Follow up meeting to FDA briefing by Office of Health Care Reform
2. PURPOSE OF MEETING	Discuss strategy of FDA issues related to Health Care Reform
3. TIME, LOCATION AND DURATION OF MEETING	Tuesday, April 5 at 11:00 a.m. Room 716-G. Approximately one hour.
4. FULL LIST OF PARTICIPANTS (PLEASE INCLUDE TITLES AND AFFILIATION)	1. Ann Witt- Advisor to Commissioner, FDA 2. Others to be determined on Monday. 3. 4. 5. 6.
5. WHAT IS EXPECTED OF DR. LEE?	To provide guidance on strategy for FDA issues.
6. CONTACT PERSON	Susanne Stoiber

April 1, 1994

Note to Dr. Lee

The attached memorandum from Ann Witt and FDA summarizes the issues that we discussed today at our agency consultation with FDA. Three of these should be considered before the Congressional mark-up begins since we may wish to develop language to clarify or correct parts of the bill that FDA has identified as potentially troublesome. The three issues that I propose to cover on Tuesday are:

- Off-label use of drugs
- Investigational treatments
- Comparative effectiveness

Susanne

Susanne Stoiber

April 1, 1994

MEMORANDUM TO SUSANNE STOIBER

From: Ann Witt

Subject: Health Care Reform Issues that Affect FDA

As you requested at this morning's meeting, FDA has identified a list of the major issues under the Health Security Act and other health care reform proposals that concern FDA's operations and mission. The list of issues follows, with explanations, where appropriate.

1. Drug Benefit Provisions (National Benefit and Medicare Benefit).

a. Reliance on compendia for reimbursement of off-label uses of drugs

- Many off-label uses are listed in the compendia without adequate assessment of their safety and effectiveness and without directions for appropriate use. Reimbursement based on listing in the compendia will <u>reduce</u> manufacturers' incentives to adequately study and obtain FDA approval of these uses. It may also encourage manufacturers to study and obtain FDA approval only of very limited indications, then seek to have the more important indications listed in the compendia. Both outcomes would diminish the supply of reliable information on appropriate drug use.

  To ensure that important off-label uses are adequately studied in an environment of universal coverage, FDA should be given express authority to require manufacturers to study widespread or medically important off-label uses. (See attached 10/11/93 memo from FDA to Dr. Lee.)

b. Investigational Treatments

- <u>"Approved Research Trials."</u> FDA is required to approve most clinical trials of drugs, biologics, and medical devices (including those conducted by other federal agencies). However, the definition of an "approved research trial" to which reimbursement is tied includes trials "approved" by a number of entities other than FDA.

If FDA approval of trials of drugs, biologics and devices is not required for reimbursement, reimbursement could be provided for care associated with research that is conducted unlawfully. Bill language should be clarified to require that FDA-regulated research be approved by FDA.

- "Treatment IND's". The HSA does not, but should, require reimbursement for drugs covered by "Treatment IND's." These are investigational drugs, not-yet-approved, that FDA has determined should be made available to patients because they:
  - Are for a serious or life-threatening disease,
  - There is no satisfactory alternative treatment available, and
  - The available evidence supports their effectiveness.

  FDA's decision to grant a Treatment IND for a drug is, in effect, a determination that the drug is medically necessary and appropriate for a certain patient population.

2. Comparative Effectiveness/Cost Effectiveness Provisions

Several of the health care reform bills and, to a lesser extent, the HSA, provide various federal agencies and boards with authority to conduct and evaluate research on the comparative effectiveness and cost-effectiveness of FDA-regulated products and to disseminate the results of this research.

FDA regulates comparative effectiveness and cost-effectiveness claims made by drug and device manufacturers, and has long-standing expertise in evaluating effectiveness studies. In addition, through its approval process, FDA has unique access to information on the effectiveness of drugs, biologics, and medical devices. However, none of the agencies, boards and councils that would have authority over research and evaluation of comparative and cost effectiveness data include FDA.

For example:

- The HSA establishes the National Quality Management Council, whose functions include development of measures for evaluating the outcomes of health care services and procedures, setting research priorities, and collecting and disseminating information on

ineffective treatments. This Council would be made up of experts from AHCPR, NIH, HCFA, but not FDA.

- "Cost-effectiveness" is a criterion, under the HSA, both for assessing the reasonableness of launch prices of breakthrough drugs and for requiring advance approval under Medicare.

- The Cooper bill establishes a new agency within HHS ("Agency for Clinical Evaluations"), whose functions would include conducting effectiveness trials, assuring evaluating of existing and new treatments, and setting research priorities for evaluations of medical treatments. This agency would include portions of many HHS agencies, but not FDA.

The activities of these agencies, boards, and councils would directly affect, and, in some cases, conflict with, FDA's regulatory responsibilities over drugs, biologics, and devices.

In addition, it is critical that health care purchasers and providers obtain valid, reliable information on comparative and cost effectiveness. Some of the kinds of research proposed in the bills to are likely to produce unreliable data. FDA's expertise in assessing the reliability of data on effectiveness would be valuable in whatever efforts are undertaken to assess comparative and cost effectiveness of competing treatments, including identification of appropriate areas where additional comparative research could yield substantial savings.

