Jackson Hole File

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 17 1995

Paul M. Ellwood Jr., M.D.
President
Jackson Hole Group
P.O. Box 350
Teton Village, WY 83025

Dear Paul:

Thank you for the opportunity to review the new draft proposal of "Responsible Choices." I am looking forward to meeting with you and others in Jackson Hole to discuss our respective ideas for improving the nation's health care system.

I have appreciated the opportunity to work with the Jackson Hole Group in the past, in large part because we share a common commitment to improving both efficiency and fairness in the health care system. I think we all agree that health reform requires three elements to be effective — expanded coverage, lower costs and improved quality — and that a restructured marketplace is essential to achieving these elements. Our ultimate goal must be universal coverage in an efficiently operating marketplace.

You and your colleagues have made a significant contribution to the health care debate in this country by recognizing the critical role that consumer choice and private innovation can play in our health care system. I think that we both agree that choice is a critical element in improving quality and efficiency.

I was surprised, then, by the direction reflected in "Responsible Choices." The draft proposal seems to abandon your previous commitment to addressing the problems of the over 40 million uninsured in this nation. I understand that the political environment has changed, and that our strategies may need to change as a result. However, that does not alter the underlying fact that middle class people who lose their jobs, or working families struggling to get by, need some assistance to be able afford adequate health insurance.

The Jackson Hole Group has recognized this fact in the past, and has advocated substantial subsidies to assist the uninsured in purchasing private insurance. It deeply troubles me that the "Responsible Choices" proposal fails even to mention the need to move towards universal coverage, let alone suggest policies (short or long-term) to do so.

In fact, the arbitrary cap on funding for the Medicaid program proposed in "Responsible Choices" would actually decrease coverage. Over the past few years, enrollment in employer-based insurance has fallen by almost six percentage points (from around 66% to around 60% of the nonelderly population), while the percentage of the population covered by Medicaid has grown significantly. Between one-third and one-half of the projected annual growth in Medicaid spending results from projected growth in enrollment.

Furthermore, I am perplexed and disturbed that you would propose an arbitrary cap on the Medicare program. Like Social Security, Medicare is an inter-generational compact. Placing an arbitrary, pre-determined cap on Medicare spending, while at the same time eliminating its status as an entitlement, would put services to the elderly at risk and would violate that compact.

A cap on Medicare puts the elderly and disabled at risk. The vast majority of Medicare beneficiaries have modest incomes. Over 75% of beneficiaries have incomes below $25,000; 30% of beneficiaries get 80% or more of their income from Social Security. So while a voucher program like that proposed in "Responsible Choices" may expand choice for some beneficiaries, it would in fact diminish choice for many by effectively forcing them into a low-cost plan and away from the providers of their choice.

This does not mean that we oppose improving Medicare — quite the contrary. We are pleased that, during the Clinton Administration, projections for the average annual rate of growth for Medicare spending for the period 1996 - 2000 have decreased — by more than a percentage point a year — just in the period between the Mid-Session Review last spring and the President's Fiscal Year 1996 Budget. We are pressing ahead with improvements in Medicare management, data processing, contractor oversight, and program integrity activities.

Among the other improvements we are making in Medicare, I believe that we share a commitment to expanding and improving the managed care choices available to Medicare beneficiaries. Today, about 74 percent of Medicare beneficiaries have access to a managed care plan, and 9% of beneficiaries have enrolled in one. Enrollment is increasing rapidly — by over 1% per month. We also are working on ways to make our existing managed care program work better. Examples include our work with the industry to improve quality measures and the AAPCC methodology for the Medicare risk contracting program, and our collaboration with Alain Enthoven to design a competitive bidding demonstration. And, as we have testified in recent weeks, we are in the process of developing new managed care options under Medicare, including a PPO option.

While managed care appears now to be reaching a critical mass in private sector health programs, at least in some areas, it has taken many years to achieve this state. Many employers that have embraced managed care have moved cautiously to avoid disruption, by maintaining a fee-for-service option at affordable levels or by offering out-of-network options through point-of-service plans or PPOs. Most Medicare beneficiaries — and particularly the most elderly among them — have not had the benefit of a gradual exposure to managed care. I am strongly committed to expanding the managed care options available in Medicare, but the emphasis must be on choice. We should learn from the private sector and recognize that we need to move prudently if we are to foster understanding and acceptance of managed care approaches among beneficiaries.

I look forward to the upcoming discussions at Jackson Hole. We need to focus on how we can improve both the private insurance market and public programs. And we must discuss ways to expand coverage for vulnerable populations. I believe that there are many points on which we can agree. To me, making responsible choices means finding ways to improve what we have, not making arbitrary cuts in important programs that can leave the elderly, disabled, and poor at risk. I hope that we can work together over the coming months to accomplish meaningful health care reform.

Sincerely,

Donna E. Shalala

THE WHITE HOUSE

WASHINGTON

February 13, 1995

MEMORANDUM FOR THE PRESIDENT

FROM: CAROL RASCO

SUBJECT: Kassebaum Medicaid for Welfare Swap

PURPOSE

To provide you with background information on the Kassebaum Medicaid/Welfare swap as a follow-up to the discussion you had with the Governors at Blair House. In addition, to provide you with a status report on the level of Congressional interest in and receptivity to this proposal.

BACKGROUND

As you know, Senator Nancy Kassebaum has proposed a major restructuring of the social welfare system in which the Federal government would take over full responsibility for Medicaid acute-care and the states would take over the food stamp, AFDC, and WIC programs. During a five-year transition period, a maintenance-of-effort requirement would bar states from reducing overall expenditures on cash and food assistance to the poor and states would continue to bear some share of Medicaid costs.

At least initially, States are attracted to this proposal because it would allow them to relieve themselves of their future Medicaid spending -- which continues to outpace inflation -- and have the Federal government take over. The downside from the Federal Government's perspective is that implementing this proposal would increase the deficit in both the short-term and the long-term. The swap could be modified to be more balanced by giving more programs to the states or by swapping only parts of the Medicaid program. However, any tradeoffs that would make the swap budget-neutral or deficit-reducing would increase costs to many or most states (certainly over the long-run) and are unlikely to be received favorably by the Governors. Since the Rebublican Congress is desperately looking to save money, it sems unlikely that this conflict will be resolved this year.

There are other significant policy implications of the Kassebaum proposal other than the deficit issue. The DPC/NEC health policy development working group raised four additional major policy concerns about the swap proposal, which are outlined in the following pages.

POLICY IMPLICATIONS OF THE KASSEBAUM SWAP

I. Likely Reductions in Welfare Programs. Experience with states over the past 25 years suggests that states will not maintain existing eligibility requirements and benefits for the welfare programs. In fact, state spending on welfare programs has declined dramatically in real terms:

- AFDC benefits in the median state have fallen 47 percent in real terms since 1970, even though the Federal government paid 50 to 80 percent of the benefit costs during this period. Combined AFDC and food stamp benefits for a family with no other income is now at the level of AFDC benefits alone in 1960, before the food stamp program was created.

