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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Lorraine Lewis to Frank W. Hunger Re: FEHB and Suits Against the Tobacco Industry (3 pages)	10/16/98	P5

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Subject File)
OA/Box Number: 23758

FOLDER TITLE:

Qualified Medicare Beneficiary

gf150

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

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RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Medicare OMB ALP

**Social Security Administration
Qualified Medicare Beneficiary Outreach Proposal**

This paper proposes an SSA outreach demonstration for \$5 million in fiscal year (FY) 1999 to promote Medicare buy-in programs targeted to elderly and disabled individuals who are eligible for these programs, but have not enrolled.

A buy-in outreach demonstration would measure the impact of increasing the amount of public information about the existence of buy-in programs and reducing public resistance to filing because of obstacles identified in the most recent study published by Families USA.

SSA is proposing three model demonstrations each of which would be conducted in five communities, for a total of 15 communities in participating States' targeted areas. Federal Register notices would invite public comment and invite states to participate. The models are:

- 1. Publicity** - Measuring the increase in welfare office buy-in participation because of a marked increase in public information including local public service radio and print announcements targeted to this population and a targeted mailing, using data available through SSA databases, to elderly and disabled residents in these areas on SSA letterhead paper. The mailing would include a local or toll-free telephone information number.
- 2. Referrals** - Measuring increases in buy-in participation resulting from mailings that invite the beneficiary to call a toll-free number or make an appointment with the local SSA office to assess potential eligibility, or to file an application with the local welfare office. SSA will facilitate application appointments with the local welfare office and follow up on referrals with the welfare office.
- 3. Co-location** - Measuring increases in buy-in participation in response to mailings and SSA referrals of applicants to a welfare worker outstationed in SSA offices to take applications for buy-in.

An independent contractor will consult on the design and evaluate the demonstration. Application referrals set up by SSA that do not result in buy-in applications will be evaluated to determine the reason that these outreach efforts did not result in an application.

This project will need to be financed with an additional \$5 million added to SSA's research and demonstration funding request for FY 1999. Congress would need to appropriate the requisite funding for this account and include appropriations language specifically authorizing the Commissioner to take an active role under section 1110a of the Social Security Act when performing a demonstration relating to Titles XVIII and XIX.

PRESIDENT CLINTON RELEASES NEW DIETARY GUIDELINES

New Guidelines Designed to Help Americans Eat Healthier

May 27, 2000

Today, in his weekly radio address, President Clinton will kick off the first National Nutrition Summit in over three decades with the release the Fifth Edition of the Dietary Guidelines for Americans, providing easily understood, science-based information to help Americans choose diets that promote good health. The President will also announce that this summer, the Department of Agriculture will propose to require nutrition labels on meat and poultry products in order to provide consumers with important information on fat, calorie, and protein content. The new version of the guidelines and the proposed rule are designed to provide sound, easy-to-understand advice to help consumers build healthy diets for themselves and their families. These proposals build on the Clinton-Gore Administration's longstanding commitment to improve the nation's nutritional health.

MILLIONS OF AMERICANS NEED TO IMPROVE THEIR DIETS. While studies indicate that Americans are eating better now than they were in the late 1980s, tens of millions of Americans have poor diets and are overweight. Specific concerns include:

- **One in three non-elderly adults are now overweight.** Fifty-eight million American adults ages 20 through 74 are overweight, and the number of overweight Americans increased from 25 to 33 percent between 1980 and 1991.
- **One in five children are at risk of being overweight.** Ten percent of children are overweight or obese. The number of overweight children has doubled over the past 15 years, and 70 percent of overweight children aged 10 to 13 will be overweight and obese adults. Most of this increase has taken place in recent years; 10 percent of children, 4 to 5 years of age, were overweight in 1988 through 1994, compared with 5.8 percent in 1971 through 1974. Recent studies indicate that this trend is associated with low levels of physical activity rather than increased food consumption.
- **Obesity is linked to an increased incidence of chronic disease.** Obesity is a risk factor for diseases such as coronary heart disease, certain types of cancer, stroke, and diabetes. Over \$68 billion is spent each year on the direct health care costs related to obesity, representing 6 percent of the nation's health care expenditures in 1999.
- **Almost 90 percent of Americans have diets that need improvement.** The Healthy Eating Index shows that 88 percent of Americans have diets that are poor or need improvement. Only 26 percent of people meet the daily dietary recommendation for dairy products, and less than 20 percent meet the daily recommendation for fruits. In particular, teenagers, and people with low incomes tend to have lower quality diets.

- **Many illnesses can be prevented or mediated through regular physical activity.** Regular physical activity reduces the risk of developing some of the leading causes of illness and death in the United States, including heart disease, high blood pressure, colon cancer, and diabetes. Physical activity has been demonstrated to reduce blood pressure and symptoms of anxiety and depression while maintaining healthy bones, muscles, and joints. More than 60 percent of adults do not engage in the recommended amount of physical activity, and approximately 25 percent of adults are not physically active at all.

PRESIDENT CLINTON ANNOUNCES MAJOR NEW ACTIONS TO HELP

AMERICANS EAT HEALTHIER. Today, President Clinton will kick-off the first Nutrition Summit in three decades and announce new actions to assist Americans in improving their diets and overall health. Today, the President will:

- **Announce the first national Nutrition Summit in 30 years.** To address the new nutritional challenges facing the country, experts from around the country will meet next week in Washington, D.C. for the first national Nutrition summit in three decades. This summit, sponsored by the Departments of Agriculture and Health and Human Services, will explore issues related to the continuing problem of hunger; the dramatic increase in overweight and obese Americans; and the role of nutrition and physical activity in health promotion and chronic disease prevention.
- **Release the Fifth Edition of the Dietary Guidelines.** Revised every five years, these guidelines are the cornerstone of national nutrition policy and are used to determine the content of School Lunch and other Federal nutrition programs, placing the latest science in an easy-to-understand format for American consumers. In addition to more strongly emphasizing the need to eat whole grain foods, the latest version of the guidelines:
 - Includes a new recommendation that both children and adults make physical activity a regular part of their routine. The new guidelines recommend that both adults and children get at least 30 minutes of physical activity daily in order to lower risk factors for heart disease, colon cancer, and diabetes.
 - Contains new guidance on how to keep food safe. Because eating even a small portion of an unsafe food can make people sick, the new guidelines emphasize preparing and storing food to help protect families from foodborne illnesses. Extra emphasis is placed on caring for perishable foods that require special care, such as eggs, meats, poultry, fish, shellfish, and milk products.
- **Announce USDA's plans to require nutrition labeling for meat and poultry products, including all ground or chopped meat.** To provide consumers with additional information to help them make more informed food choices, the Department of Agriculture will propose this Summer to require nutrition labeling for meat and poultry. Retailers would be required to provide nutrition information through product labels or at the point of purchase by posting signs or making information readily available in brochures or leaflets. The required would include information on fat, calories and cholesterol content. Providing such information currently is voluntary, but fewer than 60 percent of retailers last year did so.

CLINTON-GORE ADMINISTRATION HAS A LONGSTANDING COMMITMENT TO IMPROVING NUTRITION. The Clinton-Gore Administration has implemented several new initiatives to improve the nutritional health of Americans, including: increasing enrollment in Women Infants and Children (WIC) from 5.4 million per month in 1993 to 7.3 million per month in 1999, which provides nutritious foods, nutrition education, and access to health care to low-income pregnant women, new mothers, and infants and children at nutritional risk; the creation of the After School Snacks Program, which provides children with healthy meals in the critical hours after the end of the school day; and the release of the Food Guide Pyramid for young children, providing a nutritional roadmap for children between the ages of two and six.

Dietary Supplements File

DIETARY SUPPLEMENTS AND FTC UPDATE:

The Dietary Supplement and Health Education Act (DSHEA) of 1994 permits manufacturers to claim that a product promotes a healthy body state (strong bones, good vision, healthy digestion) without having to clear that statement through the FDA. However, the manufacturer is still required to compile information to substantiate that claim. FTC released a business guide for the dietary supplement industry today in order to resolve uncertainty about the interaction of the FTC advertising policy and the DSHEA regulations. They did not release any new policy in this guide; it is simply a restatement of current FTC policies and regulations. It was initiated in response to industry questions and developed with their input. Consumer concern was not the impetus for the development of this document. FDA was consulted on a staff level, and the policies of the two agencies are consistent on this issue. The FTC staff contact is Michelle Rusk, who can be reached at 202 326 3148.

Attached is the
press release.

I have the actual
guide if you want it.

Deborah.

~~Handwritten notes:~~
Handwritten: *Handwritten/George file*

THE WHITE HOUSE
WASHINGTON

November 24, 1998

MEMORANDUM TO THE FIRST LADY

FROM: Chris Jennings, Jennifer Klein, Jeanne Lambrew
SUBJECT: Response to Questions about Coverage Expansions
cc: Melanne Verveer, Neera Tanden, Nicole Rabner

In a recent discussion of the uninsured, you asked about several coverage expansion proposals, including a 55 to 65 coverage option, a Medicaid buy-in, a Federal Employees Health Benefit Plan (FEHBP) buy-in, and a new health insurance option for young adults. This memo summarizes these proposals, discusses their rationale, and provides you with a budget and Congressional status update. As was discussed in the memo to the President on the uninsured, the absence of substantial subsidies and the omission of an individual or employer mandate significantly limits the number of Americans who will be newly insured as a result of these policies. Having said this, each of these options (or modifications to them) can improve access to needed health insurance and are being considered for the FY2000 budget.

Medicare Buy-In / Health Insurance Options for People Ages 55 to 65

Policy. In our FY 1999 budget, we proposed three policies: (1) a Medicare buy-in for people ages 62 to 65 that is fully self-financed through an unsubsidized, two-part premium (an up-front premium plus a smaller, post-65 premium to compensate for any risk selection); (2) a similar Medicare buy-in for displaced workers ages 55 and over who have involuntarily lost their jobs and health care coverage; and (3) guaranteed access to former employers' insurance for retirees age 55 and over whose retiree health benefits have been ended. According to CBO, this entire initiative costs about \$1.5 billion over 5 years (mostly a temporary cost until the participants begin contributing their post-65 premium) and would assist about 300,000 people.

Rationale. This initiative, according to the latest data, is needed more than ever. Although still low, the number of uninsured people ages 55 to 65 grew the fastest in 1997 -- and will grow exponentially in the future since the number of people in this age cohort is projected to rise by over 60 percent by 2010. Moreover, we have increasing evidence that the individual insurance market -- relied on by this age group more than any other -- is raising its rates dramatically. Kaiser Permanente, for example, will double its individual insurance premiums for its older enrollees on January 1. This initiative gives people in this age group options to purchase insurance that they might not otherwise have. It also would be the bare minimum policy needed if the age eligibility for Medicare were raised -- an idea seriously being contemplated by the Medicare Commission.

Issues. Despite the need, this initiative was victimized by conflicting "too much - too little" criticisms. Republicans (and some conservative Democrats) claimed that the buy-in creates a huge loophole in Medicare that will ultimately lead to large costs. In part, this reflects a disbelief in our technical ability to set premiums that are self-financing in the long run. But mostly, it results from a strong belief that, even if the premium estimates are accurate, we will eventually succumb to the pressure to subsidize these premiums to make them more affordable for the lower income uninsured. In contrast, a number of traditionally liberal advocates and academics criticized the policy for helping too few people to justify the political capital that would be necessary to expend to get the proposal any serious attention by the Republican Congress.

Regardless of its political viability in this Congress, this proposal addresses a population in need, remains generally popular outside the beltway, and will continue to be seriously considered for inclusion in the FY 2000 budget. It is unclear whether it will make the final cut, however. The short-term savings needed to finance this initiative are controversial and/or likely to be used for other priorities (such as for underwriting the costs of the Jeffords/Kennedy disability coverage expansion bill). Also, there is concern about putting this proposal out so close to the final report released by the Medicare Commission this March. No matter how we resolve the budget question, however, we expect Senators Moynihan and Daschle as well as Congressman Gephardt to introduce this bill at the beginning of the next Congress.

Medicaid Buy-In

Policy. A Medicaid buy-in would allow states to charge income-related premiums for people in optional eligibility groups with income above 150 percent of poverty (the level at which states may charge cost sharing under the Children's Health Insurance Program (CHIP)). This proposal could be broadened to allow all people below a fixed income level -- not just those in current optional eligibility groups -- to buy into Medicaid.

Currently, states cannot charge premiums to Medicaid beneficiaries. A lesser known fact is that Medicaid law limits who can be covered as well. Historically, adults were eligible for Medicaid only if they were: (a) single parents, or married but unemployed parents, who receive welfare; (b) low-income elderly or people with disabilities who receive SSI; or (c) nursing home residents. During this Administration, however, new Medicaid eligibility options have been created. Welfare reform gave states the option to cover higher income single parents and unemployed married parents. The exclusion of married employed parents -- which is anti-work and anti-family -- was changed last summer with "100-hour rule" regulation. This lets states define "unemployed" as working more than 100 hours a month -- meaning that they may cover parents working 40-hour weeks if they so choose. And, in the Balanced Budget Act, we created a Medicaid buy-in for people with disabilities with incomes below 250 percent of poverty.

Rationale. A Medicaid buy-in could be an incentive for states to expand coverage to working adults, since even small family contributions improve the acceptance of such expansions. It also gives all states the flexibility that we have permitted through Medicaid waivers and supported in CHIP, as well as in the Medicaid buy-in for workers with disabilities.

Issues. Despite its sound policy basis, the likelihood that a Medicaid buy-in will significantly reduce the uninsured is low. Since large subsidies are required to encourage low-income, uninsured people to purchase health insurance, states would have to charge the families low premiums and pay for most of the costs themselves in order to get meaningful participation. Moreover, only states that have already expanded coverage to 150 percent of poverty could charge premiums to all new participants. Unfortunately, states typically cover few adults with incomes above 50 percent of poverty. Thus, premiums collected through a Medicaid buy-in would not come close to offsetting the large Federal and state costs. Additionally, while allowing premium payments from beneficiaries may be attractive to states, Republicans, and moderate Democrats, it would be vehemently opposed by advocates and liberal Democrats who believe that this opens the door to high premiums for lower-income Medicaid beneficiaries.

One idea that could possibly address the financial limitations of this proposal is to link the Medicaid buy-in proposal to a tobacco recoupment bill. The recent state tobacco settlement will likely lead to legislation about whether and under what terms states may keep the Federal share of that settlement. In such legislation, we could make expansion through a Medicaid buy-in one of the uses (or the sole use) of the Federal share. Congressional Democrats and advocates have long argued that tobacco settlements should be directly linked to health care, health insurance expansions, and Medicaid. It is possible they would accept a buy-in in a recoupment bill that assures Medicaid expansions. States, obviously, do not want any strings on the uses of the Federal share of the settlement, but may have the hardest time arguing against Medicaid investments since the settlement itself is premised on Medicaid costs resulting from tobacco use. The clear downside to this option is that money spent on expansions would limit the money used for other priorities like child care. This issue will be debated in our budget process.

FEHBP Buy-In

Policy. Another proposal for expanding coverage is opening up the Federal Employees Health Benefits Plan (FEHBP) to various groups of people (e.g., workers in small businesses, people ages 55 to 65 years old). In order to participate in FEHBP, health plans would have to offer health insurance to the designated group of eligibles. There are two options for how premiums would be set: first, new participants could be charged the same premiums as Federal employees; second, new participants could be charged premiums separately, depending on their own costs.

Rationale. The FEHBP buy-in would give certain groups of uninsured people the benefit of accessing the health plan options, information and possibly premiums that Federal government negotiates for its employees. It also reinforces our support for group health insurance purchasing, plan choices, and adequate information with which to make such choices.

