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By Dan Barry

DOCUMENTARIES
DEVOUR
PRIME TIME
By Tom Vanderbilt

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HONDURAS
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Larry Towell

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"First Run"
Not for Color

12-4-98

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Jennings
Podesta*



Their 19-month-old boy was deteriorating, and Richard and Jordana Sontag had come to Yale, desperate and angry.

An experimental gene therapy was their only hope, but the scientists were not sure it was safe.

The couple spotted Dr. Margretta Seashore in the lobby. 'Look at him,'

Richard said, thrusting Jacob in her face. 'You tell him why this protocol is delayed while he's dying. ... You look at my son dying. Tell it to him.'

Keeping Jacob Alive

By Michael Winerip

Handwritten signature: C. Jennings
Handwritten initials: RW
An arrow points from the signature towards the text above.

*S. M.
5902*

Until recently, there was no hope for a child with Canavan disease. But when the Sontags learned that their only child was born with it, they were prepared to sacrifice anything to get him the experimental treatment he needed. They didn't know that might include their marriage.

Fighting for Jacob

By Michael Winerip

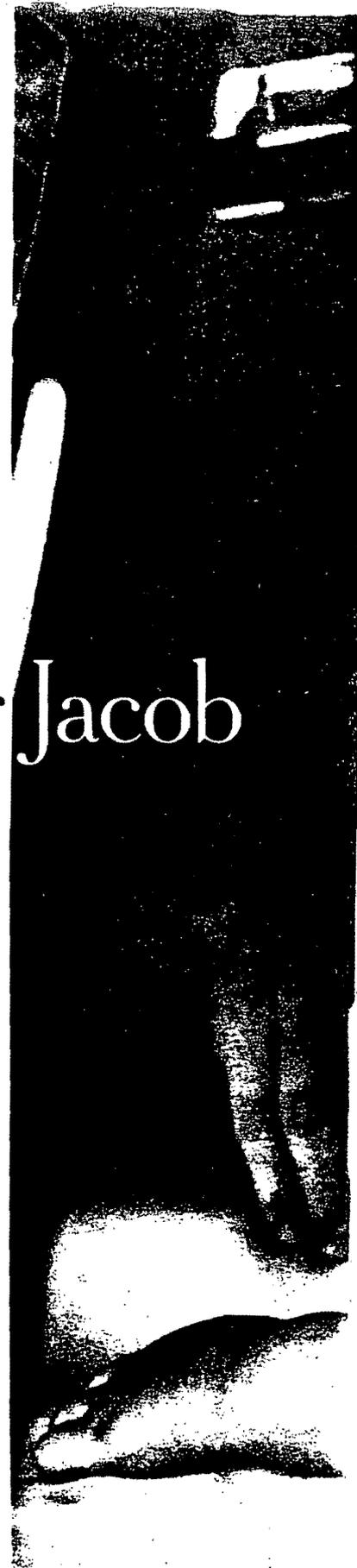
Jordana and Richard Sontag were speeding toward Yale University, angry, desperate, ready to unleash their secret weapon, which they had carefully loaded into the back of their Grand Cherokee. For a year, they had done everything in their power to save their dying baby boy, Jacob. The well-to-do young couple and relatives had donated more than \$200,000 to Yale to underwrite experimental gene-therapy research aimed at curing the rare genetic disease that plagued Jacob. They had helped pay to bring two leading researchers from the other side of the world to Yale and to transport from a lab in Germany the precious concoction of healthy genes that might save their son and a dozen other dying children with Canavan disease. They had hired lawyers and enlisted United States Senators to lobby the medical oversight committees for approval of the experimental procedure.

And then they waited. Week after week, Yale officials assured them that the medical school's review committees and the governmental agencies would soon take action. But spring had given way to summer, and summer to fall, and still nothing. Jacob's adorable blond head had grown too heavy for him to hold up, and he had little control of his limbs, which hung at his sides, making him floppy like a rag doll.

In hopes of speeding the review, Jordana had assembled two notebooks full of records documenting the complete medical history of 1½-year-old Jacob Ross Sontag, starting with the first sonogram. The names of all those committees and agencies that had to approve the experimental treatment made her head throb and at night turned her dreams dark and anxious: the Human Investigation Committee and Biological Safety Committee at Yale; the Recombinant DNA Advisory Committee at the National Institutes of Health; a staff review at the Food and Drug Administration. All had to say "yes" before the children could be treated. But as the

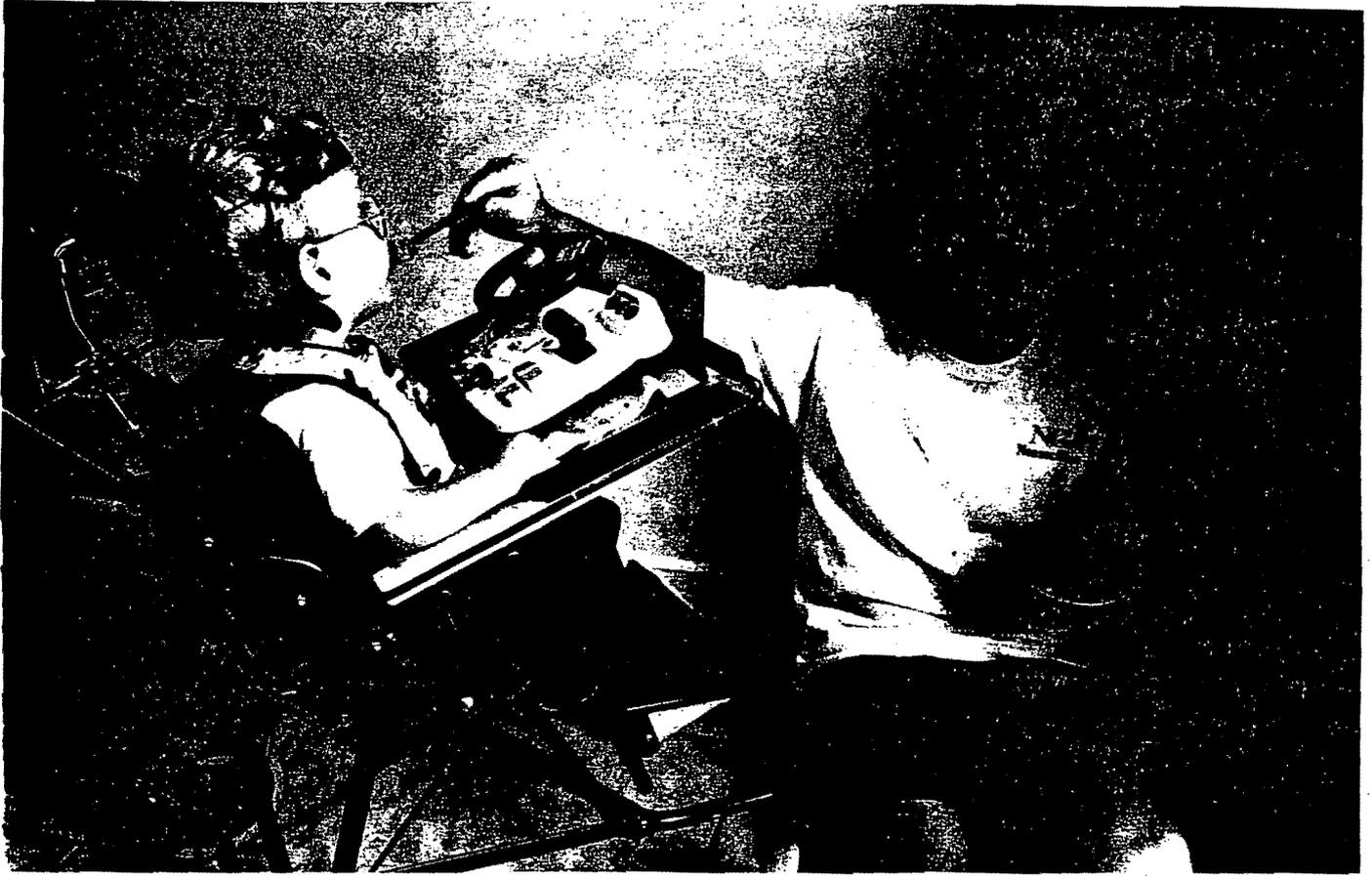
Richard and Jordana with Jacob, after he was hospitalized with a 103-degree fever.

