

Health Reform Maneuvers Begin on Capitol Hill

BY ALICIA AULT

Associate Editor, Practice Trends

Democrats and Republicans are so confident about the chances of some type of health reform in the next administration that staff meetings and hearings geared toward crafting legislation have been going on in earnest in both the House and the Senate, with the goal of being ready to go in January, according to advocates and policy watchers.

Many health policy analysts have compared and contrasted this election cycle with that of 1992, which sent Bill Clinton to the White House and launched the Clintons' health care reform efforts.

Both elections—1992 and 2008—feature a high level of public concern about access to health care and its costs, said Len Nichols, an analyst at the New America Foundation, a nonpartisan public policy institute.

For instance, a Harris Interactive sur-

vey conducted for the Commonwealth Fund in May found that 82% of Americans think the health care system should be fundamentally changed or completely rebuilt.

But the differences between the two elections are striking in a positive way, Mr. Nichols said in an interview.

First, the two major candidates themselves have acknowledged that cost is an overriding concern, he said. Also, a com-

mon theme is the use of private markets, which he called "evidence, I would say, of moderation" and, perhaps, the proposals' better legislative traction.

Both candidates—Sen. Barack Obama (D-Ill.) and Sen. John McCain (R-Ariz.)—have also learned that "no president is going to send [to Congress] a 1,400-page health bill written in a hotel room by 300 wonks," Mr. Nichols said.

Instead, "Congress is going to own this [effort] far earlier and deeper than before," he said, adding, "It's still going to require a lot of presidential leadership. But the Congress has to be an equal, more than it has before."

Several proposals are likely starting points for congressional negotiations with the new administration, he said. First is the Healthy Americans Act, introduced in January 2007 by Sen. Ron Wyden (D-Ore.) and Sen. Bob Bennett (R-Utah). It has 16 cosponsors from both parties, including Sen. Chuck Grassley (R-Iowa), the Finance Committee's ranking minority member.

The bill is being championed in the House by Rep. Debbie Wasserman Schultz (D-Fla.) and Rep. Jo Ann Emerson (R-Mo.). Rep. Wasserman Schultz is important "because she's a rising star and has impeccable liberal credentials," Mr. Nichols said.

In a paper published in the policy journal Health Affairs, Sen. Wyden and Sen. Bennett said they saw "signs of an ideological truce" on the Hill, with agreement that there is a need for the Democratic-backed universal coverage and the Republican-supported desire for market forces to promote competition and innovation. "The Healthy Americans Act strikes a balance between these ideals," they wrote (Health Affairs 2008;27:689-92).

The bill would require individuals to purchase insurance for themselves and their dependent children, and would require insurers to offer a prescribed package of benefits.

It would subsidize coverage for Americans with incomes up to 400% of the federal poverty level. Employers would convert benefit dollars into salary; such compensation would be tax free, with the goal that the money would be used to purchase coverage.

Sen. Wyden is likely to be front and center in crafting a bill, as he is a member of two of the committees of jurisdiction: finance and budget, said Mr. Nichols, adding that those committees, along with the Health, Education, Labor and Pensions (HELP) Committee, "will play very important roles."

Ron Pollack, executive director of the advocacy group Families USA, said that although Sen. Wyden may play a part, "I have little doubt that Sen. Baucus is going to be as instrumental in the process as anyone."

Sen. Max Baucus (D-Mont.), chairman of the Finance Committee, held a health care summit in mid-June. Staff from the Finance Committee and the HELP Com-

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Election
★ ★ 2008

Tekturna® (aliskiren) Tablets

150 mg and 300 mg

Rx only

BRIEF SUMMARY: Please see package insert for full prescribing information.

USE IN PREGNANCY: When used in pregnancy drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, Tekturna should be discontinued as soon as possible. See **WARNINGS: Fetal/Neonatal Morbidity and Mortality.**

INDICATIONS AND USAGE

Tekturna (aliskiren) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents. Use with maximal doses of ACE inhibitors has not been adequately studied.