Issues. Depending on how premiums are set, the FEHBP buy-in would either be costly to new participants or affect the premiums and choices of all Federal employees. Because newly eligible people who wish to purchase insurance who are healthy can likely find individual insurance that is cheaper, the population that decides to go into FEHBP is likely to be sicker. This will increase premiums of all current Federal employees if they are charged the same premium. It could also reduce plans participating in FEHBP if their enrollees include more costly, new participants than

Federal employees (which could happen in rural areas). As a consequence, most FEBHP buy-in proposals assume a risk pool separate from that of Federal employees for setting premiums. But because this pool would be a smaller and include less healthy people, premiums would be more expensive than FEHBP. As a consequence, most analysts project a relatively small effect on coverage. The only way to address this would be subsidies which carry significant cost implications. These complexities explain why there have been few FEHBP buy-in bills.

Given concerns about its use as a source of coverage, FEHBP may be better used as a model for other coverage expansion proposals. What makes FEHBP successful -- purchasing power for a large group of people; consumer information; plan choices -- could be incorporated into small businesses purchasing coalitions. These coalitions, promoted in previous budgets, provide any small business in the area with a set of plan choices and more affordable premiums. This year, we are examining options to aggressively encourage their development. For example, FEHBP managers could provide technical assistance in establishing these coalitions. They could also be granted non-profit status to facilitate private foundation support.

Catastrophic Coverage for Young Adults

Proposal. You mentioned an interest in policy options that would provide catastrophic coverage for young adults. Medicare, Medicaid, and FEHBP all provide comprehensive coverage, although we could conceivably develop a special program for catastrophic coverage. It is also possible through regulation to require individual insurers to offer such coverage to young adults.

Rationale. Young adults are more likely than any other age group to be uninsured -- nearly one in three 18 to 24 year olds lacks insurance. In part, this problem results because young adults are usually healthy and do not think that their need justifies the cost of comprehensive coverage. Thus, catastrophic coverage may be the best option for young adults since it is cheaper and protects them from the real risk of illness or injury that can be financially devastating.

Issues. Catastrophic coverage options probably would not insure many young adults. Few young adults would purchase even the lowest-cost catastrophic coverage without significant subsidies. In fact, some analysts believe that only an individual mandate will make young adults pay any level of premium for health insurance. This is because they rarely recognize their financial risk (e.g., one in four young adults sustains major injuries in a year and one in 20 is hospitalized). Second, while catastrophic coverage makes economic sense, people interested in insurance do not appear to like it. The lack of interest in the medical savings account (MSA) demonstration has shown that people prefer lower cost sharing and coverage of primary care.

Recognizing these challenges, we continue to examine policies to allow young adults to buy into Medicaid. Some of the most needing of insurance in this age group are foster care children who have aged past their 18th birthday (and thus last year of Medicaid eligibility.) We are working with OMB to provide a new state option for those Governors interested in expanding Medicaid coverage to this population. We believe it will be affordable (about \$50 million over 5), sound policy that a number of states will pick up. As of this writing, the chances of this proposal being included in the budget appear to be quite good.

CLINTON LIBRARY
PHOTOCOPY

Untested Medicines

MOST OF THOSE who have noticed the sharp increase in people's use of "alternative medicine" and nonprescription dietary supplements think the trend has something to do with a changing health care system that patients increasingly find cold, inhospitable or overly "scientific." In recent days, though, authorities have moved toward making both alternative treatments and dietary supplements a legitimate part of the medical system rather than a flight from it. It's the right move.

The Journal of the American Medical Association devoted a special issue to scientific analysis of a range of popular alternative therapies, from shark cartilage to acupuncture, and found some of them met traditional standards for therapeutic effectiveness and others did not. The Federal Trade Commission, which regulates advertising for dietary supplements (just as the Food and Drug Administration regulates their labeling), then issued a 26-page "business guide for the dietary supplement industry" outlining what constitute lawful and unlawful health claims for these non-tested substances.

The common denominator here is the refusal to abandon solid standards of health and safety research simply because a remedy is tagged "non-Western" or "alternative." A whole body of stylish academic nonsense has

grown up around the notion that not merely the products of science but the value systems underlying Western science itself—testable hypotheses, repeatable experiments, objective data—are somehow suspect. That view, though by no means mainstream, makes it all too easy to confuse worries over particular high-tech drugs with an insistence that an herbal or otherwise low-tech remedy *must* be better, whether or not any data show so.

Some adherents of dietary supplements put up a tremendous fight three years ago at rules barring health claims on supplements that had not gone through the rigorous testing process for safety and efficacy. Followers of a technique called "therapeutic touching" were similarly outraged when the Wall Street Journal spotlighted a simple science fair experiment by a 9-year-old that suggested no difference between those who received the treatment and those who did not.

The JAMA issue on alternative treatments stressed that such studies are only the first step in a larger attempt to apply demanding research methods to treatments that fall outside most medical doctors' training or experience. For some doctors, too, the idea of studying these techniques required a stretch—toward the insight that the legitimacy of a treatment should come from its testable results, not its origin.

The Washington Post

FRIDAY, NOVEMBER 20, 1998



Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

For Release: November 18, 1998

Business Guide For Dietary Supplement Industry Released by FTC Staff

Guide Will Assist Industry In Ensuring Truthful Ads

The explosion of the dietary supplement market and changes in regulation have created uncertainty in the dietary supplement industry about how to abide by advertising law. To help ensure that advertising for dietary supplements is truthful and not misleading, staff of the Federal Trade Commission today released, "A Guide for the Dietary Supplement Industry." The plain-English guide describes the basic principles of the law and uses examples from the supplement industry to illustrate how those principles apply in practice.

According to the Business Guide, "[t]he dietary supplement industry [which includes vitamins, minerals, herbal products, hormones and amino acids] is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly."

"Consumer use of dietary supplements has increased dramatically in the last few years," said Jodie Bernstein, Director of the FTC's Bureau of Consumer Protection. "This Business Guide will go a long way to ensure that consumers are getting information that is truthful and adequately substantiated. Good players in the industry will have the guidance they need. Others will continue to face vigorous enforcement by the FTC."

The guide also should help to resolve uncertainty about the interaction of FTC advertising policy and the Food and Drug Administration's regulation of labeling under the Dietary Supplement and Health Education Act (DSHEA), staff noted. The FTC and FDA operate under a longstanding liaison agreement that divides the responsibilities between the two agencies. The FDA has primary responsibility for labeling and the FTC has primary responsibility for advertising claims. Because of their shared jurisdiction, the two agencies work together to ensure that their enforcement efforts are consistent. The passage of DSHEA in 1994 created a new approach to FDA regulation of the labeling of dietary supplements and now permits certain types of claims in labeling without prior FDA authorization. Although, as noted in the Guide, DSHEA does not directly apply to advertising claims, the requirement that claims be truthful, not misleading and substantiated is common to both labeling and advertising laws.

The Guide follows a year of outreach meetings by FTC staff with industry groups, consumer organizations and government offices to identify the specific areas of uncertainty and how best to address them. The Guide is a restatement of longstanding FTC policies and is not intended to signal any change in the agency's approach to dietary supplement advertising, the staff pointed out.

The basic axiom of FTC advertising principles, the Guides points out, is that "all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims." Staff also noted that the agency's approach to substantiation of supplement claims is a rigorous but also flexible one. The amount and type of support needed will depend greatly on consumers' expectations, based on the specific claim being made, how it is presented in the context of the entire ad and how it is qualified. In evaluating the adequacy of support for a claim, the Commission consults with experts in a wide variety of fields, including those with a background in botanicals and traditional medicines.

The Guide is divided into three main sections. The first two sections explain how the FTC

identifies the claims conveyed by an ad and how it evaluates the adequacy of the substantiation for those claims. The third section covers consumer testimonials, expert endorsements, and advertising claims based on historical or traditional use of supplements. It also addresses the relevance of certain specific provisions of DSHEA to advertising.

Bernstein and her staff underscored that the FTC will continue to maintain an active enforcement presence in the dietary supplement industry, giving priority to cases that present serious safety considerations or affect sick and vulnerable consumers. In the coming months, FTC staff will also be working with industry groups to encourage and support self-regulatory efforts. "I would like to see this industry use our Business Guide as a foundation for a broad-based and rigorous self-regulatory campaign against false and deceptive advertising. Industry has a critical stake here. Consumer trust in what they see and hear will determine the ultimate success or failure of the marketplace," said Bernstein.

The FTC also released a report on a research project conducted by the staff on a number of issues relating to how consumers interpret food and supplement advertising claims. Among the issues addressed in that report is how consumers interpret claims based on emerging science and what disclosures are effective in conveying the limitations of the scientific support for a claimed health benefit. "Supplement marketers will find this research instructive when attempting to craft claims that fairly and accurately describe the state of scientific knowledge on a particular product," said Bernstein. (*See News Release dated November 18 on Food Copy Test.*)

The Commission vote to approve release of the Business Guide was 4-0.

Copies of the **Business Guide** are available from the FTC's web site at <http://www.ftc.gov> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-FTC-HELP (202-382-4357); TDD for the hearing impaired 202-326-2502. To find out the latest news as it is announced, call the FTC NewsPhone recording at 202-326-2710.

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(FTC File No. 974506)
(dietary)

Sorry this took so long - Jeanne
had comments.

ELDERLY INITIATIVES

- **Providing a long-term care tax credit.** Long-term care costs account for nearly half of all out-of-pocket health expenditures for people over the age of 65. This proposal would give people who need long term care services or their caregivers a tax credit of up to \$1,000 to help pay for both the formal and informal costs that families incur when caring for their relative.
- **Creating a Family Caregiver Support program.** Families who have a relative who develops long-term care needs often do not know how to provide such care and where to turn for help. Through grants to local organizations, this proposal would provide information, counseling, training and respite services for family members caring for elderly relatives with physical or cognitive limitations.
- **Improving the quality of nursing homes and assisted living facilities.** Widespread or repeated violations of quality provisions that result in abuse and neglect of nursing home patients often go undetected by the Health Care Financing Administration. The initiative will strengthen efforts to ensure safe and adequate care for nursing home and assisted living residents.
- **Adopting private sector, competitive pricing strategies.** This proposal will give the Health Care Financing Administration the same tools to manage Medicare's costs that private sector plans use. This includes competitive pricing for services like durable medical equipment and other supplies; expanding the competitive pricing demonstration for managed care; and adopting new payment methodologies.
- **Reducing Medicare fraud and overpayment.** Medicare fraud poses a serious threat to its financial well-being. This proposal would reduce fraud and overpayment, including provisions that reduce overpayments for drugs and ensuring Medicare does not pay for claims that ought to be paid by private insurers.
- **Protecting beneficiaries from HMO withdrawals from Medicare.** This year, a number of HMOs have pulled out of Medicare with only a few months notice, leaving 50,000 beneficiaries with no plan options in their areas. This proposal would put safeguards in place that would prevent this happening in the future.
- **Providing prescription drug coverage for Medicare beneficiaries.** The lack of coverage for prescription drugs in Medicare may be its most glaring shortcoming. Virtually every private health plan for the under-65 population has a drug benefit, in recognition of the medical community's reliance on prescriptions for the provision of much of the care provided to Americans. Options include a means-tested Medicaid option, a managed care benefit only approach, a traditional benefit for all beneficiaries, and an unsubsidized purchasing mechanism that uses Medicare's size as leverage for drug discounts for beneficiaries.

- **Redesigning and increasing enrollment in Medicare's premium assistance program** Over 3 million low-income Medicare beneficiaries are eligible but do not receive Medicaid coverage of their Medicare premiums and cost sharing. This proposal would use Social Security Offices to educate beneficiaries about this program, reduce administrative complexity for states and give them financial incentives to engage in more aggressive outreach efforts.
- **Allowing people aged 55-65 to buy-in to the Medicare program.** The latest report shows that the numbers of uninsured aged 55 to 65 are growing faster than any other age group; by 2010, the number of uninsured people in this age group will nearly double. This proposal will allow a limited number of people ages 62 to 65 and displaced workers ages 55 to 65 to buy into Medicare.
- **Cancer clinical trials demonstration** Less than three percent of cancer patients participate in clinical trials. Moreover, Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. This proposed program would cover the patient care costs associated with certain high-quality clinical trials.

OTHER INITIATIVES

- **Transitional support services for foster children.** Each year approximately 17,000 foster children turn 18 and “age out” of the public child welfare system. Unfortunately, these children are not as prepared as children from intact families to face the challenges of adulthood. These young adults often experience unstable housing and homelessness, depression, poor health, violence and incarceration. This proposal would provide these children with medical and mental health services, education and/or vocational training, employment preparation and opportunities, transitional or supported housing, and the psycho-social support they need to achieve self-sufficiency.
- **Providing work incentives to people with disabilities.** Many people with disabilities do not work because doing so would make them ineligible for Medicaid and they would lose their health care coverage. This proposal would provide working people with disabilities new options for health coverage.
- **Tax credit for work-related impairment expenses for people with disabilities.** Almost 75 percent of people with significant disabilities are unemployed; for many, the high costs of support services/devices, as well as the potential to lose Medicaid or Medicare coverage, prevent them from seeking and keeping jobs. This proposal would give a tax credit of \$1,000 to people with disabilities who work, in recognition of their formal and informal costs associated with employment.
- **Small business purchasing cooperatives.** Over a quarter of workers in firms with fewer than 10 employees lack health insurance — almost twice the nationwide average. This results in large part because administrative costs are higher and small businesses pay more for the same benefits as larger firms. This initiative encourages the development of purchasing groups modeled on FEHBP by allowing them to be considered non-profits (which will facilitate private foundation support), providing Federal grant support, and having the Office of Personnel Management provide technical assistance.

DIETARY SUPPLEMENT UPDATE

You had asked me to look into the FDA's and the FTC's activity in this area, given all the recent press interest.

Background: The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines dietary supplements, places the responsibility for ensuring their safety on manufacturers, identifies how literature may be used in connection with sales, and provides for the establishment of regulation for good manufacturing practices. Under the current interpretation of DSHEA, dietary supplements can make structure and function claims but not disease claims. A product can claim to promote a health body state, but cannot claim to cure a disease or alleviate symptoms. Current regulations state that dietary supplements that expressly or implicitly claim to diagnose, prevent or cure a disease continue to be regarded as drugs and have to meet the safety and effectiveness standards for drugs.

FTC Business Guide: FTC released a business guide for the dietary supplement industry today in order to resolve uncertainty about the interaction of the FTC advertising policy and the DSHEA regulations. They did not release any new policy in this guide; it is simply a restatement of current FTC policies and regulations. It was initiated in response to industry questions and developed with their input. Consumer concern was not the impetus for the development of this document. FDA was consulted on a staff level, and the policies of the two agencies are consistent on this issue. The FTC staff contact is Michelle Rusk, who can be reached at 202 326 3148.

FDA Proposed Rule: The proposed rule widens the definition of disease. Currently, the law states that diseases are states that cause damage to an organ. The proposed definition is "any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms. For purposes of this definition, 'signs and symptoms' include laboratory or clinical measures that are characteristic of a disease, such as elevated cholesterol fraction, uric acid, blood sugar...and characteristic signs of disease, such as elevated blood pressure or intraocular pressure." Many of the product manufacturers feel the FDA has stepped beyond its statutory boundaries, although the AMA supports the definition change and would like to expand it to include states of health leading to deviation, impairment, or interruption. The FDA has received over 100,000 comments on the proposed rule.

see two press stories from today as well.

Supplements dodge regulation

OUR VIEW And consumers take the risk of unproven, untested products.

When is chicken soup not chicken soup? When there's money to be made by touting a faddish cold remedy among otherwise routine ingredients. Then it's an "herbal supplement," immune from regulation that keeps food safe.

When is margarine not margarine? When it's a hot new product from Europe that promises big profits from a cholesterol-panicked nation. Then it's called a "dietary supplement in food form" and may escape regulation as well.

These word games are among the latest efforts to exploit a hole in consumer protection laws. If a company can avoid calling a product a food or a drug, it can evade rules that bar unsubstantiated claims and unproven products.

The same exception lets makers of the muscle candy creatine peddle their product to teen athletes and body builders even though there's no safety assurance. As USA TODAY reported recently, win-crazed high school coaches are shamelessly recruited as creatine pushers.

In this neverland where no testing for safety or effectiveness is required, the booming diet supplement industry has tripled — from \$4 billion a year in 1990 to \$12 billion now. No wonder big names like McNeil Consumer Products, Lipton, Kellogg and Monsanto are looking for a piece of the action.