- Even though state appropriations for WIC generally qualify a state for a larger Federal WIC allocation, states have been cutting state funds for WIC in recent years. In the past two years, state funding for WIC fell 33 percent in real terms.

Furthermore, if a balanced budget amendment is passed, prospects that states would maintain cash and food assistance for the poor (after the transition period requiring some maintenance of effort ends) become even less likely.

In contrast, in the two programs where benefits are 100 percent Federally-funded and national benefit standards exist -- the food stamp program and the Federal SSI program -- there has been no benefit erosion over the past 20 or 25 years.

II. Varying Impacts Among States. Any swap is likely to have different distributional impacts among states. States that spend more on welfare than Medicaid (according to Kassebaum there are 14 such states) will be losers. At least initially, the other 36 states will be winners -- meaning that Federal government will be picking up some portion of their current spending. The size of the losses and gains could vary dramatically among states.

As some states cut back on their welfare programs -- as is likely under a swap proposal -- variations in welfare benefits among states will increase even more. A key feature of the Federal food stamp program is its role in helping moderate what otherwise would be huge differences between states in the benefits they provide to poor children. Today, food stamp benefits are large in states that pay low AFDC benefits, because a family's food stamp allotment depends on its income level. This moderating effect would disappear once the food stamp program devolved to the states.

- The State of Connecticut provides a family of three that has no other income with an AFDC benefit of $680 per month, about two-thirds of the poverty line. Mississippi, by contrast, pays a family of three only about one-sixth as much -- $120 a month, which is less than 12 percent of the poverty line. When food stamps are added in, the benefit package in Mississippi climbs from about one-sixth to one-half of the size of the Connecticut package.

III. Weakening Automatic Stabilizers. The amount of Federal food stamp benefits provided in a state automatically rises when the state economy turns down and unemployment and poverty mount -- making the program the Federal government's most important automatic stabilizer after unemployment insurance. If AFDC and food stamps are devolved, states will be forced to choose among absorbing the additional benefit costs during recessions, reducing food and welfare benefits, or putting new applicants on waiting lists.

IV. Complications in Creating a Federal Medicaid Program. If the Medicaid program became entirely Federal, it would be difficult to justify maintaining the wide variations that now exist among states in the categories of households eligible for the program, the health services that are covered, and the reimbursement rates that are paid to providers. If the Federal government chose to provide uniform coverage similar to that now offered in some of the least generous states, the number of the uninsured would likely rise and beneficiaries in a number of states would lose coverage for some services. If the Federal government instead chose to provide coverage similar to that offered in the most generous states, the cost to the Federal treasury would be great.

NGA AND CONGRESSIONAL RESPONSE TO SWAP

At least at first glance, the Governors and the NGA were very interested in the Kassebaum proposal. Trading virtually anything to rid the states of their expensive, time consuming and frequently politically unpopular Medicaid obligations has real appeal. As a result, the Governors directed NGA staff to study the implications and potential of the proposal. However, in recent weeks, the Governors, the NGA staff, and the Republicans in the Congress seem to have cooled to the Kassebaum concept.

The Governors now appear to be less interested in the proposal primarily because, in an environment in which the Congressional Republicans' number one priority is obtaining large Federal savings, a Medicaid/welfare swap to achieve this seems either unlikely or will almost invariably and unevenly hurt the states. Second, proposals to block grant welfare -- that particularly the Republican Governors are advocating -- run contrary to the idea of swapping entire programs.

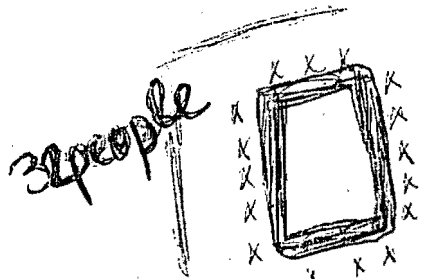
The Republicans in Congress are concluding the Kassebaum proposal has diminished appeal because they are increasingly believing that this proposal would necessitate complicated and controversial negotiations. Its attractiveness further diminishes when they contrast it with block granting proposals that are less complicated and more likely to produce larger Federal savings. Senator Dole's office reports that there is little or no interest in this proposal on the Finance Committee. This is significant because the Finance Committee (not Kassebaum's Labor Committee) has legislative jurisdiction over the Medicaid and AFDC programs.

CONCLUSION

Despite the states' desire to trade away the Medicaid program, the Congressional interest in producing significant Medicaid savings as well as the major policy implications of the proposal indicate that this type of swap is unlikely to go very far in the 104th Congress.

EXECUTIVE OFFICE OF THE PRESIDENT

23-Feb-1995 03:01pm



TO: (See Below)

FROM: Stacey L. Rubin
Domestic Policy Council

SUBJECT: HEALTH CARE MEETING 2/28 ~ 3/10 2-4pm

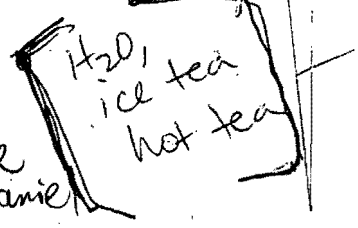
There will be a HEALTH CARE meeting to discuss coverage options for the President and political strategy on Tuesday, February 28 from 1:00 pm to 2:30 pm in the Map Room. This is a principals plus one meeting. Participants include:

1. Mrs. Clinton → Melanne 19.
2. Mrs. Gore → Skila 20.
3. Secretary Reich → Tom Glynn 21.
4. Secretary Rubin 22. Alicia Munnell
5. Secretary Shalala → Judy 23.
6. Leon Panetta John Angell 24.
7. Erskine Bowles
8. Harold Ickes
9. Carol Rasco → Bill 25.
10. Laura Tyson → Gene 26.
11. Pat Griffin → Janet 27.
12. George Stephanopoulos 28.
13. Mark Gearan
14. Mike McCurry
15. Alice Rivlin → NEM 29.
16. Ira Magaziner
17. Jack Quinn

Jack? / NO

• Stiglitz

* big table - Danie



32. Bruce Vladeck

18. Stiglitz - Mark Mazur

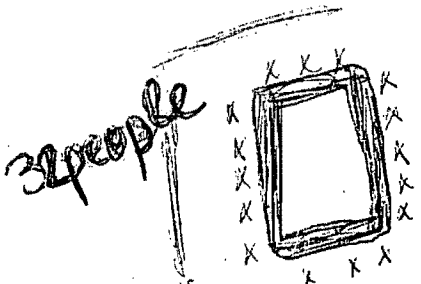
If you have any questions, please contact Stacey Rubin at 456-5585.