WARNINGS

Fetal/Neonatal Morbidity and Mortality

Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature in patients who were taking angiotensin-converting enzyme inhibitors. When pregnancy is detected, Tekturna (aliskiren) should be discontinued as soon as possible.

The use of drugs that act directly on the renin-angiotensin system during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to exposure to the drug.

In addition, first trimester use of ACE inhibitors, a specific class of drugs acting on the renin-angiotensin system, has been associated with a potential risk of birth defects in retrospective data. Healthcare professionals that prescribe drugs acting directly on the renin-angiotensin system should counsel women of childbearing potential about the potential risks of these agents during pregnancy.

Rarely (probably less often than once in every thousand pregnancies), no alternative to a drug acting on the renin-angiotensin system will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intra-amniotic environment.

If oligohydramnios is observed, Tekturna should be discontinued unless it is considered life-saving for the mother. Contraction stress testing (CST), a nonstress test (NST), or biophysical profiling (BPP) may be appropriate, depending upon the week of pregnancy. Patients and physicians should be aware, however, that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Infants with histories of in-utero exposure to a renin inhibitor should be closely observed for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion. Exchange transfusion or dialysis may be required as means of reversing hypotension and/or substituting for disordered renal function.

There is no clinical experience with the use of Tekturna in pregnant women. Reproductive toxicity studies of aliskiren hemifumarate did not reveal any evidence of teratogenicity at oral doses up to 600 mg aliskiren/kg/day (20 times the maximum recommended human dose (MRHD) of 300 mg/day on a mg/m² basis) in pregnant rats or up to 100 mg aliskiren/kg/day (seven times the MRHD on a mg/m² basis) in pregnant rabbits. Fetal birth weight was adversely affected in rabbits at 50 mg/kg/day (3.2 times the MRHD on a mg/m² basis). Aliskiren was present in placenta, amniotic fluid and fetuses of pregnant rabbits.

Head and Neck Angioedema

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren. This may occur at any time during treatment. ACE inhibitors have been associated with a higher rate of angioedema in Black than in non-Black patients, but whether angioedema rates are higher in Blacks with aliskiren is not known. Tekturna should be promptly discontinued and appropriate therapy and monitoring provided until complete and sustained resolution of signs and symptoms has occurred. Experience with ACE inhibitors indicates that even in those instances where only swelling of the tongue is seen initially, without respiratory distress, patients may require prolonged observation since treatment with antihistamines and corticosteroids may not be sufficient to prevent respiratory involvement. Very rarely, fatalities have been reported in patients with angioedema associated with laryngeal edema or tongue edema with ACE inhibitors. Patients with involvement of the tongue, glottis or larynx are more likely to experience airway obstruction, especially those with a history of airway surgery. Where there is involvement of the tongue, glottis or larynx, appropriate therapy, e.g., subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and measures necessary to ensure a patent airway should be promptly provided (see ADVERSE REACTIONS).

Hypotension

An excessive fall in blood pressure was rarely seen (0.1%) in patients with uncomplicated hypertension treated with Tekturna alone. Hypotension was also infrequent during combination therapy with other antihypertensive agents (<1%). In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those receiving high doses of diuretics), symptomatic hypotension could occur after initiation of treatment with Tekturna. This condition should be corrected prior to administration of Tekturna, or the treatment should start under close medical supervision.

If an excessive fall in blood pressure occurs, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline (see DOSAGE AND ADMINISTRATION in the full prescribing information). A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

PRECAUTIONS

General

Impaired Renal Function

Patients with greater than moderate renal dysfunction (creatinine 1.7 mg/dL for women and 2.0 mg/dL for men and/or estimated GFR <30 mL/min), a history of dialysis, nephrotic syndrome, or renovascular hypertension were excluded from clinical trials of Tekturna (aliskiren) in hypertension. Caution should be exercised in these patients because of the paucity of safety information with Tekturna in these patients and the potential for other drugs acting on the renin-angiotensin system to increase serum creatinine and blood urea nitrogen.