3. Products Liability

Several health care reform proposals include provisions that would insulate FDA-approved drugs and devices from products liability. FDA has long opposed such provisions, because the FDA review process does not take into account many of the considerations that form the basis of products liability cases. In addition, products liability provides an important check on promotional abuses by drug and device manufacturers. Given FDA's limited resources to police promotional activities, it is essential to maintain other disincentives for overpromoting drugs and devices.

4. Pharmacy provisions

FDA is responsible for enforcing the Prescription Drug Marketing Act, which imposes restrictions on the distribution and sale of drugs by pharmacists. Some of the provisions of PDMA may be in conflict with the HSA.

5. Drug Utilization (Section 2002(d)(6))

The HSA requires the Secretary to assure appropriate prescribing and dispensing practices by establishing a program to, among other things, identify "potential adverse reactions" and "appropriate use of generics." This program may overlap or conflict with FDA programs, already in place, that carry out substantially similar activities.

6. Health Care Fraud Enforcement Authority (Sections 5401-3)

The HSA creates a health care fraud control program to be carried out by the Inspector General. Violations of the Federal Food, Drug, and Cosmetic Act are defined in section 5402(d)(5) as "health care offenses," enforceable by the IG. This will significantly expand the IG's enforcement authority and create conflicts with FDA's own criminal enforcement program. In addition, section 5402(a)(1) establishes a fund made up of criminal fines from health care offenses, the proceeds of which go to the IG. Fines obtained by FDA for violations of the F,D&C Act may have to be placed in this fund, but would probably not be available for use by FDA.

Please feel free to call me at 443-2561 if you have questions about any of these issues.

Ann Witt

cc: Mary Pendergast
Diane Thompson

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date October 11, 1993

From Deputy Commissioner for Operations/FDA

Subject Coverage of Prescription Drugs under Health Care Reform Package

To Assistant Secretary for Health

The Food and Drug Administration has serious concerns about the criteria for coverage of prescription drugs in the Health Care Reform package. Under the terms of the Health Security Plan, prescription drugs are covered (1) for their FDA-approved indications and (2) for any other indications mentioned in one of three listed compendia or in any other compendium identified by the Secretary. FDA is aware that HCFA uses this formula for reimbursement for oncology drugs and recognizes that reliance on the compendia to ensure broad, consistent reimbursement may be appropriate in the unique context of treatment for cancer or other serious and life-threatening diseases. FDA believes, however, that reliance on the prescription drug compendia as a surrogate for FDA approval for all drugs will undermine manufacturers' incentives to conduct adequate studies of new indications and will diminish the availability of full and accurate information about drugs' risks and benefits.

In passing the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act, Congress determined that the American public needed protection from unsafe, ineffective and inadequately studied drugs being promoted by drug companies. To achieve this goal, Congress required manufacturers to provide substantial evidence, including adequate and well-controlled studies, that a drug or biological product was safe and effective for its labeled indications before the product could be marketed and promoted for those indications.

FDA is deeply concerned that if the Health Security Plan gives mention of an indication in a compendium recognition equal to an FDA approval decision, the objectives of the drug approval process will be compromised. Unlike FDA approval decisions, indications in compendia are not included on the basis of scientific determinations that the drugs are safe and effective for those uses; indications may be mentioned in a compendium solely on the basis of the anecdotal experience of individual physicians.

Historically, manufacturers may have failed to submit supplemental applications for new uses because of concerns about a lengthy review period for such applications. Because user fees will permit increased reviewer resources that can be allocated to cover supplemental applications for new indications, FDA will be

able to review these applications promptly. If, however, the compendia are officially recognized as alternatives to FDA approval for purposes of reimbursement, it is likely that drug companies will shift their focus from obtaining FDA approval for new indications to getting unapproved indications mentioned in the compendia. The value of obtaining FDA approval, and thus the number of adequately studied indications, will diminish.

FDA has always recognized that physicians may, in the best interests of their patients, appropriately prescribe approved drugs for unapproved indications, based upon valid information available to them. FDA would therefore support some reimbursement mechanism for unapproved indications. Whatever mechanism is adopted, however, must maintain incentives for manufacturers to study and add new uses to drug labels. Without these incentives, full and accurate information about the safety and effectiveness of new indications will not become available, to the detriment of health care decisionmaking.

FDA would support the following reimbursement scheme for unapproved uses:

> Coverage of unapproved uses of approved drugs, biological products and insulin would be permitted for medically accepted indications unless the Secretary had determined that the use was not medically appropriate because of unacceptable risk, evidence of ineffectiveness or availability of less expensive alternatives that have been shown to be effective. For serious or life threatening illnesses the National Health Board, in consultation with the FDA, could require coverage of specific types of unapproved uses. The Secretary would review the nature and extent of unapproved uses and could require the submission of studies and supplemental applications for unapproved uses that were widespread or medically important.

Jane E. Henney, M.D.

cc: Cliff Gaus
Bill Corr

MEMORANDUM

DATE: October 17, 1993

TO: Chris Jennings

FROM: Clif Gaus

SUBJECT: **CHANGE IN OUTPATIENT PRESCRIPTION DRUG BENEFIT**

Attached is a copy of the new language for coverage of drugs and biologicals in the National Benefit Package.