Distribution:

TO: Stacey L. Rubin
TO: Patti Solis HRC
TO: Margaret A. Williams HRC
TO: Nicole R. Rabner → Melanne
TO: Sara Grote HRC
TO: Cynthia L. Gire VPC
TO: Skila S. Harris Gore
TO: FAX (9219-7659, Katherine Jayne) Reich

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

23-Feb-1995 03:01pm



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H_2O, ice tea, hot tea

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TO: FAX (9219-7659, Katherine Jayne) Reich

TO: FAX (9622-0073, Linda McLaughlin) Rubin
TO: FAX (9690-6166, Secretary Shalala) Shalala
TO: Julie E. Demeo Rasco
TO: Valerie M. Owens Rivlin
TO: FAX (56958, Laura Tyson) Tyson
TO: Jennifer N. Palmieri Panetta
TO: John C. Angell Panetta
TO: Erin A. O'Connor Griffin
TO: Janet Murguia
TO: Heather Beckel Steph.
TO: Denise Ricketson Ina
TO: Erin C. Kelly
TO: Gene B. Sperling NEC
TO: Paul A. Deegan ✓
TO: William A. Galston DPC
TO: Kimberly M. Ross ✓
30. TO: Christopher C. Jennings ✓
31. TO: Jennifer L. Klein ✓
TO: Nancy-Ann E. Min OMB
TO: Kimberly J. O'Neill ✓
TO: Diane G. Limo OMB
TO: Elisabeth L. Lindemuth NEC
TO: Lorraine McHugh Comm.
TO: Julia Moffett Comm.
TO: FAX (9690-7383, Judy Feder) HHS
TO: FAX (9219-5526, Meredith Miller) Labor
TO: Steven A. Cohen Comm. / Geren
TO: John O. Sutton Ickes
TO: Julia R. Green McCurry
TO: Pamela B. Madaris Bowles

THE WHITE HOUSE

WASHINGTON

February 13, 1995

MEMORANDUM FOR THE PRESIDENT

FROM: CAROL RASCO

SUBJECT: Kassebaum Medicaid for Welfare Swap

PURPOSE

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CONCLUSION

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E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

10-Feb-1995 04:40pm

TO: (See Below)

FROM: Stacey L. Rubin
Domestic Policy Council

SUBJECT: Health Care Meeting 2/17

There will be a HEALTH CARE meeting to discuss coverage options for the President and political strategy on Friday, February 17th from 4:00pm to 5:00pm in the Roosevelt Room. This is a principals plus one meeting. Participants include:

Mrs. Clinton
Mrs. Gore
Secretary Reich
Secretary Rubin
Secretary Shalala
Leon Panetta
Erskine Bowles
Harold Ickes
Carol Rasco
Pat Griffin
George Stephanopoulos
Mark Gearan
Mike McCurry
Alice Rivlin
Laura Tyson
Ira Magaziner
Jack Quinn

If you have any questions, please contact Stacey Rubin at 456-5585.

Distribution:

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TO: Margaret A. Williams
TO: Nicole R. Rabner
TO: Sara Grote
TO: Cynthia L. Gire
TO: Skila S. Harris

TO: FAX (9219-7659,Katherine Jayne)
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TO: FAX (9219-5526,Meredith Miller)
TO: Steven A. Cohen
TO: John O. Sutton
TO: Julia R. Green
TO: Pamela B. Madaris

MEMORANDUM

To: Carol Rasco

From: Chris Jennings

Date: February 17, 1995

Re: OMB self-employed tax deduction information, regulatory review package and letter from Secretary Shalala to the "Jackson Hole Group"

Following up on our conversation, attached is current draft language of the suggested Administration position on the self-employed tax deduction. OMB is planning on sending it up to the Hill on Tuesday. If there are any problems with the draft language please call (it is fine as far I am concerned).

Also attached you will find a complete set of the regulatory briefing materials that are supposed to be sent to the Vice President tonight in preparation for Tuesday's meeting. At today's regulatory review meetings, we achieved agreement on the materials that should be sent to him for both the FDA and HCFA presentations (no small feet). Apparently, there has been an agreement between Greg Simon and Sally that the FDA and drug device programs should go first and, time allowing, the HCFA health care presentation should follow.

Lastly, I am forwarding you the final draft of Secretary Shalala's response to the Jackson Hole proposal. It is my understanding that it was faxed out to Wyoming today.

Jen and I look forward to talking to you about these and other issues on Tuesday.

cc: Jennifer Klein
Jeremy Ben-Ami

February __, 1995
(House)

DRAFT -- NOT FOR RELEASE.

H.R. 831 -- Permanently Extend the Tax Deductibility for Health Insurance Costs for Self-Employed Individuals
(Archer (R) TX and 3 others)

[NOTE POSSIBLE ADDITIONAL LANGUAGE IN BOLD.]

The Administration supports the primary purpose of H.R. 831 -- to extend permanently the 25 percent tax deduction for health insurance premiums for self-employed individuals -- and believes that the cost must be fully offset. [**NOTE**--Les Samuels' staff is considering whether the word "permanently" should be taken out.]

The Administration opposes one of the bill's offsets -- i.e., the repeal of the current tax treatment for the sale of radio and television broadcast facilities and cable television systems to minority-owned businesses. **["However, the Administration is aware of concerns about possible abuses of this program and is reviewing what steps might be taken to prevent abuses."]**

The Administration looks forward to working with the Congress on identifying appropriate offsets to extend this important health insurance tax deduction (permanently). **["Examples of possible alternative offsets are the provisions in the Gibbons substitute -- which are identical to proposals in the FY 1996 Budget -- relating to taxation of income from foreign trusts and tax treatment of renouncers of citizenship."]**

Scoring for Purposes of Pay-As-You-Go

H.R. 831 would affect receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act (OBRA) of 1990.

The Administration's preliminary scoring estimates of this bill are presented in the table below. Final scoring of this legislation may deviate from these estimates. If H.R. 831 were enacted, final OMB scoring estimates would be published within five days of enactment, as required by OBRA. The cumulative effects of all enacted legislation on direct spending and receipts will be reported to Congress at the end of the congressional session, as required by OBRA.

PAY-AS-YOU-GO ESTIMATES
(Receipts in millions)

	1995	1996	1997	1998	1999	2000	1995-2000
SE Tax	-493	-437	-474	-516	-563	-613	-3,096
FCC	+399	+449	+213	+220	+226	+233	+1,740
EITC	--	+ 14	+277	+295	+309	+332	+1,227
Other	+ 12	+ 31	+ 34	+ 37	+ 40	+ 43	+ 197
Totals	- 82	+ 57	+ 50	+ 36	+ 12	- 5	+ 68

(Note:

SE Tax = 25 percent tax deduction for self-employed persons.

FCC = Repeal of current tax treatment on sale of broadcast facilities to minority-owned businesses.

EITC = Modification of the Earned Income Tax Credit.

Other = Change in Section 1033 of the Internal Revenue Code.)

