U.S. Department of Labor

Pension and Welfare Benefits Administration
Washington, D.C. 20210

Date: 5/13/99

TO: Chris Jennings / Deverch

TELEPHONE: _____ **FAX:** 456-5557

FROM: **Leslie B. Kramerich**
Deputy Assistant Secretary for Policy
U.S. Department of Labor
Pension and Welfare Benefits Administration
200 Constitution Avenue, NW - Room S 2524
Washington, DC 20210
(202) 219-8233 - voice
(202) 219-5526 - fax

COMMENTS:

Per my voice mail

Should you experience any difficulties in receiving this transmission, please call (202) 219- 8233.

There are _____ pages including this page.

Chris
Devorah
Gary

The Senate DPC is scheduling a PBOR event for May 26. They've asked about products (it could be the maps we've talked about showing the "scope" issue) and about inviting the Secretaries of Labor and HHS. If the Finance markup on the 20th is MSA-type items only, this may be perfect timing and may help with the drive for a meaningful floor opportunity. We've received data from HHS and are working on the maps and possibly an accompanying report. Why don't we plan a meeting or conference call for early next week and talk about the status of this, as well as whether this should be an event hosted elsewhere and whether the message can be broader (i.e., other important issue differences in the various approaches, not limited to scope, to diversify the message).

DRAFT PATIENTS' BILL OF RIGHTS DOCUMENT
Friday, April 9, 1999

At the beginning of the 106th Congress, House and Senate Democrats re-introduced the Patients' Bill of Rights (H.R.358/S.6) — part of the 1999 Families First Democratic Agenda. The Patients' Bill of Rights is the only bill that will deliver real protections to millions of American families.

The Patients' Bill of Rights would allow doctors and patients — rather than insurance company bureaucrats — to make medical decisions, using the principles of good medicine. In addition, it would:

- Guarantee access to needed health care specialists;
- Provide access to emergency room services when and where the need arises;
- Provide continuity of care protections to assure patient care if a patient's health care provider is dropped;
- Give access to a timely internal and independent external appeals process;
- Assure that doctors and patients can openly discuss treatment options;
- Assure that women have direct access to an OB-GYN; and
- Provide an enforcement mechanism that ensures recourse for patients who have been harmed as a result of health plan actions.

The Senate GOP bill, on the other hand, fails to include many of these basic consumer protections. Similarly, in the House, Speaker Hastert has said some type of managed care reform bill should be passed this year — but has once again opened the door to watered-down or piecemeal efforts.

Democrats are ready to work to pass a real bill immediately so we can provide Americans with the health care protections they have been waiting for — for far too long.

In order to push Speaker Hastert and Majority Leader Lott to act, major health care organizations are launching a nationwide petition drive in support of the Patients' Bill of Rights on Friday, April 9th.

The President, Vice President, Democratic Leaders, and House and Senate Members and the public will all be able to add their name to the national petition via 120 different web sites. The 120 organizations that have endorsed the Patients' Bill of Rights have tentatively agreed to put the petition on their web sites and all names entered on any of these different web sites will automatically be collected on the central petition hosted by Families USA.

Vice President Gore – joined by House and Senate Democrats -- will hold a press conference in Washington, D.C. at 9:30 a.m. at XXX to officially unveil the on-line petition. House and Senate Members will then board buses to Philadelphia, PA for a 1:30 p.m. rally with President Clinton at XXX.

MEMORANDUM

FROM: LESLIE KRAMERICH
Deputy Assistant Secretary, PWBA

SUBJECT: Today's Supreme Court decision in Unum Life Insurance Co. v. Ward

This memo will summarize the employee story that led to the case decided today by the Supreme Court, and the ERISA arguments that were made to the Court. It will also note how the decision touches on patients rights and remedies, as well as our patients rights regulation. Finally, it shows the great number of interested parties who are not only watching this case but have gotten actively involved.

The Employee's story:

John Ward resigned his job in May, 1992 when he became permanently disabled by a painful disorder which was later diagnosed to be a result of diabetes. He asked about the possibility of continuing health insurance, and he kept his employer posted when he was found disabled under Social Security (which is often a prerequisite for other kinds of disability coverage). He had worked for the company for 9 years and had disability premiums deducted from his paycheck during that time.

In April of 1994, he came across an old booklet describing the disability coverage his employer had offered through the Unum insurance company. He asked the employer if his disability would be covered under the policy, and the employer said yes, so Mr. Ward submitted a claim to the insurance company. The company refused to pay, saying claims had to be filed within 180 days of the onset of the disability, so Mr. Ward had 6 months from May of 1992 in which to submit his claim. Mr. Ward sued to get the benefit promised to him. Unum argued that the lawsuit could not proceed because it was "preempted" or prevented by ERISA.

The Supreme Court said Mr. Ward's lawsuit is not blocked by ERISA:

Mr. Ward argued that the 180-day clock Unum wanted to impose on his ability to file a claim was satisfied because he told his former employer of his condition within that time-frame, and notice to the employer should count as if it were notice to the insurance company. In other words, he argued that the employer should be considered an agent of the insurance company and he cited a California case as standing for that rule. The Supreme Court rejected his request to rely on this argument, saying that it would affect ERISA plans too greatly and that it is not the kind of insurance law that ERISA permits to have that kind of effect. (In ERISA terminology, it would be said that the agency rule "relates to" ERISA plans and is preempted, and that it does not "regulate the business of insurance" so it is not "saved" from preemption.)

Mr. Ward also argued that a different kind of California law should be considered to fall within the category of "insurance laws" that is permitted to affect ERISA plans. On this argument, he won. California has a law, developed by court cases rather than statutes, which says that insurance companies cannot reject claims that are filed late unless that lateness hurts the insurance company's ability to process the claim (to know whether it should really be paid or not). This is the ground on which the Court permitted his case to go forward. The case now goes back to the district court so the court can determine whether or not Unum suffered any prejudice to its ability to analyze the claim by virtue of the lateness with which it was filed.

Patients rights and remedies

Unum tried to argue that Mr. Ward's suit should not proceed because he was looking for some kind of remedy or enforcement under state law, and the Supreme Court has already stated in the 1987 case of Pilot Life that ERISA is the exclusive source of any remedy or enforcement. In our brief, we argued that the Supreme Court should revisit whether Pilot Life made the correct statement about ERISA's "exclusive" nature. In today's decision, the Supreme Court decided that it was not necessary to revisit Pilot Life in this case because Mr. Ward was not looking for a "remedy" under California law. Instead, he is proposing to use a California law that helps to enforce a benefit promise and that is not something that conflicts with ERISA so it is not preempted by ERISA.

The Patients' Rights Regulation

Unum also argued that the California rule about claims that are filed late (called the "notice-prejudice rule") is something that differs from ERISA's provisions on claims processing and appeals and differs from our proposed regulation updating those provisions. The Court said that didn't matter. Because the California law "complements" ERISA's requirements and does not frustrate them or make compliance with them impossible, both remain valid.

There are a great number of interested parties participating in this case:

Mr. Ward's arguments were supported by:

- The Department of Labor
- the Council of State Governments, National Governors' Association, National Association of Counties, National League of Cities, U.S. Conference of Mayors, and International City/County Management Association;
- National Employment Lawyers Association;
- AARP;

- the States of Texas, Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia, Wyoming and the Territory of Puerto Rico; and

- National Association of Insurance Commissioners.

Unum's arguments were supported by:

- the Business Roundtable; and

- the American Council of Life Insurance,

- the Health Insurance Association of America

- and Standard Insurance Company.

Q: Isn't the UNUM decision further evidence that the courts have made a great change in their view of ERISA preemption of state laws. When you add this case to other recent decisions such as Pappas, Shea, and Giles, don't patients have much better access to remedies for benefit denials as a result?

A: No. The courts have begun to limit the reach of ERISA preemption by adopting a more common sense analysis to issues of whether a particular state law is preempted, but this does not really change the situation for plan participants who have been injured due to a denial or delay of promised benefits.

- At best, the general trend of cases in the last few years, has been to put up some fences around the reach of ERISA preemption.
  - They have helped keep ERISA from preempting everything that might have some relation to employee benefit plans, no matter how tangential, but they have not made serious inroads on preemption of state laws that guarantee rights to promised employee benefits.
  - For example, the Giles v. NYLCARE decision is one of several recent cases that have kept plans and insurers from using ERISA preemption to insulate themselves from liability when they or their agents commit medical malpractice.
  - Moscovitch v. Danbury Hospital, 25 F. Supp. 2d 74 (D. Conn. 1998) is another case where the court ruled that ERISA does not preempt state law claims for failure to properly diagnose and treat a medical condition.
  - These types of cases do not help the people like the plaintiffs in Corcoran v. United Health Care, Inc., 965 F.2d 1321 (5th Cir. 1992) or Bedrick v. Travelers Ins. Co., 93 F. 3d 149 (4th Cir. 1996) who were injured by medical decisions made in the context of benefit determinations. In those cases, and in many others, the courts held that the state law claims were preempted even though the benefit determinations involved the exercise of medical judgment.
  - The holding in Ward v. UNUM is similarly limited. It merely allows a federal court hearing a benefit claim dispute case to use a state insurance law as a rule of decision. It does not open the door to state tort remedies for a participant who is hurt due to an unreasonable benefit denial.
- Some of the cases, blur the line between the provision of medical care and claims administration, but these hardly represent a trend that will help most people whose benefit claims are improperly delayed or denied.
  - E.g., Pappas v. Asbel, 724 A.2d 889 (Pa. Supr. Ct. 1997). HMO refused to immediately authorize patient's transfer to hospital recommended by emergency room physcian. [*Note: we don't think that this case was correctly decided.*]

- As the court in Moscovitch recognized, "it is often difficult to determine when an entity . . . is arranging, supervising or providing medical treatment of a plan participant – which would be outside the scope of ERISA § 502(a) – or merely making benefit determinations – which would be within the scope of ERISA § 502(a)."

- The courts may be able to decide close cases in favor of the patient but, the language of the statute and the existing precedent will not allow major changes in the legal analysis of these situations.

- Shea v. Esentein, 107 F.3d 625 (8th Cir. 1997), actually went against the widow of a participant who was seeking to use state remedies for a failure to disclose an arrangement that gave doctors an incentive to restrict referrals to specialists. The court found a duty under ERISA to make such disclosure, but ERISA provides no real remedy for the widow in this situation.

Chris Jennings

Contact: Tom Bantle (202) 546 4996 ext 367
or Dan O'Sullivan (202) 546 4996 ext 387

March 26, 1999

Attention Editorial Writers:

Patients' Bill of Rights Under Siege in New Corporate Ad Campaign

Business Media Blitz to Hit Key Members During Congressional Recess

America's biggest corporations are again spending big bucks on a Big Lie ad campaign to scare consumers away from supporting the pro-consumer Patients' Bill of Rights bills now being debated in Congress. Two of America's biggest corporate trade associations, the Health Benefits Coalition and the Business Roundtable, announced March 22 that they will buy $2 million in radio and television ads to air in coming weeks in the districts of swing members of the House of Representatives and Senate.

The ads are designed to convince workers and consumers that allowing patients to hold HMOs and other health plans accountable in court for medical malpractice will result in much higher health care costs and threaten the loss of employer-provided health insurance.

