TO: The Secretary
Through: DS ____
COS ____
ES ____

FROM: Richard J. Tarplin
Assistant Secretary for Legislation

SUBJECT: Meeting with Representative Tom Allen (D-ME) and Key Co-Sponsors of Prescription Drug Legislation - Thursday, July 29 at 8:45am in room HC-5 of the Capitol.

PARTICIPANTS

Congressional Participants

Representative Thomas Allen (bio attached)
Representative Neil Abercrombie (D-HI)
Representative Tammy Baldwin (D-WI)
Representative Shelley Berkley (D-NV)
Representative Marion Berry (D-AR)
Representative Sherrod Brown (D-OH)
Representative Lois Capps (D-CA)
Representative Elijah Cummings (D-MD)
Representative Rosa DeLauro (D-CT)
Representative Max Sandlin (D-TX)
Representative Ronnie Shows (D-MS)
Representative Pete Stark (D-CA)
Representative Karen Thurman (D-FL)
Representative Jim Turner (D-TX)
Representative Henry Waxman (D-CA)
Representative Bob Wise (D-WV)
Representative Lloyd Doggett(D-TX
Representative Gene Green (D-TX)
Representative Ruben Hinojosa (D-TX)
Representative Christopher John (D-LA)
Representative Patrick Kennedy (D-RI)
Representative John Lewis (D-GA)
Representative Frank Pallone (D-NJ)
Representative Earl Pomeroy (D-ND)
Representative Bernie Sanders (I-VT)
Representative Janice Schakowsky(D-IL)
Representative Debbie Stabenow (D-MI)
Representative Ted Strickland (D-OH)
Representative Jim Tierney (D-MA)
Representative Tom Udall (D-MD)
Representative Robert Weygand (D-RI)

HHS Officials

Rich Tarplin, Assistant Secretary for Legislation
Jane Horvath, Deputy Assistant Secretary for Legislation (Health Legislation)
Bob Guidos, Legislative Analyst

BACKGROUND

As a result of a phone call between you and Representative Thomas H. Allen (D-ME) regarding the prescription drug benefit within the Medicare plan and his " Prescription Drug Fairness for Seniors Act of 1999" legislation, a meeting is now scheduled with him and 15 to 20 key co-sponsors of the bill. As you already know, Rep. Allen's bill would provide price reductions on prescription drugs for medicare beneficiaries.

ISSUES OF CONCERN

H.R. 664, the "Prescription Drug Fairness for Seniors Act of 1999" was introduced by Representative Allen on February 10, 1999. The bill currently has 119 cosponsors, mostly Democrats. The legislation provides for substantial reductions in the price of prescription drugs for Medicare beneficiaries and would offer Federal Supply Schedule prices to pharmacies for drugs provided to seniors. Representative Allen states that his bill "....does not impose price controls; it ends price discrimination. Companies set their best price at whatever level the market will bear."

Representative Allen's bill and the President's Medicare Plan share similar goals in that both seek to reduce prescription drug prices for Medicare beneficiaries by allowing beneficiaries to purchase discounted prescription drugs.

The difference between the two policies is that in H.R. 664, price reduction is not achieved through a government benefit. The bill does not include any federal contributions toward the price of the drug, whereas under the President's Medicare Plan, the government will pay for half of the beneficiary's drug cost from the first prescription filled each year up to the $5,000 in spending ($2,500 in Medicare payments) when fully phased in by 2008.

The President's plan also seeks to offer beneficiaries a discount similar to plans offered by many employer sponsored plans (estimated to be, on average, 10-15 percent) for each prescription purchased, whereas H.R. 664 bases it's discount on the prices available to other federally funded health care programs (Medicaid, IHS, VA, PHS) or upon the manufacturers's best price for the drug.

Representative Allen, in a June 23rd article in The Hill, stated that "Ultimately, we must expand Medicare to cover prescription drugs." He sees H.R. 664 as an important, intermediate step toward that goal. Representative Allen may see his bill as a stronger vehicle to make prescription drugs affordable for Medicare beneficiaries now that CBO estimates that the benefit would cost $50 billion more over 10 years than the HCFA Actuary predicts.

SUGGESTED TALKING POINTS

H.R. 664 and the President's plan are moving in the same -- and the right -- direction. Both are trying to provide beneficiaries with the products that will make them healthy.

1. Seniors have been unfairly treated-- they pay almost twice as much as other, more highly favored, drug customers.

2. from the beginning to the end
Reducing prescription drug prices for Medicare beneficiaries by enabling them to buy discounted drugs while using their clout as a large block of customers makes perfect sense. Seniors will be well-served by this fair approach.

3. The President believes, however, that we must go farther. That is why he has offered a Medicare prescription drug benefit that goes beyond what was contemplated in H.R. 664 to help seniors to pay for needed drugs.

4. The President's plan accomplishes this by establishing a new voluntary Medicare "Part D" prescription drug benefit that is affordable and available to all beneficiaries. The historic outpatient prescription drug benefit would:

   - Have no deductible and pay for half of the beneficiary's drug costs from the first prescription filled each year up to $5,000 in spending ($2,500 in Medicare payments) when fully phased-in by 2008.

   - Ensure beneficiaries a discount similar to that offered by many employer sponsored plans (estimated to be, on average, over 10 percent) for each prescription purchased – even after the $5,000 limit is reached. from 1st prescription to last

   - Cost about $24 per month beginning in 2002 (when the benefit starts at a $2,000 cap) and $44 per month when fully phased-in by 2008. (This is one-half to one-third of the typical cost of private Medigap premiums.)

   - Ensure that beneficiaries with incomes below 135 percent of poverty ($11,000/$17,000 single/couples) would not pay premiums or cost sharing. Those with incomes between 135 and 150 percent of poverty would receive premium

First, like your bill, ensures all pennies of a discount.

assistance as well.

° Provide financial incentives for employers to retain their retiree health coverage if they provide a prescription drug benefit to retirees that was at least equivalent to the new Medicare outpatient drug benefit. This approach would save money for the program because the subsidy given would be generous enough for employers to maintain coverage yet lower than the Medicare subsidies for traditional participants.

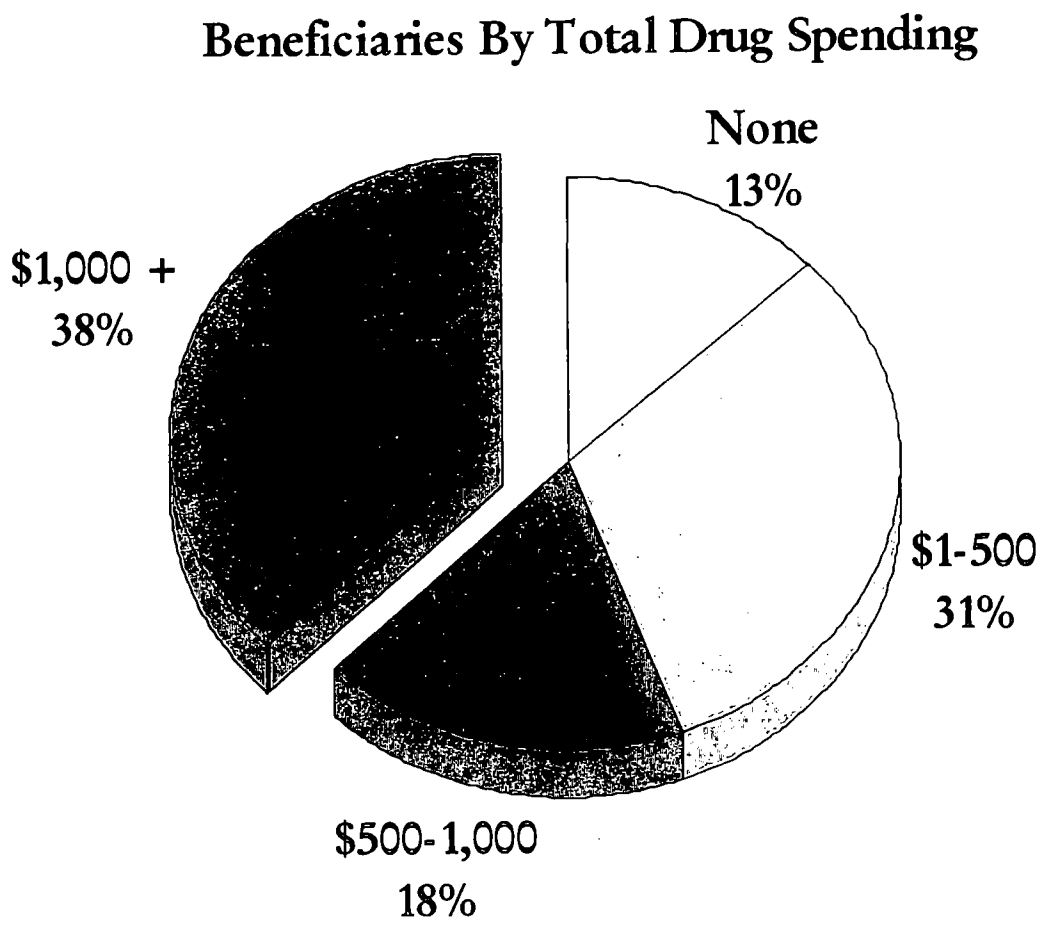
The President and HCFA actuaries believes that most Medicare beneficiaries will choose this new prescription drug option because it is attractive and affordable. Because older and disabled Americans rely so heavily on medications, about 31 million beneficiaries would benefit from this coverage each year. Cost: $118 billion over 10 years, beginning in 2002.

DISTURBING TRUTHS AND DANGEROUS TRENDS:

The Facts About Medicare Beneficiaries and Prescription Drug Coverage

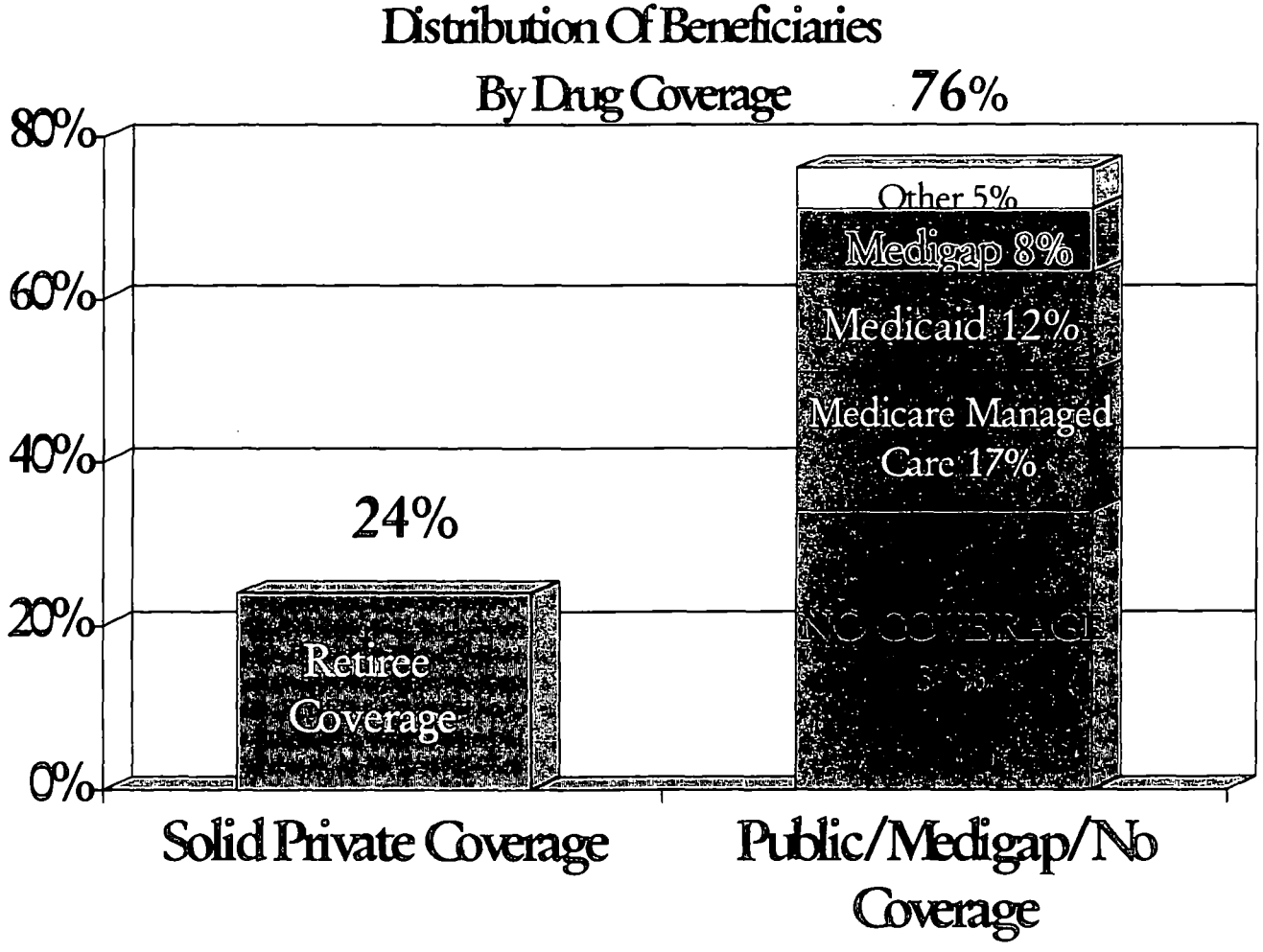
July, 1999

Medicare Beneficiaries Need Prescription Drugs



SOURCE: Actuarial Research Corporation for HHS, 2000

Three Out Of Four Beneficiaries Do Not Have Solid Private Drug Coverage



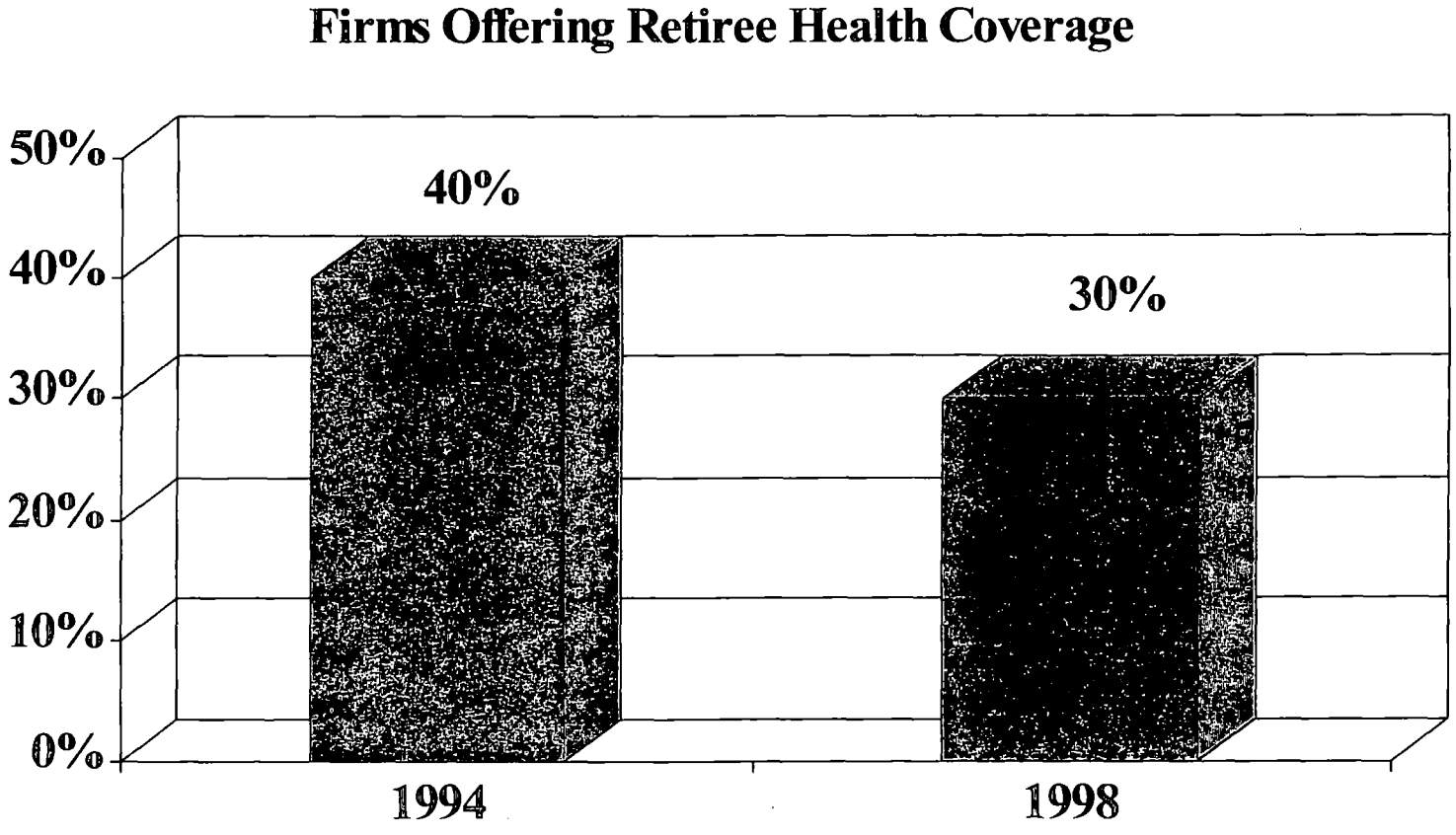
SOURCE: Actuarial Research Corporation for HHS, point-in-time, 2000

PRIVATE DRUG COVERAGE:

Unstable and Declining

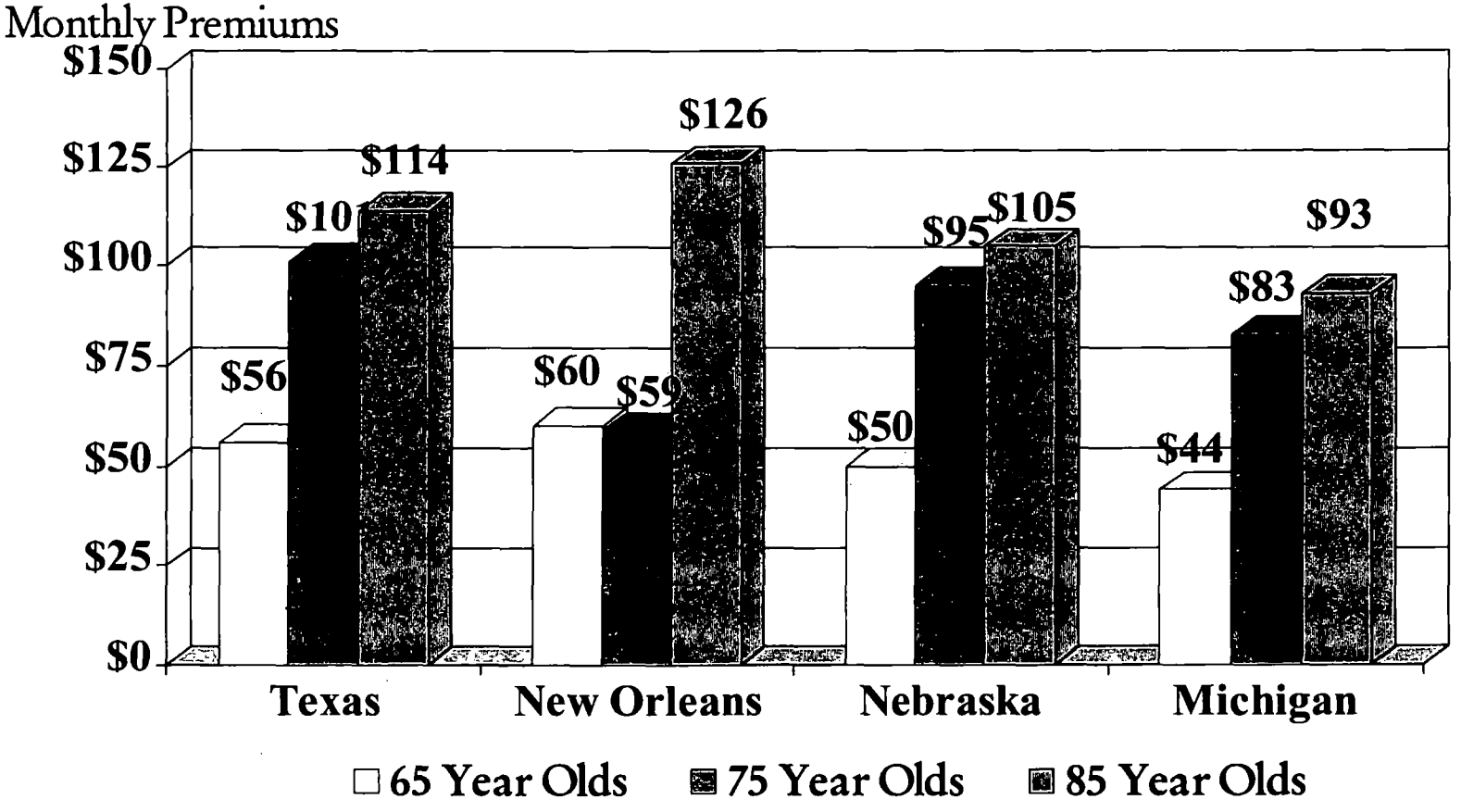
Retiree Health Coverage Is Declining

25% Fewer Firms Are Offering Retiree Health Benefits



SOURCE: Foster-Higgins, 1998

Medigap Premiums For Drugs Are High And Increase With Age, 1999

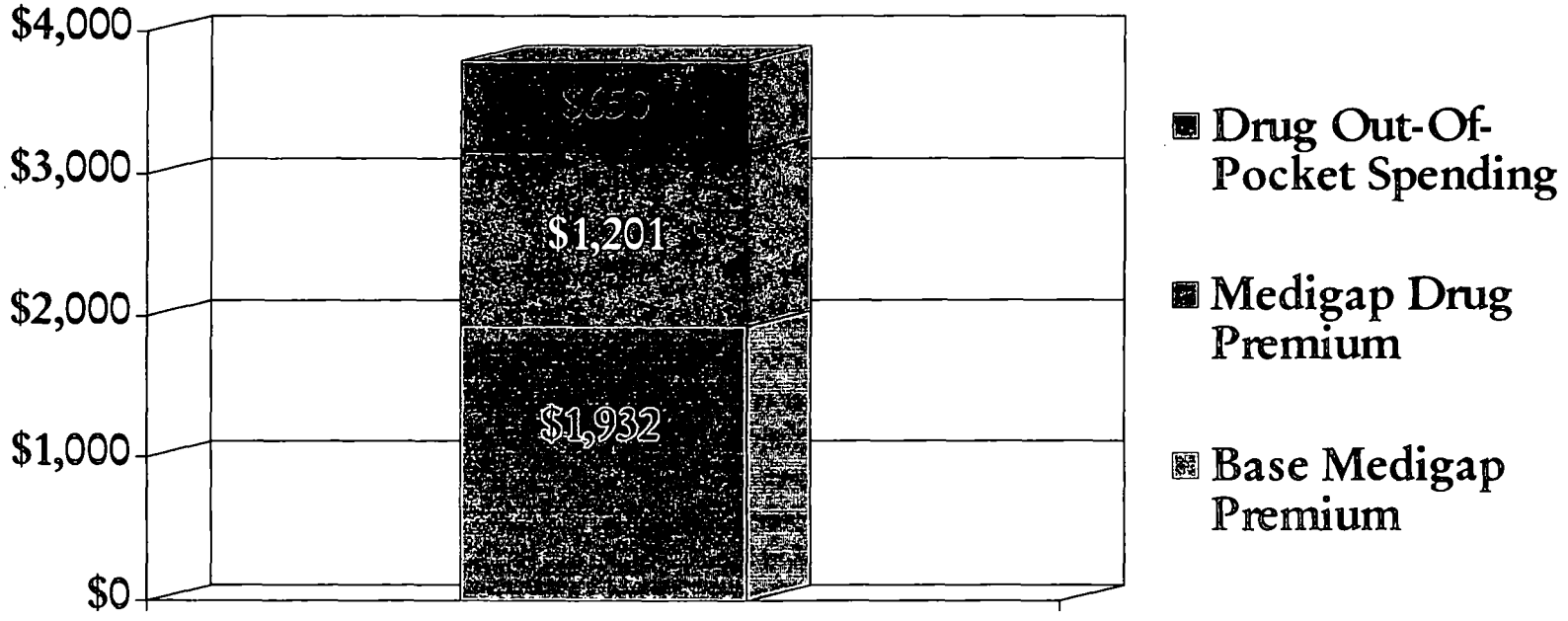


Sample Premiums for 1999. Difference between Plans I ($1,250 benefit limit) and Plan F which is similar but has no drug coverage. These premiums will be higher in 2002, when the President's proposed drug benefit will cost $24 per month.

Beneficiaries With Medigap Still Pay High Out-Of-Pocket Drug Costs

On Top Of The Premium For The Base Medigap, Beneficiaries Pay An Extra Premium For Drugs Plus Out-Of-Pocket Spending for Drugs

Medigap Annual Premiums And Out-Of-Pocket Spending

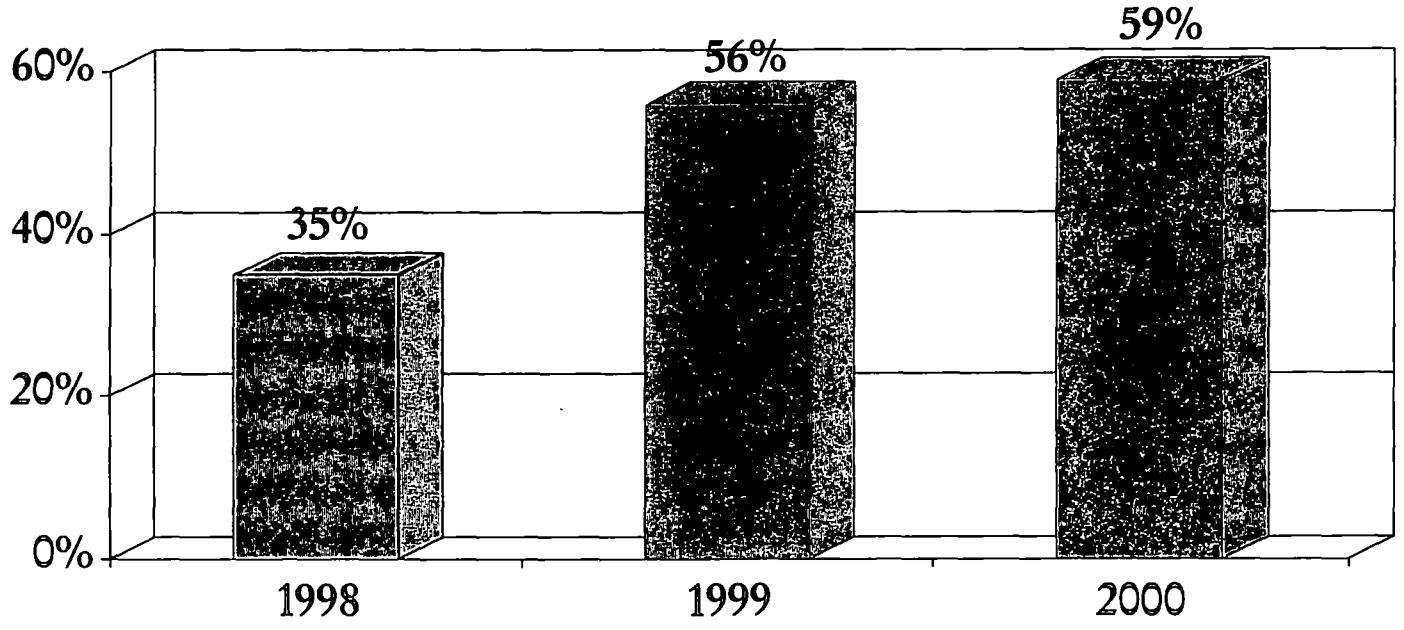


SOURCE: Actuarial Research Corporation for HHS. Premium from Texas for a 75 year old: base is $161 per month; drug addition is $101 per month

PUBLIC COVERAGE FOR PRESCRIPTION DRUGS

Value of Medicare Managed Care Drug Benefits Is Declining

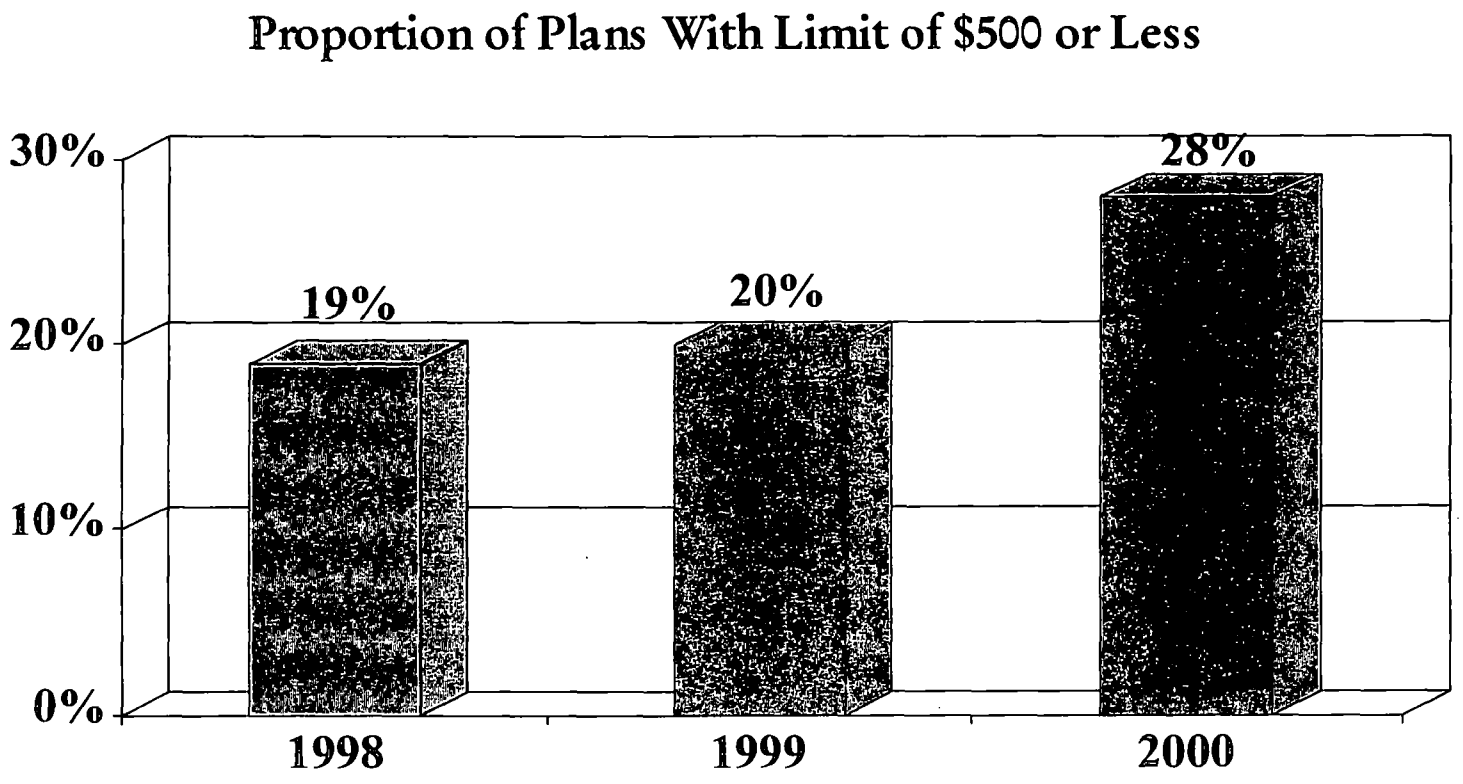
Nearly Three-Fifths Of Plans Will Cap Benefit Payments Below $1,000 In 2000



Source: HHS analysis of plan submissions for 2000; preliminary. This includes plans with unlimited generics and limited brand name drug spending

Limits on Medicare Managed Care Drug Benefit Are Getting Lower

Proportion Of Plans With A $500 Or Lower Limit Has Increased By 50%

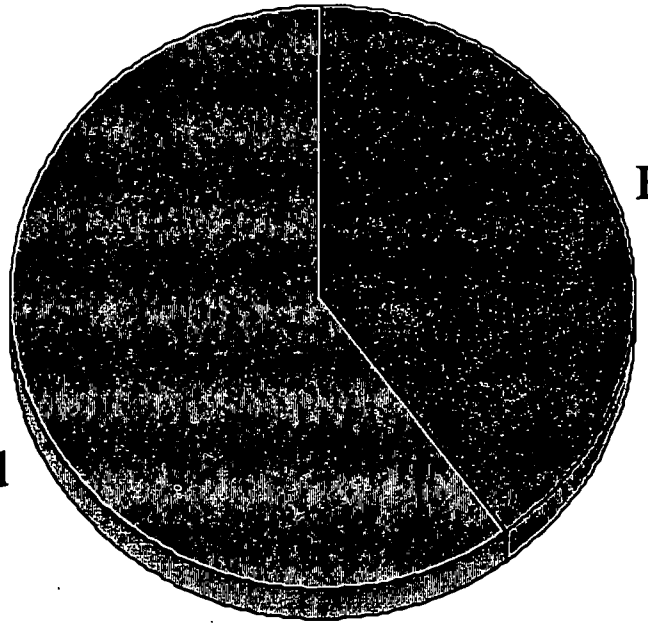


Source: HHS analysis of plan submissions for 2000; preliminary. This includes plans with unlimited generics and limited brand name drug spending

Participation In Medicaid Is Low

Only 40% Of Eligible Beneficiaries Are Enrolled in Medicaid

Eligible Medicare Beneficiaries' Enrollment in Medicaid



SOURCE: Actuarial Research Corporation for HHS. Calculated assuming that beneficiaries below 73% of poverty are eligible for full Medicaid benefits through SSI (Kaiser Commission on Medicaid & the Uninsured, May 1999)