* * * * * * *

AGENDA

REINVENTING HEALTH, DRUG, AND MEDICAL DEVICE REGULATION

February 21, 1995

I. Overview

II. Drug and Device Presentation -- Food and Drug Administration, David Kessler

- A. Drugs and Biologicals
- B. Generic Drugs
- C. Medical Devices
- D. Cross-Cutting Issues
- E. Additonal Options for Discussion

III. Health Care Presentation -- Health Care Financing Administration, Bruce Vladeck

- A. Physician Attestation -- Presentation of Working Group Consensus
- B. Health and Safety Standards for Medicare Providers -- Discussion of Alternatives
  1. Conditions of Participation: Eliminate Unnecessary Process Requirements
  2. Home Health Agency Surveys: Allow Flexible Survey Cycles
- C. Clinical Laboratories Improvement Amendments -- Discussion of Alternatives
  1. Waive Routine Survey of Users of "Black Box" Technology
  2. Clarify and Expand Waiver Criteria and Streamline the Waiver Process.

     Alternatives: (1) Exempt all tests performed in physician office laboratories from CLIA requirements; (2) amend statutory "risk" language to allow consideration of benefits and costs; or (3) repeal CLIA.

3. Use Performance Standards and Require Less Frequent On-Site Inspections of Excellent Performers.

   Alternatives: (1) Repeal quality control, quality assurance, and personnel requirements, and rely on proficiency testing and outcomes for quality control; or (2) give HCFA discretion to waive these requirements for labs that perform well.

4. Use Proficiency Testing Failures for Education and as Outcome Indicators for Laboratory Quality.

   Alternative: No longer require proficiency testing.

D. Additional Options for Discussion

1. Paperwork Reduction in Federal Programs
2. Competition in Medicare
3. Physician Review Organizations (PROs)
4. Ownership and Referral
5. Reimbursement Mechanisms

DRUG AND MEDICAL DEVICE WORKING GROUP
SUMMARY OF OPTIONS PRESENTED

DRUGS

Problem: FDA's longstanding regulations governing the marketing of new drugs place burdens on the industry that are unnecessary for the protection of the public health. For biological drugs the requirements have been especially strict.

Regulatory Approach: Streamline/reduce burden; tailor requirements to the risk involved.

Proposals	Alternatives
1) Waive pre-market approval for all manufacturing changes in new drugs that introduce no or negligible risk;	Waive FDA pre-approval of all manufacturing changes.
2) Permit manufacturers to demonstrate capability to make biotech drugs without building a new plant;	Waive entirely the requirement to demonstrate capability to manufacture a new drug before FDA approval.
3) Permit biotech drug companies to place their name on the drug produced by a subcontractor; and	
4) Eliminate special requirements for insulin and antibiotics and allow existing private standard setting body to establish testing and quality standards, similar to those required for other drugs.	Eliminate quality and testing standards entirely for insulin and antibiotics.

GENERIC DRUGS

Problem: Once the brand name drug patent has expired, generic drug manufacturers must go through the time consuming, costly, and burdensome process of purchasing the brand name drug, analyzing it, determining how to make it, and submitting an application to the FDA demonstrating that it has "guessed right" in how to make the generic version.

Regulatory Approach: Streamlining application process.

Proposal

1) Publicly release information about the manufacturing of brand name drugs before the patent expires and alleviate the need for the generic company, through reverse engineering, to attempt to determine how the brand name drug was made.

Alternatives

Review generic drugs more rapidly, thus speeding their marketing approval;

Have a two pronged approach, maintaining the current 1st approved generic, while ultimately making the patent available for more exact copies.

MEDICAL DEVICES

Problem: The medical device industry believes that the FDA's regulatory actions for medical devices have delayed the introduction of devices into the marketplace and have negatively impacted the U.S. device industry's international competitiveness. Industry concerns include (1) FDA reviews of pre-market approval applications and pre-market notification actions (requests to market a device on the ground that it is substantially equivalent to another device that is already on the market) take too much time and delay a devices entry into the marketplace; (2) FDA approval of requests to export unapproved devices in unnecessary and delays exports; (3) the device classification process in unduly burdensome because it requires classification procedures even for low risk devices; and (4) FDA has a list of firms that fail to observe good manufacturing practice (GMP) requirements when manufacturing their devices and firms are unable to determine whether they are on the list or precisely what corrective actions they should take in order to regain FDA approval to manufacture devices.

Regulatory approach: Performance standards; privatization; streamlining/reducing regulatory burden by tailoring regulation to risk; place greater reliance on industry certifications for exports; exempt certain low risk devices from pre-market approval.

Proposals	Alternatives
1) Initiate a pilot study for 3rd party review of certain device applications by private organizations;	Relying on private organizations certified by FDA. Options include: a) adopting European system or b) privately contracting out for review of all device applications; Phase-in 3rd party private sector review bodies to conduct pre-market approvals and inspections starting with lower risk devices.
2) Waive FDA review of export requests for devices that are approved for investigational use in the United States;	Permitting self-certification of exports to countries where the exported product is already approved. Could also increase penalties for export of unsafe devices to address concerns of "dumping."
3) Exempt over 140 device categories from pre-market review;	Exempting more device categories.

MEDICAL DEVICES CONTINUED

Proposals

4) No longer utilize the list of manufacturers who have good manufacturing practice (GMP) problems as a means to delay review process of a product unrelated to the product that had the GMP problem; and

5) Request authorization for device user fees; these fees would be dedicated to increasing FDA resources for receiving. device application and pre-market notifications.

CROSS - CUTTING
(Categorical Exemptions from requirements of National Environmental Policy Act)

Problem: The National Environmental Policy Act (NEPA) requires all Federal agencies to assess the environmental impacts of their actions. Before a drug, biologic, food additive, or animal drug is approved for marketing, FDA currently requires the company manufacturing the product to conduct an environmental assessment (EA). Hundreds of EAs are done each year, at a cost of $40,000-$150,000 per EA. FDA almost always finds no significant impact; thus the EAs are not believed necessary in the context of these product approvals.

Regulatory Approach: Administratively exclude product approvals from EA requirements; reduce burden.

Proposal

1) In consultation with the Council on Environmental Quality, the FDA would reclassify product approvals with de minimis environmental review requirements. For example, it is known that human excretion of a drug's residues into the environment through public sewers poses no environmental impact.

Alternatives

Have FDA staff do the EAs thus relieving the burden on regulated industry.

CROSS-CUTTING
(FDA Submission, Tracking, and Communication of Information)

Problem: FDA receives hundreds of application for approvals of new products each year, particularly from drug and biologic firms. These applications frequently comprise thousands of pages of detailed scientific information. The enormous documents require substantial space for storage, pose difficulty in retrieving information, and waste valuable time in forcing FDA medical staff to carry out analyses of findings in the data. There is a need to permit companies to submit applications electronically and communicate questions and answers with FDA electronically; and to utilize electronic tracking and analysis in reviewing the data.