In reality, as the attached documents show, the Congressional Budget Office has estimated the cost per enrollee of these consumer protections at $24 per year. This is significantly less than the $40 cost per enrollee in Oxford Health Plans, a leading managed care plan, for the executive compensation of their five top executives.

Both the Senate and the House are continuing last year's struggles over the scope of Patients' Bill of Rights bills, designed to better protect consumers in managed health care plans. A key Senate committee passed its bill March 18, which did not include provisions that would allow injured patients to hold HMOs accountable for those injuries in state courts. The Senate Republican leadership has vowed to block any bill that included a "right to sue" provision. Thus it will take a supermajority of 60 votes to overcome a threatened Republican filibuster. House committees have begun hearings on the bills.

The new disinformation campaign continues the disturbing trend begun by the infamous "Harry and Louise" ads on which the health insurance industry spent more than $17 million in 1994. Since the debate on Patients' Bill of Rights legislation began in the last Congress, the Health Benefits Coalition, the Business Roundtable, and the American Association of Health Plans have spent or announced plans to spend tens of millions more dollars on misleading media ads.

Chris Jennings

Last year's House votes on the Patients' Bill of Rights bills were extremely close. The major House substitute (Dingell-Ganske), which gave consumers the right to take HMOs to court, failed by only five votes, 212-217. In a new Congress with a narrower House majority pro-consumer forces could prevail. That's why the radio and television blitz by the Business Roundtable and the Health Benefits Coalition targets swing votes: Blue Dog Democrats and moderate Republicans.

Corporate America wants Congress to continue a special legal deal that protects HMOs and other managed care organizations from liability for injuries they inflict on patients. This special protection is given to private sector employer-paid health insurance plans. They are lobbying to keep the federal Employee Retirement Income Security Act (ERISA) provisions that immunize these managed care companies from medical malpractice and personal injury lawsuits under state law. This special protection leaves 125 million health care consumers without any mechanism to hold their health plans fully accountable for the consequences of their medical malpractice, including additional medical bills because of the complications of denied care; lost wages and other economic losses; pain and suffering due to loss of a limb, blindness or paralysis; and mental anguish.

Health care plans, shielded by the current law from full accountability to the patients they injure, are given a huge incentive to *deny* necessary and appropriate care. Allowing consumers to hold their insurers accountable in state court would give managed care companies the proper incentive to make sound medical decisions in the first instance.

The attached fact sheets detail the lies underlying this deceptive ad campaign and the importance of giving consumers the right to hold their managed care plans accountable in court. Please consider editorializing against these distorted ads and in favor of managed care accountability.

Possible House targets include:

Bud Cramer	AL-5	David Phelps	IL-19	Sherwood Boehlert	NY-23
Spencer Bachus	AL-6	Baron Hill	IN-9	Mike McIntyre	NC-7
Marion Berry	AR-1	Dennis Moore	KS-3	Steven LaTourette	OH-19
Mike Thompson	CA-1	Ken Lucas	KY-4	Tim Holden	PA-6
Ellen Tauscher	CA-10	John Cooksey	LA-5	Lindsey Graham	SC-3
Gary Condit	CA-18	Christopher John	LA-7	Max Sandlin	TX-1
Stephen Horn	CA-38	Wayne T. Gilchrest	MD-1	Jim Turner	TX-2
Loretta Sanchez	CA-46	Constance A. Morella	MD-8	Ralph Hall	TX-4
Brian P. Bilbray	CA-49	David Minge	MN-2	Kevin Brady	TX-8
Christopher Shays	CT-4	Collin Peterson	MN-7	Charles Stenholm	TX-17
Allen Boyd	FL-2	Ronnie Shows	MS-4	Zach Wamp	TN-3
Charles T. Canady	FL-12	Gene Taylor	MS-5	John Tanner	TN-8
Mark Foley	FL-16	Pat Danner	MO-6	Owen Pickett	VA-2
Sanford Bishop	GA-2	Jim Gibbons	NV-2	Norm Sisisky	VA-4
Charlie Norwood	GA-10	Charles F. Bass	NH-2	Virgil Goode	VA-5
James A. Leach	IA-1	Marge Roukema	NJ-5	Thomas Petri	WI-6
Greg Ganske	IA-4	Rodney P. Frelinghuysen	NJ-11		
Bill Lipinski	IL-3	Michael P. Forbes	NY-1		

For more information on this issue visit our website at
www.citizen.org/congress/civjus/patientsrights/health.htm

. Chris Jennings

Public Citizen Big Business Spends Big Bucks on Big Lies to Kill the Patients' Bill of Rights

Big Lie #1: Allowing consumers to hold their health care plans fully accountable in court for injuries would dramatically increase health care costs.

Fact: The real cost of giving patients the right to be fully compensated for injury is modest.

Fact: The Congressional Budget Office estimated the cost of the 1998 reform bill's provisions to end HMOs' special legal protections to be only 1.2 % of employer-sponsored plan premiums.[1] The average HMO premium cost for medium and large employers in 1997 was $2,000 for individual coverage; 1.2% would add $24 a year ($2 per month).

Fact: State and local government employers are not covered by ERISA; their employees or families have the right to go to court when they have been injured or killed to recover full compensation from their managed health care plans. A Kaiser Foundation study of three such governmental plans found "very low rates of litigation ranging from .3 to 1.4 cases per 100,000 enrollees per year."[2] The 1998 study estimated that the cost to enrollees to preserve their rights to get full compensation when injured ranged from three to thirteen cents per month.[3]

Fact: Unlike employer-sponsored health plans, doctors, hospitals, and other health care providers can be sued under state medical malpractice, personal injury, and wrongful death laws if they cause serious patient injury or death. Again, their experience proves that giving injured persons the right to sue for full compensation has a minimal effect on health care premiums. The highest estimated cost of this consumer protection is less than 1.2 % of total U.S. health costs.[4] And the low costs found in these studies do not take into account the value, both in human terms and monetary savings, of the deterrent effect of holding managed care plans accountable.

Fact: Only a tiny percentage of persons injured by medical malpractice file claims, leaving a heavy bill for patients, their families and communities, and taxpayers. A Harvard University Medical Malpractice Study of New York State showed as few as 3% of injured patients ever file claims.[5]

Big Lie #2: Subjecting employers to direct liability for health care decisions may cause employers to drop coverage out of fear of a large damage award.

Fact: The Health Benefits Coalition, Business Roundtable, and other major opponents of the Patients' Bill of Rights are deliberately misstating the provisions in the current bills that allow patients' to hold insurers accountable. The Kennedy-Dingell (S. 6/H.R. 358), Ganske (H.R. 719), and Norwood (H.R. 216) bills all specifically prohibit suits directed at employers unless the employer corporation itself is making the <u>medical</u> decisions.

Fact: For example, Section 302 (a) of both S.6 and H.R. 358 (the Kennedy-Dingell bills) specifically exempts employers from an injured employee's suit in state court. The only circumstances under which an employer could

be held accountable is if the employer actually makes the decision on whether a procedure will be covered by the health insurance plan **and** the employer's decision resulted in personal injury or wrongful death. Under this section, any corporation that contracts with an insurer to make coverage decisions could **not** be sued by the injured employee. The vast majority of employers, even those who claim to self-insure, contract out coverage decisions.

Big Lie #3: Allowing consumers to sue health plans could dramatically increase health care costs to the point that employers begin dropping coverage.

Fact: 85% of Americans with employer-paid health insurance are covered by managed care plans; three-quarters of these are for-profit firms. These companies divert 10% - 15% of premiums - billions of dollars annually - away from patient care and into such costs as advertising and promotion, high administrative overhead, and top dollar executive compensation. Compared to these market-driven expenditures, it is absurd to claim that the modest cost of allowing patients and their families to hold a health plan accountable in court for serious injury or death could force employers to drop coverage.

Fact: For-profit managed care plans dominate health care today: Between 1981 and January 1998, for-profit HMOs grew from representing 12% to 63% of total HMO enrollees, and from 18% to 74% of plans. Increasing "shareholder value," not providing the best patient care possible, is the bottom line for these for-profit firms. Market-driven behavior includes such practices as offering "loss leader" low premiums to gain market share followed by steep price increases, dumping more than 400,000 Medicare patients at the end of 1998 because profits were too low,[6] and curtailing the amount of medical care provided to keep the "medical loss ratio" at the level approved by a plan's stock analysts (as the CEO of PacifiCare recently told Wall Street he would do by "managing care").[7]

Fact: The real factors driving health care cost increases are the demand for increased profits by for-profit managed care firms' stockholders, an aging population with more costly health care needs, technological innovation, rising demand for sophisticated, high-cost services, and skyrocketing prescription drug prices. Total expenditures for prescription drugs increased by 85% between 1993 and 1998, with an estimated 17% increase from 1997 to 1998 alone, or more than four times the rate of increase for all health care expenditures in that period.[8] The extremely low cost of allowing patients and their families to hold health plans accountable in court does not begin to approach the same order of magnitude as the real cost drivers of health care inflation.

Fact: The high cost of HMO executive compensation is a far greater burden on the premium dollar than allowing consumers to take their health plan to court would be. The 25 most highly compensated HMO executives were paid more than $6.2 million in average annual compensation in 1997 - and this did not include tens of millions more in unexercised stock options.[9] For example, the CEO of Oxford Health Plans received $29.1 million; the CEO of CIGNA, $11.6 million; and the President of Aetna, $7.4 million.

Fact: The compensation of the top five executives alone at Oxford Health Plans averaged more than $40 per enrollee each year.[10] Based on Congressional Budget Office estimates, the cost of allowing consumers to sue their health plans when injured would be a little more than half that figure, and a mere fraction of that cost using the estimate made by the Kaiser Family Foundation.

Cost of Oxford Health Plans' 5 Top Executives Pay per member per month (PM/PM)	**Cost of Allowing Consumers to Sue when Injured PM/PM** **- High estimate (CBO) -**	**Cost of Allowing Consumers to Sue when Injured PM/PM** **- Low estimate (Kaiser) -**
$3.36 ($40/year)	$2.00 - $2.33 ($24-$28/year)	$.03 - $.13(<$2/year)

The Truth: Members of the industry-dominated Health Benefits Coalition are spending big bucks on big lies fighting desperately to maintain the special protection from liability that current federal law grants to just one industry: private sector employer-paid insurance plans, HMOs, and other managed care health plans.

Fact: In 1998, the members of the Health Benefits Coalition spent **more than $69 million** lobbying Congress, according to an analysis compiled by Public Citizen based on expenditure disclosure reports required under the 1995 Lobbying Disclosure Act. Of this amount, **$24 million** was spent by managed care and health insurance interests.

Fact: In 1997-1998, the Health Benefits Coalition members made **more than $8 million** in PAC and "soft money" campaign contributions, according to Federal Election Commission reports. Contributions from Business Roundtable corporations total an additional $57 million, according to the government watchdog group Public Disclosure, Inc. (www.tray.com/fecinfo).