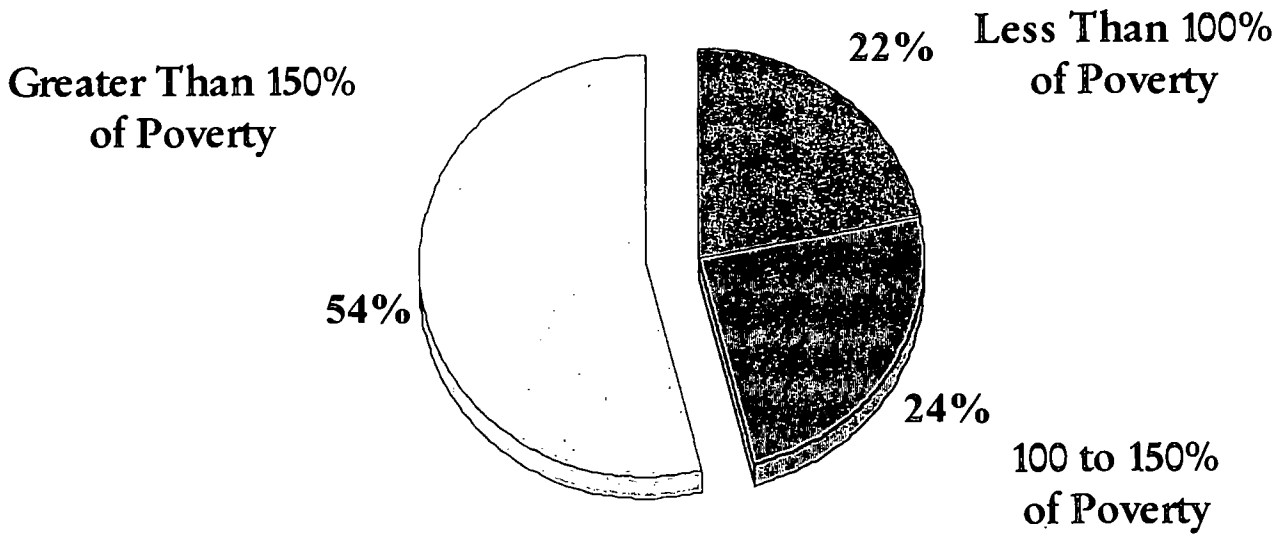
MILLIONS OF BENEFICIARIES HAVE NO DRUG COVERAGE

At Least 13 Million Medicare Beneficiaries Lack Prescription Drug Coverage

Many Uninsured In Middle Class

Over Half of Medicare Beneficiaries Who Lack Prescription Drug Coverage Are In The Middle Class

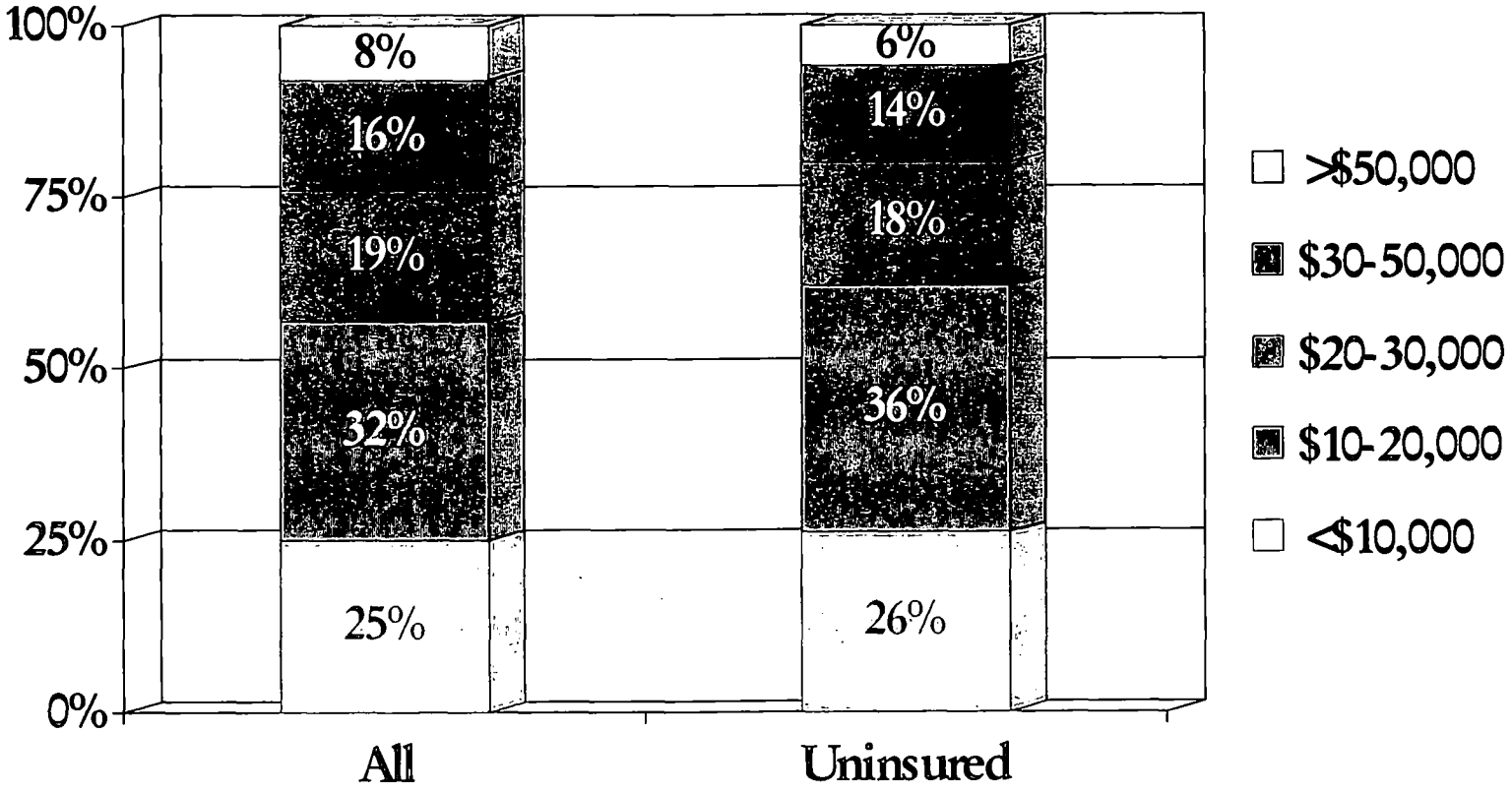
Income of Beneficiaries Without Drug Coverage (As A Percent Of Poverty)



SOURCE: Actuarial Research Corporation for HHS, 2000
In 2000, poverty for a single person is about $8,500, for a couple is about $11,400

Lack of Insurance Affects All Medicare Beneficiaries

Income of Beneficiaries Lacking Coverage Matches That Of All Beneficiaries



SOURCE: Actuarial Research Corporation for HHS, 2000

Methodology

The Actuarial Research Corporation under contract with the Department of Health and Human Services conducted most of the analysis. The basis for the estimates is the Medicare Current Beneficiary Survey (MCBS) for 1995. These data were aged to CY 2000, converted to a point-in-time estimate, and adjusted for the increase in managed care enrollment. This enrollment increase was estimated by moving beneficiaries from retiree health coverage, Medigap and the uninsured to managed care in proportion to their enrollment in those plans.

OWL PRESS RELEASE

666 11TH STREET, NW • WASHINGTON, DC 20001 • 202-783-6686 • FAX 202-638-2356

NEW OWL DATA CONNECTS MEDICARE WITH WORKING WOMEN

For Further Information:
Deborah Briceland-Betts
202/783-6686

Release: Immediate

OWL today released new data showing that strengthening Medicare, the health insurance program for retired Americans, is even more critical for American women planning to retire in the 21st Century than for today's retirees.

The data, an addendum to OWL's 1999 Mother's Day report, *The Face of Medicare is a Woman You Know,* shows that baby boom women will be the overwhelming majority of elderly Americans in the coming century. Moreover, they, like their mothers and grandmothers, will continue to pay a greater percentage of limited incomes for health expenses that are not covered by insurance.

"This report, *Medicare: Why Women Care,* establishes that Medicare is not just an issue for older women--it's a health issue for every woman," said OWL executive director Deborah Briceland-Betts. "Women's longer lives, the fact that as we get older we have more chronic illness, and because we typically survive longer on lower incomes, mean that prescription drug coverage and eliminating co-payments for preventive care are especially critical reforms for women," she said.

Among the report's findings:

- ✓ In 2035 alone, there will be nearly 40 million elderly women and 34 million older men. This large enrollment increase is a major factor in the projected exhaustion date of the Medicare trust fund.

- ✓ Higher out-of-pocket health spending. About 73 percent of women have two or more chronic illnesses compared to 65 percent of men The combination of multiple health problems and lower income results in women on Medicare paying 22 percent of their income on health care compared to 17 percent for men. Lower income women pay an even greater share of their limited incomes for health care–53 percent for the poorest.

- ✓ Lack of coverage for prescription drugs is a particular hardship for women. Total prescription drug spending for women on Medicare is nearly 20 percent more than that of men ($1,200 in 2000 compared to $1,000 for men).

- ✓ Women's incomes are lower than men's incomes, and they must stretch fewer financial resources over longer lives. Seven out of 10 Medicare beneficiaries living below poverty are women. The increased likelihood that women will live alone in their later years places them at increased risk of poverty.

- ✓ Older women will be no better off financially in the next century than they are today. Today, 12 percent of older women live in poverty. In 2020 the poverty rate for older women will be the same.

"Medicare: Why Women Care shows why we must act now to shore up the Medicare Trust Fund and modernize benefits to respond to the health needs of the majority of beneficiaries--women, said Briceland-Betts. "If we do not, we boomer women--not our mothers, not our grandmothers--might as well say goodbye to the financial and health security that Medicare so far has provided to generations of retired Americans."

OWL is the only national grassroots membership organization to work on issues unique to women as they age. OWL has 75 chapters and over 15,000 members nationwide.

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Medicare: Why Women Care

THE VOICE OF MIDLIFE AND OLDER WOMEN

	1999			2000		
	URBAN	RURAL	TOTAL (US)	URBAN	RURAL	TOTAL (US)
1) % of M+C Plans offered for $0 premium	47%	2%	50%	30%	1%	31%
2) # of Beneficiaries with Access to a $0 premium						
	% of urban elig	*% of rural elig*		*% of urban elig*	*% of rural elig*	
total with access to managed care	85%	25%	71%	82%	21%	68%
total with access to a $0 premium	75%	15%	61%	65%	9%	52%
As a % of total with access to managed care	88%	61%	85%	79%	41%	76%
3) Distribution of M+C Plan Premiums						
	Total Plans	*Total Plans*	*Total Plans*	*Total Plans*	*Total Plans*	*Total Plans*
(all plans - std. package)						
$0	47.3%	2.2%	69.5%	29.6%	1.1%	30.7%
$ 0.01 - $19.99	5.7%	0.6%	6.3%	4.5%	0.2%	4.7%
$20.00 - $39.99	18.3%	2.5%	20.8%	18.4%	1.0%	19.4%
$40.00 - $59.99	12.4%	1.7%	14.1%	14.9%	1.6%	16.5%
$60.00 - $79.99	4.1%	2.2%	6.3%	8.9%	1.2%	10.1%
$80.00 - $99.99	1.5%	0.6%	2.1%	6.3%	1.2%	7.5%
$100 - $149.99	0.3%	0.0%	0.3%	7.6%	0.5%	8.1%
above $150	0.6%	0.0%	0.6%	3.0%	0.0%	3.0%
	90.2%	9.8%	100.0%	83.2%	6.8%	100.0%
	Total Rx Plans	*Total Rx Plans*	*Total Rx Plans*	*Total Rx Plans*	*Total Rx Plans*	*Total Rx Plans*
(all plans with Rx in std. package)						
$0	50.3%	1.4%	51.7%	28.0%	0.7%	28.7%
$ 0.01 - $19.99	6.1%	0.2%	6.3%	4.6%	0.3%	4.9%
$20.00 - $39.99	18.2%	1.8%	20.0%	19.1%	1.0%	20.1%
$40.00 - $59.99	11.7%	1.0%	12.7%	13.9%	1.2%	15.1%
$60.00 - $79.99	4.4%	1.9%	6.3%	8.1%	0.8%	8.9%
$80.00 - $99.99	1.4%	0.4%	1.8%	7.0%	1.2%	8.2%
$100 - $149.99	0.4%	0.0%	0.4%	9.8%	0.5%	10.3%
above $150	0.8%	0.0%	0.8%	3.8%	0.0%	3.8%
	93.3%	6.7%	100.0%	94.3%	5.7%	100.0%
4) Average Premiums						
Total Plans						
Simple Average *(Total Plans / Total Premium)*	$20.11	$38.03	$21.84	$42.00	$51.65	$42.66

IMPORTANT: The following data is based on a preliminary analysis of information reported in the ACR/BIF filings. Information on section 1876 cost plans and certain demonstration projects is not included.