Regulatory Approach: Modernize, utilize latest technology.

Proposal

1) Embark on a program to expand and standardize the use of information systems in support of a product review process. This would include developing a system for electronic receipt, processing, tracking and archiving of all documents; provide the capability to analyze and sort complex data rapidly; and enhance communication between industry and the FDA. System would begin with drug regulation, expand later to medical devices, food additive, and other products.

Alternatives

Retain current system;

Allow computerization to occur at its own pace;

Impose a strict FDA requirement to use computerized applications in a specified manner.

CROSS-CUTTING
(Harmonization of Standards)

Problem: Various countries have differing requirements for approval of new drugs, biologics, medical devices, food additives and animal drugs. This results in multiple test on animals and drugs and different applications for marketing approval. There is substantial need to harmonize standards where ever possible while retaining basic safety precautions.

Regulatory Approach: Common international standards.

Proposal	Alternatives
1) Work jointly with other countries, particularly NAFTA partners, the European Community, and Japan to harmonize testing and product development standards with those of the U.S. Alternatives	Adopt certain foreign standards already in place such as the CE mark accepted by the European Community or standards in countries that have comparable levels of health and safety. Establish reciprocity of product approvals with certain foreign countries.

ADDITIONAL OPTIONS FOR DISCUSSION

DRUGS AND BIOLOGICS

1) The following options can be considered for relatively low risk subcategories of drug approval applications (e.g. applications for new uses of currently marketed drugs):

   - FDA contracting out to private organizations the review of new drug applications.
   - Allow drug manufacturers to gain pre-market approval through "certification" that their drugs are safe and effective from a third-party standards setting organization; manufacturer pays for the certification.
   - Allow drug manufacturers to "self-certify" that their drugs are safe and effective, market the drugs without FDA approval, then rely on FDA to find unsafe drugs and remove them from the market.

2) Further relaxing the "efficacy standard" for breakthrough drug approval; i.e., requiring less evidence of a drug's effectiveness than currently.

3) Increased access to experimental drugs, via a dual system. Drug company could 1) go through the current FDA approval process to test drugs in humans, or 2) allow use of experimental drugs with a warning to physicians and patients that the drugs have not yet been approved by the FDA when the risks are either low or the potential benefits outweigh the risks.

4) Reduce regulation of "off-label" uses for drugs; FDA would approve a drug for its first indication, additional indications could be promoted by manufacturers in advance of FDA approval. Manufacturers would still be subject to the requirements that the labeling cannot be false or misleading, thus the full disclosure that the indication is not approved would be required.

5) Revoke the biologics portion of the Public Health Service Act, thereby regulating biotech drugs and vaccines as traditional drugs, eliminating requirement for establishment licensing.

MEDICAL DEVICES

1) Legislation protecting biomaterial suppliers to medical manufacturers with liability protection if the device harms a patient.

2) Post market reporting and surveillance should be streamlined to focus on devices posing significant harm.

CROSSCUTTING

1) Reciprocity of approvals of drugs, biologics, devices and food additives with foreign countries, i.e., when another industrialized country with review programs and comparable rigor approves a product, approval would be automatic in this country.

2) Unrestricted export of unapproved drugs, biologics, and devices to countries that have already given the products their approval.

3) Creating one government wide "inspection service" under which most government inspections would be carried out (e.g., a firm would get a visit from one inspector, who would inspect for food/drug, environmental, worker safety, and other violations).

HEALTH INDUSTRY WORKING GROUP RECOMMENDATIONS

I. PHYSICIAN ATTESTATION

PROBLEM: Currently, a physician must sign an "attestation form" for each Medicare patient discharged from a hospital. The form is used to certify the accuracy of all diagnoses and procedures; without an attestation form, the hospital cannot bill Medicare. Obtaining the physician's signature is burdensome for hospitals and physicians, and resulting billing delays hurt hospital cash flow.

REGULATORY APPROACH: Streamline paperwork.

PROPOSED SOLUTION: Eliminate the requirement for the form entirely and instead hold hospitals responsible for accuracy of the diagnoses and procedures. Hospitals are better equipped to combat fraud and abuse given improvements in record keeping and coding capabilities. (This change can be implemented by regulation.)

PROS:

- Reduces paperwork burden and "hassle" on physicians and hospitals.
- Can be implemented quickly, with an immediate impact on providers.
- Implements recommendation by the Medicare Technical Advisory Group which is comprised of hospitals, intermediaries and trade associations.
- Decreases administrative costs for hospitals.
- The attestation requirement appears unnecessary. There has never been a prosecution in the 11 years of operation of the prospective payment system for hospitals.

CONS:

- Although the hospital will be responsible for accuracy of the diagnoses and procedures, this may create the impression that the Health Care Financing Administration (HCFA) is relaxing its controls on fraud.
- Despite coding/DRG complexities, physicians are viewed as most knowledgeable on care given to hospitalized patients. This may create the impression that administrators rather than doctors control patient care.

REGULATORY IMPACT: 11 million forms will be eliminated; almost 200,000 hours of physician time will be saved; hospitals will have improved cash flow and reduced labor costs.

II. HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS

PROBLEM:

- Hospitals, Home Health Agencies (HHAs), hospices, and End-Stage Renal Disease (ESRD) facilities must meet health and safety requirements to participate in the Medicare program. These requirements measure "process" (i.e., procedural and administrative requirements as proxies for quality health care) rather than "outcome" (i.e., evaluations of actual patient care) and continuous quality improvement.

- Regulatory requirements vary by type of facility and provider even when the services provided in each facility are the same, creating inequities and inappropriate incentives.

- Very little information is available for consumers on the quality of care at a given facility. Information about quality can help consumers make health care choices.

- By law, HHAs must be surveyed yearly -- even though historical data show that this frequency is excessive for many HHAs and does not improve care.

REGULATORY APPROACH: Performance standards; tailor oversight and survey frequency to performance.

PROPOSED SOLUTIONS:

A. Conditions of Participation: Eliminate unnecessary process requirements and instead:

- develop outcome-based performance standards;

- collect and analyze patient care data needed for continuous quality improvement and performance evaluation;

- increase consistency of requirements across providers; and,

- ask the customer to provide input on what the outcome measures should be, and to evaluate the services they received.

(These changes can be implemented by regulation.)

PROS:

- Eliminating unnecessary process requirements will reduce compliance and survey burdens and make it possible to focus on actual patient care.

- Educating the consumer will produce a strong, non-regulatory force to improve quality of care.

- Powerful data will be available to regulators and providers.

CONS:

- Eliminating unnecessary process requirements may be viewed by patient advocates as an elimination of patient safeguards.

- Developing patient care data requirements could be viewed as an additional burden for some providers because they do not currently report this data to HCFA.