Fact: "In May 1998, the Business Roundtable announced it would triple its annual dues to finance **$27 million** in issue advocacy advertising on health care (against managed care reform) and China's trade status . . . "[11]

Fact: In May and July 1998, the Health Benefits Coalition spent **$2 million** on ads opposing the Patients' Bill of Rights.[12] In 1998 the American Association of Health Plans, a trade association of managed care providers, spent **$2 million** on "issue ads" against "patients rights" legislation.[13]

Notes

1. "Cost Estimate of H.R. 3605/S. 1890, Patients' Bill of Rights Act of 1998." Congressional Budget Office, July 16, 1998. p. 17.

2. "Impact of Potential Changes to ERISA: Litigation and Appeal Experience of CalPERS, Other Large Public Employers and a Large California Health Plan." Kaiser Family Foundation Report, June 1998. p.7.

3. *ibid.*, p.7.

4. "From Medical Malpractice to Managed Care Liability." Conning Insurance Research and Publications (Conning is a nationally respected provider of research on the insurance industry), 1997, p.70.

5. Harvard Medical Practice Study, "Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York," 1990.

6. Patricia Neuman and Kathryn M. Langwell, "Medicare's Choice Explosion? Implications for Beneficiaries," *Health Affairs*, Vol. 18, No. 1, p. 153.

7. "PacifiCare Curbs Costs to Counter Medicare," *Los Angeles Times*, December 1, 1998, p. C-2.

8. Robert Kuttner, "The American Health Care System: Health Insurance Coverage," *New England Journal of Medicine*, Vol. 340, p. 163-168, January 14, 1999.

9. "Premium Pay: Corporate Compensation in America's HMOs." Families USA Foundation Report. April 1998. p.3.

10. "Families USA Study Examines Executive Compensation in Managed Care." Families USA Press Release. April 1, 1998. p.5

11. http://www.asc.upenn.edu/appc/issueads/profiles/brtable.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

12. http://www.asc.upenn.edu/appc/issueads/profiles/hbc.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

13. http://www.asc.upenn.edu/appc/issueads/profiles/aahp.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

. .Chris Jennings

HMO Legal Shield Hurts Consumers

When death or serious injury occurs because of an HMO's decision to deny necessary or appropriate medical care, the patient or surviving family members should have the right to go to court to seek redress and the insurer should be held accountable for the consequences of negligent or reckless decisions. There are several reasons why it is critical to enact this vital consumer protection:

◆ **Require corporate accountability: eliminate HMOs' special protection from liability laws.** Approximately 125 million Americans are covered by private sector employer-paid health insurance plans, which are immunized from malpractice and personal injury lawsuits under state law by the federal Employee Retirement Income Security Act (ERISA). A large majority receive their care from an HMO or other managed care plan; two-thirds of these are for-profit firms for which high profits mean high stock prices. Under managed care, decisions about necessary and appropriate medical care increasingly are made by insurance company bureaucrats seeking to hold down costs rather than by a physician or other health care provider. Because of the ERISA preemption, these managed care bureaucrats and corporations cannot be held accountable for the consequences of their faulty decisions; health care quality suffers as a result. No other industry has such special legal protection.

◆ **Create incentive to provide, not deny, necessary and appropriate care.** Under ERISA, injured patients and their families who are wrongly denied needed medical treatment can only recover the cost of the procedure for which the plan failed to pay and attorney's fees. They have no mechanism to recover other consequences of the denial of care such as medical costs required by the injury, lost wages of the patient or care giver, or compensation for pain or emotional distress. Because health plans can escape from the responsibility to fully compensate injured patients, the current law gives HMOs a huge incentive to deny necessary and appropriate care. Allowing consumers access to state remedies gives health care organizations the proper incentive to make sound medical decisions in the first instance.

◆ **Allow fair recovery for injured employees.** The ERISA preemption of state consumer remedies prevents many injured employees and their families from being fully compensated for the medical malpractice they suffered. Numerous judges have expressed outrage that health insurers can use the ERISA shield to avoid assuming full responsibility to injured parties. This shifts the costs of the consequences of the HMOs' wrongful decisions to the injured, their families and communities, and the taxpayers

◆ **An administrative appeals process is no substitute for litigation.** Only by having their day in court can injured patients be made whole. Independent external appeals are complementary to, not a substitute for, the patient's right to sue for compensation for injuries. At best, a successful external appeal can only force the managed care organization to reverse its care decisions; at worst, external appeals processes can encourage HMOs to deny care until an external appeals panel orders them to provide it.

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Devorah Adler

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9. "Premium Pay: Corporate Compensation in America's HMOs." Families USA Foundation Report. April 1998. p.3.

10. "Families USA Study Examines Executive Compensation in Managed Care." Families USA Press Release. April 1, 1998. p.5

11. http://www.asc.upenn.edu/appc/issueads/profiles/brtable.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

12. http://www.asc.upenn.edu/appc/issueads/profiles/hbc.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

13. http://www.asc.upenn.edu/appc/issueads/profiles/aahp.htm, The Annenberg Public Policy Center of the University of Pennsylvania.

The Truth: Members of the industry-dominated Health Benefits Coalition are spending big bucks on big lies fighting desperately to maintain the special protection from liability that current federal law grants to just one industry: private sector employer-paid insurance plans, HMOs, and other managed care health plans.

Fact: In 1998, the members of the Health Benefits Coalition spent **more than $69 million** lobbying Congress, according to an analysis compiled by Public Citizen based on expenditure disclosure reports required under the 1995 Lobbying Disclosure Act. Of this amount, **$24 million** was spent by managed care and health insurance interests.

Fact: In 1997-1998, the Health Benefits Coalition members made **more than $8 million** in PAC and "soft money" campaign contributions, according to Federal Election Commission reports. Contributions from Business Roundtable corporations total an additional $57 million, according to the government watchdog group Public Disclosure, Inc. (www.tray.com/fecinfo).

Fact: "In May 1998, the Business Roundtable announced it would triple its annual dues to finance **$27 million** in issue advocacy advertising on health care (against managed care reform) and China's trade status . . . "[11]

Fact: In May and July 1998, the Health Benefits Coalition spent **$2 million** on ads opposing the Patients' Bill of Rights.[12] In 1998 the American Association of Health Plans, a trade association of managed care providers, spent **$2 million** on "issue ads" against "patients rights" legislation.[13]

Notes

1. "Cost Estimate of H.R. 3605/S. 1890, Patients' Bill of Rights Act of 1998." Congressional Budget Office, July 16, 1998. p. 17.

2. "Impact of Potential Changes to ERISA: Litigation and Appeal Experience of CalPERS, Other Large Public Employers and a Large California Health Plan." Kaiser Family Foundation Report, June 1998. p.7.

3. *ibid.*, p.7.

4. "From Medical Malpractice to Managed Care Liability." Conning Insurance Research and Publications (Conning is a nationally respected provider of research on the insurance industry), 1997, p.70.

5. Harvard Medical Practice Study, "Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York," 1990.

6. Patricia Neuman and Kathryn M. Langwell, "Medicare's Choice Explosion? Implications for Beneficiaries," *Health Affairs*, Vol. 18, No. 1, p. 153.

7. "PacifiCare Curbs Costs to Counter Medicare," *Los Angeles Times*, December 1, 1998, p. C-2.

8. Robert Kuttner, "The American Health Care System: Health Insurance Coverage," *New England Journal of Medicine*, Vol. 340, p. 163-168, January 14, 1999.

be held accountable is if the employer actually makes the decision on whether a procedure will be covered by the health insurance plan **and** the employer's decision resulted in personal injury or wrongful death. Under this section, any corporation that contracts with an insurer to make coverage decisions could **not** be sued by the injured employee. The vast majority of employers, even those who claim to self-insure, contract out coverage decisions.

Big Lie #3: Allowing consumers to sue health plans could dramatically increase health care costs to the point that employers begin dropping coverage.

Fact: 85% of Americans with employer-paid health insurance are covered by managed care plans; three-quarters of these are for-profit firms. These companies divert 10% - 15% of premiums - billions of dollars annually - away from patient care and into such costs as advertising and promotion, high administrative overhead, and top dollar executive compensation. Compared to these market-driven expenditures, it is absurd to claim that the modest cost of allowing patients and their families to hold a health plan accountable in court for serious injury or death could force employers to drop coverage.

Fact: For-profit managed care plans dominate health care today: Between 1981 and January 1998, for-profit HMOs grew from representing 12% to 63% of total HMO enrollees, and from 18% to 74% of plans. Increasing "shareholder value," not providing the best patient care possible, is the bottom line for these for-profit firms. Market-driven behavior includes such practices as offering "loss leader" low premiums to gain market share followed by steep price increases, dumping more than 400,000 Medicare patients at the end of 1998 because profits were too low,[6] and curtailing the amount of medical care provided to keep the "medical loss ratio" at the level approved by a plan's stock analysts (as the CEO of PacifiCare recently told Wall Street he would do by "managing care").[7]

Fact: The real factors driving health care cost increases are the demand for increased profits by for-profit managed care firms' stockholders, an aging population with more costly health care needs, technological innovation, rising demand for sophisticated, high-cost services, and skyrocketing prescription drug prices. Total expenditures for prescription drugs increased by 85% between 1993 and 1998, with an estimated 17% increase from 1997 to 1998 alone, or more than four times the rate of increase for all health care expenditures in that period.[8] The extremely low cost of allowing patients and their families to hold health plans accountable in court does not begin to approach the same order of magnitude as the real cost drivers of health care inflation.

Fact: The high cost of HMO executive compensation is a far greater burden on the premium dollar than allowing consumers to take their health plan to court would be. The 25 most highly compensated HMO executives were paid more than $6.2 million in average annual compensation in 1997 - and this did not include tens of millions more in unexercised stock options.[9] For example, the CEO of Oxford Health Plans received $29.1 million; the CEO of CIGNA, $11.6 million; and the President of Aetna, $7.4 million.

Fact: The compensation of the top five executives alone at Oxford Health Plans averaged more than $40 per enrollee each year.[10] Based on Congressional Budget Office estimates, the cost of allowing consumers to sue their health plans when injured would be a little more than half that figure, and a mere fraction of that cost using the estimate made by the Kaiser Family Foundation.

Cost of Oxford Health Plans' 5 Top Executives Pay per member per month (PM/PM)	**Cost of Allowing Consumers to Sue when Injured PM/PM** **- High estimate (CBO) -**	**Cost of Allowing Consumers to Sue when Injured PM/PM** **- Low estimate (Kaiser) -**
$3.36 ($40/year)	$2.00 - $2.33 ($24-$28/year)	$.03 - $.13(<$2/year)

Devorah Adler

Public Citizen Big Business Spends Big Bucks on Big Lies to Kill the Patients' Bill of Rights

Big Lie #1: Allowing consumers to hold their health care plans fully accountable in court for injuries would dramatically increase health care costs.

Fact: The real cost of giving patients the right to be fully compensated for injury is modest.

Fact: The Congressional Budget Office estimated the cost of the 1998 reform bill's provisions to end HMOs' special legal protections to be only 1.2 % of employer-sponsored plan premiums.[1] The average HMO premium cost for medium and large employers in 1997 was $2,000 for individual coverage; 1.2% would add $24 a year ($2 per month).