Hyperkalemia

Increases in serum potassium >5.5 meq/L were infrequent with Tekturna alone (0.9% compared to 0.6% with placebo). However, when used in combination with an ACE inhibitor in a diabetic population, increases in serum potassium were more frequent (5.5%). Routine monitoring of electrolytes and renal function is indicated in this population. Concomitant use of Tekturna with potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, or other drugs that increase potassium levels may lead to increases in serum potassium. If concomitant use is considered necessary, caution should be exercised.

Renal Artery Stenosis

No data are available on the use of Tekturna in patients with unilateral or bilateral renal artery stenosis or stenosis of the artery to a solitary kidney.

Information for Patients

Pregnancy

Female patients of childbearing age should be told about the consequences of exposure to drugs that act on the renin-angiotensin system. Discuss other treatment options with female patients planning to become pregnant. Patients should be asked to report pregnancies to their physicians as soon as possible.

Angioedema

Angioedema, including laryngeal edema, may occur at any time during treatment with Tekturna. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Drug Interactions

Patients should report any medications they take with aliskiren.

Furosemide

When aliskiren was given with furosemide, the blood concentrations of furosemide were reduced significantly. Patients receiving furosemide could find its effect diminished after starting aliskiren.

Cyclosporine

When aliskiren was given with cyclosporine, the blood concentrations of aliskiren were significantly increased. Concomitant use of aliskiren with cyclosporine is not recommended.

Carcinogenesis/Mutagenesis/Impairment of Fertility

Carcinogenic potential was assessed in a 2-year rat study and a 6-month transgenic (rasH2) mouse study with aliskiren hemifumarate at oral doses of up to 1500 mg aliskiren/kg/day. Although there were no statistically significant increases in tumor incidence associated with exposure to aliskiren, mucosal epithelial hyperplasia (with or without erosion/ulceration) was observed in the lower gastrointestinal tract at doses of 750 or more mg/kg/day in both species, with a colonic adenoma identified in one rat and a cecal adenocarcinoma identified in another, rare tumors in the strain of rat studied. On a systemic exposure (AUC_{0-24h}) basis, 1500 mg/kg/day in the rat is about 4 times, and is in the mouse about 1.5 times, the maximum recommended human dose (300 mg aliskiren/day). Mucosal hyperplasia in the cecum or colon of rats was also observed at oral doses of 250 mg/kg/day (the lowest tested dose) as well as at higher doses in 4- and 13-week studies.

Aliskiren hemifumarate was devoid of genotoxic potential in the Ames reverse mutation assay with *S. typhimurium* and *E. coli*, the in vitro Chinese hamster ovary cell chromosomal aberration assay, the in vitro Chinese hamster V79 cell gene mutation test and the in vivo mouse bone marrow micronucleus assay. Fertility of male and female rats was unaffected at doses of up to 250 mg aliskiren/kg/day (8 times the maximum recommended human dose of 300 mg aliskiren/60 kg on a mg/m² basis).

Pregnancy

Pregnancy Categories C (first trimester) and D (second and third trimesters) (see WARNINGS, Fetal/Neonatal Morbidity and Mortality).

Nursing Mothers

It is not known whether aliskiren is excreted in human milk. Aliskiren was secreted in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of aliskiren in pediatric patients have not been established.

Geriatric Use

Of the total number of patients receiving aliskiren in clinical studies, 1,275 (19%) were 65 years or older and 231 (3.4%) were 75 years or older. Blood pressure responses and adverse effects were generally similar to those in younger patients.

ADVERSE REACTIONS

Tekturna (aliskiren) has been evaluated for safety in more than 6,460 patients, including over 1,740 treated for longer than 6 months, and more than 1,250 for longer than 1 year. In placebo-controlled clinical trials, discontinuation of therapy due to a clinical adverse event, including uncontrolled hypertension occurred in 2.2% of patients treated with Tekturna, vs. 3.5% of patients given placebo.

Two cases of angioedema with respiratory symptoms were reported with aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%.

In addition, 26 other cases of edema involving the face, hands, or whole body were reported with aliskiren use, including 4 leading to discontinuation.

In the placebo controlled studies, however, the incidence of edema involving the face, hands or whole body was 0.4% with aliskiren compared with 0.5% with placebo. In a long term active control study with aliskiren and HCTZ arms, the incidence of edema involving the face, hand or whole body was 0.4% in both treatment arms.