	1998			2000		
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Weighted Average *(Total avg. per county weighted by # of eligible*	$16.93	$27.87	$17.83	$36.24	$42.43	$36.70
Total Plans excluding $0 Premium *(non-zero)*						
Simple Average *(Total Plans / Total Premium)*	$42.24	$48.90	$43.23	$61.52	$61.75	$61.54
Weighted Average *(Total avg. per county weighted by # of eligible*	$30.68	$35.32	$31.06	$49.00	$46.69	$48.83
Total Plans with Rx						
Simple Average *(Total Plans / Total Premium)*	$19.76	$40.13	$21.13	$45.00	$54.29	$45.52
Total Plans with Rx excluding $0 Premium *(non-zero)*						
Simple Average *(Total Plans / Total Premium)*	$42.90	$50.53	$43.74	$64.03	$61.53	$63.65
5) Additional 'out-of-pocket' costs						
Avg. reported value of copayments *(all plans)*	—	—	$23.47	—	—	$31.60
Avg. reported value of copayments *(all non-zero plans)*	—	—	$22.01	—	—	$32.29
6) M+C Plans which include Prescription Drugs (Rx)						
	% of Urban Plans	*% of Rural Plans*	*% of Total Plans*	*% of Urban Plans*	*% of Rural Plans*	*% of Total Plans*
Plans with Prescription Drugs (Rx) in 'std' package	79.9%	54.0%	77.4%	76.1%	61.8%	75.1%
Plans which include Rx as 'Optional' benefit only	0.7%	1.6%	0.8%	2.2%	0.0%	2.1%
Plans which do not include Rx	19.4%	44.4%	21.8%	21.7%	38.2%	22.8%
	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
7) Access to Rx Benefits						
% of Medicare beneficiaries with access to Rx						
As a % of total with access to managed care	93%	77%	93%	94%	73%	93%
% of total beneficiaries	80%	19%	66%	78%	16%	63%
% of Medicare beneficiaries without access to Rx						
As a % of total with access to managed care	5.6%	1.8%	7.5%	5.5%	2.0%	7.5%
% of total beneficiaries	15.4%	19.1%	34.5%	17.1%	19.8%	37.0%
8) Rx Coverage Limits						
	% of Plans w/ Rx	*% of Plans w/ Rx*	*% of Plans w/ Rx*	*% of Plans w/ Rx*	*% of Plans w/ Rx*	*% of Plans w/ Rx*
Unlimited (Brand and Generic)	8.2%	0.8%	9.0%	13.1%	0.8%	13.9%
Unlimited Generic, Limited Brand	22.5%	1.0%	23.5%	44.9%	2.4%	47.3%
Limited Generic, Limited Brand	62.5%	5.0%	67.5%	36.5%	2.3%	38.8%
	93.2%	6.8%	100.0%	94.5%	5.5%	100.0%
9) Distribution of Rx Annual Limits						
Unlimited ic, Limited Brand						

Up to $500	2.6%	0.2%	2.8%	15.6%	0.7%	16.3%
$501 - $799	1.9%	0.4%	2.3%	3.2%	0.4%	3.6%
$800 - $999	0.6%	0.0%	0.6%	1.1%	0.0%	1.1%
$1,000	3.4%	0.2%	3.6%	10.8%	0.4%	11.2%
$1001 - $2000	10.8%	0.2%	11.0%	17.5%	1.3%	18.8%
$2001 - $2500	3.9%	0.0%	3.9%	2.2%	0.0%	2.2%
Over $2500	1.5%	0.0%	1.5%	1.7%	0.0%	1.7%
	24.7%	1.0%	25.7%	52.1%	2.8%	54.9%
Limited Generic and Brand						
Up to $500	18.1%	0.9%	19.0%	14.9%	0.4%	15.3%
$501 - $799	8.0%	0.9%	8.9%	6.1%	0.7%	6.8%
$800 - $999	5.8%	0.6%	6.4%	2.2%	0.0%	2.2%
$1,000	16.6%	1.9%	18.5%	10.7%	1.3%	12.0%
$1001 - $2000	16.8%	1.1%	17.9%	7.3%	0.2%	7.5%
$2001 - $2500	1.8%	0.0%	1.9%	0.7%	0.0%	0.7%
Over $2500	1.7%	0.0%	1.7%	0.6%	0.0%	0.6%
	68.9%	5.4%	74.3%	42.5%	2.6%	45.1%
Total Rx plans with limits						
Up to $500	20.7%	1.1%	21.8%	30.5%	1.1%	31.6%
$501 - $799	9.9%	1.3%	11.2%	9.3%	1.1%	10.4%
$800 - $1000	6.4%	0.6%	7.0%	3.3%	0.0%	3.3%
$1001 - $2000	20.0%	2.1%	22.1%	21.5%	1.7%	23.2%
$2001 - $2500	27.6%	1.3%	28.9%	24.8%	1.5%	26.3%
Over $2500	5.8%	0.0%	5.8%	2.9%	0.0%	2.9%
	3.2%	0.0%	3.2%	2.3%	0.0%	2.3%
	93.6%	6.4%	100.0%	94.6%	5.4%	100.0%

10) Distribution of Rx Copayments (per script)	% of Total Rx Plans w/ Limits	% of Total Rx Plans w/ Limits	% of Total Rx Plans w/ Limits	% of Total Rx Plans w/ Limits	% of Total Rx Plans w/ Limits	% of Total Rx Plans w/ Limits
Generic						
$0	4.7%	0.4%	5.1%	2.6%	0.0%	2.6%
Under $5	4.5%	0.4%	4.9%	4.9%	0.0%	4.9%
$6 - 10	60.0%	3.9%	63.9%	47.4%	1.8%	49.3%
$11 - 15	20.6%	1.4%	22.0%	39.9%	2.9%	42.9%
$16 - 25	3.5%	0.6%	4.1%	0.0%	0.4%	0.4%
over $25	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
	93%	7%	100%	95%	5%	100%
Brand						
$0	4.0%	0.4%	4.4%	1.6%	0.0%	1.6%
Under $5	0.0%	0.0%	0.0%	0.2%	0.0%	0.2%

	1998			1999		
	URBAN (A)	RURAL (B)	TOTAL (C)	URBAN (D)	RURAL (E)	TOTAL (F)
$6 - 10	7.8%	0.4%	8.2%	1.4%	0.0%	1.4%
$11 - 15	23.5%	2.7%	26.2%	8.8%	0.8%	9.6%
$16 - 25	42.8%	1.9%	44.8%	61.6%	3.5%	65.1%
over $25	15.9%	0.8%	16.7%	21.2%	1.0%	22.2%
	94%	6%	100%	95%	5%	100%
11) Rx Formulary						
% of total Rx plans which use formulary	79%	71%	78%	85%	82%	85%
% of above Rx plans w/ diff. copayments for non-f	15%	21%	15%	56%	64%	57%
% of Rx plans with no formulary indicated	22%	29%	22%	15%	18%	15%
12) Reported value of non-Medicare benefits *(std packages only)*						
Average reported value of non-Medicare benefits	—	—	$52.30	—	—	$51.59
As % of average HCFA premium (reported APR)	—	—	11.9%	—	—	11.3%

Baucus Amend

Social Security and Medicare Lockbox

The "Social Security and Medicare Lockbox" precludes any portion of the Social Security surplus *or* any portion of the surplus reserved for Medicare to be used for any purpose other than to strengthen and preserve these programs. Over the next 15 years, the Lockbox would protect *100 percent* of the Social Security surplus in each year, and one-third of any on-budget surplus for Medicare.

Amounts in Lockbox. The Social Security and Medicare Lockbox contains: (1) the entire Social Security surplus in every year and (2) one-third of the on-budget surplus in any year, reserved specifically to strengthen and extend the life of the Medicare program.[1]

Enforcement. The Social Security and Medicare Lockbox would be enforced through new supermajority points of order and the extension of the current paygo enforcement system.

(1) A point of order would lie against a budget resolution that would set forth an on-budget deficit in any year.

(2) A point of order would lie against any subsequent legislation (and all associated interest costs) that would cause or increase an on-budget deficit in any year, relative to CBO's capped baseline.

(3) A point of order would lie against a budget resolution that reserves less than 33 percent of the on-budget surplus for Medicare in any year based on up-to-date CBO estimates of the on-budget surplus.

(4) A point of order would lie against any legislation (and associated interest costs) that would reduce the Medicare surplus reserve (33 percent of the on-budget surplus) in any year *except for* legislation that uses a portion of the surplus to provide prescription drug coverage and also significantly extends the solvency of the Medicare Hospital Insurance Trust fund.

(5) The current pay-as-you-go system of budget enforcement is extended.

Conforming changes. This legislation makes conforming changes in the Budget Resolution for fiscal year 2000 to allow for enforcement of the Social Security and Medicare lockbox, including changes in reconciliation instructions, budget aggregates, and allocations.

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[1] The 33 percent includes the interest costs associated with a prescription drug benefit or any spending on the Medicare program.

Union Calendar No. 136

106TH CONGRESS
1ST SESSION

H. R. 2488

[Report No. 106–238]

A BILL

To amend the Internal Revenue Code of 1986 to reduce individual income tax rates, to provide marriage penalty relief, to reduce taxes on savings and investments, to provide estate and gift tax relief, to provide incentives for education savings and health care, and for other purposes.

JULY 16, 1999

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

beneficiary' means an individual who is entitled to benefits under part A, B, or C of title XVIII of the Social Security Act."

(b) CONDITIONS.—Section 213 is amended by redesignating subsection (e) as subsection (f) and by inserting after subsection (d) the following new subsection:

"(e) CONDITIONS FOR SEPARATE DEDUCTION FOR PRESCRIPTION DRUG INSURANCE COVERAGE.—For purposes of subsection (a), the conditions specified in this subsection are met if all of the following are in effect:

"(1) ASSISTANCE FOR PRESCRIPTION DRUGS FOR LOW-INCOME MEDICARE BENEFICIARIES.—

"(A) Low-income assistance to enable the purchase of coverage of prescription drugs as described in paragraph (2) or (3) for medicare beneficiaries with incomes under 135 percent of the applicable Federal poverty level, with such assistance phasing out for beneficiaries with incomes between 135 percent and 150 percent of such level.

"(B) The Federal Government provides funding for the costs of such assistance.

"(2) SUPPLEMENTAL COVERAGE OF PRESCRIPTION DRUGS.—All policies supplemental to Medicare include coverage for costs of prescription drugs.

"(3) STRUCTURAL MEDICARE REFORM.—Coverage for outpatient prescription drugs for medicare beneficiaries is provided only through integrated comprehensive health plans which offer current Medicare covered services and maximum limitations on out-of-pocket spending and such comprehensive plans sponsored by the Health Care Financing Administration compete on the same basis as private plans."