Fact: State and local government employers are not covered by ERISA; their employees or families have the right to go to court when they have been injured or killed to recover full compensation from their managed health care plans. A Kaiser Foundation study of three such governmental plans found "very low rates of litigation ranging from .3 to 1.4 cases per 100,000 enrollees per year."[2] The 1998 study estimated that the cost to enrollees to preserve their rights to get full compensation when injured ranged from three to thirteen cents per month.[3]

Fact: Unlike employer-sponsored health plans, doctors, hospitals, and other health care providers can be sued under state medical malpractice, personal injury, and wrongful death laws if they cause serious patient injury or death. Again, their experience proves that giving injured persons the right to sue for full compensation has a minimal effect on health care premiums. The highest estimated cost of this consumer protection is less than 1.2 % of total U.S. health costs.[4] And the low costs found in these studies do not take into account the value, both in human terms and monetary savings, of the deterrent effect of holding managed care plans accountable.

Fact: Only a tiny percentage of persons injured by medical malpractice file claims, leaving a heavy bill for patients, their families and communities, and taxpayers. A Harvard University Medical Malpractice Study of New York State showed as few as 3% of injured patients ever file claims.[5]

Big Lie #2: Subjecting employers to direct liability for health care decisions may cause employers to drop coverage out of fear of a large damage award.

Fact: The Health Benefits Coalition, Business Roundtable, and other major opponents of the Patients' Bill of Rights are deliberately misstating the provisions in the current bills that allow patients' to hold insurers accountable. The Kennedy-Dingell (S. 6/H.R. 358), Ganske (H.R. 719), and Norwood (H.R. 216) bills all specifically prohibit suits directed at employers unless the employer corporation itself is making the <u>medical</u> decisions.

Fact: For example, Section 302 (a) of both S.6 and H.R. 358 (the Kennedy-Dingell bills) specifically exempts employers from an injured employee's suit in state court. The only circumstances under which an employer could

Devorah Adler

Last year's House votes on the Patients' Bill of Rights bills were extremely close. The major House substitute (Dingell-Ganske), which gave consumers the right to take HMOs to court, failed by only five votes, 212-217. In a new Congress with a narrower House majority pro-consumer forces could prevail. That's why the radio and television blitz by the Business Roundtable and the Health Benefits Coalition targets swing votes: Blue Dog Democrats and moderate Republicans.

Corporate America wants Congress to continue a special legal deal that protects HMOs and other managed care organizations from liability for injuries they inflict on patients. This special protection is given to private sector employer-paid health insurance plans. They are lobbying to keep the federal Employee Retirement Income Security Act (ERISA) provisions that immunize these managed care companies from medical malpractice and personal injury lawsuits under state law. This special protection leaves 125 million health care consumers without any mechanism to hold their health plans fully accountable for the consequences of their medical malpractice, including additional medical bills because of the complications of denied care; lost wages and other economic losses; pain and suffering due to loss of a limb, blindness or paralysis; and mental anguish.

Health care plans, shielded by the current law from full accountability to the patients they injure, are given a huge incentive to *deny* necessary and appropriate care. Allowing consumers to hold their insurers accountable in state court would give managed care companies the proper incentive to make sound medical decisions in the first instance.

The attached fact sheets detail the lies underlying this deceptive ad campaign and the importance of giving consumers the right to hold their managed care plans accountable in court. Please consider editorializing against these distorted ads and in favor of managed care accountability.

Possible House targets include:

Bud Cramer	AL-5	David Phelps	IL-19	Sherwood Boehlert	NY-23
Spencer Bachus	AL-6	Baron Hill	IN-9	Mike McIntyre	NC-7
Marion Berry	AR-1	Dennis Moore	KS-3	Steven LaTourette	OH-19
Mike Thompson	CA-1	Ken Lucas	KY-4	Tim Holden	PA-6
Ellen Tauscher	CA-10	John Cooksey	LA-5	Lindsey Graham	SC-3
Gary Condit	CA-18	Christopher John	LA-7	Max Sandlin	TX-1
Stephen Horn	CA-38	Wayne T. Gilchrest	MD-1	Jim Turner	TX-2
Loretta Sanchez	CA-46	Constance A. Morella	MD-8	Ralph Hall	TX-4
Brian P. Bilbray	CA-49	David Minge	MN-2	Kevin Brady	TX-8
Christopher Shays	CT-4	Collin Peterson	MN-7	Charles Stenholm	TX-17
Allen Boyd	FL-2	Ronnie Shows	MS-4	Zach Wamp	TN-3
Charles T. Canady	FL-12	Gene Taylor	MS-5	John Tanner	TN-8
Mark Foley	FL-16	Pat Danner	MO-6	Owen Pickett	VA-2
Sanford Bishop	GA-2	Jim Gibbons	NV-2	Norm Sisisky	VA-4
Charlie Norwood	GA-10	Charles F. Bass	NH-2	Virgil Goode	VA-5
James A. Leach	IA-1	Marge Roukema	NJ-5	Thomas Petri	WI-6
Greg Ganske	IA-4	Rodney P. Frelinghuysen	NJ-11		
Bill Lipinski	IL-3	Michael P. Forbes	NY-1		

For more information on this issue visit our website at
www.citizen.org/congress/civjus/patientsrights/health.htm

Devorah Adler

Contact: Tom Bantle (202) 546 4996 ext 367
or Dan O'Sullivan (202) 546 4996 ext 387

March 26, 1999

Attention Editorial Writers:

Patients' Bill of Rights Under Siege in New Corporate Ad Campaign

Business Media Blitz to Hit Key Members During Congressional Recess

America's biggest corporations are again spending big bucks on a Big Lie ad campaign to scare consumers away from supporting the pro-consumer Patients' Bill of Rights bills now being debated in Congress. Two of America's biggest corporate trade associations, the Health Benefits Coalition and the Business Roundtable, announced March 22 that they will buy $2 million in radio and television ads to air in coming weeks in the districts of swing members of the House of Representatives and Senate.

The ads are designed to convince workers and consumers that allowing patients to hold HMOs and other health plans accountable in court for medical malpractice will result in much higher health care costs and threaten the loss of employer-provided health insurance.

In reality, as the attached documents show, the Congressional Budget Office has estimated the cost per enrollee of these consumer protections at $24 per year. This is significantly less than the $40 cost per enrollee in Oxford Health Plans, a leading managed care plan, for the executive compensation of their five top executives.

Both the Senate and the House are continuing last year's struggles over the scope of Patients' Bill of Rights bills, designed to better protect consumers in managed health care plans. A key Senate committee passed its bill March 18, which did not include provisions that would allow injured patients to hold HMOs accountable for those injuries in state courts. The Senate Republican leadership has vowed to block any bill that included a "right to sue" provision. Thus it will take a supermajority of 60 votes to overcome a threatened Republican filibuster. House committees have begun hearings on the bills.

The new disinformation campaign continues the disturbing trend begun by the infamous "Harry and Louise" ads on which the health insurance industry spent more than $17 million in 1994. Since the debate on Patients' Bill of Rights legislation began in the last Congress, the Health Benefits Coalition, the Business Roundtable, and the American Association of Health Plans have spent or announced plans to spend tens of millions more dollars on misleading media ads.

Summary on Focus of White House Conference on Nutrition and Health

We remain hopeful that this administration will use the opportunity of a White House Conference to elevate recognition of the importance of past achievements and the promise of better nutrition for the health and well-being of Americans into the next century. The time frame is constrained and so must be, as you emphasized, the breadth of this effort. A process with focus is likely to be carried out most successfully.

Our coalition of academic organizations, industry, and consumer groups, in continuing discussion with the executive branch, has responded to the challenge for focus by proposing the following themes: 1) Child nutrition with emphasis on nutrition, cognitive development, and learning and on the later life effects of nutrition at the beginning of life. Opportunities for improving nutritional quality and health outcomes of key programs like food stamps, school lunch, as well as programs in states and local levels will be formulated as will programs which serve populations at higher nutritional risk. 2) Obesity including a review of trends in child and adolescent obesity and the health outcomes relating to obesity in adult life. Trends in physical activity, school physical education programs, sedentary behavior, and eating patterns, will be examined. We intend to focus on opportunities in the private sector which interface with public programs such as school lunch and breakfast programs. The role of the private sector in enhancing physical activity and preventing obesity will be explored. 3) Nutrition, aging and the prevention of chronic degenerative disease. Emphasis on the growing population of older Americans with degenerative conditions of aging at the same time that trends in longevity and better health throughout the lifespan offer opportunities for a more productive period of life beyond retirement. We propose to take this opportunity to review our progress in understanding of nutritional and exercise factors which can slow progress towards degenerative conditions, and diminish both the effects and cost of chronic disease. We will examine progress in applying these newer insights into programs both local, state and federal, which are directed to older populations with the opportunity to emphasize both nutritional quality and exercise components of these programs. Each theme permits examination of progress and prospectives which are highly relevant to our vision of nutrition and health into the 21st century. Each could be the theme of one or more satellite conferences involving a broad spectrum of "shareholders". Each would bring recommendations for consideration by the culmination of a White House Conference.

United States Department of Agriculture
Human Nutrition Research Center on Aging
At Tufts University

Office of the Director

To: Chris Jennings
Assistant to the President for Domestic Policy
The White House

From: Irwin H. Rosenberg, MD, Tufts University
George L. Blackburn, MD, PhD, Harvard Medical School

Date: March 9, 1999

Re: Planning Meeting for the White House Conference on Food, Nutrition and Health
Enclosed Summary

Below we have outlined an agenda for a planning meeting we hope to have with you and your staff as soon as possible.

Review deliverables and schedule a date

a) Improvements in child nutrition with special emphasis on health outcomes of key programs like food stamps, school lunch and programs between the federal, state, and local organizations that focus on populations at higher nutritional risk.

b) Policy on obesity prevention, again in child and adolescent overweight but progressing to weight control in adults at risk for common chronic diseases of heart, brain, lung, endocrine and bone and joint.

c) Policy on the growing population of older Americans and the prevention of chronic degenerative disease through the interaction of a healthy diet and physical fitness. Focus on the interaction of federal, state and local programs directed to older populations.

Implementation - satellite conferences and location

a) Each theme would hold one or more satellite conferences involving a broad spectrum of shareholders. Each group would bring recommendations for consideration for the White House Conference.

b) Identify lead agencies in HHS and USDA

c) Involvement of other federal (executive, congressional), state (Governors office), industry, consumer, academic/professional society participation.

d) Identify organizing and advisory committees and source of budget (White House vs Congress)

We already have considerable input by the interested parties including members of Congress, Governor Davis' office, agencies of HHS, academia, professional societies and industry. We hope this can be a decisive meeting.

711 Washington Street
Boston, Massachusetts 02111
617- 556-3330
FAX: 617-556-3295

We, the signers of this petition, support the enactment of a

REAL Patients' Bill of Rights

that includes:

- Protection for All Patients with Private Insurance
- HMOs Can't Arbitrarily Interfere with Medical Decisions
- Effective Independent External Appeals
- Ability to Hold Plans Accountable
- Real Emergency Room Access
- Prohibition on Gag Rules and Improper Financial Incentives
- Guaranteed Access to Specialists
- Access to Out-of-Network Providers
- Guarantee Network Meets Needs
- Specialist Can Coordinate Care for Chronically Ill Patients
- Standing Referrals to Specialists
- Access to Ob/Gyn Services
- Ability to Keep Your Doctor or Health Care Professional
- Access to Needed Prescription Drugs
- Access to Clinical Trials
- Information on Plan Quality, Exclusions, and Charges
- Protection For Providers who Advocate for Patients
- Protection Against Provider/Patient Discrimination

People Who Have Already Signed The Petition.

