# Withdrawal/Redaction Sheet

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Chris Jennings to Hillary Clinton Re: Wednesday Congressional Message Group Meeting (2 pages)	11/9/93	Р5
002. memo	Chris Jennings to Ira Magaziner Re: Drafting Changes (2 pages)	11/8/93	Р5
003. memo w/attach	Chris Jennings to Hillary Clinton Re: Health Care Legislative Strategy Memo (17 pages)	11/24/93	P5

#### **COLLECTION:**

Clinton Presidential Records Domestic Policy Council Chris Jennings (Domestic Policy Council) OA/Box Number: 23754

#### FOLDER TITLE:

November 1993 HSA [2]

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

#### **RESTRICTION CODES**

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

- 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]
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- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [a)(5) of the PRA]
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#### DANIEL K. INOUYE, HAWAII, CHAIRMAN JOHN MCCAIN, ARIZONA, VICE CHAIRMAN

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COMMITTEE ON INDIAN AFFAIRS WASHINGTON, DC 20510-6450

November 29, 1993

Mrs. Hillary Rodham Clinton The White House Office 1600 Pennsylvania Avenue NW Washington, DC 20500

Dear Mrs. Clinton:

l am writing to thank you for your interest in the health care needs of the Native Hawaiian people, as evidenced by your recent meetings in Hana, Maui with Native Hawaiian health care organizations and Native Hawaiian health care providers in mid-July of 1993. Your site visit to the Hana Medical Center and discussion with the doctors, staff, and community members meant a great deal to the people of Hana and all Native Hawaiians throughout the State of Hawaii.

I am also writing to bring your attention to an upcoming visit by some of the very same people you met with in Hana, such as Dr. Emmett Aluli. The Executive Directors and the fiscal officers of each of the five Native Hawaiian Health Care Systems will be in Washington D.C. from December 6th until December 8th to attend administrative meetings. These twelve individuals -- all actively engaged in the provision of direct health care services to Native Hawaiian communities -- would very much like to pay a courtesy call upon you in order that they may provide a follow-up to the forty minute discussion they had with you in Hana in July.

I have attached for your information a fax sent earlier by Dr. Aluli and Mr. Akutagawa to your scheduler, Ms. Patti Solios. I hope that your schedule might enable you to meet with these representatives of the Native Hawaiian health care community. I look forward to hearing from you.

Sincere UYE Chairman

Attachment

#### ADVISORY COUNCIL AMENDMENT TO THE HEALTH SECURITY ACT

On page 287, line 16, at the end of the new provision quoted below, add the text in bold typeface:

(E) cost-effectiveness relative to cost of alternative courses of therapy options, including non-pharmacologic medical interventions. When evaluating cost-effectiveness, the Council should take into account improvements in quality of life offered by the new product, including but not limited to, ability to return to work, ability to perform the activities of daily living, freedom from attached medical devices, relief from discomfort or pain, alleviation of fatigue, improved mental functioning and well-being, and so forth. Pharmaceutical Daily

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Prescription drugs

Volume 1, Number 83 PD

### **Bipartisan Health Plan Puts Consensus Legislation First**

(2, -5, 0)

A two-phase bipartisan health care reform plan was announced Friday by Rep. Michael Bilirakis, R-Fla., and Roy Rowland, D-Ga., that would have Congress work first to enact reforms on which general agreement exists, such as insurance and antitrust reform.

The second phase would set up a community-based primary, prevention and acute care program focusing on providing accessible health care to the uninsured and underinsured.

Benefits such as prescription drug coverage would be left to states and communities under the plan.

The "consensus" legislation is expected to be introduced in January.

Bilirakis and Rowland represent a coalition of more than 100 members who advocate a "simpler" approach than the bipartisan managed competition plan sponsoredby Reps. Jim Cooper, D-Tenn., and Fred Grandy, R-Iowa, in the House, and Sens. John Breaux, D-La., and Dave Durenberger, R-Minn., in the Senate, a congressional aide said.

The Bilirakis-Rowland coalition last month wrote President Clinton urging the two-phase approach to reform legislation.

Clinton's written response was to urge the coalition not to take the reform package apart. "I believe this issue should be tackled in whole," he said.

Reform "requires a comprehensive solution" and the debate should not be started "by taking the package piece-bypiece," Clinton said. Bilirakis said this "all-or-nothing ap-(Continued on page 2)

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## Administration Seeks Access To Off-Label Drug Use

By Martha M. Canan

The administration is seeking to widen access to off-label uses of drugs by pressuring insurance companies to reimburse such uses and providing incentives for pharmaceutical companies to seek additional labeled uses for approved drugs when appropriate.

The agency worked with the Health Care Financing Administration to carry out these objectives in the president's health care reform plan, Carol Scheman, FDA deputy commissioner for external affairs, told a congressional staff briefing Friday.