Photographs by James Estrin





Dr. Seashore didn't tell the Sontags, but she, too



Above: Richard and Jacob at mealtime. Right: Jordana in a moment of quiet anguish.

Sontags knew, H.I.C. wouldn't act until B.S.C. did; B.S.C. preferred R.A.C. to give an expedited approval first; and R.A.C. was waiting until H.I.C. ruled. And how did the Sontags explain that to friends who asked, "How's it going?"

"We plan to see anyone who will see us," said Richard on the drive to Yale. "We'll look into offices, the cafeteria — we'll find them!" That fall day in 1997, as they hurried through the lobby of Yale-New Haven Hospital wheeling the secret weapon, they couldn't believe their luck. There was Dr. Margretta Seashore! The enemy! To the Sontags, Dr. Seashore epitomized all the bureaucratic delays that were killing them. She is an internationally known genetics professor, appointed by Yale to shepherd the experimental procedure through the review process. At 59, Seashore is careful, thorough, academic — precisely the type of person who was driving the Sontags crazy. Seashore was a generation older

Michael Winerip is a staff writer for the magazine.

than the bold team of junior Yale researchers who had actually developed the new gene therapy, tested it on 300 rats, 4 monkeys and 2 children in New Zealand and pronounced it ready to go for its first trial in the United States.

As far as the Sontags were concerned, Seashore represented the establishment, when they needed a firebrand to shake up Yale.

Seashore was waiting in the lobby to meet a group of medical students for a tutorial and was surprised to see the Sontags. She tried to make small talk, but they would not be distracted. "I'm sorry I can't sympathize," said Jordana. "We're living with a dying child the past 18 months."

Richard unfastened the secret weapon and began yelling. "You look at him!" he screamed, lifting Jacob out of the stroller and pushing him at Seashore. "You tell him why this protocol is delayed while he's dying!" The father was speaking so loud, people in the lobby were staring. Seashore noticed that her four medical students had arrived and appeared to be in shock.

"How could you prevent our child from treatment?" Richard yelled. By then, Richard was crying, Jordana was crying, Jacob was howling and Seashore looked ready to burst into tears.

"I do understand your desperation," Seashore said. "You have to understand, the biosafety committee is trying to be safe." She suggested that they consult the medical-school dean about the delays. "I'm under tremendous pressure the past months, overseeing this protocol."

"That's a luxury compared to being parents of a terminally ill child," said Jordana.

Seashore's hands were trembling. She warned she'd take herself off the protocol if this pressure continued: "If I do, this trial is dead."

"You look at my son dying," Richard screamed. "Tell it to him!"

Seashore would later call that Sept. 24, 1997, showdown a watershed. "I was shocked at their behavior in public," she said. "What that said was: We have desperate people here; they're going to blow the place up; we have to make a deci-

ught Yale's biosafety committee was stalling. "If you just tell people we're putting foreign DNA into the brains of small children, jaws drop," she said.



sion." After the Sontags' visit, the assistant to the medical-school dean spoke to members of the Yale biosafety committee and told them that it was time to decide — yes or no — but soon. The next week, the committee approved the therapy, and in the following months the other committees did, too. The Sontags' desperate plan had worked. On Jan. 2, 1998, Jacob Sontag was scheduled for surgery at Yale, the first time doctors in this country planned to treat a genetic disease by shooting a syringe full of healthy genes directly into the brain.

The four medical students who witnessed that confrontation have told Seashore it's the best clinical lesson they've had at Yale, and indeed, many of the forces shaping medical practice and research converged that day in the lobby to detonate the nasty explosion. For the Sontags, the experimental therapy was the sole hope they had to reverse the degeneration of their only child, precious Jacob, suffering from a rare disease that eventually leads to paralysis, blindness, severe retardation and death, typically between ages 5 and 10. To the Sontags, gene therapy — intro-

ducing healthy genetic material into malfunctioning cells so that they can produce a missing enzyme Jacob's body needs — was brilliant, and they knew from news articles that the approach was being used in hundreds of trials on cancer, cystic fibrosis and heart disease.

In the Sontags' corner were two junior Yale researchers, Dr. Matthew During, 41, and Paola Leone, 34, a neurobiologist. Since 1995, when parents of another dying child had begged During and Leone to apply their skills to Canavan, the two had moved at a breakneck pace. The Sontags understood these researchers had their own reasons — there will be great rewards for the scientist who figures out how to deliver large amounts of healthy genetic material to the right cells. For During and Leone, Canavan could be the template for other genetic therapies, revolutionizing medicine; the dying children promised to be the perfect human subjects. As for the parents, they just thanked God that anyone would take on such a rare "orphan" disease.

On the other side were Seashore and three dozen colleagues on Yale's oversight commit-

tees, many of them fearful that in this era of deregulation safety standards are being lowered, allowing treatments like the fen-phen diet drugs to reach the public without adequate testing. "The heart of the question," Seashore said, "is when is it time for something in a scientific lab to be made available to people?" Seashore had seen the career of one of her colleagues, the geneticist Dr. Reuben Matalon, upended by moving too quickly from the test tube to humans. In the early 1990's, Matalon thought he had developed a pregnancy screening test for Canavan. And then, to his horror, four pregnant women who had tested negative gave birth to babies with the disease. "I wasn't going to let anything like that happen to me," Seashore said.

I first met Jordana and Richard Sontag in May 1997. Richard's sister, Deborah Sontag, is a friend and colleague (the Jerusalem bureau chief of *The Times*) and had told me of her younger brother's quest. She was skeptical, but also in awe of how determined her brother and sister-in-law were to find a cure and how open they were about Jacob. A few months before, in Feb-



Richard comforting Jacob as Dr. Charles Duncan, center, and his assistant, Dr. Sung Lee, inject the new genes.

ruary 1997, to celebrate Jacob's first birthday, Richard and Jordana had rented a restaurant banquet room, hired a Musical Munchkin and invited 50 friends and relatives to the party.

Until recently, there was no hope for a child with Canavan, which is most prevalent among Ashkenazi Jews like the Sontags — affecting 1 in 6,000 Jewish infants. Both parents must be carriers for the disease to manifest in the offspring. Children have a defective gene that can't produce a key enzyme needed to break down an acid in the brain known as NAA. Scientists hypothesize that a surplus of NAA develops, which in turn interferes with the formation of myelin, the white coating that covers nerve cells. Without myelin, the brain's nerve cells can't relay messages to the body, eroding motor control to the point of paralysis. Autopsies reveal spongy brains full of tiny holes.

At birth, the baby appears normal. But by 3 months, parents notice a lack of responsiveness. Misdiagnosis is common. Jacob was first thought to have developmental and vision problems. At 4 months, he was fitted for glasses. At 5 months, a specialist said it was Leigh's disease. By the time Canavan was identified, Jacob was 7 months old.

Most families had only bleak things to tell the Sontags. They met parents who medicated

their children around the clock, who felt any physical therapy was a waste. A mother from Philadelphia said: "Don't get him glasses. It won't matter to him, and you don't want people staring." There were parents who confided that they quietly let the children die instead of rushing them to a hospital during a seizure. "The best thing you can do," they said, "is have another child who is healthy." To Jordana and Richard, this was Canavan's defeated old guard speaking.

The couple was not used to failure. In 1992, when Richard was 30, he bought out a two-man firm that produced battery-heated socks and in five years built it into Nordic Gear, a multi-million-dollar outdoor accessory company with three factories and 350 employees. At an age when many are still deciding what to be, Richard was flying to the Orient first class on business and arranging meetings with his bankers. For her part, Jordana was a creative public-relations executive, savvy enough to get one of Richard's items featured on an Oprah Winfrey pre-Christmas show highlighting great gift ideas.

In the spring of 1997, in the midst of their quest for treatment, they bought a seven-bedroom, seven-bathroom home with a pool on 1.75 acres in a wealthy Westchester County suburb. That

enormous house made Jordana uneasy, but Richard saw it as a testament to his business success.

They were determined to treat their son as normally as possible. When I first met Jacob, at 15 months, if his head fell onto his chest, Richard would say: "Pull up your head Jacob. Come on Boo." And slowly, Jacob did. "Say hi," Richard coached, and light came into Jacob's eyes, a smile appeared, his mouth opened and a tiny "Hi" came out. Then Richard would kiss him all over, turn him upside down and make gassy noises against his neck while Jacob beamed.