STATEMENT OF NEW POLICY:

- All uses (approved and unapproved) of drugs, biologicals, and insulin are covered, however plans are allowed to establish formularies.
- The National Health Board may intervene to require plans to cover certain unapproved uses for specified serious or life threatening illnesses.
- The Secretary may recommend to the National Health Board that certain unapproved uses should not be covered by plans.

IMPLICATIONS OF NEW POLICY

- Broad coverage of unapproved (off label) uses

  This new permissive language makes a strong statement to clarify coverage for unapproved uses of FDA approved drugs and biologicals.

- Clarification of FDA authority needed

  Amendments to sections 505 (drugs) and 506 (insulin) of the Federal Food, Drug and Cosmetic Act and section 351 (biological products) of the Public Health Service Act are necessary, as part of the health reform bill, to clarify the Secretary's authority to survey the nature and extent of unapproved uses and to require the submission of studies and/or supplemental applications for unapproved uses that raise public health concern because they are medically important, or are widespread and raise significant questions of safety and effectiveness.

Under a federally mandated health care system that authorizes coverage for all uses of approved drugs it is important to preserve incentives for drug manufacturers to adequately study the safety and effectiveness of unapproved uses which are widespread or for which there is preliminary evidence of ineffectiveness or lack of safety.

Clarification of existing FDA authority would permit the Secretary to fully implement existing regulations and avoid the likelihood of protracted litigation if the agency were to act solely on existing regulation.

- Requires change in Medicare benefits (including OBRA 93 and new benefit)

The Medicare outpatient drug benefit included in the plan specifies unapproved (off label) use differently and is based on the OBRA 1993 language. Off label (unapproved) use is determined by the:

Compendia: one or more citations in 3 compendia or other authoritative compendia identified by the Secretary -- *UNLESS the Secretary has determined that the use is not medically appropriate* or the use is identified as not indicated in one or more compendia; OR

Peer reviewed literature: where the carrier determines, based upon *guidance from the Secretary* to carriers for determining accepted uses of drugs, that the use is medically accepted based on supportive clinical evidence in peer reviewed literature appearing in publications *identified by the Secretary*.

This language also provides the Secretary with authority to intervene to restrict off label use but does not require amendments to the FDCA.

Outpatient prescription drugs and biologicals:

- Covers all drugs, biological products, and insulin approved by the Food and Drug Administration (FDA) for any use.

- For certain serious or life threatening illnesses, the National Health Board, in consultation with the Secretary, may require coverage of specific types of unapproved uses.

Limitation:

- The National Health Board, in consultation with the Secretary, may determine that an unapproved use of an approved drug is not medically necessary or appropriate because of unacceptable risk or evidence of non-effectiveness.

- Must be prescribed for use in an outpatient setting.

- No frequency or quantity limitations other than reasonable rules for amount to be dispensed and number of refills. Health plans are permitted to establish formularies, drug utilization review, generic substitution, and mail order programs.

Question: The Health Security Act proposes to cover FDA approved drugs for their approved indications and in certain instances, their off-label indications. Yet plans will be able to use formularies. Will patients have access to drugs even if these are not on the formulary and very expensive?

Answer:

- Yes, patients will have access to the drugs they need. The Health Security Act provides coverage for medically necessary or appropriate items and services, including drugs. To assure access to the comprehensive benefit package, the National Health Board is charged with establishing regulations to ensure uniformity of application of this benefit package across plans.

- Decisions of medical necessity or appropriateness are best left up to a health care provider and a patient and the Act does not want to infringe on the practice of medicine.

- Plans may establish formularies, and other methods to manage their benefits, but plans are certified by the States based on their ability to deliver the items and services in the comprehensive benefit package in their designated service area.

- Currently, when a patient needs a drug that is not on a plan formulary, the patient is left to argue with the plan with often little recourse. The Act establishes numerous consumer protection provisions that allow for appeals of plan decisions, at the plan, alliance, and state levels.

- Each certified health plan must establish an appeals process with the second review using an external provider. Each regional and corporate alliance is also required to establish both expedited and standard appeal review procedures as well as an office of the ombudsman. Each State is also required to establish a claims review office for appeals originating from both regional and corporate alliances. At any time, an individual may avail of standard judicial appeals processes.

- However, in situations where a drug is the only appropriate treatment for a condition, such as Saradaze for Gaucher's disease, then the plan would have to provide coverage for that drug as it is medically necessary.

In addition, plans offer expanded access under certain conditions:

- The Act allows only limited cost containment strategies to the fee for service plan. The only cost containment options are: utilization review, prior approval, and restricting services and providers based on poor quality.

- The lower cost sharing plan has the point of service option where for an additional premium, and additional cost sharing at the time of service, and individual in a low er cost sharing plan could go out of plan for items and services in the benefit package.

SPECIAL

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503

March 4, 1994

LEGISLATIVE REFERRAL MEMORANDUM

LRM #I-2170

TO: Legislative Liaison Officer -

COMMERCE - Michael A. Levitt - (202)482-3151 - 324
JUSTICE - Sheila F. Anthony - (202)514-2141 - 217
LABOR - Robert A. Shapiro - (202)219-0201 - 330
TREASURY - Richard S. Carro - (202)622-1146 - 228

FROM: JANET R. FORSGREN (for) Janet R. Forsgren
Assistant Director for Legislative Reference

OMB CONTACT: Robert PELLICCI (395-4871)
Secretary's line (for simple responses): 395-7362

SUBJECT: HHS Qs and As RE: HR 3600, Health Security Act

DEADLINE: NOON March 7, 1994

COMMENTS: Reps. Waxman and Greenwood Q&As. The appropriate pages from the hearing transcript are attached so that you can see the comments that are being clarified in the Q&As.

OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President, in accordance with OMB Circular A-19.

Please advise us if this item will affect direct spending or receipts for purposes of the the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

CC:
Nancy-Ann Min
Gene Sperling (Paul Jamieson)
Ira Magaziner
Jennifer Klein
Bob Boorstin
Jason Solomon
Meeghan Prunty
Chris Jennings
Jack Low
Steve Richetti
Melanne Verveer
Barry Clendenin
Len Nichols
Linda Blumberg
Bill Dorotinsky
Shannah Koss
Janet Forsgren

LRM #I-2170

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is **simple** (e.g., concur/no comment) we prefer that you respond by **faxing** us this response sheet. If the response is **simple** and you prefer to call, please **call the branch-wide line** shown below (NOT the analyst's line) to leave a message with a secretary.

You may **also respond** by (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); (2) sending us a memo or letter; or (3) if you are an OASIS user in the Executive Office of the President, sending an E-mail message. Please **include** the LRM number shown above, and the **subject** shown below.

TO: Robert PELLICCI
Office of Management and Budget
Fax Number: (202) 395-6148
Analyst/Attorney's Direct Number: (202) 395-4871
Branch-Wide Line (to reach secretary): (202) 395-7362

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

SUBJECT: HHS Qs and As RE: HR 3600, Health Security Act

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No objection

_____ No comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

companies to get one drug as opposed to another?

Dr. SMITS. Right. A formulary sometimes arbitrarily excludes drugs when there are three or four that are similar and of equal quality, and I think the feeling was that that has a different implication nationally than it does for an individual plan.

Mr. WAXMAN. Under the President's bill the drug companies will pay the Federal Government a 17 percent rebate on the cost of prescription drugs. It's my understanding that this rebate applies when an elderly person pays the full price for a drug because he or she has not reached the $250 deductible. Can you tell us why the rebate goes back to the government rather than to the consumer in the form of a price reduction?

Dr. SMITS. There are a variety of other price control provisions which would ensure that the ~~prescribing~~ pharmacist does charge the individual a reasonable price. That has to do with incentives to use generics where generics can be substituted, with limits on what the pharmacist charges, an acquisition price plus a prescribing fee, and with the requirement that the pharmacist must accept assignment. So there are price controls in there. It gets too complicated to try to give the rebate back in each prescription.

Mr. WAXMAN. Dr. Lee, there seems to be considerable

D-R-A-F-T
3-3-94

The Honorable Henry A. Waxman
Chairman
Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Than you for the opportunity to clarify remarks I made at the Subcommittee's February 8 hearing on prescription drugs.

Following the recent Robert Novak column ("Health Care Hawks," Washington Post, February 24), I would like to clarify my use of the term "price control" in remarks I made at the hearing. You had asked why the rebate called for in the President's plan goes to the Federal government instead of the consumer in the form of a price reduction (see page 41 ff. of the transcript). I replied that there are "price controls" in addition to the rebate to ensure that pharmacists charge individuals a reasonable price. By this I meant that the Health Security Act proposes other means to contain costs for consumers, including the use of lower cost generic drugs, when appropriate, and the requirement that pharmacists accept assignment and charge no more than Medicare will pay. Perhaps I should have more accurately used the term "cost containment provision" rather than "price control."

Ultimately, rebates provided to the Federal government should contain the overall cost of the Medicare prescription drug benefit, which will be passed on to beneficiaries in the form of lower prescription drug premiums. Also, beneficiaries would benefit from lower retail drug prices since the rebate provisions encourage manufacturers to maintain price increases at or below inflation.

Let me also refer you to my response later in the hearing to a question from Mr. Brown regarding Medicare price controls for prescription drugs (see page 80 ff. of the transcript). Here, I clearly point out that the President's plan does not contain price controls but instead includes a variety of approaches to control drug prices under Medicare.

I regret that my responses at the hearing have been mischaracterized to reflect something other than the Medicare prescription drug benefit proposed in the Health Security Act. I would be pleased to discuss this with you further if you so desire.

Sincerely,

Helen L. Smits, M.D.

If we did indeed have these breakthrough drugs developed, one would assume that there would be significant savings either in reduced hospitalization or reduced needs for other services. As we have seen, for example, when we developed penicillin, patients did not have to be hospitalized. They were cured in very short order from many conditions.

Mr. GREENWOOD. I have used my time. The concern is that the savings would not likely be seen in the same year in which the premium cap applies.

Dr. LEE. We can give you a more detailed response, if you wish, for the record on this issue. It is a complicated question. I would be glad to sort of personally develop a response and provide that to you for the record, if that is okay.

Mr. GREENWOOD. I would appreciate that very much.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Mr. Pamon.

Mr. PAXON. Thank you, Mr. Chairman.

I'm going to go back, if I could, for just a moment. I just want to make a point and then go on to some questions.

Mr. McMillan followed a line of questioning regarding exclusion under Medicare. I just want to reiterate a concern that we have, and I hope you can help us with this during your testimony today and in the future.