"We are committed to access to offlabel use," Scheman said. The bill requires that the proposed standard benefits package cover any use approved by

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FDA, and "another use of the drug" if the drug has been approved, and if "such use is supported by one or more citations" in various compendia, or "such use is medically accepted based on supportive clinical evidence," according to the bill.

Monday, November 22, 1993

The administration also wants to prod companies into filing for efficacy supplements to drug applications, "because that's how physicians learn" about how to use approved drugs, Scheman said.

The bill therefore includes a provision allowing the Health and Human Services Secretary to call for data for additional labeled use if a drug starts to be commonly used for an off-label indication, Scheman said.

eman said. (Continued on page 2)

## Folding Medicare Into Managed Care Is Big Question Mark

By Christina Barnes

Federal lawmakers Friday were making final revisions on their health care reform bills in hopes of introducing them in the last moments of this year's congressional session. But staffers said not to expect legislation to clarify how Medicare might be folded into the private sector until further discussions are held.

<sup>1</sup>Sen<sup>1</sup> John Chafee, R-R.I., who released a draft outline of a managed competition bill, was expected on Friday to introduce the full legislation on Saturday, an aide in the senator's office told *Pharmaceutical Daily*.

Other lawmakers, including Sen. Don Nickles, R-Okla., also were expected to introduce their bills by Saturday night, Susan Nestor, Senate Finance Committee aide, said Friday afternoon at a meeting of the Washington Business Group on Health and William M. Mercer Inc.

All of the Republican and Democratic lawmakers introducing bills in Congress (Continued on page 2)

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## Off-Label Drug Use ... (Continued from page 1)

"We want the drug companies to have the incentive to do the research," she said. Those who "make the profits" should do the research, she said.

FDA gets involved in the reimbursement issue through such means as writing insurance companies to persuade them to reimburse off-label uses. Scheman said. Last year's budgetreconciliation law requires reimbursement of off-label use of oncological drug therapies under Medicare, she noted.

Scheman urged the staffers to call the FDA when they begin considering off-label use provisions because the issue "is complicated and very important."

Scheman and other agency officials at the briefing also emphasized the priority that women's health issues now have at FDA.

"We have made it our business to put women's health on the

front burner," Ruth Merkatz, special assistant to the commissioner for women's health issues, said. In particular, "there is no group more in need of attention than women with AIDS," she said.

Diane Thompson, who has been named to be FDA associate commissioner for legislative affairs, said of the agency: "If it was an old boys' club, it ain't no more."

There is a strong cadre of women policymakers at the agency, which brings a "broader perspective and more analytical framework" for women's issues "that has been sorely missing," she said.

Thompson said Congress "will be seeing over the next several months... an increased presence" of FDA's office of congressional affairs to inform members and staff of agency policies and issues, particularly on women's health.

## Medicare Fold-In Is Question Mark ... (Continued from page 1)

are interested in how senior citizens could be folded into the private sector insurance system, the staffer said. "The one reason you do not see it clarified in the language is that no one is clear on just how to do it yet." Nestor said.

Under Clinton's plan, states can request of the Health and Human Services secretary Medicare money for their state, she said. The administration has said states must have their health care alliances fully operating before they can fold Medicare into the system.

But the president's bill, which staffers predicted would be introduced in the House over the weekend, may provide further incentives to move the Medicare population into managed care (*Pharmaceutical Daily*, Nov. 19, 1993).

Much of the conflict over whether and how to integrate the Medicare population into managed care comes wrapped in politics, Mary Ella Payne, legislative assistant for Sen. Jay Rockefeller, D-W Va., said.

First Lady Hillary Rodham Clinton supports such a transition, she said. "But the seniors like their plan and don't want

## Two-Phase Health Plan ..

proach joepardizes the chances for success of comprehensive health care reform. We must seize this opportunity and move forward on issues of agreement," he said.

The non-consensus bill, called the Community Health Improvement Act, would enable states and local communities to set up demonstration projects to provide accessible health care to all individuals, Bilirakis said

Participating communities would be able to convert Med-

you to fiddle with it," Payne said. The senior citizens also have a powerful lobbying group in Washington, she observed.

She said if a health care reform plan proposed Medicare be immediately folded into the private sector, then it would be dead on arrival due to the heavy opposition.

President Clinton also believes providing a new drug benefit: under Medicare "makes sense," Payne said. "But I think there's, a lot of politics involved in that as well."

Payne also indicated that the administration and some: lawmakers are not fully willing to rely on the private sector yet, which is why several regulatory provisions are included in the president's plan.

Also during the meeting, Payne indicated that meetings between Chafee, Sen. John Breaux, D-La., and Rep. Jim Cooper, D-Tenn., and other lawmakers have been continuing in hopes of finding elements of the health care reform packages that can gain bipartisan support. But she told *Pharmaceutical* Daily she did not expect Chafee's bill to reflect any negotiations made during these closed door meetings.