"Other Canavan families are amazed by Jacob," said Jordana. "They've never seen a Canavan child so advanced." The Sontags made sure Jacob had extensive weekly therapy — physical, speech, occupational — all publicly financed as part of a Federal early-intervention program for disabled preschoolers. They constantly read to him. On a trip to Philadelphia, Jordana sat in the back seat and read and sang the entire two hours while Jacob was mum, staring through his blue-rimmed glasses: "Is Clifford in his doghouse? Is that where Clifford is? Little Man, how come you're so smart?"

They were delighted he was already 25 pounds, while a 7-year-old Canavan girl they'd met, Morgan Gelblum, weighed *Continued on page 61*

The genes they had been waiting so long for, the genes that could change their son's life, had arrived, in an ice bucket that looked borrowed from a Motel 6.

just 30. Instead of giving him a mushy diet — he had limited chewing control — they fed him Cheerios, waffles, chicken soup with matzoh balls. Canavan children tend to have trouble sleeping — imagine not being able to shift your body for 10 or 12 hours — and most parents sedate them. “They put them to sleep with one pill and wake them with uppers,” said Richard. If Jacob cried, they checked on him, but let him cry himself to sleep.

Strangers saw Jacob's stylish glasses and his polo shirts and commented on how much he looked like the boy, Ray, in the film “Jerry Maguire.” “People don't realize he's handicapped,” said Jordana. But the Sontags were no fools. Jordana was constantly downloading articles, and one described how much of the brain's development is completed by age 2. “Every month he doesn't have the surgery, he's losing,” she said. “At 6 months, he wasn't far behind other children. Now at 15 months, he should be walking, and the distance from where he should be and where he is gets larger. He'll have to do so much more to catch up after the surgery.” While the Canavan literature lists retardation as a symptom, it is not clear at what age mental deterioration becomes irreversible. Jordana and Richard were convinced there was a bright little boy trapped in that body, and they based that on the light in his eyes and his beautiful smile. They were in a race against time to reach that trapped person before he disappeared forever.

THEY WERE NOT THE FIRST. THE KARLINS of New Fairfield, Conn., were. In 1994, Canavan was diagnosed in Lindsay Karlin. Her father, Roger, an internist, and mother, Helene, a psychologist, began a frantic hunt for scientists doing gene therapy and found During and Leone nearby at Yale. At the time, the researchers were using Parkinson's disease to investigate ways to deliver genes into brain cells of rats. They were testing a nonharmful virus that could be loaded with replacement genes and would then transport those genes through the membranes of brain cells.

The Karlins brought Lindsay to meet During and Leone. After several visits, the researchers agreed to focus on Canavan. The disease offered an objective measure of gene therapy's effectiveness. If, after gene injection, a brain scan showed the children's NAA decreased and their myelin increased, it would be evidence that the implanted genes had done the job. There were human reasons, too, in the Karlins' favor. Like the Sontags, they were educated people who understood the ethics of offering up their daughter and promised to be able fund-raisers.

At that time, During, a native New Zealander, was being wooed to return to Auckland. While

scores of labs in the United States were doing gene therapy, in New Zealand he would be first. He saw a chance to do more, faster, with greater resources. Indeed, shortly after returning to New Zealand, the pioneer geneticist was fielding phone calls from reporters. On March 6, 1996, he oversaw his first human gene trial — on Lindsay Karlin and on a second American child, Alyssa Mushin.

Though results were mixed, the Karlins were excited. Within weeks, they say, their daughter seemed to see more and do a better job holding up her head. Brain scans seemed to indicate a decrease in her NAA and increase in her myelin (although not for the other child). The Karlins were now anxious to have their daughter treated again and agreed with During that they should inject twice as much genetic material.

That fall of 1996, the Sontags were just beginning to confront Jacob's illness when they heard of the New Zealand experiment. In their usual take-charge style, Jordana and Richard were soon coordinating the next round of injections in New Zealand, on eight more children, including Jacob. To insure that every family could make the trip, the Sontags offered to underwrite any expenses the others could not afford. When New Zealand officials sent questionnaires asking parents if they understood the risks, Richard faxed sample answers to each family, urging them to slightly change the wording to the responses. The experiment was described as testing only the safety of gene injection: “The best we can hope for is that the procedure is safe; anything over and above that will be a bonus.” In Richard's advisory to parents he warned, “Do not say that you expect the gene therapy to save your child's life,” although that was what most hoped. Three times the Sontags had plane tickets for New Zealand, and three times they canceled as committees there raised objections. A backlash was setting in. Articles had appeared in *Science* and *Lancet*, and letters were sent to Washington regulators questioning whether During was using a distant country to circumvent United States oversight.

Night after night, Richard and Jordana phoned and E-mailed New Zealand. But the treatment was slipping away. By June, that country's officials were accusing During of pushing through the first trial without sufficient public debate, while he questioned their ethics. Sitting on this side of the world, Richard took the long view: “They don't give a damn about our kids. These aren't New Zealand kids dying.”



Dr. Margretta Seashore, the noted genetics professor at Yale.

The day they got the word, Richard and Jordana took Jacob to the playground. They wanted to be alone. Richard held Jacob in his lap as they went down slides. A woman watching asked, “Is he getting physical therapy?” She wasn't being intrusive; she simply wanted to be sure they knew it could help. “Some people try to ignore it,” said the woman.

Later, Richard said, “She was nice.”

“Yeah,” said Jordana.

“That's the first time a stranger realized,” said Richard. Jordana nodded.

THEY STARTED OVER AGAIN IN THIS COUNTRY. Richard flew to Washington with Roger Karlin to meet with lawyers about how to best pressure officials at Yale and the National Institutes of Health. The Institutes' next quarterly review was in mid-September; the Yale committees would have to act by late August for the protocol to be considered at that mid-September Federal review. “We don't know if we should get politicians involved or give Yale lots of money or go to the press,” said Karlin.

“That could backfire,” said Barbara Mishkin, an attorney at the firm Hogan & Hartson who specializes in human experimentation. “You could just get the committee upset.”

Bob Brady, another attorney, said: “We have to lower the decibel level, focus on the science. Inadvertently, the protocol has become notorious, both here and in New Zealand.”

Richard favored being aggressive: “What we tried to do is call Yale's president and thank him for letting us deposit \$250,000 in the Canavan research account and say to him, ‘Who do we contact about giving more?’”

Mishkin replied: “The research budget at Yale is multimillions. To influence them, you'll need much more than a couple hundred thousand.”

“You want us to tone it down,” said Richard. “We want to bring it up.” After two hours, he and

Karlin rose to leave. Karlin pulled out a photo to show the lawyers. "My daughter, Lindsay," he said. Richard pulled Jacob from his wallet. "The consequences if this is postponed?" Brady asked. "They may go blind, become vegetables, die," Karlin said.

JORDANA HAD STOPPED WORKING AND WAS watching Jacob like a hawk for signs of changes. Was she the only one who could feel time slipping away? "He'll get to the point of no return," she said. "The gene therapy might prolong his life, but won't help him."

Sunday morning, July 20, Richard got him out of bed. Jacob looked pale and unhappy. "A cranky baby here," Richard announced and brought him downstairs. Jordana rubbed his arms, but couldn't get a smile. His lips were chalky white. He began making jerky motions; she tried to bend his legs, couldn't, then noticed his eyes rolling. "He's seizing!" she screamed.

Doctors hospitalized Jacob for several days, but couldn't find a cause for his 103-degree fever. Not even Jordana could coax a smile from him. A dizzying parade of specialists visited. At one point, when Jordana asked a doctor a question, Richard started to answer, but she cut him off.