Response to Mr. Croonwood:

(Page 72: "The concern is that the savings [from use of breakthrough drugs over alternative treatments] would not likely be seen in the same year in which the premium cap applies.)

Breakthrough drugs can offer many benefits to a quality and cost-conscious health care system. The patient's overall health status and often lifespan can be improved, bringing benefits that extend beyond the monetary calculations. Yet normally there are also savings in health care expenditures stemming from use of the drug. These savings include both short- and long-term savings.

The case of ulcer treatment is probably an excellent example of how short- and long-term savings typically interact with one another.

Until the 1970s, serious stomach ulcers often required surgery that now costs $25,000 or more. Introduction of H2-blocker drugs in the 1980s allowed for effective nonsurgical treatment with drugs now costing under $1,000 per year. Recently, further research has pointed out the potential to replace this long-term symptomatic treatment with short-term drug therapy that actually destroys the bacterium that contributes to ulcer development. An NIH consensus conference in February endorsed a short-term antibiotic regimen costing under $100.

This means that what was once a $25,000 surgery with long-term follow-up costs could soon become a $100 course of treatment with less need for costly physician follow-up. This is a clear example of new drug therapies leading to lower medical costs in both the short- and long-run. Most breakthrough treatments seem to follow this pattern, reducing both short- and long-term costs.

In some cases, of course, the equation is not so simple. Short-term costs may actually go up if the drug is more expensive than the less effective therapies it replaces. These short-term costs are typically, but not always, overtaken by long-term savings as better patient outcomes materialize. The so-called "clot-busting" drugs such as TPA for use after heart attacks appear to fall into this category, according to recent clinical trials.

In other cases, short-term costs can drop while long-term health costs increase. This could occur if the drug provides significantly longer lives, which means medical care for a longer period than patients formerly enjoyed. Experimental gene therapies for severe immune disorders may begin to fall into this category, as patients begin living years longer than under current therapies and accordingly incur health care costs for more years than is currently possible.

The interaction of short- and long-term costs is further complicated by the fact that while costs are typically viewed in terms of health care costs, the benefits extend far beyond the health insurance system. For this reason, most evaluations of a new therapy do not stop with mere cost comparisons alone but look at indicators such as cost-efficacy, cost-effectiveness, and quality of life as well.

Because most new drugs appear to offer short-term savings over existing therapeutic alternatives, it seems unlikely that including outpatient prescription drug benefits with a standard benefits package will impose excessive short-term costs to the health care system. Yet in any case, the increase in health status that effective drug therapies can represent makes it imperative that cost-effective pharmaceutical treatments be included under health care reform.

PHARMACEUTICAL COVERAGE UNDER THE HEALTH SECURITY ACT

PRESCRIPTION DRUG COVERAGE:

THE PROBLEM

CURRENT PROBLEMS IN PRESCRIPTION DRUG COVERAGE

Despite the medical importance and general cost-effectiveness of outpatient prescription drugs, many Americans have no outpatient prescription drug coverage.

- Over 1/4 of all Americans have no coverage for outpatient prescription drugs, including about one-half of elderly Americans.

- Over 55% of outpatient Rx drug costs are paid out-of-pocket by patients -- over 64% for those 65 and older.

Spending on outpatient Rx drugs is growing far faster than the overall economy.

- Outpatient Rx drug spending rose 172% from 1981-91, compared to a 87% rise in Gross Domestic Product. This includes changes in prices, utilization, population, and technological complexity. In recent years, price increases have moderated, due in large part to a rise in managed care activity. Yet for the retail pharmacy market, price increases are still above the general rate of inflation.

New drug therapies are often beyond the financial reach of the patients who need them:

- When important breakthrough drugs reach the market, there is often no therapeutically equivalent drug product available. For many of these products, the cost has been high. For managed care providers, this often means less potential to negotiate favorable pricing for these products.

SPECIAL PROBLEMS FACING THE MEDICARE POPULATION

- Medicare beneficiaries utilize pharmaceuticals at a higher rate than the rest of the population and therefore face greater out-of-pocket financial burdens. Medicare currently does not cover outpatient drugs.

- Prescription drugs accounted for the largest out-of-pocket health care cost for three out of four beneficiaries.

- Only 54 percent of Medicare beneficiaries have some type of prescription drug coverage. The four sources of drug coverage include --

  Retiree health plans. About 30 percent of Medicare beneficiaries have drug coverage through retiree health plans. However, current retirees could lose their coverage if their former employer decides that it is too expensive to cover their pharmaceuticals. And according to employee benefits experts, fewer and fewer firms are expected to offer future retirees health and drug coverage.

  Medigap policies. About 5 percent of Medicare beneficiaries have drug coverage through individual Medigap policies. About 5 percent of Medicare beneficiaries have drug coverage through both retiree health plans and individual Medigap plans.

  Medicaid. About 12 percent of Medicare beneficiaries have drug coverage through the Medicaid program.

  State pharmaceutical assistance programs. About 2 percent of Medicare beneficiaries have drug coverage through other sources such as state pharmaceutical assistance programs.

The Health Security Act Solves Problems in Prescription Drug Coverage

Outpatient Drug Coverage under The Health Security Act

Health Care Reform promotes the availability and affordability of outpatient Rx drugs.