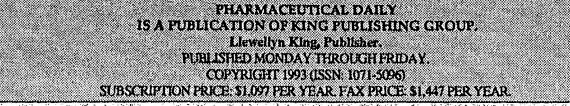
#### (Continued from page 1)

icaid funds to pay for the new system.

Community health authorities would be formed by physicians, hospitals, public health departments, community health clinics and federally qualified health centers to be governed by community officials from various sectors.

Enrolled patients would receive primary, preventive and acute inpatient and outpatient care, with services provided free or on a sliding scale based on income and assets.

-Martha M. Canan



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# Memorandum



November 12, 1993

To: Chris Jennings

From: Karen Williams

These are some of the more technical questions I'd like to raise with you and Gary Claxton (or others if you suggest). Most of these were raised briefly in our last meeting with you.

Please let us know how your schedule is shaping up for your luncheon speech on Monday, November 15 at 12:30 p.m. in the Ballroom of the Ramada Renaissance, 999 Ninth Street, NW. I can be reached at (202) 835-3530 today or at my home (301) 469-8777 over the weekend. If you can't let me know until Monday morning, call the hotel (202-898-9000) after 7:30 a.m. and ask to speak to the PMA Registration Desk.

Jones Haver

1100 Fifteenth Street, N.W. Washington, D.C. 20005 (202) 835-3400

#### Questions Regarding Pharmaceutical Benefits Under the Health Security Act

Based on provisions in the October 27, 1993 draft, several questions emerge regarding pharmaceutical benefits under the comprehensive benefit package, the Medicaid program, and the new Medicare outpatient drug benefit.

#### Duration of Medicare Rebate Negotiations for New Drugs

Question: How long is a new drug subject to "negotiation" under the rebate provisions of the new Medicare outpatient drug benefit?

Under the proposed bill, any drug approved after June 30, 1993 may be subject to a negotiated rebate if the Secretary determines that the new drug is "excessively priced". In making such a determination, the Secretary is to consider the price at which the product is sold in twenty-one other countries. Even if the product were introduced at the same price in all of these countries, currency fluctuations over time could result in significant differences. How long after a product has been approved is it considered by the Secretary to be a new drug potentially subject to such negotiated rebates?

#### Cost-Sharing for the Comprehensive Package

Question: Can combination and fee-for-service plans use a \$5.00 copay and no deductible for drugs?

Those Americans who now have drug coverage through their employers typically have no separate drug deductible. In fact, many employer fee-for-service plans waive the standard deductible and coinsurance for outpatient services in favor of a prescription card service which typically requires a flat dollar copayment throughout the year. Accordingly, most working families will experience an erosion of pharmaceutical benefits under the Health Security Act unless HMOs are much more available and working families choose to enroll in them.

Likely erosion of current pharmaceutical benefits might be softened if both combination and fee-for-service plans were able to utilize a \$5.00 copayment and no deductible for pharmaceuticals. Unfortunately, it appears that bill language in Section 1133, particularly lines 18-22 of page 79 and line 17 of page 80 could preclude such a copayment in both fee-for-service and combination plans. Given the potential savings to both the consumer and the AHP from the use of a \$5.00 copayment and the likelihood that current coverage will erode without continuation of a copayment and/or a combined outpatient deductible, such a restriction would seem unwarranted.

#### Drug Benefits Under Supplemental Insurance Standards

Question: How can supplemental insurance reduce the burden of a separate \$250 drug deductible?

It appears from language on page 242 of the draft bill that the National Health Board will determine the standard and maximum coverage available for cost sharing under private insurance which supplements the comprehensive package. On lines 20-24 of the same page, bill language refers to "equivalent level of coverage" and coverage "to the same extent as benefits under the comprehensive package". It is unclear from these brief references how supplemental insurance could reduce the burden of a separate \$250 drug deductible now included in the comprehensive benefit package. Would supplemental policies have to reduce the deductible and coinsurance proportionately (e.g., reduce the individual and family general deductible by 50% and the drug deductible by 50% to \$100/\$200/\$125 respectively)? Could supplemental insurance "level the playing field" for cost sharing associated with all acute care services including prescription drugs (e.g., a combined deductible of \$100/\$200 without a separate drug deductible)?

#### Prohibition of Balance Billing for Drugs by AHP Providers

Question: How can a patient's current freedom to choose drug therapy be maintained? Will patients still be able to purchase prescription drugs with their own money?