00003

The Signers

Sign The Petition Supporting The Patients' Bill Of Rights

First Name:
Last Name:
City:
State:

Sign the Petition | Reset

Optional Information

Address:
Zip Code:
E-mail :

☐ I would like to be e-mailed developments in The Patients' Bill of Rights.

To: Chris

U.S. Department of Labor Pension & Welfare Benefits Admn.

Washington, D.C. 20210

FACSIMILE

DATE: 3/19

TO: CHRIS JENNINGS / DEVORA ADLER

Department: WHITE HOUSE

Phone #:

Fax #: 456-5557

From: LESLIE KRAMERICH 219-8233

Office of Policy and Research
Fax Number: (202) 219-5333
Phone Number (202)219-4505

Number of pages being transmitted (including fax sheet) 2

COMMENTS: SUMMARY OF S.326

MOSES

S. 326 Mark-Up Redux

Overview: The two-day mark-up of S. 326 ended yesterday with only a few amendments passed (mostly Republican) to change the substance of the bill. Most of the Democratic-sponsored amendments failed on party lines with a vote of 10 to 8 against. Senator Bingaman crossed party lines more than once to vote in favor of Republican amendments that "improved the underlying mark." Senator Wellstone also crossed party lines to vote in favor of the Republican emergency care amendment. The amendments that passed and failed are summarized below.

Amendments Passed:

- **Prescription Drugs (Collins)**: includes similar provisions from S. 6 dealing with provider participation in the development of a formulary and exceptions from formulary restrictions for medical necessity.

- **External Review (Frist)**: clarifies that external reviewers must make an independent determination and expands the evidence the reviewer must consider. Dems' protest of a contentious "rebuttable presumption" provision which would have made it easier for plans to challenge decision in court resulted in its removal from the final amendment that passed. Bingaman voted in favor. Competing Dems amendment failed.

- **Clinical Trials Study (Frist)**: requires HHS to contract with IOM to conduct a study on clinical trials and their costs. Defeated Dems' efforts to include S. 6 access to clinical trials provisions in the mark.

- **Substance Parity/Self-Pay Option (Wellstone)**: prohibits plans that refuse to cover substance abuse inpatient care from dropping provider from network or participant from plan. Supported by all but 3 Republicans (Sessions, who voted no, and Hegel and Gregg who passed by proxy) and all Dems.

- **Specialty Care (Frist)**: requires plans to provide access to appropriate specialists, but doesn't include Dems protections re: standing referrals, access to out-of-network specialists if none participating in plan. Competing Dems amendment offering S. 6 provisions failed.

- **Emergency Services (Hutchinson)**: prohibits plans from requiring greater copays for out-of-network emergency care, but does not require coverage of post-stabilization and maintenance care. Competing Dems amendment offering S. 6 provisions failed.

- **AHCPR Rural Care (Harkin)**: requires inclusion of study of rural providers in AHCPR provisions in mark. Dems and Republicans voted in favor.

Amendments failed: continuity, ombuds program, scope, nondiscrimination for providers, involuntary disenrollment protection for mentally ill, genetic discrimination, network adequacy, prescription drugs(formulary and investigational), clinical trials, external review, medical necessity, access to specialists, whistleblowers/protection for provider advocacy, emergency care, mastectomy, point-of-service, pediatric care, liability.

U.S. Department of Labor Pension & Welfare Benefits Admn.

Washington, D.C. 20210

FACSIMILE

DATE: 3/19

TO: CHRIS JENNINGS / DEVORA ADLER

Department: WHITE HOUSE

Phone #:

Fax #: 456-5557

From: LESLIE KRAMERICH 219-8233

Office of Policy and Research
Fax Number: (202) 219-5333
Phone Number (202)219-4505

Number of pages being transmitted (including fax sheet) 2

COMMENTS: S. 326 FOLLOW-UP / NEXT STEPS

S. 326 Follow-Up/Next Steps

The summary we forwarded provides the highlights - if you want additional detail about the mark-up, we are happy to provide it.

Regarding next steps, you should know that Senator Kennedy indicated at the end of the hearing that the Dems will continue their efforts to get their issues addressed as the bill moves to the Finance Committee and as it moves forward.

You should also be aware that we have received a request from Majority staff on the House Ed. and Workforce Committee for assistance to prepare them for their hearing on AHPs next week. Apparently, Chairman Boehner wants to do something for small employers, but is keeping an open mind as to whether AHPs are the way to go. We will be sending them materials and providing them with assistance to educate them about the perils of AHPs. This hearing could be pivotal in shifting ground on this issue in the House, and is especially important given Rep. Norwood's recent inclusion of AHPs in his mini-consumer protection bill.

Good Morning. Chairman Grassley, Senator Breaux and Members of the Senate Special Committee on Aging. Thank you for the opportunity to testify on one of the most important domestic issue facing our nation: Long-term care for our elderly. I am joined today by two members of my team, Dr. Jeanette C. Takamura, Assistant Secretary for Aging, and Dr. Richard Hodes, Director of the National Institute on Aging (NIA). We greatly appreciate your bipartisan leadership on the elements of the President's long-term care initiative, particularly the Family Caregiver Support Program.

In fact, before I begin, I want to recognize the special leadership role that this committee has played in bringing greater focus and awareness to the many health and lifestyle issues facing our nation's senior citizens, including Alzheimer's disease and related disorders. I know the members of the audience and those they represent all across America join me in expressing our deep appreciation to you Mr. Chairman, and Senator Breaux, for the committee's fine work over the years.

Mr. Chairman, when the late Stanley Kubrick made *2001 A Space Odyssey* 30 years ago, his vision of the future was one of revolving space stations and rebellious computers. Now that 2001 is only two years away, we can argue about how close Mr. Kubrick came to the truth.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C. 20201

DATE: 3/19/99

PHONE: (202) 690-6311 FAX: 690-8425

****

OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
HUMAN SERVICES LEGISLATION
ROOM 413 H HUMPHREY BUILDING

TO : Chris Jennings / Jean Lambrew

OFFICE : _____

ROOM : _____

PHONE NO : _____

FAX NO : 456-5557

FROM: RICH TARPLIN

[X] MARY BOURDETTE
[ ] BARBARA CLARK
[ ] LAUREN HIGGINS
[ ] SARA COSTIN
[ ] AMY LOCKHART
[ ] LULA BARNES

TOTAL PAGES INCLUDING COVER: 13

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REMARKS

Chris + Jean —

Rich wanted you to look at this again today. It is Sec's testimony on Caregiver initiative w add'l Rich edits. Thanks— Mary B.

What we can't argue about is the changing face of America over the next 30 years. For all the images we see in movies and television of a nation that is faster, younger and healthier, the fact is we are heading for a world no demographer has ever seen before. And the color of that world is gray. By the year 2030, the number of persons in our country 65 and older will double. And people 85 and older will be commonplace.

These changing demographics are no cause for alarm. But they are cause for action. We want life not only to be long - but good. That means having the tools we need to care for those ravaged by Alzheimer's and other chronic or disabling diseases. This will be one of the central challenges of the 21st century - to make being dignified and comfortable when we're old as much a part of our national consciousness as being educated and safe when we're young.

Let me emphasize that millions of families across America already face this challenge. In fact, family members provide most of the care for older persons who are no longer able to manage on their own. So one of the reasons I am here today is to convey this Administration's strong commitment to the families and caregivers of people in need of long-term care. But we need to do more than stand with them. We need to help them. That is the purpose of the President's long-term care initiative. To give these families - and the loved ones they care for - the support, guidance and financial assistance they desperately need.

Let me be clear: This initiative is not designed to just help older Americans. It is part of a much broader strategy to help Americans of all ages who are disabled. And this initiative is not just about money. It is about providing comprehensive assistance to family members who provide and receive long-term care.

That means the hundreds of thousands of Americans living in communities across our country, struggling to raise children, hold down jobs and protect their elderly parents. Let me give you an example of the type of person I'm talking about. Frank is an older gentleman from the Chicago area. His wife is in a local adult day care center three days a week. Those three days are Frank's respite. They are a time of rest and relief - and also a time to buy the groceries and other supplies he needs to hold his family together. What Frank does is a 24-hour-a-day, seven day-a-week expression of love. At first the burden was manageable - and the fulfillment of a promise he had made on his wedding day. Now Frank says that although the added stress and exhaustion means he might end up going before her, "at least my conscience will be clear."

What about our conscience? Frank and so many others like him deserve more than our admiration; they deserve our support. Mr. Chairman, 95 percent of frail older Americans who live in the community and need long-term care receive unpaid assistance from informal caregivers, like Frank.

Research indicates that informal support for caregivers has a significant impact on the emotional well being of caregivers, as well as in delaying the need for nursing home services. A recent NIH study found that adult day care not only reduces caregiver stress, but delays the institutionalization of the care recipient. Another recent study indicates that counseling and support for caregivers of people with Alzheimer's can keep the care recipient out of a nursing home for an additional year.

Research also tells us that providing care to older persons exacts a heavy emotional, physical and financial toll. Almost three-quarters of informal caregivers are women. Many are older and vulnerable themselves, or are running households and parenting children. In fact, half of all caregivers are over 65 themselves. That means their own health is at risk. They suffer high rates of depression because they are emotionally strained. And not surprisingly, one third describe their own health as fair to poor. Many caregivers have had to cut back on their hours of work to provide elder care for their loved ones. Today, two-thirds of working caregivers report conflict between work and caregiving which require them to rearrange their work schedules, work fewer than normal hours, and/or take unpaid leaves of absence.

The National Family Caregiver Support Program

Mr. Chairman, long-term care does indeed take a huge financial and emotional toll on the family and friends who provide most of this care. Because of its complexity, however, no single

policy can "solve" this problem. Thus, the President in his FY 2000 Budget has proposed a multi-faceted initiative to provide immediate assistance with long-term care and help prepare for what will surely be one of the great challenges as the baby boom generation ages.

First, the President's long-term care initiative includes $125 million per year for the "National Family Caregiver Support Act" to provide assistance to people caring for older family members.

Through the established networks of the Administration on Aging, our proposed program will enable states, working with area agencies on aging, local service providers and consumer organizations, to create a community-based infrastructure of support for family caregivers. State offices on aging would be expected to put in place at least five important program components to meet complex and diverse care needs. These components include:

- Providing information to caregivers about available services;
- Assisting caregivers in gaining access to specific services;
- Individual counseling, organization of support groups, and provision of caregiver training to help families make decisions and solve problems related to their caregiver roles;
- Respite care to enable families and other informal caregivers to be temporarily relieved from their caregiving responsibilities; and
- Providing supplemental long-term care services, on a limited basis, to complement the care provided by caregivers.

Our proposal also includes competitive grants for the development of innovative solutions to specialized caregiver problems. The results from these demonstration projects and applied research will be put into practice through ongoing state programs. This will lead to an understanding of best practices; in other words, which programs are the most effective in helping caregivers and care recipients in the home, in the community or on tribal reservations.