- **For patients . . .**
  outpatient prescription drug coverage will be provided for all Americans, including Medicare beneficiaries.

- **For manufacturers . . .**
  universal coverage will result in higher sales volume and a larger marketplace for financing research into new products. Enhanced NIH funding means more potential for basic research breakthroughs that can lead to new drugs.

- **For pharmacists . . .**
  the Medicare program will mandate more consistent volume discounts so that community pharmacies can compete on equal footing with other purchasers. Sales volume will also increase, and professional services such as patient counseling will be required as part of Medicare reimbursement.

- **For controlling costs . . .**
  a variety of market incentives will apply in both the comprehensive benefit package and in Medicare, keeping costs affordable while avoiding any need for the government to fix prices.

For Patients . . .
Universal, Affordable Drug Coverage

For consumers of prescription drugs, the Health Security Act means:

- Coverage for all Medicare beneficiaries. Of the 36 million Medicare beneficiaries, only about half of those 65 and over currently have outpatient Rx drug coverage, typically through retiree health plans or individually purchased Medigap policies.

- Coverage for 39 million uninsured. Those without any health care insurance will now receive a benefit package that includes outpatient prescription drugs.

- Coverage for over 70 million without outpatient Rx drug coverage. Currently, over 55% of all outpatient Rx drug costs are paid out-of-pocket.

- Continued coverage for all currently eligible for Medicaid. Low income populations will be integrated into alliance health plans, receiving comprehensive coverage identical to all other enrollees.

- Coverage for off-label uses of approved Rx drugs, when supported by peer-reviewed literature or major drug compendia.

- Plans may offer other optional coverage for unapproved, experimental drugs.

- Out-of-pocket costs will be kept reasonable
  - -- Under alliance health plans, a $1,500 limit on all out-of-pocket health costs, with patients paying either $5.00 per prescription under lower cost-sharing plans or 20% coinsurance after a $250 deductible for higher cost-sharing.

  - -- Under Medicare, a $1,000 out-of-pocket limit on drug costs, with patients paying 20% coinsurance after a $250 deductible.

For Drug Manufacturers . . .
Sales Will Increase and
Market Forces Will Determine Prices

Drug manufacturers will see larger, open markets and more research opportunities:

- Sales volume will increase due to the expanded population with Rx drug coverage. For Medicare beneficiaries alone, sales will increase by $7.1 billion annually by 2000, or about $5.7 billion after accounting for rebates. Data are currently unavailable to determine the exact increase in revenues due to prescription drug coverage for the under-65 population. However, given the increase in sales due to Medicare coverage, we know that providing coverage to the entire under-65 population will lead to significant revenue increases, as well.

- Pricing decisions will be left to each manufacturer, relying principally on negotiations between buyer and seller and other market forces.

- Medicare reimbursement will be based on market prices and not federal price controls, with rebates to HCFA based upon the discounts currently offered to institutional providers. Prices on certain new drugs may be subject to the review of an advisory council reporting to the HHS Secretary, with an opportunity to negotiate special rebates under Medicare if needed.

- State alliances and individual health plans will have flexibility in delivery of the items and services in the comprehensive benefits package, and will be free to develop innovative strategies for controlling expenditures, without endangering access to important therapies.

- The comprehensive benefits package will include off-label uses of approved drugs when the use appears in peer-reviewed literature designated by the Secretary or in major drug compendia.

- Increases in funding for NIH and other research under health care reform will create more potential for basic research breakthroughs that lead to new drugs.

For Pharmacists . . .
Fairer Wholesale Pricing and a Larger Customer Base

For pharmacists, reform means universal coverage and fair access to volume pricing:

- Universal coverage for outpatient prescription drugs will expand the demand for drug products and pharmacy services. The expanded Medicare benefit alone will mean over $3 billion annually in added sales by the year 2000.

- As a condition of participation in Medicare, manufacturers would have to offer the comparable discounts to all purchasers -- including retail pharmacists -- on equal terms and conditions. These discounts must be directly proportional to the impact of the purchasers terms (i.e., single site delivery, volume purchases, use of formularies) on the manufacturers' costs.

- Patient counseling and other pharmacy services will be included under Medicare dispensing fees, recognizing the health benefits of these services.

- The dispensing pharmacist will continue to play an important role in patient counseling and in encouraging cost-effective generic products.

Affordable Benefits . . .
Without Government Price Controls

Market forces are the key mechanism for innovations that keep prices under control:

- Under the comprehensive benefit package, plans will be able to utilize proven means of keeping pharmaceuticals affordable. These might include generic substitution, formulary use, bulk purchasing arrangements, or preferred provider plans.

- Under Medicare, HCFA reimbursement to pharmacists will be based on actual prices in the marketplace, while a fixed rebate from manufacturers to HCFA will equal the discounts already widely available to institutional providers. The rebate formula will also protect against drug costs rising faster than inflation.

- No government mechanisms will affect the price of most drugs. For certain breakthrough products without therapeutic alternative (and therefore no market competition), an Advisory Council on Breakthrough Drugs (that includes private-sector experts) will advise the Secretary of HHS if it finds the market price unreasonably high. Factors considered will include:

  --- prices of other drugs in the same therapeutic class
  --- cost information supplied by the manufacturer
  --- prices of the drug in other industrial countries
  --- projected prescription volume, research costs, etc.
  --- cost-effectiveness relative to alternative treatments
  --- improvements in quality of life offered by the product

- Because the findings of the Advisory Council on Breakthrough Drugs will be available to the public, managed care providers will be better informed about the usefulness of these breakthrough drugs and will be able to use the information to negotiate with drug companies for more favorable pricing.