In the current marketplace the pharmacist's suggestion of generic substitution can be accepted or rejected at the pharmacy counter. Under many insurance plans, the insured can choose, at the time of sale, to pay the difference or a slightly higher copayment in order to obtain the multisource drug of choice. Likewise, some plans now allow patients to fill a prescription for a brand name drug which is not on the formulary for the difference between the price of that drug of choice and the price of the formulary drug. All of these current arrangements might be precluded under the "non-duplication" and "no balance billing" provisions in the Health Security Act. To what extent can enrollees retain current options to choose innovator multisource drugs over generic brands at the time of dispensing? Moreover, how can enrollees in AHPs with formularies obtain a particular pharmaceutical if the AHP generally excludes that product or denies coverage for a particular individual? Can an enrollee who is denied a drug which is medically appropriate obtain a prescription for the desired drug from an AHP physician and have the script filled <u>at his own expense</u> at either an AHP contract pharmacy or an independent pharmacy? In practical terms, to what extent will patients' existing freedom of choose for drug therapy be maintained?

#### The Extent of "Duration and Scope" Limits on Drug Benefits

Question: How does the prohibition against duration and scope restrictions by AHPs relate to pharmaceutical benefits? What limitations may an AHP apply to associated services such as physician prescribing and pharmacist dispensing?

The extent to which supplemental coverage may be needed or sought by AHP enrollees depends heavily on the AHP's ability to limit "duration and scope" of the comprehensive benefit package. For example, will AHP's be legally able to limit prescriptions to a certain number per month? To only the lowest-priced generic within a therapeutic class? To only one brand name drug in a therapeutic class? Can the AHP exclude an entire therapeutic class from coverage?

#### Authority to Restrict Coverage of Off-Label Usage

Question: What is the criteria for the National Health Board or the Secretary to limit coverage for off-label uses?

As proposed, drug provisions for the under 65 and for Medicare would permit coverage of off-label uses of FDA-approved drugs. However, the National Health Board ("NHB") and the Secretary may revise the list of compendia, select the publications referenced for peer-reviewed literature and independently determine that an off-label use is "not medically appropriate". The offlabel use will also be denied if it is identified as "not indicated" in one or more compendia.

The draft bill language does not indicate any basis or criteria which the NHB or Secretary would use to revise the list of compendia, identify referenced publications or override uses cited in these sources. Would the NHB and the Secretary base such decisions upon data not previously considered? Would such data also be subject to scrutiny by experts in the field as is the case in the compendia and peer-reviewed journals? If and when different sources disagree, why not reconcile positive and negative citations? As drafted, a negative citation in any one of the compendia automatically prevails. The bill language only contemplates the NHB or Secretary intervening to deny coverage of an off-label use. Why are AHPs given the authority to extend coverage to investigational uses but not to emerging off-label uses that have yet to appear in the compendia or the peer-reviewed literature? As drafted, even the NHB and the Secretary lack that power to authorize coverage of an off-label use based on scientific evidence or advice from, for example, the National Cancer Institute, prior to its appearance in the compendia or journals.

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#### Health Security Act Senate Co-Sponsors (11/20/93)

Akaka Baucus Boxer Bumpers Campbell Conrad Daschle Dodd Feinstein Glenn Graham Harkin 🖌 Inouye Jeffords Kennedy Leahy Levin Matthews Metzenbaum + c Mikulski<del>, K</del> Moseley-Braun Moynihan 🛩 Murray Pell Pryor Reid Riegle Rockefeller Simon

Wofford

Total: 31

#### MEMORANDUM

TO: Jeff, Marla, Bob, John

November 11, 1993

FR: Chris Jennings

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RE: Wednesday Congressional Message Group Meeting

Following up on my conversation with Marla and John today, I would like to clarify the health care "summit" proposals that were discussed during Wednesday's Message Group Meeting. Before outlining them, you need to know that the conversation never got very detailed and NO commitments were made by the First Lady. All she said was that she would like to work with the Message group on these and other proposals they might have to keep the health care issue alive during the recess break. (By the way, as it was scheduled, most of the meeting was dedicated to a discussion with Ken Thorpe on recently made available numbers.)

Finally, and most importantly, I want you to know that I have been quite explicit with the Senate DPC that we view any of their proposals as just that –- proposals. They are subject to a review with the House leadership and, most importantly, must be reviewed for feasibility and advisability within the White House communications, political, intergovernmental and scheduling departments.

#### **ISSUES DISCUSSED AT HEALTH MESSAGE MEETING:**

\* December and January Regional Summits. Senator Daschle outlined his belief that it would be desirable to develop events around the country that could assure widespread media coverage and important Congressional district coverage, while using the First Lady and other Administration resources more wisely. The discussion focused on a Northeast event (Maine, Vermont, Mass., etc.), a Great Plains event (Nebraska, the Dakotas, Iowa and Minnesoa), a Northwest event (Washington, Oregon, etc.), a Southwest event (California, Arizona, New Mexico), and possibly a Southeast event (perhaps Florida again).

<u>Outcome</u>: Pending review by House and internal review by White House.

**Who Pays -- 70/30 Issue.** Ken Thorpe gave a presentation on the most recent numbers and how to put them in the most positive light. An extensive conversation followed.

\*

\*

<u>Outcome</u>: Members felt much more comfortable and were very appreciative.