Aliskiren produces dose-related gastrointestinal (GI) adverse effects. Diarrhea was reported by 2.3% of patients at 300 mg, compared to 1.2% in placebo patients. In women and the elderly (age ≥65) increases in diarrhea rates were evident starting at a dose of 150 mg daily, with rates for these subgroups at 150 mg comparable to those seen at 300 mg for men or younger patients (all rates about 2.0%-2.3%). Other GI symptoms included abdominal pain, dyspepsia, and gastroesophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600 mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation.

Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any aliskiren use vs. 0.6% for placebo). In active-controlled trials with ACE inhibitor (ramipril, lisinopril) arms, the rates of cough for the aliskiren arms were about one-third to one-half the rates in the ACE inhibitor arms.

Other adverse effects with increased rates for aliskiren compared to placebo included rash (1% vs. 0.3%), elevated uric acid (0.4% vs. 0.1%), gout (0.2% vs. 0.1%), and renal stones (0.2% vs. 0%).

Single episodes of tonic-clonic seizures with loss of consciousness were reported in two patients treated with aliskiren in the clinical trials. One of these patients did have predisposing causes for seizures and had a negative electroencephalogram (EEG) and cerebral imaging following the seizures (for the other patient EEG and imaging results were not reported). Aliskiren was discontinued and there was no rechallenge.

The following adverse events occurred in placebo-controlled clinical trials at an incidence of more than 1% of patients treated with aliskiren, but also occurred at about the same or greater incidence in patients receiving placebo: headache, nasopharyngitis, dizziness, fatigue, upper respiratory tract infection, back pain, and cough.

Clinical Laboratory Findings

In controlled clinical trials, clinically relevant changes in standard laboratory parameters were rarely associated with the administration of Tekturna. In multiple-dose studies in hypertensive patients Tekturna had no clinically important effects on total cholesterol, HDL, fasting triglycerides, fasting glucose, or uric acid.

Blood Urea Nitrogen, Creatinine

Minor increases in blood urea nitrogen (BUN) or serum creatinine were observed in less than 7% of patients with essential hypertension treated with Tekturna alone vs. 6% on placebo.

Hemoglobin and Hematocrit

Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.08 g/dL and 0.16 volume percent, respectively, for all aliskiren monotherapy) were observed. The decreases were dose-related and were 0.24 g/dL and 0.79 volume percent for 600 mg daily. This effect is also seen with other agents acting on the renin-angiotensin system, such as angiotensin inhibitors and angiotensin receptor blockers, and may be mediated by reduction of angiotensin II which stimulates erythropoietin production via the AT1 receptor. These decreases led to slight increases in rates of anemia with aliskiren compared to placebo were observed (0.1% for any aliskiren use, 0.3% for aliskiren 600 mg daily, vs. 0% for placebo). No patients discontinued therapy due to anemia.

Serum Potassium

Increases in serum potassium >5.5 meq/L were infrequent in patients with essential hypertension treated with Tekturna alone (0.9% compared to 0.6% with placebo). However, when used in combination with an angiotensin-converting enzyme inhibitor (ACEI) in a diabetic population increases in serum potassium were more frequent (5.5%) and routine monitoring of electrolytes and renal function is indicated in this population.

Serum Uric Acid

Aliskiren monotherapy produced small median increases in serum uric acid levels (about 6 μmol/L) while HCTZ produced larger increases (about 30 μmol/L). The combination of aliskiren with HCTZ appears to be additive (about a 40 μmol/L increase). The increases in uric acid appear to lead to slight increases in uric acid-related AEs: elevated uric acid (0.4% vs. 0.1%), gout (0.2% vs. 0.1%), and renal stones (0.2% vs. 0%).

Creatine Kinase

Increases in creatine kinase of >300% were recorded in about 1% of aliskiren monotherapy patients vs. 0.5% of placebo patients. Five cases of creatine kinase rises, three leading to discontinuation and one diagnosed as subclinical rhabdomyolysis and another as myositis, were reported as adverse events with aliskiren use in the clinical trials. No cases were associated with renal dysfunction.