- For new drugs priced at levels proven unreasonable, the Secretary of HHS can negotiate rebates for the Medicare program. If a negotiated Medicare rebate cannot be set, the Secretary may take action ranging from prior approval restrictions for the Medicare program to prohibiting Medicare reimbursement for the particular drug.

OUTPATIENT DRUG COVERAGE IN THE HEALTH SECURITY ACT:

I. Description of the Comprehensive Benefit Package

DRUG COVERAGE UNDER THE COMPREHENSIVE BENEFIT PACKAGE

o **universal, comprehensive coverage.**

-- The Health Security Act covers all prescription products for all FDA-approved uses, as well as insulin and blood clotting factors.

-- It also covers off-label uses of FDA-approved products, when supported by leading compendia or peer-reviewed medical literature designated by the Secretary of HHS. Plans have the option to offer additional drug benefits, such as coverage for unapproved, experimental drugs.

o **flexibility in delivery.**

-- State alliances and individual health plans will have flexibility in delivery of the items and services in the comprehensive benefits package, and will be free to develop innovative strategies for controlling expenditures, without endangering access to important therapies. Strategies might include generic substitution, formulary use, bulk purchasing arrangements, or preferred provider plans.

-- Innovations in delivery will not interfere with a patient's access to medically necessary products.

o **affordability for patients.**

-- Out-of-pocket patient costs will be limited to $1,500 per individual ($3,000 family) for all covered benefits including drugs.

-- For lower cost-sharing plans, each outpatient prescription will cost $5.00. Higher cost-sharing plans will include 20% coinsurance with a $250 deductible.

-- For low-income families receiving AFDC or SSI, copayments are reduced by 80%, from $5 to $1 per prescription. For low-income families (less than 150% of poverty) in areas where there are no lower cost-sharing plans available, additional subsidies are available to bring cost sharing down to the levels of the lower cost sharing plan.

-- Data from the Advisory Council on Breakthrough Drugs will assist managed care organizations in negotiating for favorable pricing.

OUTPATIENT DRUG COVERAGE IN THE HEALTH SECURITY ACT:

II. Description of the Medicare Benefits

OUTPATIENT DRUG COVERAGE UNDER MEDICARE

ENROLLMENT

- Estimates assume a January 1, 1996 effective date.

- Any beneficiary enrolled in Part B will automatically be covered under the new prescription drug benefit on that date.

COST SHARING

- The annual deductible is $250 in 1996. Once the deductible is met, beneficiaries pay 20 percent coinsurance. The annual out-of-pocket limit is $1,000 in 1996.

- Both the deductible and out-of-pocket cap are indexed to assure that the same percentage of beneficiaries receive benefits as with the initial $250 deductible and $1000 cap. About 58 percent of beneficiaries are expected to meet the deductible each year.

- Low-income beneficiaries receive the same financial assistance for out-of-pocket drug costs as other cost-sharing amounts.

COVERAGE

- The Medicare drug benefit covers all drugs, biological products and insulin approved by the Food and Drug Administration (FDA) for all labelled indications and certain off-label indications.

- Current coverage of home infusion drugs and parenteral and enteral nutrition would be subsumed under the new Medicare outpatient drug benefit. Similarly, current limited coverage of outpatient drugs under Medicare such as immunosuppressive drugs would be incorporated into the drug benefit.

- The Secretary has the discretion not to cover certain pharmaceutical products listed in Section 1927(d) of the Social Security Act. Examples include fertility drugs, medications used to treat anorexia and drugs used for cosmetic purposes. However, benzodiazepines and barbiturates would be covered under the Medicare drug benefit.

COST CONTAINMENT

- **Rebate Agreements.** As a condition of participation in Medicare, drug manufacturers would sign rebate agreements with the Secretary. Once a rebate agreement is signed, all the manufacturer's currently marketed drugs are covered. Rebates apply only to single source and innovator multiple source drugs (brand name drugs). Drugs used by beneficiaries in managed care plans and the working aged are not subject to rebates.

    - **Basic Rebate**. Manufacturers pay a basic rebate to Medicare for each drug based on the difference between the average manufacturer retail price (AMRP) and the weighted average manufacturer non-retail price (AMNRP) or 17 percent of the AMRP, whichever is greater. The Secretary has the authority to verify the AMRP and AMNRP reported by manufacturers. If manufacturer price increases exceed the rate of inflation, the rebate would include the increase above the rate of inflation.

    - **Negotiated Rebate for New Drugs**. In the case of new drugs that the Secretary determines are excessively or inappropriately priced, the Secretary has the authority to negotiate an alternative rebate with the manufacturer. Such a determination by the Secretary would be based on such factors as the prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer, prices of the drug in industrialized countries, and other relevant factors. If a manufacturer refuses to negotiate or the Secretary is unable to negotiate a rebate that the Secretary determines to be reasonable within six months, the Secretary may exclude the new drug from coverage under Medicare.

- **Generic Incentives**. The drug benefit encourages the use generic drugs. Unless a brand name drug is specifically requested by the physician, payment will be based on the cost of the generic substitute.