Hain, the country's largest natural-foods company, has a whole new line of soups with echinacea, St. John's wort and other allegedly medicinal herbs. McNeil is trying to market a spread laced with a pine tree fiber that supposedly kills cholesterol. In Finland, it sells for six times the price of ordinary margarine, and they can't keep it on the shelves.

Labeled as soups or margarine they'd be subject to the laws protecting the public from untested food additives. And they'd need scientific studies for health claims. An independent study published Thursday, for example, found that echinacea, at least outside chicken soup, apparently has little effect on colds. As "supplements," back-door health claims can be made without proof or safety testing.

Creatine exemplifies what can happen when word of mouth and hucksterism propel such an unregulated product. Thousands of athletes swear by it for strength and endurance. But it's also caused diarrhea, dehydration, muscle cramping and tearing — and been suspected of worse. Effect of long-term use: unknown.

Big names like football's John Elway and baseball's Brady Anderson endorse it. Home run champ Mark McGwire uses it, along with other more controversial supplements. But there's enough concern that at least 21 professional teams tell their players not to use it.

And the industry is notorious for lax controls. A study of ginseng supplements at Rochester Institute of Technology found some contained as much as 50% caffeine. An analysis of 10 St. John's wort products for the *Los Angeles Times* found one was an automatic overdose and three had half the claimed amount.

The last time the federal Food and Drug Administration tried to bring more consumer protection to this world of amateur medication, it lost big-time. The industry and its friends in Congress carved out an even wider exemption for its activities.

Folk-remedy soups, tree-fiber margarine and other products may be OK. But no one knows for sure — or what's coming next. Until Congress escapes industry control, consumers may play Russian roulette at the store.

They pose no risk to health

OPPOSING VIEW And they don't need any more government regulation.

By Michael Q. Ford

As the nation's largest trade association for manufacturers of dietary supplements, we naturally follow news about our industry with great interest. Whether it's the latest issue of the *Journal of the American Medical Association* supporting the effectiveness of certain herbal remedies, or a supplement-taking athlete breaking records, our products make headlines. With this attention has come greater scrutiny of dietary supplements resulting in questions about safety and a call for greater regulation. There are two faulty assumptions in this diagnosis: that dietary supplements are unsafe, and that more regulation is the cure.

► First, where is the evidence that supplements are unsafe? The Food and Drug Administration (FDA) has tracked adverse reactions to dietary supplements since 1993 and has a total of approximately 2,500 in its database.

Many of these reports are anecdotal and, by the FDA's admission, there is "no certainty that a reported adverse event can be attributed to a particular product or ingredient." With over 100 million Americans using supplements,

this number is minuscule by comparison.

► Second, does regulation equal safety? According to a study published in April by a leading medical journal, in a single year reactions to prescription medications caused more than 100,000 deaths and 2.2 million injuries. This statistic led USA TODAY to conclude that "too few consumer protections exist" in the way prescription drugs are "marketed, prescribed and monitored." Obviously the rigorous regulation prescription medications undergo has not prevented adverse drug reactions from becoming the fourth leading cause of death in this country.

It is probably not surprising that a trade organization would believe that the agency charged with its regulation — the FDA — does not need greater enforcement power over its members. However, it is also the opinion of Dr. Jane Henney, the recently appointed FDA commissioner. During confirmation hearings she was quoted as saying the current law "provides adequate statutory authority to protect the public health."

Dietary supplements have been and will continue to be a safe, well-regulated way for consumers to improve and maintain health.

Michael Q. Ford is executive director of the National Nutritional Foods Association.

Microsoft's best defense is a lack of a good remedy

By Larry Downes

How do lawyers learn to separate their own feelings about a case from what they know to be an impartial view of the law?

Earlier this month, while leading second- and third-year law students through the muck of the Microsoft antitrust case, I got a bird's-eye view of the process.

The discussion was part of a course on the frontiers of technology law that I teach at Northwestern University in Chicago. That subject frequently takes us to uncomfortable places. So far this semester, we've covered everything from the free speech rights of virtual pornography to jurisdiction for online gambling and the economics of junk e-mail.

But when it came to Bill Gates and company it was clear that something more was at stake. All of my students are Microsoft customers, and most of them feel an intense dislike for the company and its business practices. Learning to be lawyers, though, is in part about learning to keep such feelings to one side.

Here's how some of the students wrestled with the problem, both in class and on our online class discussion (which you can read — and answer — at www.killer-apps.com/lawtech):

Gayle Gorvett: "If antitrust violations were found every time a competitor was hurt in his or her market, then all competition would be banned. While Microsoft has gained a level of dominance in the computer industry that is mind-boggling, it should not be thwarted from innovating and improving its products because of it."

Avi Ionascu: "Microsoft uses other companies' dependence on Windows to give itself an advantage in the development of software unrelated to Windows. Rather than stimulating innovation, this hinders the development of software and forces competitors to abandon projects that Microsoft is in competition with."

Michael Stronach: "This is a case of what happens when thieves fall out. No one is innocent. It is the struggle of ferocious competition in a highly dynamic market. The press, lawyers and politicians paint this struggle as a terrible antitrust problem, but for Silicon Valley, it's just another day in paradise."

Marc Effron: "While some believe that the markets should rule and that antitrust law is unnecessary, I for one fear such an environment. There was a reason for breaking up the oil trusts and AT&T, and a good one at that. Don't get me wrong. I'm not calling for the breakup of Microsoft, but I do worry when one private entity builds up such a massive amount of power at an unchecked pace that it may impact the entire commercial world."

At the beginning of class I asked the students to vote on their view of the case: Five found Microsoft guilty of violating antitrust laws, four thought they were not guilty, and 11 said they didn't know enough to say

By the end of class, when we voted again, there were still five guilty votes, but now nine students found Microsoft not guilty.

Why the change? I suspect what turned the most votes was the problem of a remedy.

My students have seen many examples of how early regulation of new technologies — whether by legislators, bureaucrats, or as in this case by a single federal trial judge — always seems to do more harm than good. No one wants to repeat the tragedy of Judge Harold Greene trying to run the American telecommunications industry from his chambers, which he did for over 10 years after the AT&T case. And the Microsoft case is harder, because the very nature of its products mutates all the time. They don't call it software for nothing.

Even those who believe Microsoft guilty were hard-pressed to say how to solve the problem. We started by listing as many alternatives as we could think of, and then tried to assess honestly how well we thought each of them would work. At the extremes, we considered creating an administrative commission to oversee Microsoft's product development and marketing on an ongoing basis (this from Philip Tan, a graduate student from Amsterdam) or revoking Microsoft's copyrights and patents to make it easier for others to reverse-engineer and copy their products.

One student even proposed nationalizing the Windows operating system and running it as a public utility, like the electricity or water systems.

Some of the more traditional responses we weighed included breaking up the company into a division that creates operating systems and another that does applications, much as AT&T was separated into long distance and local companies. Less severe remedies included fining Microsoft heavily for what the court determines was unfair trade practice, and hope that this serves as a deterrent against future misbehavior. Another idea is simply to undo the contracts, licenses and design features of the current products that Netscape, Sun and other competitors are complaining about.

We even found precedent for a remedy of doing nothing; that is, for finding Microsoft guilty but recognizing that there was no court-administered solution that could solve the problem any better than letting the market try to work it out on its own.

Our analysis of even the more mainstream options was pretty sobering. Only a few students thought that separating the company into a group that does operating systems and another that does applications

was even possible, and those few agreed that the likely impact of doing so would be to raise prices for the former — hardly an improvement. Banning the offending practices also seems futile. After all, the government brought the current case precisely because it disagreed with Microsoft about whether the company was holding to the terms of a previous decree. And fines seem unlikely to have much impact on a company that today can, in some sense, print money just by issuing more stock.

Dan Marlo, a second-year student, wrote to me after class that "all the proposed remedies not only do not solve the problem but they exacerbate it and end up hurting consumers in the long run." That's why, Dan said, he changed his vote from undecided to not guilty.

I share his concern. The Supreme Court has famously said that antitrust protects competition, not competitors. So even if Judge Thomas Penfield Jackson finds that Microsoft has injured the information technology industry, his job will be to fix the industry, not satisfy Microsoft's enemies. In such a complicated case, the repair will require the skill of a neurosurgeon. And given the speed with which the new economy is developing, he'll be effectively operating in the dark, with primitive tools, on a patient who won't stay on the table.

The stakes are high, and the odds aren't good.

Larry Downes is Senior Lecturer at Northwestern University School of Law, a Fellow with Diamond Technology Partners, and co-author of *Unleashing the Killer App: Digital Strategies for Market Dominance*.

PATENTS

Policy Shift Opens Door for Medicinal Herbs

By TERESA RIORDAN

Three years ago, the U.S. Patent Office published new guidelines that loosened its standards for granting certain medically related patents.

The biotechnology sector, in particular, had sought such a change, complaining that the Food and Drug Administration should determine whether a potential drug was safe and effective. The Patent Office, it argued, should stick to deciding whether something was novel enough to deserve a patent.

Under old standards for granting so-called utility patents, the Patent Office took a critical view of medicinal claims, often refusing to issue a patent if the applicant could not prove a drug's usefulness. Biotechnology companies contended that without patent protection in the first place, they could not get financing for clinical testing to prove claims.

But biotechnology companies are not the only ones to benefit from the policy shift.

A recent, informal database search suggests that herbal entrepreneurs are forging ahead with patent applications that a few years ago the Patent Office would have turned down cold. Five years ago, only a handful of patents appear to have been granted for herbal preparations with medicinal purposes. So far in 1998, at least a dozen such patents have been issued.

"I'm a little bit amazed by some of these," said Colin Sandercock, a partner at the law firm of Foley & Lardner in Washington. "What you're seeing is the Patent Office taking the position that in light of the new guidelines, they are not going to challenge the efficacy of the claimed treatment."

Many of the new patents, Sandercock said, are very limited in scope, and might be easily and legally circumvented should they prove to be popular. "With the keen interest in vitamins and herbal remedies, many people are probably getting patents primarily for a marketing edge," he said.

Here are a few patents granted this year under the new rules:

A New Application for Ancient Herbs

An herbal patent issued last week appears to be rather sweeping in its claims for the use of herbs in treating HIV, leukemia and various forms of hepatitis.

The patent was jointly granted to Shie-Ming Hwang, a chemist in Columbus, Ohio; his cousin Hsiu-Hsien Tsai, a physician in Taiwan, and Pai-Chu Kung, a pharmacist and Tsai's wife.

Tsai, who was trained in Western medicine, became frustrated with poor results when using interferon to treat patients with Hepatitis B, Hwang said. So Tsai turned to traditional Chinese herbal medicine, concocting a powder of 11 herbs that was mixed with water and taken several times a day.

"It's not a formal clinical trial, but it appeared to significantly lower levels of Hepatitis B," Hwang said.

Subsequent laboratory testing suggests that the herbal combination

may help patients with HIV and leukemia. But how is it that the use of these herbs, which have been used for thousands of years in Chinese medicine, can be patented? The answer appears to be that the three inventors have come up with a new use for the ancient herbs.

Hwang, Tsai, and Kung received patent 5,837,257.

Combining Herbs for Weight Loss

St. Johnswort has attracted considerable attention for its reputed success in combating depression. And ephedrine, an herb known for its amphetamine-like qualities, has developed a reputation for accelerating weight loss.

Brian Haveson, of Yardley, Pa., contends that the two herbs, when taken together, act synergistically to suppress appetite and burn calories. A patent he received for a combination of the herbs cites a small, unpublished study as evidence. In that study, a dozen overweight individuals lost eight pounds in six weeks by taking both St. Johnswort and ephedrine twice a day, according to the patent.

Haveson received patent 5,798,101 for his herbal combination.

Herbal Substitute for a Nicotine Patch

Plantago, a weed known as common plaintain, has been extolled for centuries for its healing properties. Since the 1920s, this herb has also been reputed to suppress the desire of smokers to reach for a cigarette.

Mary Cody, of Boonton Township, N.J., has invented the herbal answer to the nicotine skin patch: a transdermal version of Plantago. Rather than delivering nicotine slowly to the bloodstream, though, it delivers an extract of the herb.

Ms. Cody received patent 5,716,635.

Giving Chew Toys an Herbal Punch

Cats have appreciated catnip for millennia. But it has never held much allure for dogs. Enter valerian, until now mostly known for its putative sedative power over humans.

Vsande Childers-Zadah, of West Palm Beach, Fla., has patented the use of valerian root in chew toys and food treats for pets. Valerian is irresistible to both dogs and cats, the patent contends.

Childers-Zadah received patent 5,786,382.

END

Street, London and Deutsche Bank's twin towers in Frankfurt.

END

Widening the Medical Mainstream

Studies Find Sharp Increase in Americans Using 'Alternative' Therapies

By SUSAN OKIE
Washington Post Staff Writer

The number of Americans who are using "alternative" treatments such as herbal supplements, massage therapy and megavitamins is increasing dramatically and visits to alternative practitioners have become more common than visits to the family doctor, according to a new survey released yesterday.

At the same time, scientific attempts to evaluate the effectiveness of such therapies are starting to separate those that work from those that don't. For example, studies also released yesterday by a major medical journal found that burning a Chinese herb next to the toe of a pregnant woman can often make her breech baby turn head-down, but that another herb commonly sold as a weight-loss aid is useless.

The studies were among a half-dozen published today in the *Journal of the American Medical Association (JAMA)* in a special issue dedicated to alternative medicine. It marked the first such effort by a mainstream U.S. medical journal and was an attempt to meet doctors' need for high-quality scientific information on treatments that more and more patients are trying, the editor said. Altogether, the American Medical Association this week planned to publish a total 80 reports about alternative medical therapies in *JAMA* and other journals.

"It is the beginning of the beginning of acceptance of some forms of 1998 alternative medicine into mainstream medicine in the United States," said George Lundberg, the editor of *JAMA*. "Acceptance the good, old-fashioned way—by merit."

An estimated 83 million American adults—more than four out of 10—used some form of alternative medical treatment last year, according to the new survey by a Harvard research team. They reported that visits to practitioners of

alternative therapies, from herbal medicines to "energy healing," have increased 47 percent since 1990, propelled chiefly by middle-aged, health-conscious baby boomers. Half of the people between age 35 and 49 reported of using at least one of the surveyed treatments last year. The majority of users said they were turning to the therapies to prevent future illnesses rather than to treat current ones.

Jeff Sherman, 46, a real estate developer from McLean, said he has used acupuncture and homeopathy to relieve headaches and dizziness. He said many of his friends also have tried various alternative therapies.

"I think we're all of the age, and we know enough about medicine, that we're willing to consider that perhaps Western medicine doesn't have the only answer," he said.

The Harvard team, led by David M. Eisenberg, questioned 2,055 randomly selected adults about their use last year of 16 alternative therapies and compared the results to a similar survey conducted by the same team

in 1990. In addition to herbal medicine and "energy healing," therapies included in the survey were relaxation techniques, massage therapy, chiropractic, spiritual healing, megavitamins, self-help, imagery, homeopathy, hypnosis, biofeedback, acupuncture, folk remedies and various diets. The researchers tried to be more specific in a number of these areas. For example, when asked about vitamins, the surveyors specifically said they meant something other than regular daily vitamins or vitamins prescribed by a doctor.

The researchers found that Americans' use of alternative therapies increased by 25 percent during the seven-year period and that expenditures for practitioners' services increased by 45 percent. They estimated that Americans spent \$27 billion, most of it not reimbursed by insurance companies, on alternative treatments last year. Among the fastest-growing therapies were herbal remedies, massage, megavitamins, relaxation techniques and "spiritual healing."

"The fact that nearly 50 percent more people visit alternative medicine practitioners now than in 1990 is astounding," said Sen. Tom Harkin (D-Iowa), who sponsored legislation that created the Office of Alternative Medicine at the National Institutes of Health in 1991. "Consumers need and deserve better information on what works and what doesn't."

Last month, President Clinton signed a law upgrading the office to the National Center for Complementary and Alternative Medicine and increasing its annual budget from \$20 million to \$50 million.