OVERDOSAGE

Limited data are available related to overdosage in humans. The most likely manifestation of overdosage would be hypotension. If symptomatic hypotension should occur, supportive treatment should be initiated.

Storage

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from moisture. Dispense in tight container (USP).

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LAW & MEDICINE

Good Samaritan Acts

Question: On a flight from Los Angeles to Newark, a passenger developed acute chest pain and diaphoresis. A flight attendant put out an emergency call, but Dr. Brown, a general internist nearing retirement, failed to respond because he was concerned about potential litigation. Unfortunately, the passenger sustained a massive MI, and died en route.

Regarding a medical malpractice lawsuit in such a scenario, which of the following is correct?

A. The Good Samaritan statute imposes upon doctors the legal duty to treat.

B. Good Samaritan statutes immunize doctors against all liability.

C. Dr. Brown need not have hesitated, as his attempts, even if negligent, would have been protected by the Aviation Medical Assistance Act.

D. All doctors have taken the Hippocratic Oath to treat in an emergency situation.

E. But for Dr. Brown's negligent failure to act, the patient might have survived, so the doctor is at least partly liable.

Answer: C. If Dr. Brown had responded, his effort would not have put him in jeopardy even if his intervention had proved ineffective. However, there is no legal duty for anyone, even a doctor, to come to the aid of a stranger. Although doctors are generally thought to have an ethical duty to offer emergency care, the Hippocratic

Oath is silent on this matter, and the American Medical Association's Code of Medical Ethics states: "Physicians are free to choose whom they will serve. The physician should, however, respond to the best of his or her ability in cases of emergency where first aid treatment is essential" (AMA Code of Medical Ethics §8.11, 2006-2007 edition).

All 50 states have laws on their books called Good Samaritan statutes, whose intent is to encourage people to help those in acute distress. These statutes do not require doctors to come to the aid of strangers. (Vermont is an exception, imposing an affirmative duty to assist a victim in need.) Rather, they protect against liability arising out of negligent rescue, but typically they cover only ordinary, not gross, negligence. The Aviation Medical Assistance Act, enacted in 1998, is the federal equivalent of the Good Samaritan statute, covering emergency treatment during flights in the United States.

In allegations of medical malpractice, the plaintiff must first show that the doctor owed a duty of due care to the injured victim. This duty arises out of the doctor-patient relationship, i.e., whenever a doctor undertakes to evaluate or treat a patient.

In the absence of such a relationship, a doctor is not legally obligated to treat, even in an emergency.

However, to encourage aiding strangers

in distress, states have enacted so-called Good Samaritan laws to protect rescuers who act in good faith. Popularized in the 1960s in response to the perception that doctors were reluctant to treat strangers for fear of a malpractice lawsuit, these laws immunize the aid giver against allegations of negligent care. Their protective scope varies from state to state, usually offering immunity against simple negligence but not gross misconduct.

Hawaii's Good Samaritan statute is typical. It states: "Any person who in good faith renders emergency care, without remuneration or expectation of remuneration ... shall not be liable for any civil damages resulting from the person's acts or omissions, except for such damages as may result from the person's gross negligence or wanton acts or omissions" (Hawaii Revised Statutes §663-1.5 [a]).

California, the first state to enact a Good Samaritan statute in 1959, is an exception, as it may excuse even gross negligence as long as the act was done in good faith. In a litigated case, a California court declared: "The goodness of the Samaritan is a description of the quality of his or her intention, not the quality of the aid delivered" (*Perkins v. Howard*, 232 Cal.App.3d 708 [1991]).

There is no universal definition of gross negligence, but the term is frequently equated with willful, wanton, or reckless misconduct.

One can think of gross negligence as aggravated negligence, involving more than mere mistake, inadvertence, or inattention, and representing highly unreasonable conduct, or an extreme departure from or-

dinary care where a high degree of danger is apparent (Prosser, W.L. et al., eds. "Prosser and Keeton on Torts," 5th ed., St. Paul, Minn.: West Publishing Co., 1984, pp. 211-4).