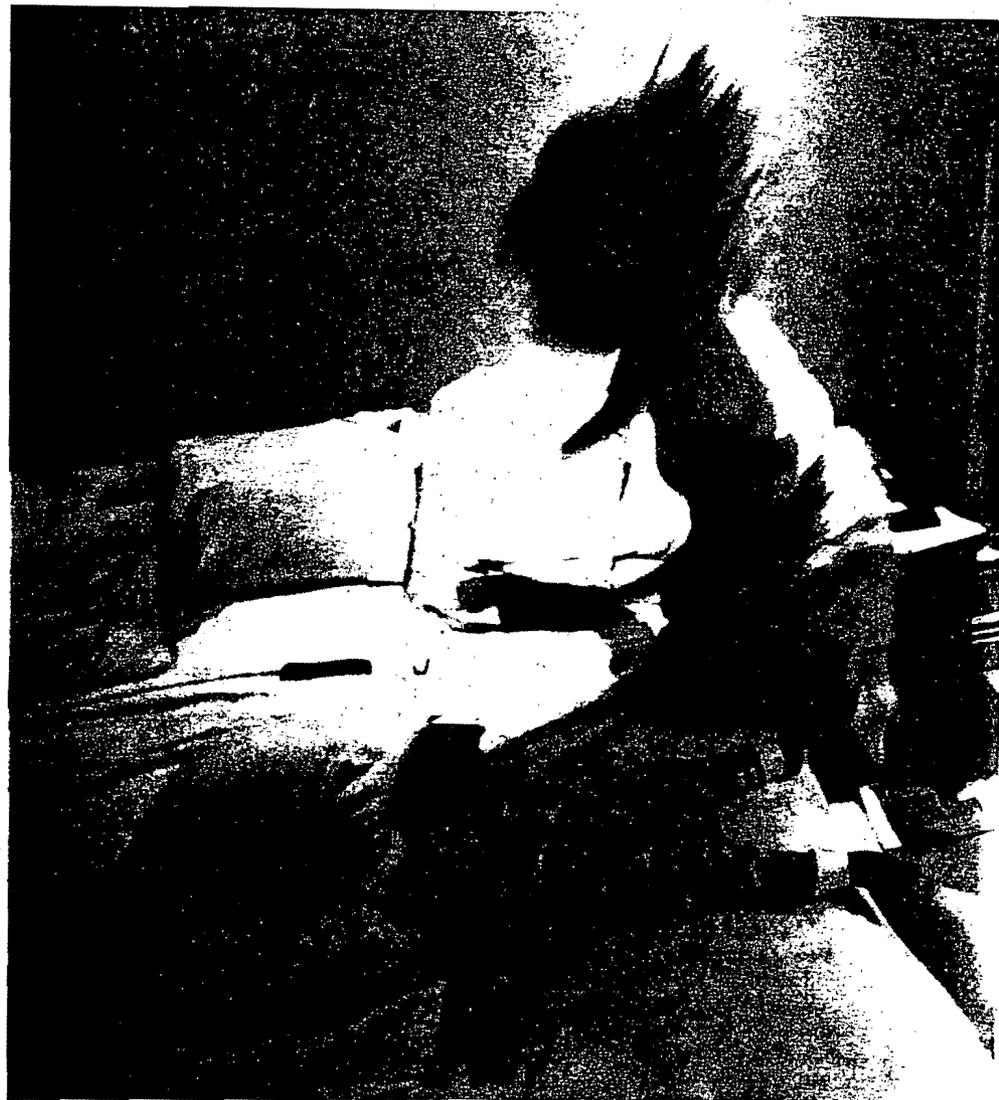
"You always do that," she said to Richard. "You jump in and answer my questions. I have important questions I don't get to ask."

"Write them down," Richard said.

"I don't have to write them down!" said Jordana. "I just don't want my son being dead because some doctor doesn't know how to treat a child with Canavan." Doctors said there should be no damage from the seizure, but the Sontags worried. Who was Jacob? A little boy with light in his eyes and a delicious smile, who liked best to be rocked in his mother's arms. There was no sign of that Jacob. Was he still in there?

For weeks they weren't sure. He was crankier, often seemed in pain. For the first time, he was having trouble sleeping, and they argued over how to handle it. When his crying persisted one night, Jordana picked him up. "Why'd you bring him out here?" said Richard. "Of course he's sweating when he's crying; he's crying himself to sleep. What's wrong? He's fine. Put him back."

He was having trouble lifting his head, too. On Aug. 15, Jordana said: "Something's definitely not the same. I can't pinpoint it yet. Richard thinks one of his eyes is starting to turn; the muscle has weakened. None of the therapists noticed anything, but it seems he used to see me sooner when I came into a room. If he was on the couch and I walked from the kitchen to



Romping with Jacob — aka Boo, Bubbles, Mr. Head or Little Man — at home.

the front door, he'd see me, want me and cry."

Jordana knew the optical nerve can degenerate without myelin and on Aug. 20 took Jacob for a checkup. The ophthalmologist found significant deterioration and strengthened Jacob's glasses. This scared her. "I can't imagine what it would be like if he couldn't see my face or Richard's," she said. "If something started to go wrong with his eyes — it's unacceptable to me."

Jordana got United States Senators involved. One Canavan child was from South Dakota, and an aide to that state's senior Senator, Tom Daschle, was particularly aggressive about pressing Yale. Still, many at Yale did not feel the same urgency. At a Sept. 2 biosafety meeting, members said there were still too many questions and postponed a decision. The earliest Federal action would now be the December quarterly meeting. Jacob would be nearly 2.

"Jordana's going to explode," said Richard. "She's holding everything in. She's talking about

chaining herself to the White House fence."

Little things were destroying her: a 2-year-old niece asking when Jacob would stop being a baby. Even his pockets depressed her. "A little boy his age starts enjoying his pockets," she said, "putting different things in there, and he doesn't even know they are there." Richard would come home from work and there was nothing in the refrigerator. She had stopped grocery shopping. "It made me crazy," said Richard. "I'd say, 'Jordana what's going on — no food in the house?' She'd say to Jacob, 'Your Daddy thinks I'm crazy.'"

She had tried to explain how difficult it was taking Jacob shopping, but Richard always had an answer: "Put him in the baby seat. What's the problem?" She didn't tell Richard, but she couldn't do that to Jacob, a 1½-year-old sitting flopped in an infant seat. "It's not that I care what people think," she said. "It's making Jacob a spectacle when I'm shopping."

I don't know why you're feeling that way," Richard said, but Jordana cut him off. "We're not even away from this marriage seminar for 24 hours," she said, and you're trying to fix everything."

his head," she said. "Maybe he'll say the words he knows now, loud and clear.

"What I envision is this little boy coming out of his shell — 'I'm here! Hi! Here I am!' I want him to be set free in a way. I hope he'll walk. He has the desire to walk. I put him down, he tightens his leg. You know, I'll be grateful if he can just sit up, play on his own, grab things.

"If he could just roll over. I put him to bed at night on his belly. In the morning, I come in, he's in the same position. I think about how nice it would be for him, if he could roll over and stretch — so there are my hopes."

Knowing those hopes, it was easier to understand why each new delay seemed the cruelest. On Sept. 18, Yale's biosafety committee again met without deciding. On Sept. 19, the Sontags were invited to attend a memorial service at the Jewish Guild for the Blind in Manhattan for 7-year-old, 30-pound Morgan Gelblum, who died over the summer. On Sept. 24, Jordana told Richard that whether or not he came, she and Jacob were going to Yale to confront Seashore and anyone else she could find. Richard would later say, "I was on the fence about going," but he went, as much to save his marriage as his son.

SEASHORE DIDN'T TELL THE SONTAGS, but she, too, thought Yale's biosafety committee was stalling, afraid to make the leap. However, she also saw a need for caution. "If you just tell people we're putting foreign DNA into the brains of small children, jaws drop," she said.

There were other reasons members did not feel an urgency: many doubted it would work. While gene therapy had captured the imagination of the public and media (most hometown newspapers had done a hopeful feature on their local Canavan child), the scientific community was skeptical. An article in *Nature* that fall of '97 reviewed all gene protocols to date, including treatments for cancers, heart disease and immunodeficiencies and put it bluntly: "Although more than 200 clinical trials are currently under way worldwide with hundreds of patients enrolled, there is still no single outcome that we can point to as a success."