Only about 40 percent of people who use alternative therapies tell their doctors, the survey found. And as many as 15 million people who take prescription drugs also are using herbs or high-dose vitamins, raising concerns about possible side effects from combining treatments, Eisenberg said. "We raise the question of whether these 15 million adults are at risk for drug-herb or drug-vitamin interactions," he said.

The six studies tested various alternative therapies using a classic research design, the randomized clinical trial in which one group of patients receives a treatment and another group receives a placebo. In most of them, doctors and patients didn't know who was receiving what. Some of the results were surprising.

For instance, one study found that moxibustion, a traditional Chinese therapy in which an herb, *Artemisia vulgaris*, was burned next to an "acupuncture point" on the toe, proved safe and effective for stimulating fetuses in the wombs of pregnant women to turn over from a breech (feet-first) position to a head-first position, which is safer for delivery, said Francesco Cardini, an Italian gynecologist who conducted the study in China.

After two weeks, breech fetuses had turned over in 75 percent of the 130 women who received moxibustion daily or twice a day but in only 48 percent of 130 women who didn't get the treatment, he said. He said the therapy, which is painless, increases fetal movement, perhaps by

changing nerve stimulation to the uterus.

"This treatment is quite strange for us, but it is easy, cheap, safe and can be done at home," said Cardini. "If it fails to attain the result, another therapy can be done later."

In another study, a stretching regimen based on yoga was found to help relieve hand pain and weakness produced by carpal tunnel syndrome, which is caused by compression of a nerve at the wrist. And a third study found that a mixture of traditional Chinese herbs helped alleviate symptoms—such as abdominal pain, constipation or diarrhea—in people with irritable bowel syndrome.

But spinal manipulation by chiropractors was not shown to relieve tension headaches. An herb, *Garcinia cambogia*, commonly found in supplements marketed to dieters was no more effective than a placebo for promoting weight loss. And acupuncture turned out to be no better than a placebo for pain caused by nerve damage in people with AIDS.

Lundberg said a study that finds that an alternative therapy, such as

traditional Chinese herbs, is effective for a particular problem shouldn't be viewed as a blanket endorsement. "It is not proper to make a giant leap from one study to immediately say, 'That means Chinese herbs are okay from anybody's closet, for anything,'" he said at a Washington news conference where the research was released.

Some medical experts also have expressed concern that herbal products, which do not have to meet any official government purity or manufacturing standards, may carry dangerous impurities.

Gary Kaplan, a family practitioner and chronic pain specialist who runs an integrative medicine clinic in Arlington, applauded the studies. Kaplan said he and other practitioners at his clinic use a variety of treatments including manipulation, acupuncture, guided imagery, biofeedback, nutritional counseling and homeopathy.

"I'm very pleased to see this stuff being studied," he said. "What's going on is really something of a quiet revolution in medicine. We're going to see an expanded concept of health and illness."

The Washington Post

WEDNESDAY, NOVEMBER 11, 1998

Copied
Jennings
COS

FEHBP File

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 23, 1998

STATEMENT BY THE PRESIDENT

The Federal Employees Health Care Protection Act of 1998, H.R. 1836, that I have signed into law makes several critical improvements to the Federal Employees Health Benefits Program (FEHBP). For example, it gives the Office of Personnel Management's Inspector General critical new debarment authority to crack down on fraudulent providers and, when necessary, to debar those who defraud the program; it contains essential new provisions to maintain and improve consumer choice, the hallmark of FEHBP, by allowing fee-for-service plans to rejoin FEHBP; it makes health care more affordable for certain Federal employees and retirees of the Federal Deposit Insurance Corporation and the Federal Reserve Board by allowing them to participate in the FEHBP; and finally, it ensures that certain Federal physicians who provide high quality services will receive appropriate compensation for their services, which is critical to attracting and maintaining a high quality Federal physician work force.

I want to note, however, my objection to a provision in this legislation that appears to expand preemption of State law remedies for FEHBP enrollees who are injured as a result of wrongful benefit delay or denial by their plan. As I have consistently stated, I believe that a right without remedy is not a right at all. I strongly believe that Federal employees should have the right to legally enforce-able remedies, including under State law, to protect them when health plans do not provide contractually obligated patient protections. I therefore want to clarify that my enactment of this legislation should in no way be construed to indicate my support for this preemption provision. I also would like to reiterate my disappointment that the Congress has adjourned without passing a Patients' Bill of Rights that would give new protections and remedies to all Americans, including Federal employees. Assuring that health plans provide needed patient protections and adequate remedies will be one of my top priorities for the next Congress.

WILLIAM J. CLINTON

THE WHITE HOUSE,
October 23, 1998.

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. letter	Lorraine Lewis to Frank W. Hunger Re: FEHB and Suits Against the Tobacco Industry (3 pages)	10/16/98	P5

**This marker identifies the original location of the withdrawn item listed above.
For a complete list of items withdrawn from this folder, see the
Withdrawal/Redaction Sheet at the front of the folder.**

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Clinton Presidential Records
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FOLDER TITLE:

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RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

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RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

OFFICE OF MANAGEMENT AND BUDGET

*Legislative Reference Division
Labor-Welfare-Personnel Branch*

FEHBP File

Telecopier Transmittal Sheet



URGENT

FROM: Bob Pellicci -- 395-4871

DATE: 9/23

TIME: 11:15 am

Pages sent (including transmittal sheet): 10

COMMENTS: REVISED OPM testimony

Re: 1999 Benefits + Rates for FEHBP.

Comments due by 2 p.m. today. Thanks

TO:
Dan Mendelson
Chris Jennings

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

STATEMENT OF
WILLIAM E. FLYNN, III
ASSOCIATE DIRECTOR FOR RETIREMENT AND INSURANCE
U.S. OFFICE OF PERSONNEL MANAGEMENT

at an oversight hearing of the

SUBCOMMITTEE ON CIVIL SERVICE
COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT
U.S. HOUSE OF REPRESENTATIVES

on

FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM
1999 PREMIUM RATES

SEPTEMBER 24, 1998

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

THANK YOU FOR THIS OPPORTUNITY TO DISCUSS THE RESULTS OF OPM'S RECENTLY CONCLUDED NEGOTIATIONS ON 1999 BENEFITS AND RATES UNDER THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM. AS YOU KNOW, 1999 WILL BE THE PROGRAM'S FIRST YEAR USING THE NEW GOVERNMENT CONTRIBUTION FORMULA WHICH CONGRESS APPROVED AS A PART OF THE BALANCED BUDGET ACT OF 1997.

THE SIGNIFICANT NEWS FOR FEDERAL EMPLOYEES AND RETIREES IS THAT THE PROJECTED INCREASE IN THEIR HEALTH PLAN PREMIUMS FOR 1999 IS ABOUT ONE-HALF OF THE 1998 RATE INCREASE THAT OPM ANNOUNCED LAST FALL. WHILE PREMIUM RATES FOR THE FEDERAL EMPLOYEE PROGRAM ARE

PROJECTED TO RISE AN AVERAGE OF 10.2 PERCENT NEXT YEAR, THE IMPACT ON THE AVERAGE ENROLLEE COST WILL BE CONSIDERABLY LESS-7.4 PERCENT. BY COMPARISON, THE EXPECTED AVERAGE INCREASE IN ENROLLEE COSTS FOR 1998 WAS 15.4 PERCENT.

FOR NEXT YEAR, THE IMPACT OF PREMIUM INCREASES ON PROGRAM PARTICIPANTS WILL BE SUBSTANTIALLY MITIGATED BECAUSE THE GOVERNMENT WILL ASSUME A LARGER SHARE OF PREMIUM COSTS UNDER THE NEW "FAIR SHARE" GOVERNMENT CONTRIBUTION FORMULA THAN WOULD HAVE BEEN THE CASE UNDER THE "BIG 6" PHANTOM FORMULA. THE FAIR SHARE FORMULA WILL MAINTAIN A CONSISTENT LEVEL OF GOVERNMENT CONTRIBUTIONS, PEGGED AT 72 PERCENT OF THE PROGRAM-WIDE WEIGHTED AVERAGE OF SELF ONLY AND SELF AND FAMILY PREMIUM CHARGES, REGARDLESS OF THE CONFIGURATION OF PARTICIPATING PLANS.

WHILE THE PROJECTED COST INCREASE TO ANNUITANTS AND NON-POSTAL EMPLOYEES IN 1999 WILL AVERAGE 7.4 PERCENT, THE INCREASE IN THE GOVERNMENT CONTRIBUTION WILL AVERAGE 11.4 PERCENT. IN DOLLARS RATHER THAN PERCENTAGES, ENROLLEES SUBJECT TO THE FAIR SHARE FORMULA WILL PAY AN AVERAGE OF \$3.39 MORE BIWEEKLY IN 1999 (COMPARED TO AN AVERAGE \$5.08 INCREASE IN 1998) WHILE THE AVERAGE BIWEEKLY GOVERNMENT INCREASE WILL BE \$12.07 IN 1999 (COMPARED TO \$5.02

THE PREVIOUS YEAR).

THE COMPARATIVELY LARGER INCREASE IN GOVERNMENT CONTRIBUTIONS WILL BE A ONE-TIME OCCURRENCE CAUSED BY THE MOVE FROM THE BIG-6 TO THE FAIR SHARE FORMULA. IN FUTURE YEARS, WE EXPECT RATES OF CHANGE IN AVERAGE CONTRIBUTIONS FOR BOTH THE GOVERNMENT AND THE ENROLLEES TO CLOSELY APPROXIMATE THE RATES OF CHANGE IN THE OVERALL PROGRAM.

IT IS IMPORTANT TO NOTE THAT OPM'S PROJECTION OF AVERAGE PREMIUM COSTS AT THE CONCLUSION OF CONTRACT NEGOTIATIONS ASSUMES THAT ENROLLEES WILL STAY IN THEIR PRESENT HEALTH PLANS DURING THE UPCOMING YEAR. BUT, ALL ELIGIBLE PARTICIPANTS HAVE THE OPTION OF CHANGING HEALTH PLANS DURING THE ANNUAL OPEN ENROLLMENT PERIOD-- WHICH IN 1998 WILL RUN FROM NOVEMBER 9 TO DECEMBER 14. CHOICE AMONG A WIDE VARIETY OF HIGH QUALITY HEALTH COVERAGE, AND CAREFULLY DESIGNED MATERIALS TO ASSIST ENROLLEES WITH HEALTH PLAN COMPARISONS AND SELECTION OF A PLAN TO MEET THEIR NEEDS AT AN AFFORDABLE COST, ARE HALLMARK FEATURES OF THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM. AS A RESULT OF THE OPEN SEASON PROCESS FUNCTIONING AS INTENDED, THE 1998 PROJECTED AVERAGE INCREASE IN INDIVIDUAL ENROLLEE COSTS OF 15.4 PERCENT FELL TO A REAL AVERAGE

INCREASE OF 12.5 PERCENT DUE TO ENROLLEE SELECTION OF MORE COST EFFECTIVE PLANS. THIS HAS BEEN A COMMON OPEN SEASON OCCURRENCE, AND WE EXPECT TO SEE THIS TREND CONTINUE FOR THIS YEAR'S OPEN SEASON, MAKING THE ACTUAL 1999 AVERAGE INCREASE LESS THAN 7.4 PERCENT.

THE 1999 FEDERAL EMPLOYEE HEALTH PLAN PREMIUM INCREASES REFLECT WHAT IS OCCURRING THROUGHOUT THE HEALTH CARE MARKETPLACE AND ARE IN LINE WITH INCREASES FACING LARGE AND MID-SIZED EMPLOYERS. HEALTH COSTS ARE GOING UP. THIS PAST JUNE, A MANAGEMENT CONSULTANT FIRM, WATSON WYATT WORLDWIDE, RELEASED THE RESULTS OF A SURVEY THAT LOOKED AT EMERGING COST TRENDS FOR 1999 FOR ORGANIZATIONS WITH 500 OR MORE EMPLOYEES IN MAJOR METROPOLITAN MARKETS NATIONWIDE. THE SURVEY PREDICTED DOUBLE DIGIT INCREASES FOR FEE-FOR-SERVICE PLANS AND SOMEWHAT LOWER INCREASES FOR HMOs. IT ALSO PREDICTED THAT HEALTH CARE PROVIDERS WOULD BE LESS WILLING TO NEGOTIATE FEES.

THE STUDY STATED THAT COST INCREASES WERE DUE TO CIRCUMSTANCES THAT AFFECT BOTH THE NATIONAL AND THE FEHB HEALTH CARE MARKET PLACES. NATIONALLY, MANAGED CARE DISCOUNTING HAS REACHED SATURATION POINTS IN MANY MARKETS AND HMO STOCK PRICES AND

EARNINGS HAVE BEEN HARD HIT BY INCREASING COSTS. IN THE FEHB PROGRAM, STRONG MANAGED CARE EMPHASIS SINCE THE EARLY 1990'S HAS RESULTED IN THE VAST MAJORITY OF ENROLLEES ACCESSING CARE VIA HMO OR PREFERRED PROVIDER NETWORKS. DEEPER DISCOUNTS ARE DIFFICULT TO OBTAIN AND HAVE LESS IMPACT ON RISING MEDICAL COSTS.

NATIONALLY, TECHNOLOGICAL ADVANCEMENTS ARE DRIVING COSTS HIGHER. THE FEHB PROGRAM IS STRUCTURED TO ALLOW BENEFITS TO EVOLVE IN RESPONSE TO MEDICAL PRACTICE SO THAT PROGRAM PARTICIPANTS ARE ASSURED ACCESS TO QUALITY AND UP TO DATE HEALTH SERVICES.

NATIONALLY, AN AGING POPULATION IS PUTTING EVER MORE PRESSURE ON THE HEALTH CARE DELIVERY SYSTEM. THE AVERAGE AGE FOR ENROLLEES IN THE FEDERAL EMPLOYEE PROGRAM (EXCLUDING DEPENDENTS) HAS INCREASED FROM 56.18 IN 1996 TO 57.08 IN 1998.

FINALLY, THE WYATT SURVEY IDENTIFIED PRESCRIPTION DRUG BENEFITS AS A MAJOR COST DRIVER, LARGELY DUE TO USAGE AND MANY NEW AND EXPENSIVE DRUGS COMING TO MARKET. FOR 1999, IT PREDICTED PRESCRIPTION DRUG INCREASES OF UP TO 22 PERCENT. THE MOST RECENT FEHB EXPERIENCE IS 17 PERCENT WITH ABOUT ONE IN FIVE DOLLARS EXPENDED FOR DRUG BENEFITS.

SUBSEQUENT TO THE INVITATION TO TODAY'S HEARING, THE CHAIR ASKED FOR A HISTORY OF RESERVE LEVELS FOR OUR PARTICIPATING FEE-FOR-SERVICE HEALTH PLANS AND AN EXPLANATION OF HOW THE RESERVES HAVE INFLUENCED RATES. THIS INFORMATION HAS BEEN FURNISHED. BUT, I WANT TO CLARIFY FOR THE RECORD, THAT WHILE OPM REGULATIONS SPECIFY MINIMUM RESERVE LEVELS FOR EXPERIENCE-RATED PLANS, THE RATE-SETTING PROCESS INVOLVES VERY JUDICIOUS USE OF RESERVES RATHER THAN MECHANICAL DECISIONS TO DRAW DOWN OR REBUILD RESERVES TO TARGET LEVELS IN THE SHORT TERM. IN 1999, OUR USE OF RESERVES IN LIEU OF PREMIUM INCREASES SLOWED, CONTRIBUTING TO THE AVERAGE PREMIUM INCREASE. WHILE OPM DOESN'T REGULATE RESERVES HELD BY COMMUNITY-RATED HMOs, MAINTAINING APPROPRIATE RESERVES IS AN IMPORTANT ISSUE THERE AS WELL, AND WE PAY CLOSE ATTENTION TO THIS IN CONTRACTING WITH THEM.