Re-Start Up of Health Care Univerity on Hill and Perhaps in
States Too. Senator Daschle thanked us for reinstituted some health care university classes this week for topics of particular interest. Steve E. had set up two classes (one on Veterans health issues by Vick Raymond and one on "who pays" by Ken Thorpe) for earlier that day.

<u>Outcome</u>: Senator Daschle was very appreciative and reported that both classes were extremely well received.

\* **Theme Weeks.** Senator Daschle briefly outlined his hope that we would use this week as Veterans Week and have next week focused on children.

<u>Outcome</u>: All parties agreed and we promised to help with supplemental materials to the extent possible.

\* **Spouse Briefing.** Members wanted to know the final status of the spouse briefing, originally scheduled for next Wednesday morning. The Senate believes it is very important and should not be postponed. There has been some concern raised (by Howard and possibly some in the House) about holding it on the same day of the NAFTA vote.

<u>Outcome</u>: The First Lady confirmed that the briefing would proceed as scheduled. The Members were quite pleased.

That's a quick summary. Hope it is somewhat useful. If you have any questions, please give me a call. I will be in Ohio most of the day tomorrow with the First Lady, but you can reach me through Signal if you there is any need. Talk to you soon.

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gf112

#### MEMORANDUM

TO: Greg L.

November 1, 1993

FR: Chris J.

RE: Drug Technicals

Greg, just in case you did not get a copy of the drug technicals forwarded by Peter Hickman that we discussed tonight, I am attaching them for your use. As I write in my note at the end of the document, I told the retail pharmacy guys who were complaining about the equal access provision to be extremely happy with what they got.

Thanks for your help... Call me with any questions...

#### DRUG TECHNICALS

#### Title I -- Health Care Security Subtitle F-- Federal Responsibilities Part 1 -- National Health Board

#### Sec. 1503, p. 257, line 24 -- General Duties and Responsibilities

<u>Proposed change</u>: The provision "Encouraging the Reasonable Pricing of Breakthrough Drugs" should be deleted.

<u>Description</u>: It was recently decided that the Breakthrough Drug Committee would no longer part of the National Health Board. Instead, the Secretary would appoint an Advisory Council on Breakthrough Drugs (See Subtitle F, Sec. 1572, p. 286, line 17).

#### Title II -- Now Benefits Subtitle A - Medicare Outpatient Prescription Drug Benefit

### Sec. 2001, p. 340, line 22 -- Coverage of outpatient prescription drugs

<u>Proposed change:</u> Current coverage of immunosuppressive should also be subsumed under the new Medicare outpatient drug benefit. Therefore, subparagraph (J) should be added to this conforming amendment.

<u>Description</u>: Only current coverage of osteoporosis and oral cancer drugs are subsumed under the new drug benefit. Coverage of immunosuppressive drugs was inadvertently omitted.

#### Sec. 2002, p. 347, line 11 -- Payment Rules and Related Requirements for Covered Outpatient Drugs

<u>Proposed Change</u> - "average manufacturer non-retail price for the drug (as defined in section 1850(f)(2))" should be changed to "published average wholesale price for the drug".

Description - Drug benefit was priced using 93% of AWP not AMNRP!

### Sec. 2002, pgs. 349 - 350 , lines 23 - 7 -- Payment Rules and Related Requirements for Covered Outpatient Drugs

<u>Proposed change</u>: Strike subparagraph (B) as currently drafted and replace it with two additional provisions. First, the Secretary should have the authority to require advance approval for a covered outpatient drug which is subject to misuse or inappropriate use, which is not cost effective, which is a multiple source drug with a restrictive prescription, or is subject to special rebate negotiation for new drugs. Second, the Secretary should also have the authority to establish maximum quantities per prescription and limits on the number of prescription refills.

<u>Description</u>: The deleted provision is no longer necessary given the off-label drug provisions in Sec. 2001, p. 337, line 14. The additional provisions were both included in earlier drafts of the bill and may have been inadvertently omitted. They were both assumed as part of the cost containment program. They are not included in 1927(g) and therefore need to be in the bill.

Sec. 2002, p. 354, line 25 -- Payment Rules and Related Requirements for Covered Outpatient Drugs

Proposed change: Change "1995" to "1996".

<u>Description</u>: We had assumed 12/93 enactment in Department draft. We will not award a contract prior to 1995, we need waivers to ensure timely awarding of contract.

Sec. 2003, p. 357 - 358, lines 17 - 3 -- Medicare Rebates for Covered Outpatient Drugs

<u>Proposed change</u>: Delete clause (ii) -- (B) would read "..Drugs subject to rebate with respect to the calendar quarter are drugs which are dispensed by pharmacies..."

<u>Description</u>: Sec. 4003 mandates assignment for all part B services and eliminates the distinction between participating and non-participating providers. This proposed change is consistent with that section. The references to participating and nonparticipating pharmacists should be deleted here and throughout the bill.