Second, the President's initiative includes a targeted $1,000 tax credit for caregivers or family members who are receiving care. For some families, the tax credit will help to offset some of the direct costs of long-term care, such as adult day care or home health care visits. For others, it will help offset indirect costs such as unpaid leave taken from work.

Third, the President's initiative includes an expansive educational effort to inform all Medicare beneficiaries about long-term care options. Since most people who develop long-term care needs are Medicare beneficiaries, Medicare can be used to provide information on the limitations of its coverage, alternative sources of long-term care services and financing, and how best to choose the most appropriate options.

Fourth, the President's proposal also calls for the federal government to offer private long-term care insurance at group rates to federal employees, annuitants and their families. Participants would be responsible for paying the full amount of the premium and the market

leverage of the federal government is expected to save an estimated 15 to 20 percent from the cost of individual long-term care policies.

Fifth, we propose to expand access to home and community-based care services to people of all ages with significant disabilities. That is why in our FY 2000 budget, we propose that states be allowed to provide Medicaid coverage to people with incomes up to 300 percent of the federal Supplemental Security Income level who would be eligible for nursing home care but who would prefer to live in the community. This new Medicaid option will make eligibility for nursing homes and community-based services more comparable - and will eliminate one of the sources of Medicaid's "institutional bias."

Sixth, the President's budget provides $100 million in competitive grants to enable existing HUD elderly subsidized (Section 202) projects to convert some or all units into assisted living facilities that provide additional services many older Americans need to continue living as independently as possible. Finally, the Vice President has started a series of forums on family caregiving, raising important issues and educating people about their options.

Mr. Chairman, there are adult children in this country who day in and day out live in terror that their mom or dad will wander off or hurt themselves because of Alzheimer's or a similar disease. We want to keep families from having their lives wracked by stress, worry and despair. I speak from some personal experience. When I was home in Cleveland over

Christmas, my cousins were talking to me about one of my aunts who has Alzheimer's disease. My cousins are rushing home from work in the middle of the day, every day, to make sure that their mother gets the help she needs. They are loving. But they are stressed. And they need help. Unfortunately, there is little help for them because they are middle income and do not qualify for Medicaid.

Frankly, my cousins' case is just one example of many. We know that the lives and needs of caregivers are varied. We know that there is no "one size fits all" answer. A complicated challenge requires a comprehensive solution. Overall, our initiative is a pragmatic response to the growing problems of long-term care. It provides comprehensive assistance, not just financial assistance to those requiring or providing long-term care. Our proposal is an historic first step that represents a compassionate response to what I have already said will be one of our nation's most compelling problems in the 21st century. We must, as the President has said, "give care to caregivers." The President's initiative helps to meet that challenge.

The Department's Alzheimer's Initiatives

Alzheimer's disease exacts a heavy toll on its victims, their families, and our health care system. Each year new research helps to sharpen the effectiveness of care for people with Alzheimer's disease. Nevertheless, the nearly four million people in the United States who have Alzheimer's disease, or related disorders, is expected to double in the next 20 years. Each victim

will eventually require full-time care. This dreaded disease affects patients, their families, caregivers and society. We must continue to evaluate the various models of care for people with Alzheimer's and models of support for their families so that successful approaches can be given broader implementation.

That is why I have directed the National Institute on Aging, under the leadership of its Director, Dr. Richard Hodes, to step up its efforts to study Alzheimer's disease and related disorders. The NIH Alzheimer's disease prevention initiative is being developed to expedite our progress in delaying or preventing the onset of Alzheimer s disease. In collaboration with other federal agencies and the private sector, this initiative will foster new approaches to basic biological and epidemiological research; increase focus on drug discovery and development; improve methods for early identification of people at increased risk of developing Alzheimer's; and facilitate testing of possible new treatments in clinical trials. The initiative will also develop strategies for improving patient care and alleviating the burden of caregiving.

Just last week NIA launched a nationwide treatment study targeting people with mild cognitive impairment, also known as MCI, a condition characterized by memory deficit, but not dementia. Accurate and early evaluation and treatment of MCI individuals might prevent further cognitive decline including the development of Alzheimer's disease. This study is the first such Alzheimer's disease prevention clinical trial carried out by NIH, and will be conducted at 65-80 medical research institutions throughout the United States and Canada. Other trials are in the

pipeline, many of which will piggy back cognitive studies onto ongoing trials for the treatment or prevention of other conditions.

For those who now have Alzheimer's disease, research and information efforts are being intensified to help alleviate part of the overwhelming patient and caregiver burden, with special emphasis on the needs of a diverse patient population. The NIA is also taking steps to make information about Alzheimer's disease clinical trials more accessible to the general public. As part of a NIH-wide initiative on all major clinical trials, the NIA's Alzheimer's Disease Education and Referral Center (ADEAR), in collaboration with the Food and Drug Administration, is developing a database of ongoing Alzheimer's disease clinical trials. When complete, both government and commercial trials will be represented. The database will be accessible on the World Wide Web, and information will also be available through trained information specialists of the ADEAR toll-free hotline (1-800-438-4380).

The Administration on Aging's Alzheimer's disease demonstration grants will help states to take advantage of research findings and demonstrate effective models of non-medical care for people with Alzheimer's disease. The demonstration programs have proven to be very successful in reaching out to, and providing support services to people with Alzheimer's disease and their family caregivers. Special attention is being paid to minority, low-income and rural families. Building on the approach instituted by the Health Resources Services Administration (HRSA), AoA supports states in developing model practices for serving people with Alzheimer s disease

Chairman Grassley, Senator Breaux, members of the Special Committee on Aging, I greatly appreciate your leadership on long-term care and other issues affecting senior Americans. I look forward to working with you to meet the challenges and opportunities of the gift of longevity. We have much to accomplish and many families to help. They are our friends, our neighbors, our fellow citizens. The time to offer them the supportive hand they need is now.

My colleagues and I would be happy to address any questions you might have.

March 18, 1999

HMO Bill Moves Forward in Senate

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 7:57 p.m. EST

By The Associated Press

WASHINGTON (AP) -- While bills that would clamp down on HMOs are piling up on Capitol Hill, one actually moved forward as Senate Republicans look to prove they are interested in more than talk on the popular patient protections.

The Senate Health, Education, Labor and Pensions Committee approved a GOP bill along party lines Thursday evening. Democrats failed in a series of attempts to broaden the bill, but they promised to raise those issues again when the measure goes to the Senate floor, probably this spring.

Throughout the two-day debate, Democrats tried to claim the high ground, saying they were looking out for patients and doctors while Republicans only cared about insurance companies.

``People die, families suffer and it's unnecessary,'' Sen. Christopher Dodd, D-Conn., said in a typical argument, in this case in favor of ensuring greater access to clinical trials.

Republicans repeatedly emphasized the need to control costs and prevent unintended consequences that could come from overly broad provisions.

Committee Chairman Jim Jeffords, R-Vt., acknowledged that many of the same debates are likely when the bill hits the Senate floor, but he predicted that President Clinton would ultimately support it.

``He will recognize this is a huge step forward,'' Jeffords said.

Clinton actually weighed in before the committee finished its debate, saying the GOP measure ``falls far short of the legislation the American people deserve.''

Last year, the Senate did not vote on managed care legislation. The House narrowly approved a Republican bill and is again promising

to take up the issue, which all parties agree has more momentum this year.

Democrats complained most loudly that the Senate bill does not cover enough people, does not give patients new rights to sue their insurance companies and does not include a provision guaranteeing payment for what doctors -- not insurance companies -- believe is ``medically necessary'' care.

The bill does offer a series of popular protections that even the insurance industry has little problem accepting. It guarantees patients the right to reasonable emergency room payments and direct access to gynecologists for women. It allows pregnant women and terminally ill patients to keep their doctors for 90 days if the doctors are dropped from the plan's network.

But these provisions apply only to about 48 million Americans covered by federally regulated health insurance plans. Other patients are covered by state regulations, Republicans argue.

Democrats complained that all Americans deserve these protections, and they say that many of them do not go far enough. Democrats, for instance, want to give other patients in the middle of treatments the right keep their doctors for 90 days -- even if they are not pregnant or terminally ill.

The GOP bill also requires health maintenance organizations and other managed care plans to give patients the right to take disputes over payments to an independent group of experts outside the health plan. This provision applies to all Americans in employer-sponsored plans.

Democrats also want to give patients the right to sue a health plan for malpractice if the company wrongly denies care. Republicans say that would lead to more lawsuits and drive up the cost of insurance.

Well before the vote was taken, the rhetorical themes were established.

Sen. Ted Kennedy, D-Mass., said only the Democratic bill has be ``recommended by the patients in our country, the doctors in our country, the nurses in our country, the families in our country.''

But Sen. Bill Frist, R-Tenn., said he could not justify a broader measure. ``I refuse to support a bill,'' he said, ``that drives costs up and increases the ranks of the uninsured.''

Business

The New York Times ON THE WEB

March 18, 1999

ECONOMIC SCENE

External Review of Patient Care Still Undecided

By MICHAEL M. WEINSTEIN

Who should control patient **care** -- doctors at the patient's bedside or doctors working for the patient's insurance company? The Senate Labor Committee appears poised to answer "neither" when it votes this week on patient protections.

The committee plans to turn the ultimate decision in cases where bedside physicians and insurance companies disagree over to expert panels, some at faraway academic medical centers.

Exactly how to implement external review remains controversial. But if the idea is handled creatively, it could sweep away the brawl over legal liability that doomed last year's efforts to pass a patients' "bill of rights."

Democrats and Republicans acknowledge the need to respond to patient complaints that **health** plans persistently deny them reimbursement for necessary medical **care**. The number of such complaints is small, but the ones with merit can reflect shockingly callous behavior by **health** plans.

The Democrats have led the way in proposing changes. Until now, they have focused on giving patients covered at work the right, largely prohibited under current law, to sue **health** plans for economic and punitive damages. But that almost certainly won't fly, given that a Republican controlled Congress is highly unlikely to approve what would amount to a trial lawyers relief act.

So what's the alternative? Some advocates admit privately that the right to sue may not be necessary, at least for the near future, if Congress passes two other provisions as part of an overall bill.

The first would guarantee that patients could appeal denials to an outside panel of experts. The second, recently proposed by two Senators, Jack Reed, D-R.I. and Ron Wyden, D-Ore., would have states set up networks of counselors to guide patients through appeals to their plan and to external panels.

Though the principle of mandatory external review garners bipartisan support, actual proposals do not. The Democrats propose defining medically necessary **care** in law, using what might be called a prudent doctor test: is the doctor following "generally accepted principles of professional medical practice."

The Democrats would prohibit plans from "arbitrarily interfering with the decision of the treating physician." What could be wrong with those standards?

"Plenty," replies Karen Ignagni, president of the American Association of **Health** Plans, which represents about 1,000 private managed-**care** plans. She says the Democratic language, though claiming to leave the decision up to

expert panels, "in fact stops them, as well as the **health** plan, from reviewing whether decisions by physicians are medically appropriate."

Dr. Robert H. Brook of RAND **Health** recently testified, after reviewing dozens of studies, that "20 to 30 percent of the **care** given to patients is unnecessary," yet "patients do not receive perhaps as many as one-third of services they should receive."