A MAJOR INITIATIVE TAKEN FOR 1999 IN COLLABORATION WITH CARRIERS WAS THE IMPLEMENTATION OF PRESIDENT CLINTON'S PATIENT BILL OF RIGHTS. AT AN ADDITIONAL PREMIUM COST OF LESS THAN 25 CENTS A YEAR, SHARED BY THE GOVERNMENT AND ENROLLEES, ALL FEHB PARTICIPANTS WILL BENEFIT FROM THE FOLLOWING:

- DIRECT ACCESS TO WOMEN'S HEALTH CARE PROVIDERS FOR ROUTINE AND PREVENTIVE WOMEN'S HEALTH SERVICES;

- USE OF THE "PRUDENT LAYPERSON" STANDARD WHEN DETERMINING THE NECESSITY OF EMERGENCY CARE VISITS FOR COVERAGE;
- TREATMENT PLANS PROVIDING DIRECT ACCESS TO A QUALIFIED SPECIALIST IN PLAN PROVIDER NETWORKS FOR INDIVIDUALS WITH COMPLEX OR SERIOUS MEDICAL CONDITIONS REQUIRING FREQUENT CARE;
- EXTENSIVE INFORMATION ABOUT PLAN CHARACTERISTICS AND PERFORMANCE, PROVIDER NETWORK CHARACTERISTICS, AND CARE MANAGEMENT; AND
- A REGULATORY PROHIBITION ON "GAG" CLAUSES IN PROVIDER CONTRACTS THAT COULD LIMIT COMMUNICATION ABOUT MEDICALLY NECESSARY TREATMENT.

ALSO, PLANS WILL TAKE ANOTHER STEP FORWARD IN COVERING SERVICES RELATED TO MENTAL HEALTH CONDITIONS LIKE SERVICES FOR OTHER HEALTH CONDITIONS. ALL PLANS WILL NOW COVER PHARMACOTHERAPY FOR MENTAL HEALTH CONDITIONS UNDER GENERAL MEDICAL BENEFITS RATHER THAN MENTAL HEALTH BENEFITS, WITH NO REDUCTION IN EXISTING COVERAGE FOR MENTAL HEALTH SERVICES. PHARMACOTHERAPY INVOLVES THE PRESCRIPTION OF MEDICATIONS, OFFICE VISITS FOR OBSERVATION OF PATIENT RESPONSE AND REGULATION OF DOSAGES, AND LABORATORY TESTS TO MONITOR THEIR EFFECT. OPM CONCLUDED THAT IT IS REASONABLE THAT MANAGEMENT OF THE PHYSIOLOGICAL ASPECTS OF MENTAL HEALTH CONDITIONS SHOULD BE REIMBURSED THE SAME AS PHARMACEUTICAL MANAGEMENT OF ANY OTHER DISEASE. THIS CHANGE WILL INCREASE AVERAGE 1999 PREMIUMS BY A TOTAL OF 3/100 OF 1 PERCENT--OR ABOUT 80

CENTS A YEAR FOR SELF ONLY COVERAGE AND ABOUT \$1.82 A YEAR FOR SELF AND FAMILY COVERAGE. ENROLLEES PAY ONLY A PORTION OF THIS AMOUNT.

NEXT YEAR A TOTAL OF 285 HEALTH PLANS WILL PARTICIPATE IN THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM, DOWN FROM 350 PLANS OFFERED IN 1998. THE DRIVING FORCES BEHIND THIS DECLINE WERE THE SHAKE OUT OF PLANS UNABLE TO ATTRACT SUFFICIENT NUMBERS OF FEDERAL ENROLLEES OR MAINTAIN COMPETITIVE RATES, PLAN CONSOLIDATIONS, AND OTHER CHANGES IN MANAGED CARE AND POINT OF SERVICE PLANS. NONE OF THE PLANS WHICH WITHDREW DID SO IN RESPONSE TO OPM'S INITIATIVES ON MENTAL HEALTH COVERAGE OR PATIENT PROTECTIONS. THIS CHANGE TOO REFLECTS NATIONAL TRENDS IN THE HEALTH INSURANCE MARKET AND WILL NOT ADVERSELY AFFECT FEDERAL ENROLLEES.

ONLY ONE FEE-FOR-SERVICE PLAN-BENEFICIAL ASSOCIATION OF CAPITOL EMPLOYEES WITH ABOUT 1,200 ENROLLEES-WILL CEASE PARTICIPATION IN 1999. THE OTHER PLANS WERE HEALTH MAINTENANCE ORGANIZATIONS AND POINT OF SERVICE PLANS AND ALSO WERE AMONG THE SMALLER PLANS PARTICIPATING. ALTOGETHER, LESS THAN 2 PERCENT OF OUR ENROLLED POPULATION WILL BE AFFECTED BY THESE PLAN CHANGES.

WHILE ANY INCREASE IN COSTS IS ALWAYS A CONCERN FOR US, OPM BELIEVES

THAT THIS YEAR'S AVERAGE INCREASE WILL LIKELY BE LOWER THAN THE AVERAGE INCREASE IN PRIVATE SECTOR EMPLOYER PROGRAMS, AS HAS BEEN THE CASE FOR MOST OF THIS DECADE. OUR PROGRAM IS A RECOGNIZED LEADER IN THE PROVISION OF QUALITY, AFFORDABLE HEALTH CARE AND OPM IS COMMITTED TO MAINTAINING THAT POSITION.

OPM WILL CONTINUE TO LOOK FOR WAYS TO MODERATE COST INCREASES WHILE CONTINUING TO MONITOR THE QUALITY OF CARE DELIVERED TO FEDERAL EMPLOYEES. LIKE OTHER LARGE EMPLOYERS, WE BELIEVE THAT STRATEGIES THAT PROMOTE VALUE-BASED PURCHASING CAN ACHIEVE THESE RESULTS. WE WILL BE EXAMINING APPROACHES THAT HAVE BEEN USED EFFECTIVELY BY OTHERS IN THE PURCHASER COMMUNITY TO SEE IF AND HOW THEY MIGHT BE APPLIED IN THE FEHB PROGRAM.

I WILL BE HAPPY TO ANSWER ANY QUESTIONS YOU HAVE AT THIS TIME.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

July 6, 1998

Medicare QMB File

PRESS BRIEFING
BY P.J. CROWLEY, JOE LOCKHART,
AND THE PRESIDENT'S HEALTH POLICY ADVISOR CHRIS JENNINGS

The Briefing Room

1:14 P.M. EDT

MR. LOCKHART: P.J. and I will be glad to take your questions on other subjects, but we want to have Chris Jennings, the President's Health Policy Advisor, come and speak to you first about the event we did today, and then P.J. and I will be glad to fill in behind him.

MR. JENNINGS: Good afternoon. This morning, as you saw, the President announced the launching of a new outreach campaign to target and enroll 3 million older Americans and people with disabilities who have no protections on premiums although they are eligible for it. As you saw today, the Families USA advocacy organization released a report that documented this problem and said that federal and state governments need to do a better job of targeting and enrolling these eligible populations.

Just as a reminder, these are populations that are between probably 50 percent of poverty and 175 percent of poverty. They're very low income Medicare beneficiaries who have the right to have these protections, but because we have not done as good a job as we can both at the state and federal government level at getting these folks signed up, they are paying much higher out-of-pocket costs, both through premiums, deductibles, and co-payments.

This action today actually is very much consistent with the action the President took just a few weeks ago talking about targeting the eligible children who are eligible if not enrolled for the CHIP* and Medicaid programs. And this just is an illustration of are ongoing commitment to make sure that the people who have eligibility for these programs get the protections that they need and they deserve, and they are, in many cases, entitled to.

Briefly, just to go over what some of the initiatives are, and then I would be happy to answer any questions -- first, this is a joint activity between two departments, both the Social Security Administration and the Department of Health and Human Services, hence the participation of Donna Shalala and Ken Apfel earlier this morning. I would say that they're divided into a number of different categories.

First, we have a major new initiative to educate beneficiaries about the program in the first place. We'll be sending information about the program both through our mailings through the Social Security, through the cost of living adjustment announcement that happens in the fall, through a whole series of pamphlets to 38 million Americans, Medicare beneficiaries, to every new Medicare beneficiary who enrolls. That's about 1.8 million a year will have access to this information as well.

We will also be making sure that Social Security offices, which frequently is the place where Medicare beneficiaries go to get information about programs that they're eligible for, have these pamphlets, as well as have posters plastered all over the place so they can see, oh, I might be eligible for this important program.

Remember that this is a population where these costs in terms of cost-sharing protections can mean the difference between hundreds of dollars a year, which, for many a Medicare beneficiary, means the difference between buying a prescription or not, or being able to go to another physician's office visit. For us, we think that's very, very critically important, that we get out the word that this program is available and people should take advantage of them if they are eligible.

Secondly, we are -- what we're also finding out is that the administrative -- the signing-up enrollment process is extremely complicated. People don't know what forms they're supposed to find, they think it's overly complicated. In response, this month, the Department of Health and Human Services, through the Health Care Finance Administration, will be sending a letter to each Medicaid director that will enclose a simplified application form, which will -- and will encourage all states to use this, because it is a joint state-federal program, and we'll ask them to use for the enrollment of eligible populations.

Thirdly, we're going to be creating a new task force, both federal, state and consumer task force, that is designed to get new ideas, new concepts on how best we can target and enroll these populations and new creative options to do that. We'll have the Administration on Aging, the SSA -- Social Security Administration -- HCFA, as well as the National Governors Association and consumer advocates, as well. We will also be working with the state insurance counseling assistance programs to make sure that they're well aware of these programs.

In essence, it's about a 10-point program that the President is unveiling today. We think it's critically important that Medicare beneficiaries know that they may well be aware of these benefits. In some cases, it makes a difference between whether elderly people actually go into poverty or not because of the out-of-pocket costs that they otherwise would not have to have if they took advantage of this benefit. That's something that we think is critically important and also something we want to avoid at all cost.

We've provided you a background piece, which I think is pretty self-explanatory, but I'd be happy to take any questions about this program or other issues.

Q What about this New York Times story? Does that tie in at all with what you're --

MR. JENNINGS: I think the extent to which it ties in is, obviously, we're talking about in this case low-income elderly populations. But the Times article today was what we would probably characterize as a piece of a story and not the whole story. As you know, the President is very committed to patient's rights and is pushing the Patient's Bill of Rights legislation. In this article it's suggesting that some managed care plans, some HMOs are leaving the Medicaid program because of reimbursement rates.

As it turns out, we're finding that actually there are more managed care plans that are participating than there have before in the Medicaid program. And many HMOs decide not to participate because they have -- there are so many plans competing that they can't get as much of a market share to compete.

Now, where reimbursement rates are so low as to question the ability of plans to provide quality, that's something that the President obviously is quite concerned about. We don't yet have the information to conclude that it is that problem. As the Secretary mentioned earlier today, she's going to be forwarding a memo to the President that gives the state of affairs with regard to this issue. I think if you contact the Governors Association today, they will tell you that they haven't had many problems with plans wanting to participate in the Medicaid program. But it is something that we're going to have to watch very carefully as we go forward.

Q On the thing you're announcing today, how many Americans do you think are eligible for this additional help, how many are currently getting it, and how many could you handle under the money currently appropriated?

MR. JENNINGS: A total of number of people who are eligible is approximately 8 million Medicare beneficiaries. Those who are currently getting it is roughly around 5 million Medicare beneficiaries. So we're about 3 million, 3.5 million short of the people who are eligible for this program who are getting it.

As to whether the cost -- it's already in the baseline. It's part of current law, so it would be incorporated in the baseline. It would not require an additional act by Congress.

Q You could cover 3 million additional people if they applied tomorrow?

MR. JENNINGS: We could cover that, because that's part of current law. It would obviously require more dollars out of the Medicare program, but that's part of current law. It is anticipated that these populations are eligible for this benefit, and that's why Congress passed this legislation both back in 1988, they kept it in 1989, and they expanded it just last year in the Balanced Budget Act.

Q What's the health event tomorrow?

MR. JENNINGS: The health care event tomorrow is something that we're still working on and cannot announce at this point in time.

Q But do you know how many people out there are eligible, but not getting it? Isn't there a way to just give it to all the people you know are eligible?

MR. JENNINGS: What we've found, actually, in the outreach programs is, it's a much more difficult job than that. It really involves a lot of hard work. First of all, many beneficiaries don't even know that they're eligible in the first place, so it has a lot to do with the information and education campaigns that just currently don't exist. You don't want to just say automatically anyone in the world gets it because you just don't know. You have to make sure that people meet the current incomes breaks; otherwise, you would be wasting taxpayer dollars inappropriately.

But the best way to do this is to work with the states. The states administer this program through the Medicaid program. Some states have been very creative in targeting these populations. Republican Governor George Voinovich from Ohio actually has been working on this as well and has had more successes than we've seen in recent days in other states.

So it's a matter of constant work going to the Social Security field offices, going to the other enrollment centers where people go.

Just as we've done in the children's health care, we want to go to the providers, we want to go to the senior centers, the adult day centers, nursing homes and other places where we can target the populations who are eligible.

Q So, Chris, do you think that this is benign neglect, or is there intentional neglect going on where like it would increase state costs as well, right, to go after these people? I mean, do the state governments sort of not necessarily want to be aggressive in finding these lost populations?

MR. JENNINGS: Well, I think that in order to make this work, you have to make it a priority. It is -- I don't think people are saying, I'm not going to cover people, but what we've learned with the children's outreach is that you have to work at it. You cannot just stand by and say you have a program and we have it, and if you go to the program we'll enroll you. You have to go out and target the populations. In some states that have made it higher priority, they have had a greater participation rate.

We're going to do our job from the federal government's perspective. To do our job, we're going to have to work with the National Governors Association to make sure that they do their job. We're very pleased that they have announced today that they will participate in our task force that we're announcing today. And we think their recommendations, their input -- in fact, they have to be invested in this process for this to work, and our sense is that we're seeing a real signal of willingness to do that today.

Q Chris, what's the prospect of passage of the Patient's Bill of Rights this year, and what obstacles are the main ones on the Hill?

MR. JENNINGS: Political will. I mean, we think that this is -- we are seeing that Republicans and Democrats alike have agreed today, just as of last week, that all of them are agreeing that there should be federal standards in law to provide for basic protections for patients. The House -- just to show, the House Republican -- the Gingrich plan, just last week, I believe it was, did make some progress. We think it has fallen short in a number of areas and for that reason, we -- that is not an acceptable bill as it currently is constructed. It doesn't have the specialists, it doesn't have the continuity of care, it doesn't have a whole host of financial incentives protections, and it does not have a strong enforcement mechanism.

But we think that there are a lot of members of Congress on both sides of the aisle who are very much committed to ensuring those protections are there. Our belief is, we saw in the Time magazine, they're dedicating a whole issue this week to this issue. We think this is an issue whose time has come. It would be almost beyond comprehension that the Congress couldn't pass a strong bipartisan piece of legislation this year. And if it doesn't, then it will be a failure of the federal government to respond to some real needs of the public in this regard.

Q We're hearing that maybe the Democrats on the Hill are saying let's leave this unresolved and use it as another stick to beat the Republicans in November. Are you running into this problem as you go up there --

MR. JENNINGS: I believe that most Democrats are taking the position that if it's a strong Patient's Bill of Rights, it should be passed and signed into law, and for the most part, we've run into only that. And we have to make sure it is, and if it is, they will validate that this bill should be passed this year. And it is our intention to make sure that both Democrats and Republicans assure that end.

Q Back on the managed care HMO Medicare issue, should it be of concern if there are whole geographic areas or even whole states where there are no managed care plans enrolled in the Medicare program, and if so, why, or why not?

MR. JENNINGS: I think that you want to provide as many choices to Medicare beneficiaries as you possibly can. In the last Congress, Republicans and Democrats from rural states in particular raised concerns that the reimbursement rates for managed care in those areas was insufficient. As a consequence, we included provisions in the BBA that increased the reimbursement rates, and we expect that we'll see a significant growth in those areas of managed care.

There may be areas of the country where you won't see as much growth as you've seen in the past, because we've seen a proliferation of managed care in certain parts of the country, but we think that if we can enhance options for Medicare beneficiaries in all areas of the country, that is a positive end.