- **Prior Approval**. Finally, the prescription or dispensing of certain drugs may require prior approval from Medicare. Drugs subject to prior approval could also include drugs subject to inappropriate use or clinical misuse and new drugs for which the Secretary has not yet negotiated a rebate. In addition, the Secretary may require that physicians obtain prior approval before prescribing brand-name drugs if a generic substitute is available.

PHARMACY REIMBURSEMENT

- **Brand Name Drugs.** For brand name drugs, payment is the lower of actual charges, the 90th percentile of actual charges in a previous period, or the estimated acquisition cost (EAC) plus a dispensing fee.

- **Generic Drugs**. For generic drugs, payment is the lower of actual charges or the median of all generic EACs in the same therapeutic class times the number of units dispensed plus a dispensing fee.

- **Estimated Acquisition Cost**. The Secretary has broad discretion to determine the EAC. The EAC may equal a percentage of the published Average Wholesale Price (AWP) or the Secretary may determine the EAC by surveying pharmacies and wholesalers. However, the EAC cannot be established at greater than AWP minus 7 percent.

- **Dispensing Fee**. The dispensing fee is initially established at $5, annually indexed to the Consumer Price Index (CPI). All pharmacies that receive Medicare payment would be required to accept assignment on all prescriptions, answer beneficiaries' questions regarding medication usage, and submit drug claims on behalf of beneficiaries.

DRUG UTILIZATION REVIEW

- The drug benefit includes a program for Drug Utilization Review (DUR) to assure quality and contain costs. The program would include prospective and retrospective components.

  - **Prospective DUR**. Prospective DUR involves screening the incoming claim against previously paid prescriptions to determine whether any potential drug therapy problems exist before dispensing the medication. Prospective DUR will identify the following potential drug therapy problems --

    - **Drug-drug interactions** -- a prescribed drug will adversely interact with other drugs taken by the beneficiary;

    - **Therapeutic duplication** -- a drug duplicates the effect of drugs currently taken by the beneficiary.

    - **Early refills** -- a beneficiary returns to the pharmacist for a refill prescription before his current prescription is less than 75 percent depleted.

    In addition, prospective DUR systems may also alert the pharmacist or claims processors to potential fraud and abuse situations.

  - **Retrospective DUR**. Retrospective DUR is a screening process that will occur after the medication has been dispensed. Retrospective DUR attempts to identify patterns of inappropriate prescribing, medically unnecessary care, fraud and abuse.

- If it is determined that the medication prescribed or dispensed was inappropriate and there is no suspicion of fraud or abuse, some type of educational intervention directed at the physician or pharmacist may be initiated by Medicare. Interventions could include a letter or phone call to the physician or pharmacist.

CLAIMS PROCESSING

- Claims will be processed electronically by pharmacists at the point-of-sale. This electronic claims system will be used to determine eligibility, process and adjudicate claims, and provide information to the pharmacist about the patient's drug use under the Medicare drug program.

EQUAL ACCESS TO DISCOUNTS

- As a condition of participation in Medicare, manufacturers would have to offer the same discounts to all purchasers on equal terms and conditions.

- Manufacturers would not be permitted to offer discounts to purchasers based solely on their class of trade.

- The intent of this provision is NOT to require manufacturers to give all purchasers the same discounts regardless of the impact of the purchasing terms. Rather, the intent is to require manufacturers to offer the same discounts to those that purchase under the same terms (including single site delivery, volume purchases, use of formularies, and other terms that reduce manufacturers' costs).

IMPACT OF MEDICARE OUTPATIENT DRUG BENEFIT ON THE PHARMACEUTICAL INDUSTRY ($ billions)

Calendar Year	1996	1997	1998	1999	2000
TOTAL INCREASE IN DRUG SALES[1]	$7.7	$8.2	$8.8	$9.4	$10.1
To manufacturers of brand name drugs	4.1	4.3	4.6	4.9	5.3
To manufacturers of generic drugs[2]	1.3	1.4	1.5	1.6	1.8
To pharmacists	2.3	2.5	2.6	2.8	3.0
REBATE AMOUNTS					
Basic	2.5	2.7	3.0	3.2	3.4
CPI-Penalty	0	.2	.2	.2	.2
Total Medicare Rebates	2.5	2.9	3.1	3.4	3.7
Medicaid	(1.1)	(1.7)	(1.5)	(1.9)	(2.3)
NET REBATES	$1.4	$1.2	$1.7	$1.5	$1.4
NET IMPACT ON					
Manufacturers of brand name drugs	2.6	3.1	3.0	3.4	4.0
Manufacturers of generic drugs	1.3	1.4	1.5	1.6	1.8
Pharmacists	2.3	2.5	2.6	2.8	3.0
TOTAL	**$6.2**	**$7.0**	**$7.2**	**$7.8**	**$8.8**

NOTE: Totals may not add due to rounding.
SOURCE: Office of the Actuary, Health Care Financing Administration

---

[1] Assumes that approximately 70% of the increase in sales will go to the manufacturers of drugs and 30% will go to retail pharmacists, wholesalers and distributors.

[2] Assumes that generic substitution would continue at the same rate, 25%, under the proposed Medicare drug benefit as it does under the current Medicaid drug benefit.