Ms. Ignagni fears that the Democrats' bill would insulate customary, often wasteful, practices from challenge.

Mary Nell Lehnhard of the Blue Cross and Blue Shield Association, agrees. "If the plans are forced to prove that each inappropriate treatment is in fact inappropriate, we will turn back the clock to the days of unnecessary overtreatment and unchecked medical inflation," she says.

So how should expert panels make decisions in a world where physician practices vary widely? Should the burden of providing proof be placed on the plan or the physician? Because scientific evidence is often indecisive, the side that bears the burden of proof may often lose the appeal.

David Richardson, president of an organization that performs external review for Medicare enrollees and private plans, would ordinarily allow plans to choose treatments from among those customarily practiced unless the panel found that the treatment was inappropriate.

The bill proposed by James M. Jeffords of Vermont, the Republican chairman of the Senate Labor Committee, answers the question by not answering the question. He would not define medical necessity or place the burden of proof on either side, essentially leaving it up to the expert panels to decide by a preponderance of the scientific and medical evidence, however murky.

The new wrinkle in the debate is the emergence of managed-**care** leaders who embrace external review. Michael Stocker, the president of Empire Blue Cross and Blue Shield of New York state says that external panels of experts can be trusted to make the right decisions if they are held up to professional scrutiny because "there usually is general agreement."

Dr. Arthur Leibowitz, medical director of Aetna U.S. Healthcare,which already offers enrollees the right to external appeal, agrees, though he opposes federal mandates.

Mandating external appeal is only part of the solution, says Wyden. The Reed-Wyden bill, supported by patient advocates like Ron Pollack, executive director of Families USA Foundation, would turn money over to the states to set up networks of counselors to help steer patients through appeals.

The idea, says Wyden, "is to intervene early, resolving modest-sized grievances in a nonadversarial way before they mushroom into huge grievances that need costly litigation." Supporters of the proposal expect it to soften the controversy over litigation by largely eliminating the need to take **health** plans to court if and when Congress makes that possible.

U.S. Department of Labor

Pension and Welfare Benefits Administration
Washington, D.C. 20210

DATE: 3/18

TO: Chris/Devorah

TELEPHONE: _____ **FAX:** _____

FROM: Leslie Kramerich

Office of the Assistant Secretary
Pension and Welfare Benefits Administration
U. S. Department of Labor
200 Constitution Avenue, NW - Room S2524
Washington, DC 20210
(202) 219-8233 - voice
(202) 219-5526 - fax

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Leslie -
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Marked up
S. 326

CONGRESSIONAL BUDGET OFFICE
U.S. CONGRESS
WASHINGTON, DC 20515

Dan L. Crippen
Director

March 17, 1999

Honorable James M. Jeffords
Chairman
Committee on Labor
and Human Resources
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

At your request, the Congressional Budget Office has prepared the enclosed cost estimate for S. 326, the Patients' Bill of Rights Act.

Sincerely,

Dan L. Crippen

Enclosure

cc: Honorable Edward M. Kennedy
Ranking Minority Member

CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

March 17, 1999

S. 326
Patients' Bill of Rights Act

As introduced on January 28, 1999

SUMMARY

Title I of the Patients' Bill of Rights Act would amend the Employee Retirement Income Security Act (ERISA) to give members of self-insured health plans rights to obtain certain services, require group health plans and health insurance issuers to provide certain information to enrollees and potential enrollees, and establish internal and external review procedures for group health plans and health insurance issuers. Title II would require all health plans, health care providers, and other entities to protect the confidentiality of health information and would allow individuals to inspect and copy their own medical records. Title III would prohibit health plans from discriminating on the basis of genetic information. Title IV would redesignate the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality and would reauthorize the agency.

The proposed patient protections and grievance procedures would increase the premiums for employer-sponsored health insurance, substitute non-taxable fringe benefits for taxable wages, and reduce federal receipts from income and payroll taxes. The Congressional Budget Office (CBO) estimates that these provisions would reduce federal tax revenues by $20 million in 2000 and by $0.5 billion over the 2000-2004 period.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated effect of the bill on direct spending and receipts is shown in Table 1. The costs of this legislation fall within budget function 550 (health).

Table 1. Estimate of the Budgetary Effects of S. 326, Patients' Bill of Rights Act

	By fiscal year, in billions of dollars									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Revenues										
Income and HI Payroll Taxes	a	a	-0.1	-0.1	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2
Social Security Payroll Taxes	a	a	a	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
Total	a	-0.1	-0.1	-0.1	-0.2	-0.2	-0.3	-0.3	-0.3	-0.3
Authorizations of Appropriations										
Healthcare Research and Quality	a	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.1	a

SOURCE: Congressional Budget Office.
NOTE: HI = Hospital Insurance.

a. Less than $50 million.

BASIS OF ESTIMATE

Revenues

The proposed rights to medical care and advice, informational requirements, and grievance procedures would affect the federal budget through their effect on premiums for employer-sponsored health insurance. Although the rights to medical advice and care would apply only to self-insured ERISA plans, other plans are likely to be affected by them as well. Federal legislation to regulate a significant part of the health insurance market could stimulate action on the part of both states and health plans to develop consistent policies on coverage. Taking such spillover effects into account, CBO estimates that the provisions for medical care and advice, patient information, grievance procedures, and confidentiality of patient information would raise average premiums by about 0.5 percent. Table 2 shows the estimated effect of each provision on premiums, before employers modify their behavior to offset some of the increase. The effects are expressed as a percentage of total premiums for all nonfederal employer-sponsored plans, including plans that would face no increase in costs.

Why? should be on target populatio

CBO

TABLE 2. ESTIMATED EFFECT OF THE PATIENTS' BILL OF RIGHTS ACT ON PREMIUMS FOR EMPLOYER-SPONSORED HEALTH INSURANCE (In percents)

Provision	Increase in Premiums	
Title I		
Subtitle A—Right to Medical Advice and Care		5.4
Access to emergency care	0.1	.2
Offering choice of coverage options	0.1	.1
Access to obstetric and gynecological care	a	.1
Access to pediatric care	a	
Continuity of care	0.1	.2
Protection of patient-provider communications	a	
Subtitle B—Right to Information About Plans and Providers	0.1	
Subtitle C—Right to Hold Health Plans Accountable	0.1	.3
Title II		
Personal Medical Information	a	
Title III		
Genetic Information and Services	a	
Total	0.5	

a. Less than 0.05 percent.

The estimate assumes that about 60 percent of the increase in premiums would be offset through decreases in fringe benefits and that about 40 percent would be passed on to employees as lower wages. CBO estimates that the increase in premiums would reduce federal tax revenues by $20 million in 2000 and by $0.5 billion over the 2000-2004 period. Social Security payroll taxes, which are off-budget, account for about $160 million of the five-year total.

Right to Medical Advice and Care. Subtitle A of title I contains a number of patient protections for enrollees in self-insured ERISA health plans. Those provisions include a prohibition against interference by health plans with medical communications between physicians and their patients, a requirement that plans pay for hospital emergency visits when the prudent layperson standard is met, a requirement for direct access to an obstetrical and

gynecological specialist for covered routine obstetrical and gynecological care, a requirement for direct access to pediatricians for covered routine pediatric services, the right to continue care for 90 days with a provider whose contract has been terminated by a health plan, and a requirement that health plans offer employees a point-of-service option when the existing health plan offerings do not provide choice among provider groups. CBO estimates that these rights to medical care and advice would ultimately increase costs across all nonfederal employer-sponsored health plans by about 0.1 percent. -.3

Right to Information About Plans and Providers. Subtitle B of title I would require all ERISA group health plans to provide certain kinds of information on plan provisions to enrollees and to make other kinds available on request. Most of the required information is typically provided now as part of a plan's handbook or could easily be incorporated into that document. Although some documents would have to be amended to meet the requirements of this provision, such documents are continually changed to reflect new terms. Plans would be responsible for making available to participants any data on quality or performance that they collect, but they would not be required to collect such data. Plans would have to make minor investments in personnel and systems to assure and monitor compliance with those requirements. CBO estimates that the informational requirements would increase costs across all nonfederal employee sponsored health plans by slightly less than 0.1 percent.

Right to Hold Health Plans Accountable. Subtitle C of title I would require all ERISA group health plans to abide by specific time limits for making coverage determinations and to have an internal review process for reconsidering coverage decisions within defined time limits at the request of the enrollee. For those coverage decisions involving medical necessity or investigational treatments, a physician with the appropriate expertise would have to conduct the internal review. Plans would also have to provide for external review of medical necessity decisions involving claims exceeding a significant dollar threshold or investigational treatments for life threatening illnesses. The findings of the external review would be binding on the health plan.

Most plans today have a functioning internal appeals process, but they operate with more flexibility on timing than they might have under this provision. Consequently, a few plans would have to invest in more review personnel to meet the specified time limits. Costs would also increase because of the requirement for external review, which would be new to most plans. CBO estimates that the net cost of this subtitle would be 0.1 percent of employer-sponsored health plan costs.

Personal Medical Information. Title II would require health care providers, health plans, employers, health or life insurers, schools, and universities to provide a patient with access

to his or her medical records and allow the patient to request amendments to the record. These entities, as well as health oversight agencies, public health authorities, and health researchers would have to provide a written statement of their confidentiality policies. Along with law enforcement officials, they would also be required to implement appropriate safeguards to protect the confidentiality of individually identifiable health information.

The provisions regarding access to medical records would impose small administrative costs, most of which could be passed on to the requestor of the information through fees. The requirements for the protection of the confidentiality of health information might impose small costs on entities that do not already have such safeguards in place. CBO estimates that these provisions would increase premiums by less than 0.05 percent.

Genetic Information and Services. Title III would prohibit all health plans and health insurers from using predictive genetic information in setting premiums for groups or individuals. It would also prohibit plans from requesting such information except when the information was needed for diagnosis, treatment, or payment relating to the provision of health services. Even then, plans could not require such information and would have to provide the individual with a description of the procedures in place for protecting the confidentiality of such information. Although this provision would keep health insurers and health plans from reducing their costs through favorable risk selection based on genetic information, its cost to private employer-sponsored health plans as a whole would be negligible.

Authorizations of Appropriations

Healthcare Research and Quality. Title IV would redesignate the Agency for Healthcare Policy and Research as the Agency for Healthcare Research and Quality and respecify its mission. To support the activities of AHRQ, S. 326 would authorize $185 million in fiscal year 2000 and such sums as may be necessary for fiscal years 2001-2006. Assuming appropriations of the authorized amounts, CBO estimates that this title would increase discretionary spending by about $20 million in fiscal year 2000 and $660 million over the 2000-2004 period.

PAY-AS-YOU-GO CONSIDERATIONS

Section 252 of the Balanced Budget and Emergency Deficit Control Act sets up pay-as-you-go procedures for legislation affecting direct spending and receipts. The net changes in outlays and governmental receipts that are subject to pay-as-you-go procedures are shown in Table 3. For purposes of enforcing pay-as-you-go procedures, only the effects in the current year, the budget year, and the succeeding four years are counted.