(c) DEDUCTION FOR PRESCRIPTION DRUG INSURANCE COVERAGE ALLOWED WHETHER OR NOT TAXPAYER ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 (defining adjusted gross income) is amended by inserting after paragraph (18) the following new paragraph:

"(19) PRESCRIPTION DRUG INSURANCE COVERAGE.—The deduction allowed by section 213(a) to the extent of the expenses described in the second sentence thereof."

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

Legislative News

Medicare Reform

Ways and Means Nears Approval of Tax Bill With Deduction for Drug Coverage

The Medicare reform debate in Congress began sooner than expected July 14 as Republicans on the House Ways and Means Committee put aside Democratic objections and were close to approving a tax deduction for prescription drug insurance as part of its huge tax bill (H.R. 2488), which was expected to be passed late in the day.

The committee, by a party line vote, defeated a Democratic attempt to provide prescription drug coverage through a tax credit and was expected to vote down an amendment that would have reduced the tax cut in the bill by $375 billion over 10 years to provide funds for Medicare and prescription drug coverage.

While pledging to put bipartisanship aside to implement major Medicare reforms later this year, the often rancorous debate underscored the difficulty the House will have in accomplishing that, as each side accused the other of using the tax bill to push its Medicare reform agenda.

The Medicare debate began early and consumed much of the time devoted to marking up the "Financial Freedom Act of 1999," which would provide $864 billion in tax cuts over 10 years.

President Clinton has said he would veto the measure because the magnitude of the tax cut would take away money that could be used to shore up Medicare and Social Security.

Both sides disagreed about the nature of the prescription drug provision offered by Republicans, contained in a substitute amendment to the bill, introduced by committee chairman Bill Archer (R-Texas).

Three Conditions Specified. The deduction would not be implemented until three conditions were met: the federal government would have to provide financial assistance for beneficiaries with incomes up to 135 percent of poverty, all 10 Medigap plans must provide coverage, and drug coverage would only be available through managed care plans. Under the proposal, fee-for-service plans would compete "on the same basis" as private plans.

Medicare beneficiaries would be allowed to take the deduction whether or not they itemize their tax return, according to a copy of the substitute amendment.

Republicans maintained that the provision was merely a placeholder that would allow the committee at a later date to consider using the tax code to provide drug coverage as part of a more comprehensive package of program reforms since legislation would be needed to enact the three qualifying conditions.

The provision is "part of a balanced, multifaceted approach" to providing drug coverage to beneficiaries, said Rep. Philip S. English (R-Penn.)

Democrats charged that the provision was an attempt by Republicans to write into law part of the failed "premium support" proposal put forth earlier this year by the National Bipartisan Commission on the Future of Medicare.

Millions Without Help. The White House in a statement issued July 14 harshly criticized the GOP drug proposal, saying it "does not come close to meeting any definition of meaningful drug coverage for Medicare beneficiaries."

The biggest problem with the plan, the administration said, is that only about half the elderly file taxes, leaving millions of seniors without any help in obtaining coverage.

Beneficiaries would continue paying retail price for drugs under the GOP provision; requiring Medigap plans to provide coverage may cause insurers to leave the Medicare market, the White House said. Only three Medigap plans now are required under federal law to offer drug coverage.

"Today's fragmented, patchwork system is unworkable and unstable, and to ensure that all beneficiaries who need a meaningful prescription drug benefit have access to such coverage, it can only be done efficiently and equitably through [a] modernized Medicare benefit," the administration said.

Because the provision would not be implemented unless all three conditions were met, the tax deduction would not be scored as costing money in the bill, Republican staff said. A similar deduction for the actual cost of drugs, which would kick in after a beneficiary spent $200, would cost $18 billion over 10 years, staff said.

Democrats countered with an amendment offered by Rep. Fortney H. Stark (D-Calif.) that would provide a 50-percent refundable tax credit to Medicare beneficiaries to help pay for $2,000 per year in drug costs in 2002, rising to $5,000 in 2008. The credit would be available to all, regardless of income level, Stark said.

Stark said the proposal is similar to that put forth June 29 by Clinton in his Medicare reform plan but is paid for through the tax code rather than by program savings and the predicted federal budget surplus as the president proposed (10 MCR 743, 7/2/99).

Double the Cost. The White House said its plan would cost $118 billion over 10 years; but, because Stark said his proposal would not use Medicare Part B premiums to help pay for coverage, his amendment would cost $270 billion over 10 years, to be paid for by making a pro rata reduction in the tax breaks contained in the rest of H.R. 2488.

"Only by putting the benefit into the core Medicare package or by offering help through the tax code can we guarantee everyone coverage," Stark said.

Republicans objected to the amendment, saying it provides no solution to the problem, harming future at-

its first month on the market, according to IMS Health. Avandia is indicated for monotherapy and in combination with metformin.

Revised labeling for Rezulin limits initial use of the drug to second-line therapy in combination with sulfonylureas or metformin. According to IMS, Rezulin represented 7.1% of the antidiabetic market as of July 2.

Actos' lipid profile is another area of differentiation Takeda and Lilly will likely highlight in seeking to distinguish the drug from Avandia, emphasizing the reduction in triglycerides and increase in HDL cholesterol observed in Actos trials.

Avandia labeling states that in clinical trials rosiglitazone combination and monotherapy "was associated with increase in total cholesterol, LDL and HDL, and decreases in free fatty acids." Changes in triglycerides during treatment with Avandia "were variable and were generally not statistically different" from placebo or glyburide controls, labeling adds.

As recommended by FDA's Endocrine & Metabolic Drugs Advisory Committee April 23, Actos and Avandia both carry glitazone class warnings referencing Rezulin liver toxicity.

Similar to Avandia, Actos labeling cautions that "pioglitazone is structurally related to troglitazone, which has been associated with idiosyncratic hepatotoxicity and rare cases of liver failure, liver transplants and death."

Labeling acknowledges, however, that in more than 4,500 patients treated with Actos in clinical trials, "there was no evidence of drug induced hepatotoxicity or elevation of ALT levels."

Actos labeling recommends liver monitoring at baseline and every two months during the first year. The same monitoring schedule is recommended with Avandia use.

Labeling recommends that monotherapy be initiated at 15 mg or 30 mg once daily, and increased to 45 mg once daily if necessary. Actos in combination therapy should be initiated at 15 mg or 30 mg once-daily, labeling says. Dose adjustments with Actos/metformin combination therapy are unlikely to be necessary, labeling notes, though specific adjustments are suggested if hypoglycemia occurs during combination therapy with the other antidiabetics. ◆◆

Sen. Roth Tax Proposal Does Not Address Medicare Rx Drug Premium Tax Deduction

The "tax relief" plan unveiled July 16 by Senate Finance Committee Chairman William Roth (R-Del.) does not include a tax deduction for Medicare beneficiaries for the cost of drug benefit premiums.

In contrast to the Roth plan, the tax relief bill moving through the House Ways & Means Committee provides an "above-the-line" deduction for half of the costs of prescription drug insurance premiums for Medicare beneficiaries with incomes above 150% of poverty. The new deduction would be contingent upon Congress adopting a broad Medicare restructuring plan.

When asked if he would consider such a deduction, Roth replied he would be "happy to give it serious consideration."

Roth said that he intends for the Senate Finance Committee to put together a Medicare reform plan in September, and that "certainly a key part of that reform will be a tax deduction" for prescription drug insurance premiums.

Roth will introduce the tax package prior to the Finance Committee's July 20 walk-through of the bill, according to committee staff. The committee will meet again July 21 to begin marking up the bill. The statutory deadline for the committee to report out a tax bill is July 23.

While the Roth proposal does not address Medicare reform or the possibility of a drug benefit, it phases in tax deductions for health insurance and long-term care insurance premiums and includes other measures designed to reduce taxes related to health care expenses.

The plan would phase in an above-the-line deduction for individuals who pay at least 50% of their health insurance premiums, according to a plan summary. The deduction would be 25% in the years 2001-2003, 50% in 2004-2005, and 100% thereafter.

The deduction would not apply to any month in which the taxpayer is enrolled in Medicare, Medicaid, the Federal Employees Health Benefits Program, the Children's Health Insurance Program, Champus, VA, or the Indian Health Service.

The plan would also phase in an above-the-line deduction for long-term care insurance for which the taxpayer pays at least 50% of the premium. The plan proposes a phase-in period identical to that proposed for health insurance premiums: 25% the first three years, 50% the following two years, and 100% thereafter.

Like the House bill, the Roth proposal also allows long-term care insurance to be offered in "cafeteria plans," and provides an additional dependency deduction to caretakers of elderly family members.

The Roth plan also would add the Streptococcus Pneumoniae vaccine to the federal vaccine insurance program, and would reduce the tax on the vaccine from $.75 to $.25 per dose beginning in 2005.

As an alternative to Roth's $794 bil. tax cut package, Senate Finance Committee ranking member Daniel Moynihan (D-N.Y.) unveiled a $295 bil. Democratic measure July 16. In announcing the smaller tax cut proposal, Moynihan said he favors using only about one-third of the approximately $1 tril. budget surplus for tax relief, while earmarking the remaining two-thirds for Medicare and discretionary spending.

The Democratic measure includes $27 bil. in tax reductions under three health care provisions. One provision, championed by Sen. John Breaux (D-La.), would give uninsured individuals making up to $20,000 and couples making up to $40,000 a 30% tax credit for the purchase of health insurance. The provision would be capped at $1,000 for individuals and $2,000 for couples, Breaux said in a statement.

The Democratic bill also would provide full health insurance tax deductibility for self-employed individuals and tax breaks for long-term care costs, according to a summary of the bill. ●●

[See chart next page]

BRIEFS

Alteon: Former Ergo Science Senior VP-Marketing & Business Development Ken Andrews is appointed Alteon senior VP-operations, a newly created position. Andrews has served as consultant to Alteon since January 1999....

Avant: Alistair Wheeler, MD, joins Avant as VP-medical affairs, a newly created position. Previously, Wheeler served as an independent consultant and Astra senior director-clinical operations....

Catalytica: Mountain View, California-based Catalytica will acquire Wyckoff Chemical for approximately $60 mil. South Haven, Michigan-based Wyckoff supplies products to generic and branded companies, including Bristol, Mylan, Pfizer, and Watson. The merger, to be completed in the fourth quarter, would approximately double Catalytica's chemical reactor capacity to over 100,000 reactor gallons....

Bigmar: American Pharmaceutical Partners will distribute six Bigmar generic oncology products in North America: daunorubicin, two versions of leucovorin and three versions of methotrexate. APP will not distribute Bigmar's other product, fluorouracil, because it already has a supplier, Johnstown, Ohio-based Bigmar indicated ...

Folic acid: CDC would receive $20 mil. in FY 2000 to launch a national folic acid education campaign highlighting the vitamin's preventative qualities regarding birth defects, under the Folic Acid Promotion and Birth Defects Prevention Act of 1999. Introduced by Rep. Lucille Roybal-Allard (D-Calif.), the bill also would provide funding through 2004 in support of the education campaign. Companion legislation was introduced in the Senate by Spencer Abraham (R-Mich.) along with Sens. Herb Kohl (D-Wisc.) and Kit Bond (R-Mo.). Bond was the primary sponsor of the Birth Defects Prevention Act, which passed last session....

Medicare reform hearing: HHS Secretary Donna Shalala will testify at a Senate Finance Committee hearing on President Clinton's Medicare reform proposal July 22, according to a committee statement. The second witness panel will feature Congressional Budget Office Director Dan Crippen, PhD, and General Accounting Office Comptroller General David Walker....

to meet future claims made under the Vaccine Injury Compensation Program.