Now, that doesn't mean that you just throw money at the problem. You want to make sure that you've got a health care infrastructure necessary to provide those services in the first place. And that's the balance that we're dealing with, with the Health Care Financing Administration.

Q You said that the Republican proposal doesn't-- it lacks a strong enough enforcement mechanism. What is a minimal acceptable enforcement mechanism to the White House? Does it require increasing the court remedies for consumers who sue health plans for denials of medically necessary care?

MR. JENNINGS: Well, as you know, we've consistently said that a right without remedy is not a right. But that does not mean that there aren't alternative remedies to ensure that right. There's federal court approaches, there's state court approaches, there's departmental enforcement activities that might make some sense. We're open to those things. We've found, at least to date, that at least the Gingrich plan that has been at least partially unveiled in the House the last couple of weeks did not go far enough in that regard. We don't have the details; we look forward to seeing that. But we've got to have some strong enforcements to make sure that these rights --

Q But these --

MR. JENNINGS: It may or may not be, but most likely it probably would be. But we would have to make sure that there would be a strong enforcement mechanism. If it was not going to be court, it would have to be something that actually made a difference to consumers who have had real problems in this area.

Q What's the White House view of the health mart proposal and the other types of new associations that the Republican plan outlines?

MR. JENNINGS: Well, as you know, we've raised serious concerns about the MEWA provisions in the past, and the health marts -- the only reason why I'm hesitating is only because in a document the Republican leadership released last week, there wasn't a lot of detail, shall we say. And, therefore, it would be very hard for me to comment on that proposal.

Certainly, the President is very supportive of voluntary purchasing coops that empower small businesses to group together to purchase more affordable health care, and if that's what the design of this alternative is, that would be very consistent with the presidential

priority. But, again, the devil is in the details, as is the case with all health care initiatives.

Q One other quick one -- the President's Medicare expansion proposal is not something we've heard a lot about lately. Is that still viable for this year? Any chance that something like that will pass this year?

MR. JENNINGS: You mean the new choice option --

Q The age group expansion that was proposed.

MR. JENNINGS: The 55 to 65, to provide more choices for beneficiaries who have no choice at all right now. (Laughter.) Yes, that's something that we do care a lot about. It's something that, as you know, Senator Moynihan and the Democratic leadership proposed this year. It obviously doesn't appear the Republican leadership is moving that quickly in this Congress. It's something the President still feels strongly about. We'll have to see.

I think that it would be unrealistic for me to stand up here to say that I see a fast-moving train moving through the Congress on that piece of legislation. So we're focusing particularly on getting something that we know we can get done and we should get done for the public, and that's the Patient Bill of Rights.

Thank you very much.

MR. LOCKHART: Before you grill P.J. with the really tough ones, a couple of announcements. The President will travel to Florida on Thursday. He will land at Daytona Beach and then visit residents and rescue workers in Volusia County. The decision to travel there and the logistics of who we're going to see and where we're going to go were made in consultation with James Lee Witt and FEMA, and Governor Lawton Chiles and his office.

Q Are you going to take the press plane and everything with you?

MR. LOCKHART: They're working on that.

Q -- that plane?

MR. LOCKHART: No, in addition to. As you know from the released schedule, we were going from Atlanta down to Miami, so we'll make a stop on the way down.

As the paper indicated that we released a few moments ago, the President announced today that he has accepted an invitation from President of the Russian Federation Boris Yeltsin to meet in Russia in early September. The President underscored the vitality of the U.S.-Russian relationship and looks forward to engaging President Yeltsin and the Russian leadership on a broad range of issues. The President asked Vice President Gore to use his July 23-24 meetings in Moscow with Russian Prime Minister Kiriyenko to help prepare the agenda for the summit.

Q I thought we were waiting for action by the Duma before the President would go.

MR. LOCKHART: I told you the tough ones would go to P.J.

Q What happened to the Duma?

COLONEL CROWLEY: Well, we have a range of important issues to discuss with the Russian President, from Kosovo, to the Russian economic

situation, and we never directly linked the two issues. We always thought that the meeting would be most productive in a post-START II ratification timing, but obviously, the relationship is important enough to continue and the Presidents will have lots to discuss in early September.

Q Well, P.J., I mean, you may never have explicitly linked the two, but there was always an implicit link that was quite explicitly stated by you guys -- (laughter) --

COLONEL CROWLEY: David, we clearly favored a meeting following START II ratification by the Duma; no question about that. However, the range of important issues that we have with Russia are such that we believe there's plenty for the two Presidents to discuss, including where we go on arms control once the Duma does ratify START II.

Q Well, I mean, what's the point of having relationship with Russia where you say to them, look, when we get together next it's going to be after the Duma's ratified this arms control agreement and they say, sorry, no can do, and we go, okay, that's fine, we'll come anyway?

COLONEL CROWLEY: Well, I think the two Presidents share a perspective on working with their respective legislative bodies and sometimes the Executive Branch has to move forward in certain directions while waiting for the legislative branch to catch up.

Q How is Yeltsin's future? I mean, there has been talk of impeachment and so forth. I mean, is he in the strong position -- as much as you can judge?

COLONEL CROWLEY: I think the President has a very good working relationship with President Yeltsin. They've done some productive work in the past and we look forward to a productive meeting in September.

Q Was there a lot of pressure from the Russians to have this meeting because of the fact that they are going through this economic crisis and it would look good if President Clinton came to Moscow at this time and look good for the people?

COLONEL CROWLEY: I think it's more a case -- you know, this is a very important relationship to the United States, when you think about the issues the two countries are working on together, from Kosovo to the impacts of the Asian financial crisis to arms control and the future, to move ahead toward START III negotiations once the Duma has ratified START II -- a very important relationship. And it's certainly appropriate for the Presidents to meet. And from our standpoint, there are scheduling issues as well in terms of when the respective Presidents are available.

Q But isn't it true Russia wanted it more than the United States?

COLONEL CROWLEY: I would simply say, we have had annual meetings between the two Presidents, and as the year comes along, we think it's important for the two to get together.

Q Does the administration back the IMF -- a plan that's been suspended basically? I mean, this could help towards releasing that.

COLONEL CROWLEY: I think the reforms that the Russians have already put in place are moving them in a positive direction. I don't know what more specific questions you have.

Q Well, the austerity plan that Yeltsin wants to get through the Duma, is it hoped that maybe by announcing that Clinton will go visit there, that that will prompt that to go through and therefore the IMF.

funding, which is conditioned on that?

COLONEL CROWLEY: We support the additional conditional funding through the IMF and clearly that's something that two Presidents will discuss, how the Russian economic reforms are moving and what additional support the Russians feel they require.

Q How about Ireland, going to Ireland on that trip?

COLONEL CROWLEY: The President has said that he desires an opportunity to return to Ireland and Northern Ireland, but at this point we have nothing to announce.

Q Is it a possibility?

COLONEL CROWLEY: The President has said that he looks forward to returning to Ireland and Northern Ireland. We have no specific plans at this point.

Q So that's a yes.

COLONEL CROWLEY: What we have announced today is the President is going to Russia in early September.

Q How early is early, P.J.? Is this before Labor Day or after?

COLONEL CROWLEY: Early September. Stay tuned for more details.

Q Why don't you have a date?

Q What about India and Pakistan? Are you sending any delegation from here to discuss a trip?

COLONEL CROWLEY: I believe the next step is that both India and Pakistan are sending representatives here this week for meetings at the State Department as we continue to evaluate whether or not the President will go to India and Pakistan later in the year.

Q How high is their representative?

COLONEL CROWLEY: I think they're at the ministerial level, or sub-ministerial level.

Q You keep referring to the Duma, saying once they pass it. Is there any contingency for what point you finally give up and say that they're not going to?

COLONEL CROWLEY: I think the Duma has simply said that they will defer consideration of the START II treaty until the fall. The government of Russia continues to press the Duma to take that action, and we would expect them to bring it up in early September, somewhat proximate to the meeting of the two Presidents.

Q How long a trip do you envision?

COLONEL CROWLEY: I think that that remains to be seen.

Q Are there any specific deals or agreements you're looking to cut with Yeltsin while you're over there? And when you talk about Kosovo, what do you hope both will say about it?

COLONEL CROWLEY: Paul, I think --

Q Is this just a meeting to meet or --

COLONEL CROWLEY: That's an area where Russia and the United States, as members of the Contact Group, will continue to -- first of all, a lot will presumably have happened between now and early September, so it's hard to predict, other than the fact that this has been an issue that the Russian government and the United States government have been engaged in as part of the Contact Group. Meanwhile, we continue to work the issue diplomatically and press the two parties to open negotiations as quickly as possible.

Q So you're not going to Russia to try to come to -- to cut some deal with Yeltsin on Kosovo or any other issue?

COLONEL CROWLEY: We are just presuming that among the issues that Russia and the United States are cooperating on, Kosovo is one of them, and that will be a subject of discussion.

Q The Greek Minister of Defense will be in town today for an official visit. I'm wondering if he's going to meet also with the White House officials officially or privately, including Mr. Sandy Berger.

COLONEL CROWLEY: The Greek Defense Minister is in town this week. He will be meeting with a range of administration officials, primarily Secretary of Defense Cohen. While members of the National Security Council staff will be meeting him as part of those meetings that he will have here in Washington, there are no scheduled meetings here at the White House.

Q How do you assess his visit at such a crucial time for the Greek-Turkish relations over the Aegean and Cyprus, in which President Clinton particularly is playing now a very important role for improvement?

COLONEL CROWLEY: Obviously, Greece is one of our important NATO allies. We welcome his visit here. There are a range of issues that are of interest to both the United States and Greece in terms of both issues in the Balkans, as well as issues in the Aegean. And I'm sure we'll have a wide range of issues being discussed, primarily through Secretary Cohen and other administration officials.

Q While we're on meetings, P.J., is the President going to be meeting with Prime Minister Hashimoto July 22nd -- do you know when that --

COLONEL CROWLEY: Prime Minister Hashimoto will be here from July 21st through 23rd. I believe the meeting will be on the 22nd.

Q This Friday he meets with Poland's Prime Minister. Any details on what will be discussed and what the day's agenda looks like?

COLONEL CROWLEY: I think primarily it's the first meeting -- or first visit by a Polish leader to the United States since the Senate formally ratified NATO enlargement. The Vice President will host a lunch for the Prime Minister and I would expect the other meetings, including the meeting with the President, to address their anticipated entry into NATO, other regional issues involving cooperation in Central and Eastern Europe, and just steps to kind of deepen our bilateral relationship.

Q P.J., if you could just go through what they're going to be talking about -- Hashimoto and Clinton. Do you think the main focus will be the President's trip to China? As you might know, there's a lot of concern in Japan that there's a sort of Japan passing phenomenon going on; the U.S. is turning its attention increasingly to China. Will he try to assuage Japanese concerns in that regard?

COLONEL CROWLEY: I think we have long held that the United States relationship with China and the United States relationship with Japan is not a zero sum game. You know, the President met with Prime Minister Hashimoto at the G-7, had a bilateral meeting in Birmingham. Secretary Albright was over in Tokyo over the weekend following our departure from China, and the President will welcome Prime Minister Hashimoto here. I'm sure that the Asian financial situation will be, perhaps, the leading topic of discussion, but I'm sure there will be a wide range of issues, including a debrief from the President on China and other Asian security issues, as well.

Q P.J., back to the START II. Are you saying there is some -- you believe there's some chance the treaty will be ratified before Clinton and Yeltsin meet?

COLONEL CROWLEY: I suspect it will not -- I mean, the Duma has just simply said they are going to take up the issue again in September. I would doubt that it would be -- actually be completed by the time the President gets there.

Q Will the President ask President Yeltsin to limit Russia's arms and military technology sales to the Persian Gulf states and to the Middle East?

COLONEL CROWLEY: I'm sure that our continuing efforts, together with Russia, to limit missiles sales, specifically to Iran, and our joint objectives in terms of nonproliferation will be discussed, yes.

Q Race Commission question. Is the Wednesday -- is it a town hall or what is it? And is this the last event the President will do on the issue?

MR. LOCKHART: I don't know going into the future. I mean, we view -- the President looked to set out to work over a year on the Race Commission, and that we have from now until the end of September. So I don't know particularly going forward into the future that this will be the last event. It will be one of the town halls. We've done them, as you know, in various different formats, from a very standard town hall setting, which we did in Akron, to the ESPN, to now this PBS, which will be a smaller setting with some of the PBS correspondents and some experts brought in. And I think it will be much more -- probably a more focused discussion than the free-wheeling discussion we saw on race and sports.

I don't know -- again, I don't know in particular between now and the end of September and beyond. I mean, I'm certain, whether it comes under the rubric of the commission and the work that they will be doing --

Q But you don't know of any other town hall meetings?

MR. LOCKHART: Yes, right -- to finish up their work and to begin doing the reports, whether under that rubric or some other, he'll be continuing to participate in this kind of dialogue.

Q Joe, a couple of questions if you don't mind. In this morning's event, the President said that he plans to use "the authority of the presidency" from time to time. Is this the hint that he's going to step up his use of legislation through executive order?

MR. LOCKHART: Well, not legislation through executive order. I mean, the President has always said that he wants to work in cooperation with Congress to get the people's business done. And in some areas where we're stalled or blocked by those who don't share the President's

agenda, he's always sought to use the powers that he has through executive orders, through, as he also said, the powers of persuasion from the bully pulpit.

Q May I follow up? Another issue, this weekend Lanny Davis said that he thinks the President should continue to not testify voluntarily before Starr's grand jury, that Starr has demonstrated that he has some vendetta. Does the President agree with Lanny Davis on that?

MR. LOCKHART: I have not talked to the President in particular on any comments that Lanny's made recently. As far as that issue, as far as I know, there's been no change. That issue has been addressed by the President's attorney. Unfortunately, for those of you who are trying to get in touch with him, he's on vacation this week, so I obviously don't expect any change this week, but I know he'll be back.

Q I don't think we'd notice. (Laughter.)

MR. LOCKHART: Well, I'm telling you.

Q Who's on vacation?

MR. LOCKHART: David Kendall.

Q How realistic is it to think that they're going to pass comprehensive tobacco legislation-patient bill of rights with all of those things?

MR. LOCKHART: I guess the best -- I mean, let me anecdotally answer that question, which is I was flipping around this morning, I was watching one of the -- a riveting panel debate on C-SPAN with political consultants. And one of the Democrats sort of fired over and said, we're going to run a great campaign this fall on the Congress not doing anything. And the Republican consultant shot back by saying, well, you guys said that in 1996 and look what we got done in August.

The congressional calendar can be peculiar and doesn't necessarily always follow a logical schedule. And we're going to continue to press for the things that we've talked about, whether it be tobacco, child care, worker bill of rights a retraining bill of rights, which is moving through Congress now. So there's a lot of issue that we're going to continue to push on.

Q But if they can pass a Patient Bill of Rights that just isn't up to your standard, and they can pass tobacco legislation that just isn't up to your standard, it's not that they're doing nothing, it's that they're not doing what you want. Isn't that going to be difficult to sell to the voters?

MR. LOCKHART: Well, I think, then we'll have to put it to the voters. Whether they think a tobacco legislation that mirrors what the tobacco companies have said is acceptable to them, or tobacco legislation that we think will protect children. That is --I mean, that will be a choice the voters will ultimately have to make. But I don't think we -- we don't want to concede the point that we're at that point. There are only 38 legislative days yet, but a lot of work can get done quickly when both sides feel the incentive to cooperate.

Q Are you going to sign on to Hatch's legislation? Are you ready to --

MR. LOCKHART: Well, I don't know what we've seen of Hatch's legislation, but it's pretty -- the standard for whether we'll support tobacco legislation is fairly easy to judge -- whether it meets the

criteria. And from the reports I've seen, I think it does fall somewhat short.

MR. TOIV: Yes, I'd leave it at that. (Laughter.)

MR. LOCKHART: Thank you. (Laughter.)

Q You were asked this morning what the President thought of Starr's decision -- apparent decision not to send an interim report to Congress. Did you ask him?