It wasn't a question of whether they could deliver genes to the cells. They could. It was how many and how long they'd work. Matthew During estimated that the new genes would reach 10 million of the 100 billion brain cells, or 1 in

10,000. Delivery was primitive: They shot the genetic fluid into a liquid cavity of the brain known as the ventricle and hoped it would be absorbed by adjoining brain cells. This was like pouring it into a river and seeing how much was absorbed by the surrounding land; you'd find a lot in the riverbed, some along the banks, but not much inland. The low "hit" rate was the major misgiving voiced by committee members. Even if inserting the genes proved benign, the surgery had a risk. Implanting the plastic reservoir in the brain to pump genes into the ventricle carried a 5 percent risk of serious infection, possibly death. Put another way: for the 16 children waiting, there was a 1-in-20 chance of a life-threatening crisis.

Complicating matters was During's status. He was a hero to parents, but because the protocol had bounced from Yale to New Zealand and back and was publicly criticized, some at Yale regarded him as a cowboy. Committee members questioned how successful the procedure really was in New Zealand. While both girls had a temporary decrease in NAA, the more important indicator, myelin growth, was less clear-cut. To ensure uniformity, the committees decided that all M.R.I.'s would be done in one place, Children's Hospital of Philadelphia.

With During still in New Zealand, Yale had taken the unusual step of asking Seashore to shepherd the protocol, though she was not involved in the research. "Acrimonious" things were said about Matt During that weren't fair," she said. "But I would not let that happen to me. If I had to be the bad guy to parents, I'd be the bad guy."

Seashore remembered too well what had happened to her longtime friend and colleague, Dr. Reuben Matalon. At Miami Children's Hospital in the 1980's, Matalon made the key breakthroughs in Canavan research, including identifying the mutation responsible for the disease. Canavan parents considered him a godsend. In 1990, he thought he had another score, a Canavan screening for pregnant women. What happened next has never been reported in the media, but it stunned geneticists who pieced the facts together. In a 1992 issue of the *Journal of Inherited Metabolic Diseases*, Matalon published a paper detailing how his test on pregnant women had correctly predicted whether a baby would be born with Canavan 13 of 13 times. His conclusion: "It is possible to determine Canavan disease prenatally." But then, in a last-minute postscript, came the shocker: "Note Added in Proof: Subsequent to the submission of this manuscript, we determined that one" *Continued on page 78*



Jacob would wake at 4 A.M., they'd struggle to get him to sleep and then were up until morning, arguing. They began seeing a marriage counselor. Jordana complained Richard bullied her; Richard complained Jordana was running from life.

In mid-September, she asked for a divorce. Richard wanted to know if there was someone else. Jordana said there was not a soul — that was the problem. She was finding she couldn't talk to anyone about Jacob. "Every day there's some stupid new development, we're so immersed," she said. "It's so lonely. Even when Richard and I talk, we have totally different views." They disagreed about things as basic as the gene therapy. Richard was hardheaded: he expected the small improvements Lindsay Karlin's parents had reported, but felt a cure was years away. "I'm not in la-la land on this," he said.

Jordana thought Jacob would thrive, because he'd been an advanced Canavan child and would get twice the dose of genes that the first two girls received in New Zealand. "At some point, not right after, I see him lifting

CANAVAN

Continued from page 63

of the pregnancies predicted to be normal resulted in an affected baby."

That affected baby was Molly Green, born June 18, 1991, in Arlington, Va. Molly's parents, David, a lawyer, and Wendy, a psychologist, had already buried one Canavan child, Eli, in 1990. After hearing of Matalon's new test, Wendy got pregnant again. "He told us it was experimental," said David, "but there was nothing like an informed consent procedure or peer review. We were desperate to have a child. Our attitude was, sounds good enough to me." The pregnant Wendy sent a fluid sample to Matalon. "We were informed the results were sparkling," said David. "We were having a healthy baby."

Molly seemed perfect at birth and was even chosen as the poster baby for the Na-

tional Tay-Sachs and Allied Diseases Association, which was undertaking its annual fund-raiser. Three months later, after Molly had gone floppy and her parents knew the truth, one of the first calls the father made was to the foundation. "Rip up all those postcards of Molly," he said. "She has it." She died March 1, 1992. Three more women with sparkling screenings gave birth to Canavan babies, and two of those sued and later settled. "Reuben made a mistake," Seashore said, "but he was pressed very hard by the families to bring something into clinical service before it was ready."

In the end, the Canavan protocol was approved at Yale for very human reasons. The children were as disabled as any on the planet, and they probably would not be harmed and might benefit, or at least provide insight for researchers. I asked Dr.

Charles Duncan, one of the nation's pre-eminent pediatric neurosurgeons and the man slated to operate on Jacob, "Would you do it if it were your child?" "Oh yes," he said. "I wouldn't be doing the surgery if I didn't think so."

There was more good news. The National Institutes of Health had recently made a policy change: under streamlined guidelines, Yale's approval meant the Federal committee did not have to give its go-ahead.

Seashore, however, insisted that the protocol go for that Federal review anyway. "I don't want to be the first protocol that doesn't," she said. Leone, who had worked so closely with the parents, fought her. "They saw me as an obstacle," Seashore conceded. "I saw them as loud. It was only a couple more weeks."

THAT NOVEMBER, THE Sontags hired divorce law-

yers and put the house up for sale. The previous spring it had felt to Richard like a symbol of his power, but now, as winter neared, he seemed to have lost control of things that mattered, and the big house embarrassed him. Many rooms were still unfurnished.

Just before Thanksgiving, Jacob had a brain scan scheduled in Philadelphia to establish a baseline for myelin before gene therapy. Richard and Jordana took separate cars — agreeing to meet there. On the George Washington Bridge, Richard spotted Jordana and Jacob and waved. He knew she'd be nervous about driving alone, and sure enough, she pulled behind him. As they caravanned south on the New Jersey Turnpike, he picked up his car phone and dialed her in the Cherokee. They talked for 20 minutes, their first conversation in weeks.

Trying to get the IV in for

the anesthetic was always the worst moment of an M.R.I. Jacob's arms were flaccid and nurses were trouble pricking a vein. He cried as Richard and Jordana held him. Soon they were sobbing, too, their tears falling together on their son. The nurse tried to comfort them, saying that the IV really didn't hurt Jacob much, but that was not why the Sontags were crying.

That night, they left Jacob with their sitter and took a hotel room.

BY DEC. 18, THE FEDERAL agencies had given their approval. Jacob's therapists prepared evaluations, to measure changes that might come later. Vivian Kahn Adler, the speech therapist, noted deterioration in recent months. When she started, "he used at least five different sounds — 'hi,' 'more,' 'ma.' At that age it was very encouraging; he was a baby. Now he's not

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using many." She didn't know why Jacob had lost speech. It could be physical — his breath support had weakened. Or maybe, she said, cognitive. She was trying to get him to communicate by gazing at the food he wanted on his tray. During her Dec. 18 lesson, he sneezed and his head fell on his chest; he couldn't lift it. His eyes were crossed now, too. "A lot of kids you feel are stuck at the 3- to 6-month level," Adler said. "With Jacob, I feel there's a bright little kid in there. Sometimes he can wave. It'll take a while. If you don't have patience, you'll miss that wave."

The researchers decided the Sontags or Karlins would go first. They'd worked the hardest and raised the most money. At a diner, they flipped a coin. Jacob won. Jordana felt like a pioneer. She was hearing from families from around the world. "I feel great," she said, "like we've spared them the pain of all the fighting we've been through. I saw a video this family in Canada sent of their baby — his name's Jacob, too. He's 5 months, lifting his head, looking around. Can you imagine what this could do for him?"

SURGERY WAS TO BE done in two phases. On Friday, Jan. 2, at 8 A.M., Duncan used an air drill to cut a 9-millimeter hole in Jacob's skull. A tube was lowered into the ventricle; then a plastic, egg-shaped reservoir was attached to the tube and imbedded below the scalp, making a bump over Jacob's forehead. The reservoir would remain to facilitate future injections. This took less than an hour. Then Jacob was to be observed that weekend for signs of infection, and on Monday the genes would be implanted.

It was not to be. Sunday night he had a 103-degree fever, and Richard slammed

the nearest table. "Twelve hours away!" he said. Duncan came to the hospital past midnight to get a sample of Jacob's brain fluid to test for infection. While Richard held his son, a young doctor assisting Duncan put the syringe into the reservoir to withdraw a specimen. Jacob's brain fluid came rushing out, splashing on the floor. Richard's eyes widened; brain surgery wasn't like he'd envisioned. Duncan felt Jacob just had the flu, but didn't want to take chances. He said he'd have to consult Seashore before deciding when to proceed.