SEC. 507. ABOVE-THE-LINE DEDUCTION FOR PRESCRIPTION DRUG INSURANCE COVERAGE OF MEDICARE BENEFICIARIES IF CERTAIN MEDICARE AND LOW-INCOME ASSISTANCE PROVISIONS IN EFFECT.

(a) IN GENERAL.—Subsection (a) of section 213 is amended by adding at the end the following new sentence: "The 7.5 percent adjusted gross income threshold in the preceding sentence shall not apply to the expenses paid during the taxable year for prescription drug insurance coverage of a medicare beneficiary who is the taxpayer, the taxpayer's spouse, or a dependent (as defined in section 152) if—

"(1) the Secretary certifies that, throughout such taxable year, the conditions specified in subsection (e) are met, and

"(2) the amount paid for such coverage is either separately stated in the contract or furnished to the policyholder by the insurance company in a separate statement.

Expenses to which the preceding sentence applies shall not be taken into account in applying such threshold to other expenses. For purposes of this subsection, the term 'medicare

July 27, 1999

MEMORANDUM TO JOHN PODESTA

CC: STEPHEN RICCHETTI
MARIA ECHAVESTE
GENE SPERLING
LORETTA UCELLI
LARRY STEIN
KAREN TRAMANTANO
JOEL JOHNSON
CHRIS JENNINGS

FROM: MARY BETH CAHILL
BARBARA WOOLLEY

RE: MEDICARE OUTREACH MEETINGS

During the week of July 19, OPL organized 8 meetings with over 130 organizations to review our timeline for action on Medicare reform, to thank them for their efforts to date and to encourage the organizations to conduct more outreach activities on Medicare. Enclosed a list of the groups met with and a copy of the information provided to the groups.

Attachments:

- List of organizations
- Charts: July 16, President's Budget Plan
  July 16, President's Plan to Modernize and Strengthen Medicare
  July, 1999, President's Plan to Modernize & Strengthen Medicare for the 21st Century

Medicare Coalition Group List

AAUW
AIDS National Network
Alzheimer's Association
Alzheimer's Association
Am. Federation of State, Council, & Municipal Employees
American Academy of Family Physicians
American Academy of Nurse Practitioners
American Academy of Physician Assistants
American Assoc. of Pastoral Counselors
American Association of Homes and Services for the Aging
American Association of Physicians of Indian Origin
American Cancer Society
American College of Gastronomy
American College of OBGYN
American Counseling Association
American Diabetes Association
American Federation of Teachers Retirees
American Gastroenterological Association
American Healthcare Association
American Heart Association
American Lung Association
American Managed Behavioral Healthcare Assoc.
American Medical Association
American Medical Rehabilitation Provider Association
American Medical Women's Association
American Nurses Association
American Nurses Association
American Occupational Therapy Association
American Osteopathic Association
American Physical Therapy Association
American Psychiatric Association
American Psychiatric Nurses Association
American Public Health Association
American Society of Gastronomists
American Speech Language and Hearing Association
Amyotrophic Lateral Sclerosis Association
APRI
Arthritis Foundation
Asian & Pacific Islander American Health Forum
Association for the Advancement of Psychology
Association of Women's Health Obstetric and Neonatal Nurses
Asthma and Allergy Foundation of America
Bass and Howes
Bazelon Center for Mental Health Law
Business and Professional Women USA
Cambodian Network Council
Catholic Charities USA

CBTU
CDH Health
Center for Policy Alternatives
Colitis
Community Pharmacist Association
COSSMHO
CWA Retirees
Digestive Disease National Coalition
Epilepsy Foundation
Evangelical Lutheran Church in America
Family Health Project
Federation of American Health Systems
Feminist Majority
Fresenius Medical Care No. America
General Federation of Women's Clubs
Gray Panthers
Hispanic Medical Association
Hispanic Working Group on Healthcare
Hispanic-Serving Health Professional Schools
Hmong National Development Inc.
IAM & Retirees
Interstitial Cystitis Association
Juvenile Diabetes Foundation
Leadership Conference on Civil Rights (LCCR)
League of United Latin American Citizens
League of Women Voters
Leukemia Society of America
MANA, A National Latina Organization
March of Dimes
Mexican American Legal Defense and Education Fund
Myositis Association of America
NAACP
NAPAS (National Association of Protection and Advocacy Services)
National Alliance for the Mentally Ill
National Asian Pacific American Families Against Substance Abuse
National Assoc. of Social Workers
National Assoc. of State Mental Health Program Directors
National Association for Hispanic Elderly
National Association for Homecare
National Association of Area Agencies on Aging
National Association of Chain Drug Stores
National Association of Commissions for Women
National Association of Community Health Centers
National Association of Developmental Disabilities Council
National Association of People with AIDS
National Association of Retired Federal Employee
National Association of Rural Health Clinics
National Black Deaf Advocates
National Black Deaf Advocates New York City Chapter

National Black Nurses Association
National Breast Cancer Coalition
National Caucus and Center on Black Aged, Inc.
National Center on Women and Aging, Brandeis University
National Comm. To Preserve SS and Medicare
National Council of Jewish Women
National Council of La Raza
National Council of Negro Women
National Council of Senior Citizens
National Council on Aging
National Education Association Retirees
National Family Farm Coalition
National Farmers Union
National Health Council
National Hispanic Council on Aging
National Hospice Organization
National Medical Association
National Mental Health Association
National Minority AIDS Council
National Multiple Sclerosis Society
National Osteoporosis Foundation
National Pacific Center on Aging
National Partnership for Women and Families
National Prostate Cancer Coalition
National Puerto Rican Coalition
National Rainbow/PUSH Coalition
National Rural Health Care Association
National Senior Law Center
National Sleep Foundation
National Urban League
National Woman's Law Center
National Women's Health Network
Natnl. Assoc. of Psychiatric Health Systems
NISH (formerly known as National Institute of Severely Handicapped)
Older Women's League
Older Women's League
Paralyzed Veterans of America
Radcliffe Public Policy Institute
RESNA (Rehab Engineering and Assistive Technology Society of North America)
Rural Housing Service, USDA
Self-Help for the Elderly
Service Employee Internat Union Retirees
Sjorgen's Syndrome Foundation
Summit Health Institute for Research and Education, Inc.
The Arc
The Los Angeles Eye Institute
United Church of Christ
United Jewish Communities
United Methodist Church - General Board of Church and Society

US Catholic Conference
Working Women Department, AFL-CIO
YWCA of the USA

Manufacturers Division of the
NATIONAL PHARMACEUTICAL ALLIANCE

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Draft Rev: 5/17

Position of the
National Pharmaceutical Alliance (NPA)
On Drug Price Competition
and Patent Term Restoration Act of 1984

Congressional Opportunity to Increase
Consumer Benefits through Hatch-Waxman Act Expansion

May 18, 1999

EXECUTIVE SUMMARY
NPA POSITION ON HATCH-WAXMAN

Objective: Congress should restore the legislative balance and strengthen the rights of consumers to have a fair and competitive market for pharmaceutical products.

Background

In 1984, the United States Congress approved the Drug Price Competition and Patent Term Restoration Act, which is commonly referred to as the Hatch-Waxman Act. Hatch-Waxman was a delicate compromise that formalized the modern U.S. generic drug approval process, while simultaneously providing the brand pharmaceutical industry with patent extensions that protected them from generic competitors. Hatch-Waxman balanced these two competing objectives by seeking to encourage competition from generic pharmaceuticals while maintaining the brand industry incentives to invest in the development of innovative drugs.

In formalizing the generic pharmaceutical approval process, Hatch-Waxman has provided American consumers and taxpayers with multi-billion dollars of savings in health care costs. According to a 1998 Congressional Budget Office study, the substitution of generic pharmaceuticals for off-patent brand counterparts has generated annual savings in excess of $8-10 billion. Fifteen years after Hatch-Waxman was signed into law, generic pharmaceuticals account for approximately 42% of all prescriptions dispensed, while totaling less than a dime of every dollar spent by American consumers and health care payers for prescriptions.

Opportunities to Extend the Consumer Benefits of Hatch-Waxman

Given the financial benefits and the increased access to affordable health care that have resulted from Hatch-Waxman, the National Pharmaceutical Alliance (NPA), the generic industry's largest trade organization, strongly encourages Congress to preserve the fundamental provisions of the Act while simultaneously expanding the benefits of this landmark consumer legislation.

NPA encourages Congress to consider amendments to Title 21 and Title 35 of the U.S. Code, in order to clarify and strengthen the Act to provide consumers with an expanded market of safe, effective and affordable pharmaceuticals.

- Establish penalties for filing frivolous patent litigation and protect the Bolar Amendment.

- Clarify Title 21 to permit scientifically advanced testing avenues for FDA-regulated drug and biologic products; clarify the 180 day exclusivity provisions to eliminate the confusion that has occurred due to inconsistent agency and court decisions, and facilitate consumers' early access to generics; eliminate the listing of irrelevant patents in the Orange Book; and create a "Grey Book" for related patents.

- Expand both Title 21 and Title 35, to require parties alleging patent infringement in response to a Paragraph IV certification to make an affirmative showing of the merits of the suit, and to eliminate the 30 month stay against generic drug approvals when parties allege patent infringement.

HATCH-WAXMAN ACT HAS CREATED SIGNIFICANT CONSUMER BENEFITS

Since being signed into law in September 1984, the Hatch-Waxman Act has provided American consumers and taxpayers with multi-billion dollars of savings in health care costs. A delicate compromise, the Hatch-Waxman Act has generated significant savings while both the brand pharmaceutical and generic pharmaceutical industry have grown steadily and enjoyed profit growth.

- According to a 1998 Congressional Budget Office Report, availability of generic medicines saved consumers $8-10 billion in 1994 alone.

- The ten leading brand pharmaceutical companies had an operating profit of more than $25 billion in 1998, according to *Fortune* Magazine.

- Generic drug sales to drug stores and hospitals have grown from $3.6 billion in 1991 to an estimated $9.2 billion in 1998.

Despite brand industry arguments to the contrary, the Hatch-Waxman Act has been successful in generating extraordinary health care cost savings while protecting brand product patent life and encouraging brand company investment in new product innovation.

- "Under the Hatch-Waxman Act, drugs that contain a new chemical entity never before approved by the FDA can qualify for an extension of their patent term. Fifty-one drugs approved between 1992 and 1995 received an extension." (CBO Report, 1998)

- "Between 1983 and 1995, investment in R&D as a percentage of pharmaceutical sales by brand-name drug companies increased from 14.7 percent to 19.4 percent. Over the same period, U.S. pharmaceutical sales by those companies rose from $17 billion to $57 billion (in current dollars). Overall, then, the changes that have occurred since 1984 appear to be favoring investment in drug development." (CBO Report, 1998)

The 1984 Hatch-Waxman Act has overwhelmingly achieved its objective of dramatically increasing consumer access to more affordable pharmaceutical products while simultaneously preserving the financial incentives for brand name drug companies to invest in the research and development of new medicines.

Any debate regarding amending this milestone legislation must be prefaced by a complete recognition of the importance of maintaining the competitive and free market balance that has generated these billion dollar savings. In the 15 years since passage of this landmark legislation, the GATT implementation legislation and the FDA Modernization Act of 1997 have provided windfall patent extensions for a number of brand products beyond those extensions guaranteed by Hatch-Waxman. Legislation that amends the Hatch-Waxman Act must not be similarly "captured" by the brand industry.