MR. LOCKHART: I did not ask directly, but my understanding is that the President believes that that is a decision that Mr. Starr and the Office of the Independent Counsel needs to make for themselves and he has no guidance to offer.

Q Can you just tell us what's the significance of the health care event for tomorrow?

MR. LOCKHART: The significance?

Q Yes.

MR. LOCKHART: That the President continues to use, his good offices to try to increase quality and access to health care.

Q Pretty ambitious litany of things he listed this morning. How much of that do you realistically think is possible?

MR. LOCKHART: Well, we think there are a number of areas from -- on the education front, from after-school programs that are now moving through -- that are in the appropriation process; the America Reads programs; the child care program that he laid out just after the State of the Union; the increase in NIH funding; the Health Care Bill of Rights; again, the G.I. worker retraining. I can't predict for you what will get through, but the President has an aggressive agenda, one that I think the American public supports. And it's now up to this White House and this Congress to find a way to cooperate to move it forward.

Q You mentioned that IMF legislation was the chief bill to pass before fast track. Today in the Rose Garden the President said Africa trade and Caribbean Basin Initiative. Has IMF sort of lost --

MR. LOCKHART: No. I think if you look at the -- I think he was particularly thinking on other trade issues -- but if you look at what needs to get done and how we prioritize those issues, I would say that IMF and also Africa trade, those are issues we feel are important to move forward on now, that have support, that Congress -- we can move forward on -- and those would be our priorities before we brought fast track up again.

Q But you would equate Africa trade and Caribbean Basin Initiative with IMF? Is it that --

MR. LOCKHART: We're not in the business of trying to score, that this gets this score and that gets that score. These are issues that I think we can move forward on. There's bipartisan support on these issues. And particularly with IMF, there is a pressing need to move forward on given the financial conditions in Asia.

Q Joe, given that it is an ambitious agenda and there's not a lot of time left, is there any thought given to try and keep Congress in town during August to get some of this stuff done? Any discussion on that?

MR. LOCKHART: Well, actually -- I mean, I think we have -- again, the legislative days are dwindling, but I think if we move in a cooperative effort, I don't know that there will be a need to do anything that adds time. I mean, I haven't heard any concrete discussion of anything like that.

Q Does the President have any plans to sit down with the House or Senate leadership to discuss this agenda?

MR. LOCKHART: I'm not aware of any specific meetings. I mean, I think on a staff level, we're talking constantly. The President is also in regular touch with both the leadership and members on a variety of issues. So I don't know if there's any specific meeting planned to bring people down here.

Q Do you know when he last spoke to the Majority Leader and the Speaker?

MR. LOCKHART: I don't know. I know that -- I believe he spoke to them just before he left, at least to the Majority Leader. But, I mean, I can go back and look. I don't know exactly. I don't think there were calls during the trip.

Q Senator Wellstone says the President isn't doing enough to try to settle the GM strike. What's your answer to him?

MR. LOCKHART: Well, I think, as you all know, that the standard that has to be reached on Taft-Hartley is awfully high. Secretary Herman has been in touch with both parties. We continue to monitor the situation and I think Secretary Herman has done a good job of keeping the President informed on what the situation is.

Q How badly does it restrict the economy so far?

MR. LOCKHART: I'm not qualified to make an assessment on that. I think there are certainly economists out there who have made projections, and if you are looking for something more specific, we may have something out of CEA, but I haven't seen anything specific.

Q Is the White House confident now that there was no U.S. use of nerve gas during the Vietnam War?

MR. CROWLEY: I believe the Defense Department has been investigating that, but I also believe that CNN has disavowed that story. So I don't think that we are aware of any use of nerve gas during the Vietnam War.

Q Are you guys satisfied --

Q CNN said there was no evidence, but the individual people who were fired are still saying it's true.

MR. CROWLEY: I think CNN has disavowed that story. You might check with the Defense Department to see if they have actually concluded their report, but their preliminary indications were that those reports were false.

Q Are you satisfied with the way Time and CNN have handled this and punished the people they think deserve --

MR. CROWLEY: I'm not sure that's a judgment for us to make. That's a judgment for the individual news organizations to make.

Q Oh, go ahead. (Laughter.)

MR. LOCKHART: It will be fun, P.J., come on. (Laughter.)

Q Is the President pleased with Japan's economic recovery plan, or does he think that taxes should be cut, some more steps taken?

MR. CROWLEY: I believe he addressed that point on Friday, that this moves Japan in a positive direction. They still have to follow through on the steps that they've announced and he expects that the Prime Minister will be taking more action following the election early next week.

Q On the legislative agenda, do you have any expectation that any more ambassadors will be confirmed before they get out of session?

MR. CROWLEY: I have expectations that we'll have ambassadorial nominations to announce when we have them to announce. I have nothing

--

Q What about -- what is the Hill saying about confirmation?

MR. CROWLEY: I don't know.

Q You've spoken to this before, but what's the President's position on this religious freedom act that's being -- passed the House and going through the Senate?

MR. CROWLEY: The domestic one on school prayer?

MR. LOCKHART: I'm sorry. The question?

Q -- pertaining to religious freedoms in foreign countries and --

MR. LOCKHART: I was ready on the domestic one.

MR. CROWLEY: Are you specifically talking about Wolf, Specter and Nickels, or which -- I mean, which specific piece of legislation are you talking about?

Q There is a piece of legislation that has passed the House, it's working its way through the Senate, that pertains to the imposition of some form of redress on the part of the United States for nations that we believe are not exercising or allowing religious freedom to be exercised in their countries?

COLONEL CROWLEY: Why don't we talk afterwards if there is a specific piece -- I mean, there are several pieces of legislation out there, depending on which specific piece you're talking about.

Q How does the President assess how he did in China? Have you heard him on that subject?

COLONEL CROWLEY: I think the President spoke eloquently about that in great detail to the White House press corps that were there on Friday. I would defer to the President, I think. This was -- he thought this was an excellent trip, an excellent opportunity to further relations between the two countries. And we'll see between now and in the coming weeks how China follows up. However, it's put the relationship between the United States and China on much more positive footing.

Q Can I follow up on that? On Taiwan we're getting two different signals, though. How is the administration reassuring Taiwan, after what the President said on China?

COLONEL CROWLEY: Nothing that the President said in China changes

our relationship with Taiwan. There was no change in any element of the communiques. Our relationship with Taiwan is specifically spelled out in the communiques and the Taiwan Relations Act.

Q So if China attacks Taiwan, the U.S. is still obligated to defend Taiwan?

COLONEL CROWLEY: Our responsibilities with respect to Taiwan are spelled out in the three communiques and the Taiwan Relations Act, and nothing that occurred in this trip has changed that.

Q Thank you.

COLONEL CROWLEY: Thank you.

END

1:56 P.M. EDT

File Quality Commission

TESTIMONY OF CONGRESSMAN PETE STARK
BEFORE THE ADVISORY COMMISSION ON CONSUMER PROTECTION &
QUALITY IN THE HEALTH CARE INDUSTRY

June 26, 1997

Secretary Shalala, Secretary Herman and Members of the Commission:

Thank you for this opportunity to present testimony concerning critically needed consumer protections for the millions of Americans in managed care plans.

Background

Health care consumers who entrust their lives to managed care plans have consistently found that many plans are more interested in profits than in providing appropriate care. In the process of containing costs patients are often harmed. My constituent mail has been full of horror stories explaining the abuses that occur at the hands of HMOs and other forms of managed care.

For example, David Ching of Fremont, California had a positive experience in a Kaiser Permanente plan and then joined an employer sponsored HMO expecting similar service. He soon learned that some plans would rather let patients die than authorize appropriate treatment. His wife developed colon cancer, but went undiagnosed for 3 months after the first symptoms. Her physician refused to make the appropriate specialist referral because of financial incentives and could not discuss proper treatment because of the health plan's policy. Mrs. Ching is now dead.

This tragedy and others like it might have been avoided if the patient had known about the financial incentives not to treat, or if the physicians had not been gagged from discussing treatment options, or if there had been legislation forcing health plans to provide timely grievance procedures and timely access to care. It is too late for some victims, but it is not too late to provide these protections for the millions of people in managed care today.

A few years ago, Congress recognized a crisis in the health care industry. Expenditures were soaring and overutilization was the rule. At that time, I chose to address this problem with laws that prohibited physicians from making unnecessary referrals to health organizations or services that they owned.

Others responded by pushing Americans into new managed care plans that switched the financial incentives from a system that overserves to a system that underserves. They got what they asked for. The current system rewards the most irresponsible plans with huge profits, outrageous executive salaries,

and a license to escape accountability. Unfortunately, patients are dying unnecessarily in the wake of this health care delivery revolution. It must stop.

Several states have already addressed the managed care crisis. In 1996, more than 1,000 pieces of managed care legislation flooded state legislatures. As a result, HMO regulations were passed in 33 states addressing issues like coverage of emergency services, utilization review, post-delivery care and information disclosure. Unfortunately, many states did not pass these needed safeguards resulting in a piecemeal web of protections that lacks continuity. The states have spoken; now it is time for federal legislation to finish the job and provide consumer protections to all Americans in managed care.

H.R. 337 -- The Managed Care Consumer Protection Act of 1997

I have introduced a bill -- H.R. 337 -- The Managed Care Consumer Protection Act of 1997 which includes a comprehensive set of protections that will force managed care plans to be accountable to all of their patients and to provide the standard of care they deserve.

This legislation includes measures to protect patients from the abuses of managed care on several fronts. One particular provision in the bill would require the managed care plan to at least see the patient and perform some form of preventive health screening before the Federal government pays the monthly capitated dollar amount. We should not continue to pay plans a monthly fee when many times, the plan has never seen the beneficiary face-to-face. If one of the goals of managed care is to focus on preventive care, the patient must -- at the very least -- first be seen by the managed care plan.

I am pleased that many of the provisions in my bill were included in the recent Medicare proposals in both the Ways and Means and the Commerce Committees. I have attached a summary of the bill for your review.

Many Members testifying today have introduced legislation with similar provisions. In that light, I will focus on only a few issues.

A Plea to Revisit the Physician Financial Incentive Issue

I am the author of the law limiting physician financial incentives to withhold care. I am very disappointed in the regulation implementing this law.

The regulation allows a plan to place a doctor 25% at risk.

How many of you flew here on an airline that gave 25% bonuses to its airplane mechanics NOT to spend too much time checking the plane's safety? Good luck going home.

What is particularly disappointing about the 25% figure is that there is some data that the industry average is closer to 19%. The 25% figure should be lowered. I urge you to recommend that it be phased down over a period of years to a level where the average patient would not be offended or suspicious.

If you think the 25% figure is okay and won't change behavior in strange ways, I refer you to a *Wall Street Journal* article of two weeks ago, which talked about doctors selling Amway products to their patients to make extra money on the side. The doctor featured in the article had seen his income decline from \$400,000 a year to \$300,000, so he was selling soap to everyone in sight. Think about it!

Need to Reform Government Oversight Structure

HCFA has an impossible task: to promote managed care and at the same time to try to regulate it on behalf of consumers. The two missions are inconsistent: you can't do both well. Note the current controversy over the *Grijalva* case, where HCFA has come down on the side of the HMO companies, much to the anger of every consumer group in the nation.

We need a new structure of governance as managed care grows.

I urge the Commission to recommend a restructuring of government to address this problem. Let HCFA be the promoter and payer of managed care plans. That is certainly their bureaucratic culture and history.

For the public and the consumer, we need a new, independent consumer commission that will make coverage, consumer appeals and grievance, and quality measurement decisions. I recommend to you the SEC-type model suggested in several books and articles by Professor Marc Rodwin of Indiana University. This Commission should be composed of consumers and must be structured so it is never captured by the industry.

We need an independent consumer commission now. We will need it more each passing day. I do not believe that HCFA has yet made Medicare coverage decisions on the basis of cost to the program. But as the Baby Boom generation retires and the financial pressures on the program become more intense, will people be able to trust their government to make medically honest coverage decisions? Will HCFA become a rationing system that controls costs but may not be good for our health? Various right-to-life groups are already questioning the program. An independent consumer commission that would address coverage issues would prevent this government rationing issue from becoming a future divisive issue in our aging society.

A wise industry would support such a Commission: it is their only hope to show the public that there is an independent, honest ombudsmen whom families can turn to in matters of life and death concerning health care. The managed care industry is facing a weekly drumbeat of ridicule in the one place that truly has the pulse of the American public--the nation's comic strips and political cartoons. The last page of my testimony attaches two cartoons from just the Washington Post of the last week. What would it be worth to the HMO industry for these cartoons to go away? They will go away when the public no longer thinks they are funny and when they no longer resonate. An independent, pro-consumer Commission is the single best answer to ending the ridicule and bad press.

The impending crisis in rural managed care

I urge the Commission to take a special look at what I believe is an impending crisis in rural health care.

In the Medicare Reconciliation bill, Congress is preparing to place a very high floor on payments to managed care plans in rural counties--a floor far above their cost of serving the beneficiaries who live in those communities. At the same time, we are making it easy for local doctors and hospitals to form Provider Sponsored Organizations or "baby HMOs" that serve as few as 500 enrollees. PSOs in rural America, where there is already a shortage of providers, will certainly look like monopolies.

The combination of the high managed care payments and the new PSOs will work to force most rural Americans into brand new HMO-type organizations. The good news is that the payment floors will be so high that (if the ACRs are calculated honestly) rural Americans will be offered a wide range of extra benefits. The bad news is that it may be hard for rural Americans to get referrals to urban or out-of- area providers who can provide better quality care than their local rural PSO.

I believe we will need some special measurements of these new rural PSOs to ensure that we are not trapping millions of rural residents in monopolistic low- quality plans.

Managed Care and Anti-Fraud

The HHS Inspector General, in cooperation with the GAO, has undertaken a system-wide audit of Medicare. Their report will be issued in about three weeks.

According to press reports, they will find that in fee-for-service Medicare last year we lost about \$23 billion to fraud, waste, and abuse. Over five years that

would be about \$115 billion--the exact size of the Medicare Budget cuts the House passed yesterday.

Some will say that this proves we need to move faster to managed care. I submit there is substantial fraud in managed care as well. I urge the Commission to encourage HCFA to do a better job of rooting out managed care fraud.

There is the fraud of under-service and denial of care--the fraud that can kill.

There is the fraud of the Adjusted Community Rates (ACR) that companies tell us equal the cost of serving their commercial business. Time after time an HMO does not provide extra benefits and says that its ACR does not require such extra benefits. Then when a second or third managed care plan enters the market, all of a sudden the plan finds that it can offer zero premiums, drug benefits, and eyeglasses. On its face, the plan that for years offered no or few extra benefits was committing a type of fraud.

I've attached an exchange of correspondence with the OIG that makes the point that if fee-for-service Medicare has a 10 to 14% fraud, waste, and abuse factor built into its rates, we certainly should not base managed care payment rates on that fraudulent, inflated base. It is a mathematical fact that the payment rate to HMOs should be less than 90% of the current fee-for-service rate--unless you want to pay twice for fraud.

Thank you for this opportunity to present my ideas about much needed consumer protections in managed care.

"MANAGED CARE CONSUMER PROTECTION ACT OF 1997"

CONGRESSMAN PETE STARK

SUMMARY

- I. MANAGED CARE ENROLLEE PROTECTIONS -- APPLIES TO MEDICARE MANAGED CARE AS WELL AS PRIVATE PLANS
 - A. Utilization Review
 1. Any utilization review program that attempts to regulate coverage or payment for services must first be accredited by the Secretary of Health and Human Services or an independent, non-profit accreditation entity;
 2. Plans would be required to provide enrollees and physicians with a written description of utilization review policies, clinical review criteria, and the process used to review medical services under the program;
 3. Organizations must periodically review utilization review policies to guarantee consistency and compliance with current medical standards and protocols;
 4. Individuals performing utilization review could not receive financial compensation based upon the number of certification denials made;
 5. Negative determinations about the medical necessity or appropriateness of services or the site of services would be required to be made by clinically-qualified personnel of the same branch of medicine or specialty as the recommending physician;
 - B. Assurance of Access
 1. Plans must have a sufficient number, distribution and variety of qualified health care providers to ensure that all enrollees may receive all covered services, including specialty services, on a timely basis (including rural areas);
 2. Patients with chronic health conditions must be provided with a continuity of care and access to appropriate specialists;
 3. Plans would be prohibited from requiring enrollees to obtain a physician referral for obstetric and gynecological services.