"If Dr. Seashore makes the call," Richard moaned, "we'll be waiting another year." At 10 the next morning, Leone wheeled in a cart with a black plastic container. Richard could not stop staring. The genes they had been waiting so long for, the genes that could change their son's life, had arrived, in an ice bucket that looked borrowed from a Motel 6.

For days, Jacob was too sick with flu for the injection. On Jan. 9 at 6 A.M., Jordana was watching him sleep when she noticed his pinkie finger tremble, then his arms, then the whole body. His eyes opened wide and she thought he was dying. The nurses could not stop the seizure and moved him to intensive care. Would there be anything left of him to save?

Not until Jan. 22 was he strong enough. The actual procedure was so simple that it was done in an examination room. Jacob was laid on his stomach, screaming, Richard and Jordana holding him down. Duncan took a syringe and inserted it into a pin in Jacob's scalp that looked like the needle used to blow up a football. With his left hand he injected the syringe's fluid and with his right thumb he pumped the implanted reservoir 16 times. After 14 months, it was over in three minutes.

The new genes were floating down the river Jacob.

"RICHARD AND I HAVE this joke," Jordana said. "Jacob will sit up and say, 'I don't know about this gene therapy.'" Jordana's mother urged, "Keep your camera out for when he lifts his head." They upped physical therapy to five days a week to capitalize on any improvement and thought they saw a million little things. "I was feeding him," said Jordana. "He put his hand on the spoon three or four times. He's done that before, but it was like right on my hand." When Richard held him, Jacob seemed to lift his head off Richard's chest more to look around. "Every day is exciting," said Jordana. "Lots of hope."

What was not encouraging was Jacob's sleeping patterns. He was constantly waking at night now and often would not go back to bed. "We're exhausted," said Jordana in mid-February. "We haven't had a good night's sleep in a month and a half." Their pediatrician prescribed a sedative for Jacob, but Jordana resisted. "We didn't want to do that," she said. "I hate giving in to this disease." For his part, Richard had surrendered. His attitude was, "Get the chloral hydrate!" The researchers told the Sontags his wakefulness might be positive, a sign gene therapy was working. They reasoned the new genes had so stimulated his brain, a sensory rush was keeping him awake.

Or it could be that Jacob was experiencing the classic sleep problems of an aging Canavan child.

Exhausted, Jordana no longer cared. The researchers didn't have to get up with him at 4 A.M. On Feb. 20, she was in tears. "Jacob did not sleep at all," she said. "I'm sorry we did the procedure. The only thing we got out of all this — he can't sleep! It's so cruel."

Plus, they were pushing

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him for any physical gain while the new genes were fresh. With Jacob screaming, his physical therapist put on his stiff leg supports and led him a few steps. Richard placed him on the floor, legs crossed in a yoga position, his head flopped on his chest, and pleaded, "Lift it — come on Boo," but the head did not budge.

On Feb. 24, Jacob turned 2. They celebrated quietly, the three of them. At one point, Richard left the room so Jordana would not see him cry.

That week, Jordana gave in. She explained her decision to medicate Jacob this way: "I think we're better off as a family if the baby sleeps." They began giving him Klonopin, a muscle relaxant. It was the turning point. The muscle relaxant relaxed the parents, too.

Jacob's stiffness decreased; he stopped grinding his teeth. "Jacob is doing phenomenal," Richard said in mid-April. "He is in a fabulous mood." Why? "He's stoned," said Richard. "It's hard to know how much is Klonopin or the gene therapy or physical therapy five times a week. There are so many variables."

Jordana's fantasy, that he'd sit up, hadn't happened. "Not yet," she said. "In the past, I'd be devastated. But I feel I don't have to worry now. We got him the gene therapy; we've done all we can. I guess if I had to choose between motor skills and the cognitive, I'd choose this. He'll hang out in bed with us. We just lay him flat and play with him. Everything is funny to him now. Richard brought him in the other morning. I said, 'Little Man.' He starts smiling. 'Hi, Little Man.' He says, 'Hi.' I heard him!"

Jordana did not wait for During's lab to call with the latest results; she phoned Philadelphia herself and wormed it out of the M.R.I. people. "They gave me an

unofficial report that Jacob has myelin!" she said on June 5. "They still have to do a comparison with the last M.R.I., but I have a feeling it's in the area that controls cognition."

Four days later, she left a message: "Wanted to let you know we received the report, and it says there have not been significant changes. He does have myelin, but it's the myelin he had prior to gene therapy."

JORDANA RETURNED to work part time. They sold the big house and moved to an attractive ranch house that was half the price. It was a nice fit, on one floor, easy for Jacob. All the rooms had furniture.

She was busy raising money for the Canavan Research Fund the families had founded. She spoke with rabbis and doctors about publicizing the new prenatal screening test for Canavan that was developed in the mid-1990's after Matalon's failure.

On June 19, the Sontags met with a lawyer about a "wrongful birth" lawsuit they had filed against the doctors Jordana used when she was pregnant with Jacob. In the lawsuit, Jordana claims she had repeatedly requested all relevant prenatal screening tests and had been given several but not the new one for Canavan. During the meeting, Jordana held Jacob and explained how they had struggled to enrich his life. So it wasn't until the end that the lawyer, Bruce Clark asked the awkward question, "You would have had an abortion had you known?"

"Absolutely," said Jordana. "Even with this little man in my arms, I would."

"It's not fair," said Richard. "Trapped in that body."

THE PREVIOUS YEAR, RICHARD had dismissed the National Tay-Sachs and Allied Diseases conference as too

touchy-feely, but this year they went and were the last to leave a seminar on how people with a disabled child can hold a marriage together. The therapist had couples take a personality test, and it turned out Richard was a "fixer" while Jordana was a classic "turtle." And when the turtle complained, the fixer felt he had to make everything all right, scaring the turtle instead of just giving that little turtle a hug. "I know this sounds totally ridiculous," Jordana would say later, "but it made perfect sense at the time."

The next day, the three Sontags were at a deli getting Jacob his matzoh-ball soup when Jordana realized she'd forgotten an appointment to visit a school for Jacob. "I know why," she told Richard. They had run into three families just back from a Little League game, all these messy, jumpy, little noodgie boys, and here the Sontags were heading to some depressing handicapped school. "I don't know why you're feeling that way," Richard started, but Jordana cut him off. "We're not even away from this marriage seminar for 24 hours," she said, "and you're trying to fix everything, Mr. Fixer," which made Richard laugh. The turtle was out of her shell, snapping.

ON SEPT. 9, JACOB WENT to Yale for his second injection. He was home in two days. Thomas Jefferson University Hospital, in Philadelphia, where During and Leone now work, was also doing the procedure.

THAT MONTH, NINE THERAPISTS and social workers gathered to discuss the new program Jacob was starting at the Saint Agnes rehabilitation center, where the typical disabled child receives \$33,000 a year in government-financed services. Jacob's home

Continued on page 112

HOLIDAY SHOPPING AT HOME



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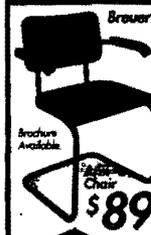


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CANAVAN

Continued from page 82

therapists, were there to advise the school therapists who would be taking over.

Richard and Jordana took turns rocking their 2½-year-old and giving him a bottle. "He has been making tremendous strides," Richard said. Adler, the speech therapist, explained how much of her time was spent working on chewing and swallowing. She didn't say it, but most Canavan children wind up on feeding tubes. "He'll drink from a cup, but there's still spillage on the sides," she said. She warned that he sometimes choked on solids, "a bit of a safety issue." As if on cue, Jacob began gagging on a waffle Jordana was feeding him, coughing and turning red. The room went dead. "Breathe," said Jordana. There was a moan and Jacob's normal color returned.

"He never used to cough so well," said Nancy Wolff, his physical therapist. "This is good."

Someone asked if he could flip a switch, and his occupational therapist said no. When the center's medical director, Dr. Maria Pici, asked what gains he had made, the physical therapist said he could roll on his side if she helped. "If I give him minimal facilitation depending on his mood and I tell him, 'Jacob bring your arm over, bring your leg over,' and of course I'm aligning him, he can roll," Wolff said.