NPA believes that Congress has the opportunity to strengthen the Act and enhance the consumer benefits it provides by amending Title 21 and Title 35 of the U.S. Code. Under these amendments, NPA urges Congress to proceed along two tracks:

1. Clarify sections of the Act, and

2. Strengthen the purpose of the Act.

Clarify the Act

NPA proposes four potential areas of consideration where Congress can clarify sections of the Act that would lead to enhanced consumer benefits. These include:

- Codify the regulatory definitions of bioavailability and bioequivalence to facilitate FDA's ability to use new scientific methods to approve Abbreviated New Drug Applications for a variety of drug products for which advanced testing must be utilized;

- Protect the Bolar Amendment to ensure timely introduction of generic competition upon patent expiry; and

- Clarify that biologics can be approved through a generic drug application;

- Clarify the 180-day Exclusivity Provisions related to brand product patent challenges.

Strengthen the Act

To strengthen the purpose of Hatch-Waxman, NPA proposes that Congress consider action to:

- Penalize companies that initiate frivolous patent litigation; and

- Eliminate the abuse of patent listing provisions.

OPPORTUNITIES TO CLARIFY THE HATCH-WAXMAN ACT

Codify the Regulatory Definitions of Bioequivalence

FDA's regulations permit a variety of types of scientific testing to be performed in order to demonstrate that one drug is bioequivalent to another. 21 C.F.R. part 320. This flexibility is essential for the pharmaceutical industry to benefit from advances in technology in the scientific field. Despite these regulations, the brand drug industry often asserts that the bioequivalence testing performed by generic drug manufacturers is either inadequate or impermissible under the statutory scheme.

In order to strengthen FDA's authority in this area, Congress should codify the regulatory definitions of bioavailability and bioequivalence. In turn, the codification would facilitate FDA's use of multiple, scientifically reliable methods to assess the comparability between drug products. This codification is particularly important to facilitate the approval of ANDAs for topical products, ophthalmic products, and other non-systemic pharmaceutical products for which specific types of advanced testing must be performed.

Protect the Bolar Amendment

The Hatch-Waxman Act contains a provision which specifically permits drug manufacturers to "make, use, or sell a patented invention solely for uses reasonably related to the development and submission" of drug applications. 35 U.S.C. § 271(c). This provision is commonly referred to as the "Bolar Amendment". In simple terms, the Bolar Amendment permits generic drug makers to conduct non-commercial research and development activities during a drug's patent period so that they can submit a drug application to FDA for review. Although in most cases FDA can begin to review the generic drug application during the brand drug's patent period, FDA cannot approve the application until the patent period has expired. Thus, the Bolar Amendment merely enables generic drug makers to develop their generic product and get it ready for marketing, pending the patent expiry of the brand drug. Consumers benefit through timely access to those generic products that are approved by FDA on the date of patent expiration of the innovator product.

Bolar-type laws have been attacked in such countries as Canada and Israel. If the U.S. Bolar Amendment were repealed, generic drug makers would be precluded from conducting any research or development until the applicable brand drug patent had completely expired. Assuming that the generic development period includes one year for product development and testing, and two years for FDA review,[1] brand drug manufacturers would receive a de facto extension of three years of product monopoly for every drug currently covered by a patent. Elimination of the Bolar

[1] FDA's median approval time was 18 months in 1998, according to Douglas L. Sporn, Director of FDA's Office of Generic Drugs (data provided during speech to the NAPM 1999 Annual Meeting on February 3, 1999).

Amendment would lead to a multi-million dollar increase in health care costs for American citizens and government health programs by delaying the availability of generic drugs.

NPA maintains that the Bolar Amendment should not be changed in any way that would limit its applicability to testing and other activities necessary for the filing and approval of generic drug applications.

Clarify the Biological Products Approval Process

Presently under the statutory scheme, drugs that are considered to be "biologics" are regulated by FDA under the Public Health Services Act (PHSA), while other drugs (including some that are biologically derived) are regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA). In order to limit competition in the biologics market, the brand industry has argued that the Hatch-Waxman Act does not apply to drugs regulated under PHSA.

Section 123 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) clarified that the provisions of the FFDCA apply equally to both drugs and biologics. FDAMA also directed FDA to harmonize its procedures for approving drugs and biologics and minimize the differences between the two approval avenues. The plain language of FDAMA declares that biologic products are eligible for approval under Section 505 of the FFDCA, including Section 505(j) (which created the abbreviated new drug application). Thus, the FDA must permit generic applications to be filed for biologic products.

However, the brand industry continues to assert that biologics must be treated differently from other drugs and are not eligible for generic approval. To clarify its intent under FDAMA, NPA encourages Congress to add statutory language now to confirm that the Hatch-Waxman Act applies to products regulated under Section 351 of the PHSA.

Scientific technology has grown exponentially since 1984 when the Hatch Waxman Act formalized the avenue for generic drug approvals. Today, scientific technology is capable of fully characterizing the naturally occurring constituents in biologic products. Presently, there is no reason why bioequivalence studies cannot be developed to appropriately test generic biologicals. For these reasons, Congress should clarify that biologics can be approved through a generic drug application.

Clarify the 180 Day Exclusivity Provisions

According to the Hatch Waxman Act, FDA is to award 180 days of market exclusivity to the first company that seeks to market a generic drug product and, in so doing, challenges the scope or validity of an existing patent covering the brand drug product. Numerous administrative challenges and court cases have ensued over the statutory provision itself and over how FDA has interpreted it. Given the confusion that has generated from these inconsistent decisions, Congress should clarify the meaning of the 180 day exclusivity provisions to facilitate early access to generic products for American consumers.

OPPORTUNITIES TO STRENGTHEN THE PURPOSE OF THE HATCH-WAXMAN ACT

Penalize Those Who Initiate Frivolous Patent Litigation

The Hatch-Waxman Act provides that a drug maker must certify, if applicable, that its drug application does not infringe the patent(s) of a brand drug (or that the patent is invalid), and must provide notice of the certification to the patent owner and the NDA holder. 21 U.S.C. §§ 355(c)(2), (j)(2)(B). Once this "Paragraph IV" certification is made, the patent owner and NDA holder have 45 days to sue the manufacturer for patent infringement. If a suit is commenced, a 30-month stay occurs, during which time FDA cannot approve the generic drug application unless the court finds in favor of the generic manufacturer. 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B).

Eliminate the 30-month stay provision. This 30 month stay is no longer appropriate and should be eliminated from the Act. During the Hatch-Waxman negotiations, it was argued that a 30-month stay would give the courts time to work through the patent issues without harming the generic applicant, since FDA's generic drug approval times were at least 30 months long in 1984. Now, however, due to internal efficiencies adopted by FDA's Office of Generic Drugs, generic drug approval times have dropped to a median of 18 months. Given this decrease, the 30-month stay is now punitive, blocking generic drug approvals well beyond current agency review times.

The 30-month stay provides an undeserved windfall to the brand drug manufacturer by prolonging its protected market. Moreover, the 30-month stay is unnecessary because any injury incurred by the patent holder from marketing the generic during the litigation period is more appropriately addressed through monetary damages arising out of the litigation itself. The elimination of the 30-month stay also would support a more appropriate balance between the two possible outcomes of the suit, i.e., the generic company will pay damages if the brand company prevails in the litigation.

In fact, the generic industry is aware of a number of instances where brand companies initiate frivolous patent lawsuits for the express purpose of gaining the 30-month stay while posing implausible patent infringement arguments. The abuse of this provision grants an unjustified "safe harbor" to brand drugs that disserves consumers by denying them product choice as well as the benefits of price competition intended by Hatch-Waxman.

Affirmative showing of merit. NPA maintains that brand drug patent litigation initiated in response to a Paragraph IV certification should be governed by the same standards as all other patent litigation filed under Title 35. Specifically, a party alleging a patent infringement under Sections 505(c)(3) and 505(j)(2) would be required to post a bond, show cause that the claim has a likelihood of success, and follow all other Title 35 requirements.

Penalty for frivolous litigation. A penalty clause should be added to the statute that provides for the recovery of treble damages based on projected lost profits by the generic drug manufacturer, as well as attorneys' fees and court costs, if the NDA holder or patent owner files an infringement action that is later determined by the court to be frivolous.

Eliminate the Abuse of Patent Listing Provisions

The generic industry has been concerned for some time about the brand industry's abuse of patent listings in the Orange Book (FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*). The Hatch-Waxman Act requires that FDA compile the Orange Book, and that NDA applicants submit patent information to FDA for inclusion in the Orange Book. 21 U.S.C. §§ 355(b)(1), (j)(7)(A). FDA may not approve a generic drug application until the listed patent terms have expired. For generic applicants, the listing of patents in the Orange Book triggers the Paragraph IV certification requirement discussed above. Thus, whenever an NDA holder has a patent listed in the Orange Book, the NDA holder is eligible to exercise the statutory 30-month stay against generic competition, thereby extending its product monopoly.

With such a lengthy monopoly period at stake, it is no surprise that NDA applicants submit patent information to FDA that is only tangentially related to the drug at issue. In so doing, the brand companies once again deny consumers the intended benefits of Hatch-Waxman – incentives for expanded product choices and price competition. Presently, the statute does not provide FDA with clear authority to refuse to list these unrelated patents. NPA recommends three statutory changes to prevent the Orange Book listing of irrelevant patents.

Limit patents eligible for listing in the Orange Book. Congress should enhance the Act's patent listing and protection provisions to limit listings to patents that claim a new active molecule(s) of a pharmaceutical product. Only those new molecule patents would require a Paragraph IV or other patent certification. Furthermore, if eligible patents are submitted to FDA later than 30 days after the date the patents are issued, as required by Section 505(c)(2) of the Act, generic drug applicants would be excused from making the patent certification.

Develop a "Grey Book" for patents that are merely related to the drug product. In addition, Congress should require that all NDA holders list all other patents related to a new drug product, including the use of the drug product or the method of manufacturing the drug product, in a new book to be compiled by FDA called the "Grey Book." Patents listed in the Grey Book would not require patent certification by generic drug applicants.

Provide administrative relief for improperly listed patents. Congress should authorize FDA, with assistance from the Patent and Trademark Office, to identify and remove improperly listed patents from the Orange Book. As a penalty for submitting improper patents to FDA, the patent holder and NDA applicant should lose the right to enforce the patent against a generic drug applicant.

Hatch-Waxman intended to balance the rights of the drug product patent holder against the rights of generic manufacturers to enter the market with competing products upon patent expiry. The beneficiaries of the Act were to be American consumers. Over the past 15 years, consumers have reaped the benefits of timely access to safe and effective generic drug products, expanded product choices, and price competition. Yet, the brand industry has undermined the law and subverted its original intent to protect their profit margins. Congress should restore the legislative balance and strengthen the rights of consumers to have a fair and competitive market for pharmaceutical products.

United States Senate

WASHINGTON, DC 20510

July 29, 1999

The Honorable Bill Clinton
The President
The White House
Washington, D.C. 20500

Dear Mr. President:

We write to ask your help in safeguarding our nation's Medicare and Social Security programs. We urge you to veto any tax bill this year that fails to allocate all of the off-budget surplus for Social Security, and one-third of the on-budget surplus to extend the solvency of Medicare and provide its beneficiaries with affordable prescription drug coverage.

Since 1965, Medicare has helped reduce poverty rates among senior citizens from 30 percent to 10 percent. Still, Americans over the age of 65 spend an estimated 19 percent of their income on health care costs, and three-quarters lack meaningful prescription drug coverage. Remarkably, one-third of recipients rely on Social Security for virtually all of their income.

With Medicare set to become insolvent in 15 years, and with the number of America's seniors projected to double in 30 years, we must take advantage of our unprecedented economic prosperity and ensure the integrity of these programs.

We applaud your continued leadership, and look forward to working with you to protect Social Security and Medicare for America's senior citizens.

Sincerely,