Sec. 2003, p. 362, line 23 -- Medicare Rebates for Covered Outpatient Drugs

<u>Proposed change</u>: Change "shall notify pharmacies that are participating suppliers under this part" to "shall notify pharmacy".

<u>Description</u>: Sec. 4003 mandates assignment for all part B services and eliminates the distinction between participating and non-participating providers. This proposed change is consistent with that section.

Sec. 2003, p. 357, line 18 -- Medicare Rebates for Covered Outpatient Drugs

<u>Proposed change</u>: Revised language for the "Agreement to Give Equal Access to Discounts" provision was not incorporated into the draft.

Saction 2004, p. 371, lines 1 - 10 -- Counselling by Participating Pharmacies

#### Proposed change: Delete this section.

<u>Description</u>: This section is not required since the reference to 1927(g) in Sec. 2002, p. 350, line 19 would permit the Drug Utilization Review program to include similar counselling requirements for pharmacists.

Section 2007, p. 379, line 10 -- CMPs for Excessive Charges

<u>Proposed change</u>: Section should be dropped. Under general Medicare provisions, physicians and suppliers will have to accept Medicare's payment as payment in full. Provision had been meant as a limit on what non-participating pharmacies could charge.

<u>Description</u>: Sec. 4003 mandates assignment for all part B services and eliminates the distinction between participating and non-participating providers. This proposed change is consistent with that section.

Greg: torget my conversation with you on the pharmacy equal access provision change. I told them to cool out and thank God for what they have . hours 110

#### HEALTH CARE FINANCING ADMINISTRATION Office of Legislation and Policy

#### NOTE TO CHRIS JENNINGS

FROM PETER HICKMAN AND LUCIA GIUDICE

SUBJECT: ADDITIONAL TECHNICALS AMENDMENTS TO MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT (Title II, Substitle A)

#### Sec. 2001 -- Coverage of Outpatient Prescription Drugs

Page 337, line 11

<u>Proposed change</u>: Strike "intravenously" and insert ""through infusion" after "administered."

<u>Description</u>: The reference to <u>intravenously</u> administered products is inconsisent with the covered home <u>infusion</u> drug definition (Page 338, line 20).

#### Section 2003 -- Medicare Rebates for Covered Outpatient Drugs

Page 363, line 20

Proposed change: Strike "(4) and insert "(3)."

<u>Description</u>: The reference to paragraph (4) is incorrect. The correct reference is paragraph (3) -- Negotiated Rebate Amount for New Drugs.

cc: Barbara Cooper, AAP Wayne Sulfridge, ASMB

#### MEMORANDUM

TO: Hillary Rodham Clinton

November 3, 1993

FR: Chris Jennings

RE: Senator Moynihan's ammunition tax bill

cc: Melanne, Steve, Jack, Jeff, Marla, Bob, Distribution

Today, during the Finance Committee hearing, Chairman Moynihan announced his intention to introduce legislation that would significantly increase taxes on handgun ammunition. Following the hearing, he talked to a group of reporters and stressed that it was his desire to incorporate this legislation into the health reform legislation.

As you know, there is extraordinary interest in this issue by both the media and the general public. Attached for your information is the press release and accompanying materials that I had the Finance Committee forward to me.

Other news updates:

The Finance Committee was very interested in getting updated information on the how many pay more issue, but were fine with Secretary Bentsen's non-response.

We should be prepared to release the updated information at Leon Panetta's hearing before the Finance Committee. I have given the Chairman's staff the heads up that this might occur.

Ira has approved taking care of the Baucus concerns.

We are meeting tonight again with Senator Rockefeller's VA Committee to work out an agreement with them. COMMITTEE ON FINANCE UNITED STATES SENATE SD-205 Dirksen Building Washington, DC 20510

#### PRESS RELEASE FOR IMMEDIATE RELEASE November 3, 1993

#### SENATOR MOYNIHAN INTRODUCES BILL TO TAX HANDGUN AMMUNITION

(Washington, D.C.) -- Senator Daniel Patrick Moynihan (D-NY), Chairman of the Senate Committee on Finance, today introduced legislation to increase significantly federal taxes on handgun ammunition. Senator Moynihan stated that he intends to incorporate the bill introduced today into comprehensive health care reform legislation to be considered by the Congress next year.

"The purpose of this legislation is to bring the cost of ammunition in line with the costs it imposes on our society," Senator Moynihan said. "Handgun ammunition is used to kill more than 24,000 Americans each year. It accounts for two-thirds of all firearm-related deaths. It seems to me we must view the public health impact of bullets - death and injury - much as we view an epidemic. Such a public health epidemic must be addressed as part of reform our overall health care system."

The legislation introduced today would increase from 11 percent to 50 percent the tax on handgun ammunition, except .22 caliber rim fire ammunition typically used in target shooting. The bill would also impose a \$10,000 occupational tax on manufacturers and importers of handgun ammunition.