They asked what Jacob liked. "Human contact," said Wolff. "And silliness. He loves silliness."

"Gassy noises, he loves them," Richard said.

"He's there," his physical therapist said. "Definitely," his occupational therapist said.

Jacob's Oct. 21 report from Children's Hospital in Philadelphia showed no new myelin. While researchers kept the other children's results confidential, parents talked, and Jordana learned that none of the children's M.R.I.'s showed myelin. Or, as Jordana put it, "at least not yet." Still, she saw potential in another: new development. Jacob's ophthalmologist had found evidence of new myelin in his eyes. It wasn't likely to help Jacob see better, but the doctor found it "fascinating."

Some families grew discouraged. One dropped out, and even Helene Karlin had mixed feelings. "I don't even want to talk to the other par-

ents," she said. "I don't want them to hear any discouraging note. They need to fight." There was another setback. The 5 percent risk from implanting the reservoir — it happened. In September, one child developed a serious complication and the reservoir was removed. Doctors sought to determine if there was brain damage.

SOME STORIES DO NOT END AS YOU expect. A year and a half ago, I could see the two central themes clearly. First, the curse of science: how a new medicine like gene therapy could seem to offer so much hope and yet cause so much pain, because it is still only promise. And second, the blessing of science: how the pursuit of new medicine could lead to a prenatal screening that would allow the Sontags to have a healthy baby the next time. I envisioned the story closing joyously, with Jordana giving birth to a new child.

What I witnessed instead was the hardships of the pioneer family. At the Sontags' meeting with the lawyer last summer, he asked if they would try to have another child. "We've only started to discuss that," Richard said softly.

Last month, Richard called as I was finishing the article. He was concerned I hadn't seen Jacob in weeks. "He's a whole new child," said Richard. "They love him at school," said Jordana.

On Nov. 5, I spent the day with Jacob. That morning at Saint Agnes, a well-staffed, bright, state-of-the-art rehab center, Jacob fell asleep while two speech therapists were having him practice eating a Ritz Bits cracker. In class, it took more than an hour to feed him a pureed lunch. His teachers and aides talked about how much he loved the computer, but when placed in front of it, he fell asleep again.

Then at home that night, Jacob was another child. His face lit up when Richard returned from work and kissed him hello. For two hours, the Sontags roughhoused. They called him Boo and Bubbles, Mr. Head and Little Man, and the noisier and louder and sillier they all grew, the more Mr. Stinky Butt beamed and his eyes shone. It was wonderful to see, and for once I stopped trying to guess how much was going on inside. This was medicine more remarkable than new genes, Klonopin or physical therapy five times a week — a parent's love. ■

**MEDICAID/HEALTH CARE INVESTMENT
PRESENTATION**

12/20/96

Our FY 97 Budget

- OMB: \$59 billion over 6 years
CBO: \$54 billion over 6 years
- Per capita cap on growth rates
- Disproportionate Share Hospitals (DSH)
 - Cuts and retargets DSH funding
 - Large and small "pools" that offset DSH cuts
- Expands State flexibility

What Has Changed: Large Medicaid Baseline Reductions

(Fiscal Years, Dollars in billions)

	1997 - 2002	Change Relative to April 1996 Baseline
OMB April 1996 Baseline	774	
OMB June 1996 Baseline	750	-24
OMB December 1996 Baseline	702	-72
Republicans' FY 97 Budget	731	

Note: The President's FY 97 Budget saved **\$59 billion** relative to the April 1996 Baseline.
The Republicans' FY 97 Budget saved **\$72 billion** relative to the April 1996 CBO Baseline.

CONFLICTING PRESSURES

- **Balanced Budget Pressures**
- **Budget Table:** Currently Carrying \$30 billion over 5 years and \$17 billion in 2002
- **Democratic Governors/Base Democrats and Groups**
- **Health Investments**

Options for Alternative Medicaid Policies
FY 1998 President's Budget Baseline Scoring
(Dollars in Billions)

	<u>5-Year Total</u> 1998-2002 ¹	<u>6-Year Total</u> 1998 - 2003 ²
FY 98 President's Budget Baseline	603.2	753.9
Per Capita Growth	5.5%	5.7%

Option A: Moderate Per Capita Cap/Large DSH Hit		
Total Savings	-27.7	-42.2
Total Savings in FY 2002	-10.7	
<u>Savings From:</u>		
Per Capita Cap* ³	-7.2	-13.8
Net DSH Savings	-20.5	-28.5
Resulting Per Capita Growth Rate	3.8%	4.0%
*Growth Index of Per Capita Cap	4.9%	4.9%

¹ Growth rates for the five-year total are measured from FY 1997 - 2002.

² Growth rates for the six-year total are measured from FY 1997 - 2003.

³ Per Capita Cap does not produce savings until FY 2000.

Options for Alternative Medicaid Policies
FY 1998 President's Budget Baseline Scoring
(Dollars in Billions)

	5-Year Total <u>1998-2002¹</u>	6-Year Total <u>1998 - 2003²</u>
FY 98 President's Budget Baseline	603.2	753.9
Per Capita Growth	5.5%	5.7%

Option B: Moderate Per Capita Cap/Less Severe DSH Hit		
Total Savings	-22.4	-36.0
Total Savings in FY 2002	-9.7	
<u>Savings From:</u>		
Per Capita Cap* ³	-7.2	-13.8
Net DSH Savings	-15.2	-22.2
Resulting Per Capita Growth Rate	4.0%	4.1%
*Growth Index of Per Capita Cap	4.9%	4.9%

¹ Growth rates for the five-year total are measured from FY 1997 - 2002.

² Growth rates for the six-year total are measured from FY 1997 - 2003.

³ Per Capita Cap does not produce savings until FY 2000.

Options for Alternative Medicaid Policies
FY 1998 President's Budget Baseline Scoring
(Dollars in Billions)

	5-Year Total <u>1998-2002</u>¹	6-Year Total <u>1998 - 2003</u>²
FY 98 President's Budget Baseline	603.2	753.9
Per Capita Growth	5.5%	5.7%

Option C: Moderate Per Capita Cap With No Savings/Less Severe DSH Hit		
Total Savings	-15.2	-23.7
Total Savings in FY 2002	-7.1	
<u>Savings From:</u>		
Per Capita Cap*	0.0	0.0
Net DSH Savings	-15.2	-23.7
Resulting Per Capita Growth Rate	4.4%	4.7%
*Growth Index of Per Capita Cap	6.0%	6.0%

¹ Growth rates for the five-year total are measured from FY 1997 - 2002.

² Growth rates for the six-year total are measured from FY 1997 - 2003.

Options for Alternative Medicaid Policies
FY 1998 President's Budget Baseline Scoring
(Dollars in Billions)

	5-Year Total <u>1998-2002</u>¹	6-Year Total <u>1998 - 2003</u>²
FY 98 President's Budget Baseline	603.2	753.9
Per Capita Growth	5.5%	5.7%

Option D: Moderate Per Capita Cap With No Savings/Moderate DSH Hit		
Total Savings	-10.2	-16.2
Total Savings in FY 2002	-4.6	
<u>Savings From:</u>		
Per Capita Cap*	0.0	0.0
Net DSH Savings	-10.2	-16.2
Resulting Per Capita Growth Rate	4.8%	5.0%
*Growth Index of Per Capita Cap	6.0%	6.0%

¹ Growth rates for the five-year total are measured from FY 1997 - 2002.

² Growth rates for the six-year total are measured from FY 1997 - 2003.

Health Care Coverage Initiatives

	Coverage by End of 2000	Cost in FY 02	5 Year Cost (FY 98 - 02)
Kennedy Kids' Package (75 cent cigarette tax)	6 to 7 million children	\$8 to \$9 billion	\$24 billion
1. Workers' In Between Jobs	700,000 children (2.3 million adults)	\$3 billion	\$3 billion*
2. Expanded Medicaid Outreach (Not likely to be included in the budget)			
A: 33% success rate	1 million children	\$736 million	\$2.4 billion
B: 66% success rate	2 million children	\$1.5 billion	\$4.7 billion
3. Enhanced State Partnerships	1.5 million children	\$750 million	\$3.75 billion
4. 12 Month Eligibility Option	1.25 million children	\$1.1 billion	\$3.5 billion

Note: All numbers are based on preliminary HHS estimates and are subject to change.