REGULATORY IMPACT:

- Produces savings because providers are free to achieve high quality outcomes in the most cost-effective manner. (Note: Outcome measures focus on results whereas process regulations require providers to follow certain procedures. To the extent we can evaluate quality by looking at results, we can discontinue the use of required procedures).

B. Home Health Agencies: Seek an amendment to Section 1891(c)(2)(A) of the Social Security Act to allow flexible survey schedule for HHAs.

PROS:

- Reduces burden on good providers (on-site inspections involve extensive provider staff participation).

- Enables survey agencies to target scarce on-site survey resources to problem providers.

- Reviews problem providers more thoroughly, which will improve care or get them out of the program.

- Provides a positive incentive to furnish good care continuously.

CONS:

Some out-of-compliance HHAs may fall through the cracks under a flexible system.

REGULATORY IMPACT: Approximately $8.8 million in savings to the Federal Government.

ALTERNATIVES NOT RECOMMENDED:

(1) Seek flexible survey cycle for nursing homes.

(2) Eliminate surveys altogether for providers with good records.

WHY NOT RECOMMENDED:

(1) Current nursing home survey cycle allows some discretion (i.e., allows a maximum of 15 months between surveys for a given home while requiring a 12 month average for each State). Greater flexibility would be inappropriate due to the vulnerability of the nursing home population, generally low level of professional supervision, and historical problems with the quality of nursing home care.

(2) Quality of care at an institution can go from good to bad virtually overnight as a result of change of ownership, high turnover of non-professional staff, loss of key professional staff, reduction in census/client base, changes in patient mix (e.g., influx of patients who need hi-tech care), etc. Flexibility in surveying all providers reduces costs while keeping all providers alert to the possibility of inspection.

III. CLIA

The Clinical Laboratories Improvement Amendments (CLIA) of 1988 established baseline quality standards that ensure the accuracy, reliability and timeliness of laboratory testing. These requirements are based on the complexity of the test performed in the laboratory, rather than where the test is performed. Compliance with the standards is determined through on-site inspection.

PROBLEM: CLIA is unnecessarily burdensome (especially for small and physician office laboratories), and laboratories fear sanctions for failure of proficiency testing.

REGULATORY APPROACH:

- Reduce oversight for certain test systems.
- Establish performance standards.
- Use information and education as a substitute for sanctions.

PROPOSED SOLUTIONS:

A. Waive the routine 2-year survey of users of "black box" technology, conducting surveys only if there are indications of problems or complaints, and to validate a 5% sample. Develop and implement criteria for accurate and precise "black box" technology that will be followed to determine if the technology qualifies for waiver of the routine 2-year survey. Black box technology refers to simple and easy to use test systems that have demonstrated accuracy and precision through scientific studies. (These changes can be implemented by regulation.)

PROS:

- Creates incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems.
- Reduces paperwork and costs for providers, especially for physician office laboratories, as well as costs of program management.

CONS:

- Less oversight and monitoring of quality in physician office laboratories.

REGULATORY IMPACT: The dollar magnitude of savings cannot be predicted.

ALTERNATIVES NOT RECOMMENDED:

(1) Do not create new testing category to recognize "black box" technology.

(2) Seek legislation to waive all requirements for "black box" technology.

WHY NOT RECOMMENDED:

(1) Limits incentives to develop new technology and does nothing to reduce burden.

(2) Our approach achieves a similar end administratively without requiring a statutory change.

B. Clarify and expand the waiver criteria and streamline the waiver process so that more tests can be waived from CLIA requirements. In addition, waive all tests approved by FDA for home use (i.e., tests that do not require trained personnel). (These changes can be implemented by regulation).

PROS:

- Decreases burden, especially for physician office laboratories because of less regulatory oversight.

- Increases access to greater variety of tests. Physician office laboratories may expand the range of tests they perform without an increase in costs/burden.

- Creates incentives for manufacturers to develop more test systems that meet the clarified waiver criteria and criteria for approval for home use.

CONS:

- Removes quality protections for a greater number of tests.

- Major groups of laboratory professional scientists such as the American Society of Clinical Laboratory Scientists and the College of American Pathology may protest this reduction in requirements.

REGULATORY IMPACT:

- Eliminates inspection fees for many of the 60,000 physician office and other small laboratories that perform only tests from the expanded waiver category.

- Many additional laboratories will face lower inspection fees because, while they will continue to perform non-waived tests, many more tests will fall into the expanded waiver category.

- Minimizes regulatory requirements.

ALTERNATIVES NOT RECOMMENDED:

(1) Exempt all tests performed in physician office laboratories from CLIA requirements.

(2) Amend statutory "risk" language to allow consideration of net benefits and costs.

(3) Repeal CLIA.

WHY NOT RECOMMENDED:

(1) Complex tests, if incorrectly performed, can cause irreparable harm to a patient. Data from inspections indicate that a significant percentage of tests critical to the diagnosis and treatment of patients are not accurately performed.

(2) A proposed waiver rule has already been developed that delineates a set of criteria to objectively define what constitutes a test that will have negligible risk of an erroneous result, thus allowing for waiver from CLIA standards. Once these criteria are finalized and disseminated, manufacturers and others will have a clear understanding of negligible risk. Manufacturers will have incentive to produce high quality tests that are accurate and precise and have only a negligible risk of error.

(3) Due to serious problems (e.g., incorrectly read Pap smears), public concern has demanded oversight of laboratory testing in the U.S. HCFA inspections have since confirmed the existence of quality problems.

C. Use performance standards and require less frequent on-site inspections (surveys) of excellent performers. Approve private accrediting organizations for deemed status when their accreditation standards are as stringent as CLIA. Exempt labs from CLIA requirements when the State where they are located has requirements equal to or more stringent than CLIA's. (These changes can be implemented by regulation.)

PROS:

- Reduces inspection burdens.
- Rewards good performers with fewer inspections. This is a positive incentive to improve performance.
- Educational emphasis on the inspection process has generated a positive response from the laboratory community.
- Approving organizations for deemed status offers laboratories oversight by peers.
- Approving States for CLIA exemption allows expanded role for States with strong licensure programs.

CONS:

- Without frequent inspections of all laboratories quality may decline.

REGULATORY IMPACT:

- Less oversight.
- Lower burden for laboratories.
- Lower user fees needed to offset the costs of the inspections.
- Deemed status allows for privatization; State exempt status allows for State role.

ALTERNATIVES NOT RECOMMENDED:

(1) Repeal quality control, quality assurance, personnel requirements (except in cytology laboratories), while relying on proficiency testing and outcomes as the basis for quality control.

(2) Amend the statute to allow for waiver of quality control, quality assurance and personnel qualification requirements to allow HCFA to waive such requirements for high performing laboratories.