Senator Moynihan stated that the bill will include a 10,000 percent tax on the Winchester 9-millimeter hollow tipped "black talon" bullet and all .50 caliber bullets, including a .50 caliber Israeli-made military bullet.

"These bullets have no purpose other than to cause the greatest possible destruction of human life. We must effectively tax these hyper-bullets out of circulation."

Senator Moynihan noted that in 1989, the most recent year for which statistics are available, 34,776 people in the U.S. lost their lives from bullets. Studies suggest bullet related injuries account for an additional 175,000 bullet injuries per year.

Senator Moynihan also noted the epidemic of homicide, though prevalent for all Americans, was particularly acute for black males ages 15 to 34. Among this group the risk of death from homicide is 1 in 28, twice the risk of battle death faced by marines serving in Vietnam. ъ

#### The Real Cost of Handgun Ammunition Act

The Real Cost of Handgun Ammunition Act would increase the excise tax on the sale of handgun ammunition from 11% to 50%. Handgun ammunition is defined as any centerfire ammunition that has a cartridge case of less than 1.3 inches in length. According to Bureau of Alcohol, Tobacco and Firearms, this definition targets all handgun ammunition except .22 caliber rimfire, which is the primary round used for target shooting and in sporting competitions. Rifle ammunition would not be affected.

The Act would increase the excise tax to 10,000% on 2 particularly deadly handgun rounds -- the 9mm "Talon" and the "Desert Eagle" 50 caliber round. The Desert Eagle is manufactured for use in tank-mounted machine guns but has been used in specially-manufactured handguns since the mid-1980's. The Talon, as one gun magazine describes it,

> "expands to expose razor-sharp reinforced jacket petals. These cut tissue in the wake of the penetrating core. Toward the end of the bullet travel, the Talon

bullet typically turns sideways... From this point on, it penetrates soft tissue like a throwing star -- very nasty; very effective; a real improvement in handgun ammo." (<u>Handguns for Sport & Defense Magazine</u>, 11\92).

The Act also would impose a new "occupational tax" of \$10,000 annually on each manufacturer and importer of handgun ammunition, similar to the occupational tax that applies to manufacturers of machine-guns, sawed-off shotguns and the like. This tax would not apply to manufacturers who conduct business exclusively with police departments, the military, and other government entities. 11/03/93

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103D CONGRESS 1ST SESSION

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#### IN THE SENATE OF THE UNITED STATES

Mr. MOYNIHAN introduced the following bill; which was read twice and referred to the Committee on

## A BILL

- To amend the Internal Revenue Code of 1986 to increase the tax on handgun ammunition, to impose the special occupational tax and registration requirements on importers and manufacturers of handgun ammunition, and for other purposes.
  - 1 Be it enacted by the Senate and House of Representa-
  - 2 tives of the United States of America in Congress assembled,
  - **3** SECTION 1. SHORT TITLE.

7

4 This Act may be cited as the "Real Cost of Handgun5 Ammunition Act".

6 SEC. 2. INCREASE IN TAX ON HANDGUN AMMUNITION.

(a) INCREASE IN MANUFACTURERS TAX.—

11/03/93

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1	(1) IN GENERAL.—Section 4181 of the Internal
2	Revenue Code of 1986 (relating to imposition of tax
3	on firearms) is amended—
4	(A) by striking "Shells, and cartridges"
5	and inserting "Shells and cartridges not taxable
6	at 50 percent or 10,000 percent", and
7	(B) by adding at the end the following:
8	"ARTICLES TAXABLE AT 50 PERCENT
9	"Any centerfire cartridge which has a car-
10	tridge case less than 1.3 inches in length.
11	"Any cartridge case which is less than 1.3
12	inches in length.
13	"ARTICLES TAXABLE AT 10,000 PERCENT
14	"Any jacketed, hollow point projectile
15	which may be used in a handgun and the jacket
16	of which is designed to produce, upon impact,
17	evenly-spaced sharp or barb-like projections
18	that extend beyond the diameter of the unfired
19	projectile.
20	"Any cartridge with a projectile measuring
21	.500 inch or greater in diameter which may be
22	used in a handgun.".
23	(2) ADDITIONAL TAXES ADDED TO THE GEN-
24	ERAL FUND.—Section 3(a) of the Act of September
25	2, 1937 (16 U.S.C. 669b(a)), commonly referred to