Statutory protection is generally excluded for Good Samaritan acts performed within a hospital setting under the theory that doctors have an ongoing relationship with the hospital and are already obligated to provide emergency care within its walls. A minority of states such as California and Colorado do provide immunity irrespective of the location of aid.

Commentators have observed that very few lawsuits have involved Good Samaritan doctors and that such laws are both unnecessary and ineffective. Those who are averse to helping will remain on the sidelines even with the protection of the law.

In a 1963 AMA survey, approximately half of responding physicians said they would render emergency help, and this did not depend on whether there was a Good Samaritan statute in place (Sanders GB. First Results: 1963 Professional-Liability Survey. *JAMA* 1964;189:859-66).

DR. TAN is professor of medicine and former adjunct professor of law at the University of Hawaii, Honolulu. This article is meant to be educational and does not constitute medical, ethical, or legal advice. It is adapted from the author's book, "Medical Malpractice: Understanding the Law, Managing the Risk" (2006). For additional information, readers may contact the author at siang@hawaii.edu.



BY S. Y. TAN,
M.D., J.D.

Continued from previous page

mittee, led by Sen. Edward M. Kennedy (D-Mass.), have been coordinating meetings with those two panels and the Budget Committee, Mr. Pollack said in an interview.

Committee chairs have the greatest influence on the legislative process, he said. Both Mr. Pollack and Mr. Nichols also expect Sen. Kennedy to play a very significant part in creating the legislation, as much as his cancer will allow.

Even so, "to pass anything of significance will require bipartisanship," said Mr. Pollack, noting that Sen. Baucus and Sen. Grassley have worked closely on many bills.

The House is not as far along in preparing for health reform, but staffers on the four relevant committees with jurisdiction over health care have been meeting, Mr. Pollack said.

"I think there's significant movement underway in anticipation of health care reform being a top domestic priority," he said. But, "I don't think any of the proposals that have come out so far are going to be the proposals," Mr. Pollack added.

Instead, the expectation is that a health reform bill will be developed during the transition period between November and January, "and that's what we should look at most seriously," he said. ■

Still Concerned About Health Care After All These Years

Harry and Louise, who became infamous in a 1993-1994 television ad lambasting the Clinton administration's health care reform plan, were dragged briefly out of mothballs to appear in a new commercial that urged Congress and the next president to make such reform the top domestic policy priority.

The effort was bankrolled by five groups that by their own admission have "historically divergent views about health care reform": the American Cancer Society's Cancer Action Network, the American Hospital Association (AHA), the Catholic Health Association (CHA), Families USA, and the National Federation of Independent Business (NFIB).

"We intend to transcend ideology and partisan politics," said Families USA Executive Director Ron Pollack at a press conference. The multimillion-dollar campaign aired nationally for 2 weeks during the Republican and Democratic conventions.

The new ad featured Harry and Louise, back at their kitchen table. The characters were portrayed by the same

two actors, now 14 years older. Harry noted that health care costs are going up again and that small businesses are being forced to drop their plans. Louise said that a friend just found out he has cancer and can't afford a plan. Harry remarked that "too many people are falling through the cracks." Finally, Louise said that "whoever the next president is," health care should be "at the top of his agenda," and that he should bring everyone to the table and "make it happen."

The campaign did not advocate any specific solution. The sponsors said their goal was to create momentum for change, and that they believed that, unlike 14 years ago, there is a consensus that reform is inevitable and necessary.

"The status quo is no longer acceptable," said Rich Umbdenstock, AHA president and CEO.

"We simply can't be having this conversation 14 years from now," added Sister Carol Keehan, CHA president and CEO.



Harry and Louise were back at their kitchen table in a new ad promoting health care reform.

The NFIB joined the effort because its membership said that "health care costs are their No. 1 concern," said Todd Stottlemeyer, president and CEO.

The five groups were joined at the briefing by Karen Ignani, president and CEO of America's Health Insurance Plans. AHIP (back when it was known as the Health Insurance Association of America) launched Harry and Louise the first time, helping to defeat the Clinton reform plan.

But Ms. Ignani said times are different now: "Our commitment is to make sure no one falls through the cracks," she said.