WHY NOT RECOMMENDED:

(1) Elimination of quality and personnel requirements will have an adverse impact on the accuracy of laboratory tests and their use for patient diagnosis and treatment. It is important to note that:

- Inspection data indicate that significant numbers of laboratory tests are not accurately performed; good quality control and quality assurance practices are not being followed by many laboratories.
- Proficiency testing results reveal that the failure rates for previously unregulated labs are double that of previously regulated labs.
- Deficiency rates in physician office laboratories are two to three times that of previously regulated labs.

(2) Adherence to quality and personnel requirements is what defines sound laboratory practices in high performing laboratories. If these requirements are waived there would be no standards available to evaluate the laboratory in the event their performance deteriorated. Further, proficiency testing alone is unreliable as the sole indicator of laboratory performance.

D. Use proficiency testing (PT) "failures" for education and as an outcome indicator in laboratory quality. (PT is testing samples of known values to assess the accuracy of a laboratory's results). Sanctions (i.e., loss of Medicare payment or loss of approval to do testing) are imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on proficiency testing. (This change can be implemented by regulation.)

PROS:

- Less intrusive than traditional regulation and oversight.
- Reduces anxiety in the physician office laboratory community while maintaining opportunity for self-assessment and improving performance.
- Allows use of proficiency testing as an outcome measure to monitor laboratory performance and provide laboratories with feedback on test quality.

CONS:

- Difficult to prevent egregious disregard for quality testing.

- Physicians do not think that this action by itself reduces burden sufficiently.

REGULATORY IMPACT: Minimizes the fear of sanctions in 60,000 non-waived labs.

ALTERNATIVES NOT RECOMMENDED: No longer require proficiency testing.

WHY NOT RECOMMENDED: Proficiency testing is a valuable outcome indicator and educational tool.

OTHER ALTERNATIVES FOR REGULATORY REFORM

1. **Paperwork Reduction in Federal Programs.** Although many Federal programs require the use of the HCFA 1500, use of the form is not required by the Federal Employees Health Benefit Plan (FEHBP). In addition, instructions for the form vary across programs.

   Alternative: Ask the Office of Personnel Management (OPM) to require participating carriers to announce to providers that they accept the HCFA 1500 for claims filed under FEHBP. Ask HCFA, the Department of Defense, the Department of Veterans Affairs and FEHBP to develop a single set of instructions for filling out the HCFA 1500 in order to streamline further the claim filing process.

   Concerns: This will reduce paperwork for providers and consumers, but may be an added burden on insurers who do not yet use the form. OPM is concerned that insurance carriers, particularly HMOs or fee-for-service plans with preferred provider arrangements, have established data systems suited to their individual informational needs. These carriers would be required to create new data systems to process FEHBP claims (although most of these carriers already serve Medicare patients and therefore already process the HCFA 1500).

2. **Competition in Medicare.** The Administration is considering proposals (as part of health reform discussions) that would offer beneficiaries greater choice among managed care plans. Competition among organized delivery systems has the potential to promote greater efficiency and increase consumer choice.

   As we broaden managed care options for Medicare beneficiaries, we must:

   - Be aware of the practical limitations of a rapid expansion of managed care; the movement to managed care cannot outpace the capacity of managed care plans to serve large numbers of new enrollees, particularly those with the expensive and special health needs of the Medicare program.

   - Improve payment methods to managed care plans. Currently, Medicare pays 5.7 percent more for every enrollee in managed care rather than fee-for-service. Efforts are underway to improve the current payment methodology by adding health status adjusters.

   - Continue to assure quality and preserve beneficiary choice. Increasing managed care options for Medicare beneficiaries will succeed only if beneficiaries recognize the benefit of the coordination of care and case management that high quality managed care plans can provide.

Alternative: Proposals are being discussed to create a voucher system under which private insurers bid for Medicare patients. The Administration has opposed these voucher proposals.

Concerns: Any discussion of voucher proposals should be informed by some facts about Medicare beneficiaries.

- Currently, the major areas of growth for the Medicare population are older seniors age 85 and older, women, and persons with disabilities.
- Second, there is an inverse relationship between income and health status and per capita Medicare expenditures.
- Third, per capita health care spending for aged beneficiaries is four times the average for the under 65 population.

Because problems of risk selection and premium and marketing discrimination in the private insurance market have not been addressed adequately, a voucher system could put the most vulnerable beneficiaries at risk, and could effectively eliminate real plan choice for many older persons. Any broad structural changes to Medicare will be seen by beneficiaries, providers and advocates as an attempt to cut, or even destroy, the program.

3. **Physician Review Organizations.** Physician Review Organizations (PROs) work with local communities and hospitals to assess variations in processes, quality and outcomes of care. Because there is a substantial emerging market in private utilization review, continuing government intervention may be unnecessary.

Alternatives: (1) Set Medicare standards for hospital quality and utilization review and allow hospitals to contract for review either through PROs or other third parties; or (2) eliminate the PRO program entirely.

Concerns: Medicare has a responsibility to ensure that its beneficiaries receive high quality care. The newly structured PRO program has the potential to improve quality, and hospitals and physicians support the new program.

4. **Ownership and Referral.** Current law prohibits physicians from referring patients to health care facilities in which they have an ownership interest. The prohibition is intended to address over-utilization rather than self-referral; therefore, restrictions and penalties should be structured to address excessive referral more directly. In addition, the current prohibition is arbitrary because it does not apply to vertically integrated facilities (e.g., labs or x-ray facilities that are part of a clinic).

Alternative: (1) Replace the ban on self-referral with restrictions on over-utilization (i.e., referring patients too often to any facility); and (2) impose heavy penalties on physicians who refer patients excessively to facilities in which they have an ownership interest.

Concerns: Studies by the Government Accounting Office, the Office of the Inspector General and non-government groups have concluded that physicians who have financial relationships with health facilities tend to refer their patients to those entities more frequently than other physicians. These studies suggest that self-referral is an effective proxy for the over-utilization of services. It may be difficult to measure and prove over-utilization in the absence of the ban on self-referral.

4. **Reimbursement Mechanisms.** Reimbursement and coverage rules under Medicare are often arbitrary and inefficient. For example, some services may be reimbursed if performed in one type of facility but not in another. In other cases, a provider may be forced to give higher cost care because a lower cost alternative is not reimbursable, or may be unable to use a new treatment or technology because it is not yet covered by Medicare.

Some examples are: (1) Medicare requires a 3-day hospitalization before it will reimburse for care in a skilled nursing facility; (2) telemedicine is reimbursed at the same rate as a face-to-face encounter, even though telemedicine is a less intensive interaction that can produce savings; and (3) reimbursement rates vary for identical care performed in inpatient and outpatient facilities.

Alternatives: (1) Identify inappropriate constraints and reform Medicare coverage and payment rules that prevent physicians and hospitals from providing lower cost care; and (2) reimburse for experimental drugs and devices administered in clinical trials for diseases for which there are no adequate proven therapies.