006

11/03/93

1 the "Pittman-Robertson Wildlife Restoration as 2 Act", is amended by adding at the end the following 3 new sentence: "There shall not be covered into the 4 fund the portion of the tax imposed by such section 5 4181 that is attributable to any increase in amounts 6 received in the Treasury under such section by rea-7 son of the amendments made by section 2(a)(1) of 8 the Real Cost of Handgun Ammunition Act, as esti-9 mated by the Secretary." 10 (b) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after December 31, 1993. 11 12 SEC. 3. SPECIAL TAX FOR IMPORTERS, MANUFACTURERS, 13 AND DEALERS OF HANDGUN AMMUNITION. 14 (a) IN GENERAL.— 15 (1) IMPOSITION OF TAX.—Section 5801 of the Internal Revenue Code of 1986 (relating to special 16 17 occupational tax on importers, manufacturers, and 18 dealers of machine guns, destructive devices, and 19 certain other firearms) is amended by adding at the 20 end the following new subsection: "(c) SPECIAL RULE FOR HANDGUN AMMUNITION.-21 22 "(1) IN GENERAL.—On first engaging in business and thereafter on or before July 1 of each year, 23 24 every importer and manufacturer of handgun ammu-25 nition shall pay a special (occupational) tax for each

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place of business at the rate of \$10,000 a year or fraction thereof.

"(2) HANDGUN AMMUNITION DEFINED.—For purposes of this part, the term 'handgun ammunition' shall mean any centerfire cartridge which has a cartridge case of less than 1.3 inches in length and any cartridge case which is less than 1.3 inches in length."

9 (2) REGISTRATION OF IMPORTERS AND MANU-10 FACTURERS OF HANDGUN AMMUNITION.—Section 11 5802 of the Internal Revenue Code of 1986 (relating 12 to registration of importers, manufacturers, and 13 dealers) is amended—

14 (A) in the first sentence, by inserting ",
15 and each importer and manufacturer of hand16 gun ammunition," after "dealer in firearms",
17 and

18 (B) in the third sentence, by inserting ",
19 and handgun ammunition operations of an im20 porter or manufacturer," after "dealer".

21 (b) CONFORMING AMENDMENTS.—

(1) CHAPTER HEADING.—Chapter 53 of the Internal Revenue Code of 1986 (relating to machine
guns, destructive devices, and certain other firearms) is amended in the chapter heading by insert-

5 "HANDGUN AMMUNITION," 1 after ing 2 "CHAPTER 53-". 3 (2) TABLE OF CHAPTERS.—The heading for chapter 53 in the table of chapters for subtitle E of 4 5 such Code is amended to read as follows: "Chapter 53-Handgun ammunition, machine guns, destructive devices, and certain other firearms." 6 (c) EFFECTIVE DATE.— 7 (1) IN GENERAL.—The amendments made by this section shall take effect on July 1, 1994. 8 9 (2) ALL TAXPAYERS TREATED AS COMMENCING 10 IN BUSINESS ON JULY 1, 1994.—Any person engaged 11 on July 1, 1994, in any trade or business which is 12 subject to an occupational tax by reason of the 13 amendment made by subsection (a)(1) shall be treat-14 ed for purposes of such tax as having 1st engaged 15 in a trade of business on such date.

SENATE FINANCE

009

S.L.C.

11/03/93

18:07

DETERMINED TO BE AN ADMINISTRATIVE MARKING Per E.O. 12958 as amended, Sec. 3.2 (c) Initials:  $\cancel{123}$  Date:  $\cancel{8 \cdot 18 \cdot 05}$ 

#### PRIVILEGED AND CONFIDENTIAL MEMORANDUM

TO: Hillary Rodham Clinton

November 17, 1993

FR: Chris J.

RE: Durenberger/Domenici Medicare Managed Care Bill

cc: Melanne, Ira, Steve

Melanne asked me to check into the status of the Durenberger Medicare reform bill that was referenced in Health News Daily the other day. In response, I called Senator Durenberger's office (Susan Foote) and Senator Domenici's office (Jim Capretta) -- who is apparently the other lead Senate sponsor.

The most important news is that they are weeks to months away from introducing anything, so any bill will obviously not be introduced prior to Congress leaving for the year. The primary goal in this effort appears to be to try to make certain that the reformed Medicare program looks much more like the private sector than vice versa. (They are concerned that once our bill goes through the House Committees, that the legislation will look more like a Medicare-based structure, rather than a private sector-based system.)

Durenberger and Domenici want to develop incentives for Medicare beneficiaries to go into managed care plans. Although they have talked about requiring these plans to provide increased benefits (drug coverage, lower deductibles, etc.) to beneficiaries who enroll in these plans, they have not even made a final decision about that. This is because it is unclear whether a Medicare managed care plan can actually deliver a benefit with any increase in benefits at the same or less cost than the Medicare (reimbursement regulated) fee for service plan is currently paying.

# Withdrawal/Redaction Marker

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. memo	Chris Jennings to Hillary Clinton	11/24/93	P5
w/attach	Re: Health Care Legislative Strategy Memo (17 pages)		

### 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.

#### **COLLECTION:**

Clinton Presidential Records Domestic Policy Council Chris Jennings (Domestic Policy Council) OA/Box Number: 23754

#### FOLDER TITLE:

November 1993 HSA [2]

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

**RESTRICTION CODES** 

gf112

- 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.
- PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
- 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]