Table 3. Summary of Pay-As-You-Go Effects

	By Fiscal Year, in Millions of Dollars									
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Change in outlays	0	0	0	0	0	0	0	0	0	0
Change in receipts	-20	-60	-100	-150	-200	-240	-250	-270	-280	-300

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

S. 326 would amend ERISA and the Public Health Service Act to establish a number of new requirements governing health care benefits and insurance. However, plans offered by state, local, and tribal governments are exempt from ERISA, and those governments would be able to opt out of the requirements under the Public Health Service Act. Consequently, these provisions would not be intergovernmental mandates as defined by UMRA, and they would have an impact on the budgets of state, local, or tribal governments only if those governments chose to comply.

S. 326 would require entities that provide health care services to permit an individual to inspect and copy protected health care information, with some exceptions regarding life and safety issues and confidentiality of external sources. The requirement to provide access would be an intergovernmental mandate for governmental health care providers. However, the cost of providing access to records would likely be minimal. The costs of copying the information could be passed on to the individual.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill would impose several private-sector mandates as defined in UMRA. They include the rights to medical care and advice, requirements to safeguard and grant patients access to their medical records, and requirements for plans to establish appeals procedures for handling patients' grievances. CBO estimates that the direct costs of those mandates to private-sector entities would significantly exceed the threshold specified in UMRA ($100 million in 1996, adjusted annually for inflation) every year after 2000.

ESTIMATE PREPARED BY:

Federal Cost Estimate: Linda Bilheimer (226-2673), Tom Bradley (226-9010), Jeanne De Sa (226-9010), and Judith Wagner (226-2653)

Impact on State, Local, and Tribal Governments: Leo Lex (225-3220)

Impact on the Private Sector: Judith Wagner (226-2653)

ESTIMATE APPROVED BY:

Paul N. Van de Water
Assistant Director for Budget Analysis

Wright

DATE: 3/10

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROOM 405H, HUMPHREY BUILDING
200 INDEPENDENCE AVE, SW
WASHINGTON, D.C. 20201

PHONE: (202)690-7450 *FAX: (202)690-8425*

FROM:

TO: Devorah A.

OFFICE: _____

ROOM: _____

PHONE: _____

FAX: 456 5557

[ ] **JANE HORVATH**
[ ] **HOLLY BODE**
[ ] **SHARON CLARKIN**
[ ] **BOB GUIDOS**
[ ] **GREG JONES**
[ ] **ANDREA LEVARIO**
[X] **ROGER MCCLUNG**
[ ] **TANISHA PARKER**
[ ] **JON RETZLAFF**
[ ] **MARC SMOLONSKY**
[ ] **STEPHANIE WILSON**
[ ]

(INCLUDING COVER): 4

REMARKS:

A Public Announcement of the Proposed "Select Agent" Provisions of the Crime Bill Would Undermine Current Policies To Protect the Nation against Bioterrorism.

What the Provision Does:

Section 6151 of the proposed bill would criminalize a number of activities related to the handling, transfer and failure to report possession of "select agents". The Secretary of HHS would be required to promulgate regulations governing such prohibitions, to conduct inspections, and generally to regulate and make legal determinations about such activities.

Why it is a Bad Idea:

1. The Proposal would expose to the threat of criminal prosecution the very researchers, universities, health care providers, and first responders who the government is trying to lure into research, preparedness, and response activities. As such, it may have a negative impact on research into vaccines, state and local preparedness and effective response to bioterrorist activities.

2. The public announcement of the Proposal would take place without there having been any vetting among the parties most affected, and would likely unleash substantial opposition from the research, and health provider communities. It is unwise to alienate these communities ---particularly when they have not been given an opportunity to gain training in the proper handling of agents.

3. The Proposal places responsibilities for effectively regulating criminal behavior in an Agency ill-suited to the task. HHS is well-equipped to provide technical guidance and assistance regarding select agents. It would function poorly as a law enforcement agency on criminal behavior wholly unrelated to health care.

4. The proposal establishes a series of standards that may simply not be practicable, e.g. whether agents have been "handle(d) in a manner creating an unreasonable risk"; whether possession is for "peaceful purposes"; what constitutes "reasonable quantities" etc..The very existence of such standards may well chill research and other activities central to the President's overall plan. Also, such standards will vary widely with research, preparedness and national security needs, and should not first be developed in the context of a criminal law.

5. The legislation does not reflect a considered policy on the most effective means of safeguarding security interests. It is unlikely to deter rogue actors; and, it is an ill-judged effort to induce honest researchers, health care workers, and emergency responders to take adequate precautions.

6. ADDED SAFEGUARDS ARE NEEDED. HHS STANDS READY TO BEGIN WORK IMMEDIATELY WITH THE JUSTICE DEPARTMENT TO DESIGN A POLICY THAT MEETS ITS LAW ENFORCEMENT NEEDS without jeopardizing progress in research and preparedness.

More Formal Comments Prepared By CDC follow:

CDC COMMENTS TO DOJ DRAFT LEGISLATION, "EXPANSION OF THE BIOLOGICAL

WEAPONS STATUTE"

1. CDC nonconcurs with Sections (a)(1)(G), and that part of Section (b)(1) that adds a new Section (e), inasmuch as those Sections would require persons possessing certain agents to report such possession to the Secretary, and require the Secretary to regulate such possession. CDC strongly believes that regulating the possession of these agents, much like regulating controlled substances, is primarily a law enforcement matter rather than one handled by public health personnel. As such, reporting to the Attorney General would be more appropriate.

2. That part of Section (b)(1) that adds a new Section (e)(6) may have a negative impact on necessary medical research because some facilities could view the cost burden of conducting such checks to outweigh the perceived benefits of the research. In addition, these provisions raise several unanswered questions. Who is covered by these provisions, any person who may work in a lab that handles a select agent? Who will do the background checks? The draft does not affirmatively state that employers are required to conduct background checks. Do the persons covered have to undergo periodic drug screening? In CDC's view, these provisions may be viewed as very provocative by the scientific community and could be difficult to enforce. We suspect there will be strong opposition to these provisions.

3. The clause in Section (A)(1)(G) "... to ensure that such possession is for peaceful scientific research or development," the terms "prophylactic, protection, or other peaceful purpose" as used in that part of Section (b)(1) that adds a new Section (c)(1), and Section (b)(3)(B) requiring a determination of whether an agent is held for peaceful purpose could be problematic. Making these determinations would require some judgment call over which types of research are legitimate and which are not. The answer to this question will not always be clear, as demonstrated by the first incident involving Larry Wayne Harris. It is our understanding that Mr. Harris claimed he needed Y. Pestis as he was allegedly trying to find a rat that was resistant to the fleas that transmit Y. Pestis.

4. Determining whether a person "handles a [biological agent] ... in a manner creating an unreasonable risk," as used in that part of Section (b)(1) that adds a new Section (c)(2)(A) may be difficult, since, at this time, clear safety guidelines/regulations defining how these agents should be handled in a safe manner is lacking for the toxins and is somewhat vague for the other agents. The BMBL describes general biosafety guidelines, as opposed to biosecurity procedures, for handling many of the agents. These guidelines may be too general for use as a legal standard. These same comments apply to the clause in Section (b)(3)(B), which, in the context of inspections, requires a determination of whether agents are handled in a safe manner.

5. The 72 hour enactment period in that part of Section (b)(1) that adds a new Section (e)(1) seems unrealistic because facilities will need time to determine whether they are subject to the legislation, what agents they possess, and whether the agents must be reported. Also, an infrastructure will need to be established in the agency that handles the reporting, a process which will take some time and resources to establish.

6. Determining what constitutes a quantity reasonable for a particular purpose as used in Section (b)(3)(B) will vary greatly depending upon the situation and may be difficult to enforce. For example, in order to market a toxin overseas, a facility may produce twice as much toxin as they ultimately need to ensure sufficient quantities are delivered for overseas approval.

7. The statement in Section (a)(1)(F) that "mere possession of biological agents and toxins is a potential danger" may be an overstatement since storing an aliquot of any of them alone in a freezer presents little risk of danger. It is only when additional steps are taken to distribute the agents that they become a danger.

8. Finally, in order for any agency to carry out the responsibilities mandated in the legislation, funding authority should be addressed contemporaneously with this legislation.

DATE: 3/16

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROOM 405H, HUMPHREY BUILDING
200 INDEPENDENCE AVE, SW
WASHINGTON, D.C. 20201

PHONE: (202)690-7450 *FAX: (202)690-8425*

TO: Chris J. / Deborah A

OFFICE: _____

ROOM: _____

PHONE: _____

FAX: 456 5557

FROM:

[ ] JANE HORVATH
[ ] HOLLY BODE
[ ] SHARON CLARKIN
[ ] BOB GUIDOS
[ ] GREG JONES
[ ] ANDREA LEVARIO
[X] ROGER MCCLUNG
[ ] TANISHA PARKER
[ ] JON RETZLAFF
[ ] MARC SMOLONSKY
[ ] STEPHANIE WILSON
[ ]

(INCLUDING COVER): 2

REMARKS:

Dec 2017

Susan Dentzer

for Health Affairs

To: Rich T, Chris J.

SUBJECT: PBOR "Message Amd." Groupings From LAST Year.

FROM: L. Roven HHS, ASPE

→ The Amendments were never actually drafted and/or offered in these packages. This is just what we recommended, and how we grouped the issues in our talking points. But the Senate never took this approach, instead they drafted their amendments to follow the sections in the Democrat bills, section-by-section (except the 3 grievance and appeals sections were grouped into one amendment).

- Scope
- Access to Providers (access to specialists generally, access to Ob/Gyn, adequacy of provider network, continuity of care).
- Appeals (internal appeals and external appeals).
- Emergency Care.
- Restoring the Doctor/Patient Relationship (included gag rule, protection for patient advocacy, rules re financial incentives, access to Rx drugs, mastectomy and reconstructive surgery, medical necessity).
- Liability
- Information
- Clinical Trials
- POS

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 17, 1999

STATEMENT BY THE PRESIDENT

Today, the Congress is beginning its work on patients' rights legislation. This issue is critical to assuring Americans high quality health care in the 21st Century, so I am pleased that we are moving forward.

Unfortunately, the proposal by the Chairman of the Senate Health, Education, Labor, and Pensions Committee falls far short of the legislation the American people deserve. Because it applies patients' rights only to those in self-insured plans, this proposal leaves 120 million Americans in insured and individual plans without the guarantee of critical protections. Millions of Americans should not be held hostage to the hope that their state might pass legislation providing these protections. In fact, while states have the authority to pass patient protections for these plans, not one has enacted all of these protections. That is why we need strong Federal legislation to ensure that all health plans provide patients these important rights.

Even for those it does cover, the Chairman's proposal leaves out many of the most fundamental protections. For example, it does not have an adequate enforcement mechanism to ensure that patients are compensated when they are injured or die as a result of a health plan's decisions; it does not assure patients access to specialists, such as oncologists or heart specialists; and it leaves out continuity of care protections. That is why every major patient, doctor, and nurse advocacy organization has concluded that this proposal is simply inadequate.

Today represents the first test of whether this new Congress is serious about providing Americans with a strong, enforceable patients' bill of rights to assure high quality health care. I urge the Committee to do everything it can to pass this test and give Americans the health care protections they need.

30-30-30