Concerns: The Health Care Financing Administration (HCFA) is conducting demonstration projects to explore alternatives to current reimbursement programs, including reimbursement for telemedicine and prospective payment for outpatient care, skilled nursing and home care. However, constraints on reimbursement and coverage control utilization and costs. Expanding reimbursement and coverage will increase the volume of services provided and may therefore increase total costs for both beneficiaries and the Federal government.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FEB 17 1995

Paul M. Ellwood Jr., M.D.
President
Jackson Hole Group
P.O. Box 350
Teton Village, WY 83025

Dear Paul:

Thank you for the opportunity to review the new draft proposal of "Responsible Choices." I am looking forward to meeting with you and others in Jackson Hole to discuss our respective ideas for improving the nation's health care system.

I have appreciated the opportunity to work with the Jackson Hole Group in the past, in large part because we share a common commitment to improving both efficiency and fairness in the health care system. I think we all agree that health reform requires three elements to be effective — expanded coverage, lower costs and improved quality — and that a restructured marketplace is essential to achieving these elements. Our ultimate goal must be universal coverage in an efficiently operating marketplace.

You and your colleagues have made a significant contribution to the health care debate in this country by recognizing the critical role that consumer choice and private innovation can play in our health care system. I think that we both agree that choice is a critical element in improving quality and efficiency.

I was surprised, then, by the direction reflected in "Responsible Choices." The draft proposal seems to abandon your previous commitment to addressing the problems of the over 40 million uninsured in this nation. I understand that the political environment has changed, and that our strategies may need to change as a result. However, that does not alter the underlying fact that middle class people who lose their jobs, or working families struggling to get by, need some assistance to be able afford adequate health insurance.

The Jackson Hole Group has recognized this fact in the past, and has advocated substantial subsidies to assist the uninsured in purchasing private insurance. It deeply troubles me that the "Responsible Choices" proposal fails even to mention the need to move towards universal coverage, let alone suggest policies (short or long-term) to do so.

In fact, the arbitrary cap on funding for the Medicaid program proposed in "Responsible Choices" would actually decrease coverage. Over the past few years, enrollment in employer-based insurance has fallen by almost six percentage points (from around 66% to around 60% of the nonelderly population), while the percentage of the population covered by Medicaid has grown significantly. Between one-third and one-half of the projected annual growth in Medicaid spending results from projected growth in enrollment.

Furthermore, I am perplexed and disturbed that you would propose an arbitrary cap on the Medicare program. Like Social Security, Medicare is an inter-generational compact. Placing an arbitrary, pre-determined cap on Medicare spending, while at the same time eliminating its status as an entitlement, would put services to the elderly at risk and would violate that compact.

A cap on Medicare puts the elderly and disabled at risk. The vast majority of Medicare beneficiaries have modest incomes. Over 75% of beneficiaries have incomes below $25,000; 30% of beneficiaries get 80% or more of their income from Social Security. So while a voucher program like that proposed in "Responsible Choices" may expand choice for some beneficiaries, it would in fact diminish choice for many by effectively forcing them into a low-cost plan and away from the providers of their choice.

This does not mean that we oppose improving Medicare — quite the contrary. We are pleased that, during the Clinton Administration, projections for the average annual rate of growth for Medicare spending for the period 1996 - 2000 have decreased — by more than a percentage point a year — just in the period between the Mid-Session Review last spring and the President's Fiscal Year 1996 Budget. We are pressing ahead with improvements in Medicare management, data processing, contractor oversight, and program integrity activities.

Among the other improvements we are making in Medicare, I believe that we share a commitment to expanding and improving the managed care choices available to Medicare beneficiaries. Today, about 74 percent of Medicare beneficiaries have access to a managed care plan, and 9% of beneficiaries have enrolled in one. Enrollment is increasing rapidly — by over 1% per month. We also are working on ways to make our existing managed care program work better. Examples include our work with the industry to improve quality measures and the AAPCC methodology for the Medicare risk contracting program, and our collaboration with Alain Enthoven to design a competitive bidding demonstration. And, as we have testified in recent weeks, we are in the process of developing new managed care options under Medicare, including a PPO option.

While managed care appears now to be reaching a critical mass in private sector health programs, at least in some areas, it has taken many years to achieve this state. Many employers that have embraced managed care have moved cautiously to avoid disruption, by maintaining a fee-for-service option at affordable levels or by offering out-of-network options through point-of-service plans or PPOs. Most Medicare beneficiaries — and particularly the most elderly among them — have not had the benefit of a gradual exposure to managed care. I am strongly committed to expanding the managed care options available in Medicare, but the emphasis must be on choice. We should learn from the private sector and recognize that we need to move prudently if we are to foster understanding and acceptance of managed care approaches among beneficiaries.

I look forward to the upcoming discussions at Jackson Hole. We need to focus on how we can improve both the private insurance market and public programs. And we must discuss ways to expand coverage for vulnerable populations. I believe that there are many points on which we can agree. To me, making responsible choices means finding ways to improve what we have, not making arbitrary cuts in important programs that can leave the elderly, disabled, and poor at risk. I hope that we can work together over the coming months to accomplish meaningful health care reform.

Sincerely,

Donna E. Shalala

AGENDA

REINVENTING HEALTH, DRUG, AND MEDICAL DEVICE REGULATION

February 21, 1995

I. Overview

II. Drug and Device Presentation -- Food and Drug Administration, David Kessler

- A. Drugs and Biologicals
- B. Generic Drugs
- C. Medical Devices
- D. Cross-Cutting Issues
- E. Additonal Options for Discussion

III. Health Care Presentation -- Health Care Financing Administration, Bruce Vladeck

- A. Physician Attestation -- Presentation of Working Group Consensus
- B. Health and Safety Standards for Medicare Providers -- Discussion of Alternatives
  1. Conditions of Participation: Eliminate Unnecessary Process Requirements
  2. Home Health Agency Surveys: Allow Flexible Survey Cycles
- C. Clinical Laboratories Improvement Amendments -- Discussion of Alternatives
  1. Waive Routine Survey of Users of "Black Box" Technology
  2. Clarify and Expand Waiver Criteria and Streamline the Waiver Process.

     Alternatives: (1) Exempt all tests performed in physician office laboratories from CLIA requirements; (2) amend statutory "risk" language to allow consideration of benefits and costs; or (3) repeal CLIA.

3. Use Performance Standards and Require Less Frequent On-Site Inspections of Excellent Performers.

   Alternatives: (1) Repeal quality control, quality assurance, and personnel requirements, and rely on proficiency testing and outcomes for quality control; or (2) give HCFA discretion to waive these requirements for labs that perform well.

4. Use Proficiency Testing Failures for Education and as Outcome Indicators for Laboratory Quality.

   Alternative: No longer require proficiency testing.

D. Additional Options for Discussion

1. Paperwork Reduction in Federal Programs
2. Competition in Medicare
3. Physician Review Organizations (PROs)
4. Ownership and Referral
5. Reimbursement Mechanisms