4. Plans would demonstrate that enrollees with chronic diseases or who otherwise require specialized services would have access to designated Centers of Excellence;

C. Access to Emergency Care Services

1. Plans would be required to cover emergency services provided by designated trauma centers;
2. Plans could not require pre-authorization for emergency medical care;
3. A definition of emergency medical condition based upon a prudent layperson definition would be established to protect enrollees from retrospective denials of legitimate claims for payment for out-of-plan services;
4. Plans could not deny any claim for an enrollee using the "911" system to summon emergency care.

D. Due Process Protections for Providers

1. Descriptive information regarding the plan standards for contracting with participating providers would be required to be disclosed;
2. Notification to a participating provider of a decision to terminate or not to renew a contract would be required to include reasons for termination or non-renewal. Such notification would be required not later than 45 days before the decision would take effect, unless the failure to terminate the contract would adversely affect the health or safety of a patient;
3. Plans would have to provide a mechanism for appeals of termination or non-renewal decisions.

E. Grievance procedures and deadlines for responding to requests for coverage of services.

1. Plans would have to establish written procedures for responding to complaints and grievances in a timely manner;
2. Patients will have a right to a review by a grievance panel and a second review by an independent panel in cases where the plan decision negatively impacts their health services;
3. Plans must have expedited processes for review in emergency cases.

F. Non-discrimination and service area requirements

1. In general, the service area of a plan serving an urban area would be an entire Metropolitan Statistical Area (MSA). This requirement could be waived only if the plan's proposed service area boundaries do not result in favorable risk selection.
2. The Secretary could require some plans to contract with Federally-qualified health centers (FQHCs), rural health clinics, migrant health centers, or other essential community providers located in the service area if the Secretary determined that such contracts are needed in order to provide reasonable access to enrollees throughout the service area.
3. Plans could not discriminate in any activity (including enrollment) against an individual on the basis of race, national origin, gender, language, socioeconomic status, age, disability, health status, or anticipated need for health services.

G. Disclosure of plan information

1. Plans would provide to both prospective and current enrollees information concerning:
 - Credentials of health service providers
 - Coverage provisions and benefits including premiums, deductibles, and copayments
 - Loss ratios explaining the percentage of premiums spent on health services
 - Prior authorization requirements and other service review procedures
 - Covered individual satisfaction statistics
 - Advance directives and organ donation information
 - Descriptions of financial arrangements and contractual provisions with hospitals, utilization review organizations, physicians, or any other health care service providers
 - Quality indicators including immunization rates and health outcomes statistics adjusted for case mix
 - An explanation of the appeals process
 - Salaries and other compensation of key executives in the organization
 - Physician ownership and investment structure of the plan

- A description of lawsuits filed against the organization
 - Plans must provide each enrollee annually with a disclosure statement regarding whether the plan restricts the plans malpractice liability in relation to liability of physicians operating under the plan.
2. Information would be disclosed in a standardized format specified by the Secretary so that enrollees could compare the attributes of all plans within a coverage area.

H. Protection of physician - patient communications

1. Plans could not use any contractual agreements, written statements, or oral communication to prohibit, restrict or interfere with any medical communication between physicians, patients, plans or state or federal authorities.

I. Patient access to clinical studies

1. Plans may not deny or limit coverage of services furnished to an enrollee because the enrollee is participating in an approved clinical study if the services would otherwise have been covered outside of the study.

J. Minimum Childbirth benefits

1. Insurers or plans that cover childbirth benefits must provide for a minimum inpatient stay of 48 hours following vaginal delivery and 96 hours following a cesarean section.
2. The mother and child could be discharged earlier than the proposed limits if the attending provider, in consultation with the mother, orders the discharge and arrangements are made for follow-up post delivery care.

II. AMENDMENTS TO THE MEDICARE PROGRAM, MEDICARE SELECT AND MEDICARE SUPPLEMENTAL INSURANCE REGULATIONS.

A. Orientation and Medical Profile Requirements

1. When a Medicare beneficiary enrolls in a Medicare HMO, the HMO must provide an orientation to their managed care system before Medicare payment to the HMO may begin;

2. Medicare HMOs must perform an introductory medical profile as defined by the Secretary on every new enrollee before payment to the HMO may begin.
- B. Requirements for Medicare Supplemental policies (MediGap)
1. All MediGap policies would be required to be community rated;
 2. MediGap plans would be required to participate in coordinated open enrollment;
 3. The loss ratio requirement for all plans would be increased to 85 percent.
- C. Standards for Medicare Select policies
1. Secretary would establish standards for Medicare Select in regulations. To the extent practical, the standards would be the same as the standards developed by the NAIC for Medicare Select Plans. Any additional standards would be developed in consultation with the NAIC.
 2. Medicare Select Plans would generally be required to meet the same requirements in effect for Medicare risk contractors under section 1876.
 - Community Rating
 - Prior approval of marketing materials
 - Intermediate sanctions and civil money penalties
 3. If the Secretary has determined that a State has an effective program to enforce the standards for Medicare Select plans established by the Secretary, the State would certify Medicare Select plans.
 4. Fee-for-service Medicare Select plans would offer either the MediGap "E" plan with payment for extra billing added or the MediGap "J" plan.
 5. If an HMO or competitive medical plan (CMP) as defined under section 1876 offers Medicare Select, then the benefits would be required to be offered under the same rules as set forth in the MediGap provisions above.
- D. Arrangements with out-of-area dialysis services.
- E. Coordinated open enrollment
1. The Secretary would conduct an annual open enrollment period during which Medicare beneficiaries could enroll

in any MediGap plan, Medicare Select, or an HMO contracting with Medicare. Each plan would be required to participate.

F. Comparative Information

1. The Secretary must provide on an annual basis for publication and use on the internet information in comparative form and standard format describing the policies offered, benefits and costs, disenrollment and complaint rates, and summaries of the results of site monitoring visits.

G. Office of Medicare Advocacy

1. Establishes Office of Medicare Advocacy within the Health Care Financing Administration. The purpose of the office is to act on behalf of Medicare recipients, especially to address complaints and concerns. A toll free telephone number would be established to facilitate communication. Additional outreach programs such as town meetings would be developed and an internet site would be established for posting information.
2. The office would have authority to provide for an expedited review and resolution of complaints under emergency circumstances as described in the bill.

H. Exclusion from Medicare and Medicaid Program

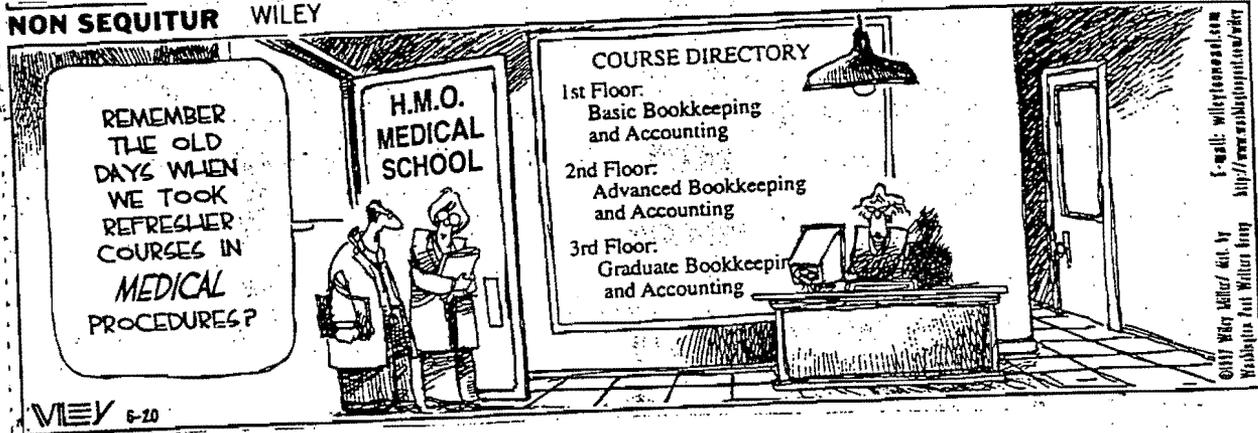
1. If plan submits information relating to the quality of services provided that is material and false, the Secretary shall exclude the plan from continuing to qualify for Medicare and Medicaid payments.

III. AMENDMENTS TO THE MEDICAID PROGRAM

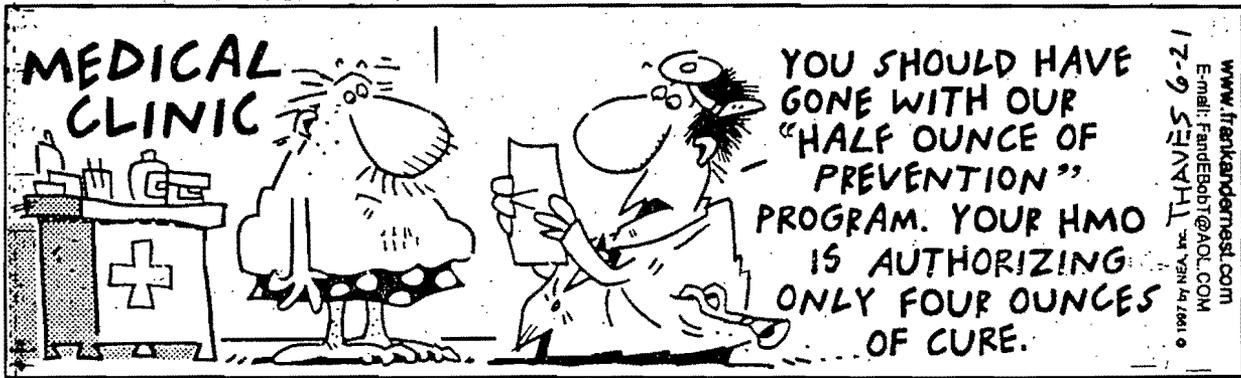
A. Orientation and Immunization Requirements

1. When a Medicaid beneficiary enrolls in a Medicaid HMO, the HMO must provide an orientation to their managed care system before Medicaid payment to the HMO may begin;

2. Medicaid HMOs must perform an introductory medical profile as defined by the Secretary on every new enrollee before payment to the HMO may begin.
3. When children under the age of 18 are enrolled in a Medicaid HMO, the immunization status of the child must be determined and the proper immunization schedule begun before payment to the HMO is made.



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COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

May 14, 1997

The Honorable June Gibbs Brown
Inspector General
Department of Health and Human Services
330 Independence Ave., S.W.
Washington, D.C. 20201

Dear Ms. Brown:

Over the years the Department of Justice, GAO, the Inspector General of the Department of HHS and State Medicaid fraud units have made extensive findings, reported, and testified concerning the pervasive scope and depth of fraud and abuse in private and public health care programs, including Medicare.

In that regard, I am considering an amendment to Medicare's HMO payment provisions to require deletion of the estimated costs of fraud and abuse from the base upon which HMO's 95% of the "average adjusted per capita costs" of the non-HMO population is calculated. This would be apart from other adjustments which are being recommended to moderate overpayments.

Medicare payments to HMOs are supposedly at 95% of the adjusted average per capita costs for beneficiaries not in HMOs. That amount is supposed to reflect the relative efficiency of managed care over fee-for-service in delivering care to Medicare eligibles. But that 95% represents a significant overpayment because of inflated fee-for-service costs. According to studies prepared for the Department of HHS, the overpayments are on the order of 5-7% or even more. Since Medicare payments to HMOs are expected to increase, (according to CBO) from some \$16 billion in the current fiscal year to \$70 billion by FY2004, the overpayments become huge.

The HMO reimbursement structure appears to require another vitally necessary but heretofore overlooked adjustment in the interest of equitable payment and comparison with the costs of covered care under fee-for-service. We should remove from the outside per capita costs base on which 95% is paid, the estimated percent of costs attributable to fraud and abuse. Fraud and abuse definitely should not be part of any comparison of the costs of covered care.

The effect of including the costs of fraud and abuse in the base upon which HMOs are paid by Medicare is to compound the costs of fraud and abuse. For example, assume the total Medicare costs of non-HMO beneficiaries upon which the HMO's 95% is based totals \$175 billion. Assuming, not unreasonably based upon experience, that 10 percent of that \$175 billion base is attributable to fraudulent and abusive practices, then, in addition to the wasted \$17.5 billion in the fee-for-service sector, that waste is calculated in setting the base for paying HMOs 95% of the fee-for-service adjusted average per capita cost. How's that for charging the taxpayers double for nothing!

In the case of the non-HMO beneficiary costs base, I am considering proposing a flat percentage adjustment - initially at what is generally conceded to be the low level of the range of the estimated costs of fraud and abuse - namely, five percent. Subsequently, an annual adjustment, promulgated prospectively would be based upon the average of the then-current estimates of the percentage of Medicare fraud and abuse submitted to the Secretary of HHS by the Attorney-General, the Comptroller-General, and the Inspector-General of HHS.

It is also important that States reimbursing Medicaid managed care programs and other entities through payment of a percentage of outside provider or program costs consult with their State Medicaid fraud units concerning appropriate adjustments to remove the estimated costs of fraud and abuse from any percentage payments to managed care and similar programs.

In sum, the virtues of an amendment along the above lines would be to:

1. Avoid compounding the costs of fraud by adding another 95% of those fraud costs in payments to HMOs; and
2. Save billions which could be applied toward required budget targets.

I would appreciate the OIG's comments on this idea. Would it make sense to weed out the cost of waste, fraud, and abuse from setting the AAPCC rate for paying HMOs? Is the 5 to 10% figure justifiable as a general level of fraud, waste, and abuse? Would there be other ways to weed out this "double payment"?

Thank you very much for your thoughts and ideas on stopping fraud, waste, and abuse from being built into the HMO program.

Sincerely



Pete Stark

Ranking Democrat



JUN 12 1997

The Honorable Fortney Pete Stark
Ranking Minority Member
Subcommittee on Health
House of Representatives
Washington, D.C. 20515

Dear Mr. Stark:

This is in response to your letter of May 14, 1997 concerning the effects of the costs of fraud and abuse in the Medicare fee-for-service program on payment rates to Medicare health maintenance organizations (HMO).

As you stated in your letter, rate setting methodologies for risk-based HMOs are based on expenditures in Medicare's fee-for-service program. We share your concerns that abusive practices which drive up costs in the fee-for-service program are included when the HMO rate setting methodologies are applied. This is especially disconcerting when considering payments to HMOs are expected to increase throughout the decade as more beneficiaries opt to join HMOs.

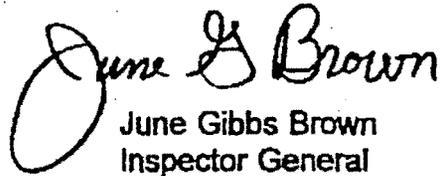
Our work over the years has shown significant fraud, waste, and abuse do exist in the Medicare fee-for-service program. Although we have not been able to conclusively quantify the amount of fraud involved in the Medicare program, our current audit of the Health Care Financing Administration's financial statements under the Chief Financial Officers Act may give us some quantifiable insights into this general area of incorrect payments in the Medicare program. Although this audit will not be completed until the end of this month, preliminary indications are that several areas of the Medicare program have significant payment improprieties.

When our financial statement audit is complete, we will do further analysis of the data to determine if it would be feasible to adjust HMO payment rates to take into account incorrect payments made in the fee-for-service base (including fraud and abuse).

Page 2 - The Honorable Fortney Pete Stark

We look forward to working with you and your staff to help ensure that HMO rates are calculated using cost-effective and equitable methodologies. If you need additional information, please call me or have your staff contact Helen Albert, Director of External Affairs, at (202) 619-0275.

Sincerely,

A handwritten signature in black ink that reads "June Gibbs Brown". The signature is written in a cursive style with a large, looping initial "J".

June Gibbs Brown
Inspector General