* There is no increase in the five-year number for this initiative because the current budget tables are carrying financing for this package from FY 98 - 01.

Health Care Coverage Packages

Package	Coverage by End of 2000	Cost in FY 02	5 Year Cost (FY 98 - 02)
A. Includes: *Workers' In Between Jobs; *Expanded Medicaid Outreach (66% success rate); *Enhanced State Partnerships; & *12 Month Eligibility Option.	2.3 million adults 5 million children	\$6.4 billion (\$4.9b in budget)	\$15 billion (\$10.3b in budget)
B. Includes: *Workers' In Between Jobs (less FY 02 financing); *Expanded Medicaid Outreach (66% success rate); *Enhanced State Partnership; & *12 Month Eligibility Option.	2.3 million adults 5 million children	\$3.4 billion (\$1.9b in budget)	\$12 billion (\$7.3b in budget)
C. Includes: *Workers' In Between Jobs (less FY 02 financing); *Expanded Medicaid Outreach (66% success rate); & *Enhanced State Partnerships or 12 Month Eligibility Option.	3.5 million children	\$2.3 to \$2.6 billion (\$0.8b to \$1.2b in budget)	\$8.3 to \$8.5 billion (\$3.6b to \$3.8b in budget)
D. Includes: *Workers' In Between Jobs (less FY 02 financing); *Expanded Medicaid Outreach (33% success rate); & *Enhanced State Partnerships or 12 Month Eligibility Option.	2.0 to 2.5 million children	\$1.5 to \$1.8 billion (\$750m to \$1b in budget)	\$5.9 to \$6.1 billion (\$3.5b to \$3.7b in budget)

Note: All packages are based on preliminary HHS estimates and are subject to change. There is likely to be some double counting. However, the 1 million children expansion that is already in the baseline should act as a rough offset.

December 18, 1996



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Barry Clendenin

TYPE OF DELIVERY:

HOTBOX *OVERNIGHT* _____ *Attached cc: Sarah Bianchi* _____

With informational copies for:

Subject: Medicare Presentation
Materials

From: HFB

Phone: 202/395-4922

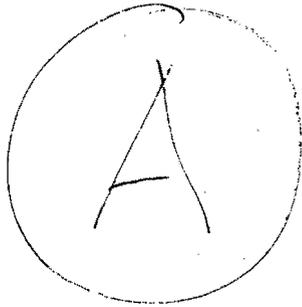
Fax: 202/395-3910

Room: NEOB #7025

As discussed, we have attached the material's for the meeting with the President.

Tab A: Yesterday's recommended package (slightly revised to correct a growth rate estimate and provide a breakout of the Part A savings), with a 5-year total of \$114 billion, a 6-year total of \$157 billion and a 2002 total of \$38 billion.

Tab B: Today's recommended package with a 5-year total of \$99 billion, a 6-year total of \$138 billion and a 2002 total of \$35 billion.



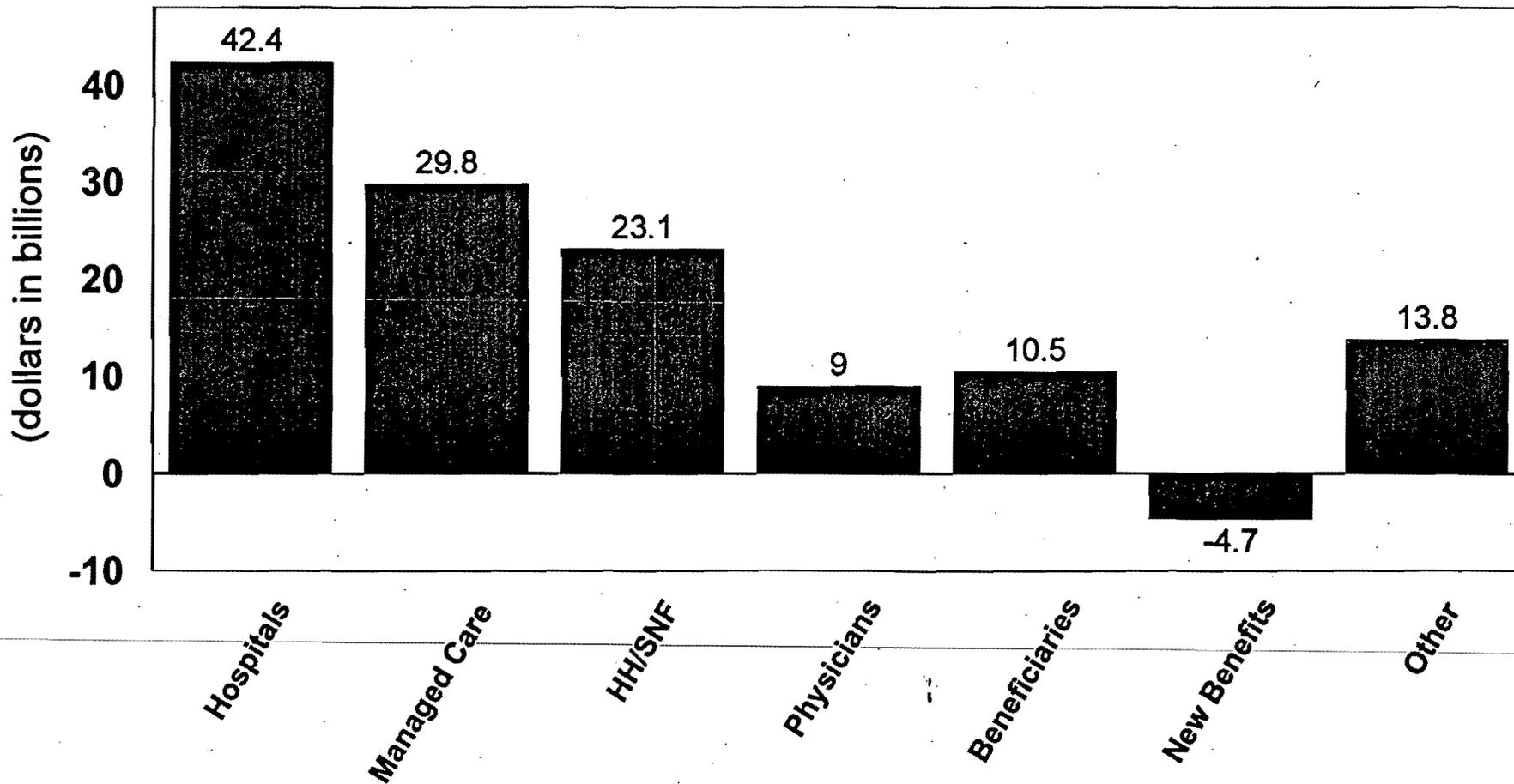
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Composition of FY1997 Budget Package Savings

- Proposed \$124 billion in savings over 1997-2002 (\$36.9 billion in 2002)
- Extended HI trust fund insolvency to FY 2006
- Major Policies
 - Reduce payments to hospitals, managed care plans, physicians and other providers
 - Implement prospective payment for home health and skilled nursing
 - Maintain the Part B premium at 25 percent of total Part B costs

Composition of Savings in FY 1997 Budget (1997-2002)

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Composition of FY1997 Budget Package Structural Reforms

- Common to both plans
 - Prospective payment for HH/SNF
 - Provider-sponsored organizations
 - Reduction in geographic variation in managed care payments

 - Policy differences
 - Medigap community rating (1997 PB)
 - Outpatient PPS (1997 PB)
 - Extra billing (GOP)
 - Medical savings accounts (GOP)
 - Income-related premium (GOP)
-

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Composition of FY1997 Budget Package New Benefits

- Mammography
 - Respite care
 - Colorectal and diabetic screening
 - Flu shot administration
-

DRAFT

Recommended FY 1998 Budget Package Savings

- Achieves \$114 billion in savings over 1998-2002 (\$38 billion in 2002)
- Extends the HI trust fund insolvency date to early FY 2007
- Includes all FY 1997 Budget Proposals (including structural reforms, new benefits and savings) with the following major modifications:
 - Income-related Part B premium
Introduces fairness into Part B financing
 - Managed care payment reform
Corrects systematic overpayment in current methodology
 - Lower magnitude of hospital savings

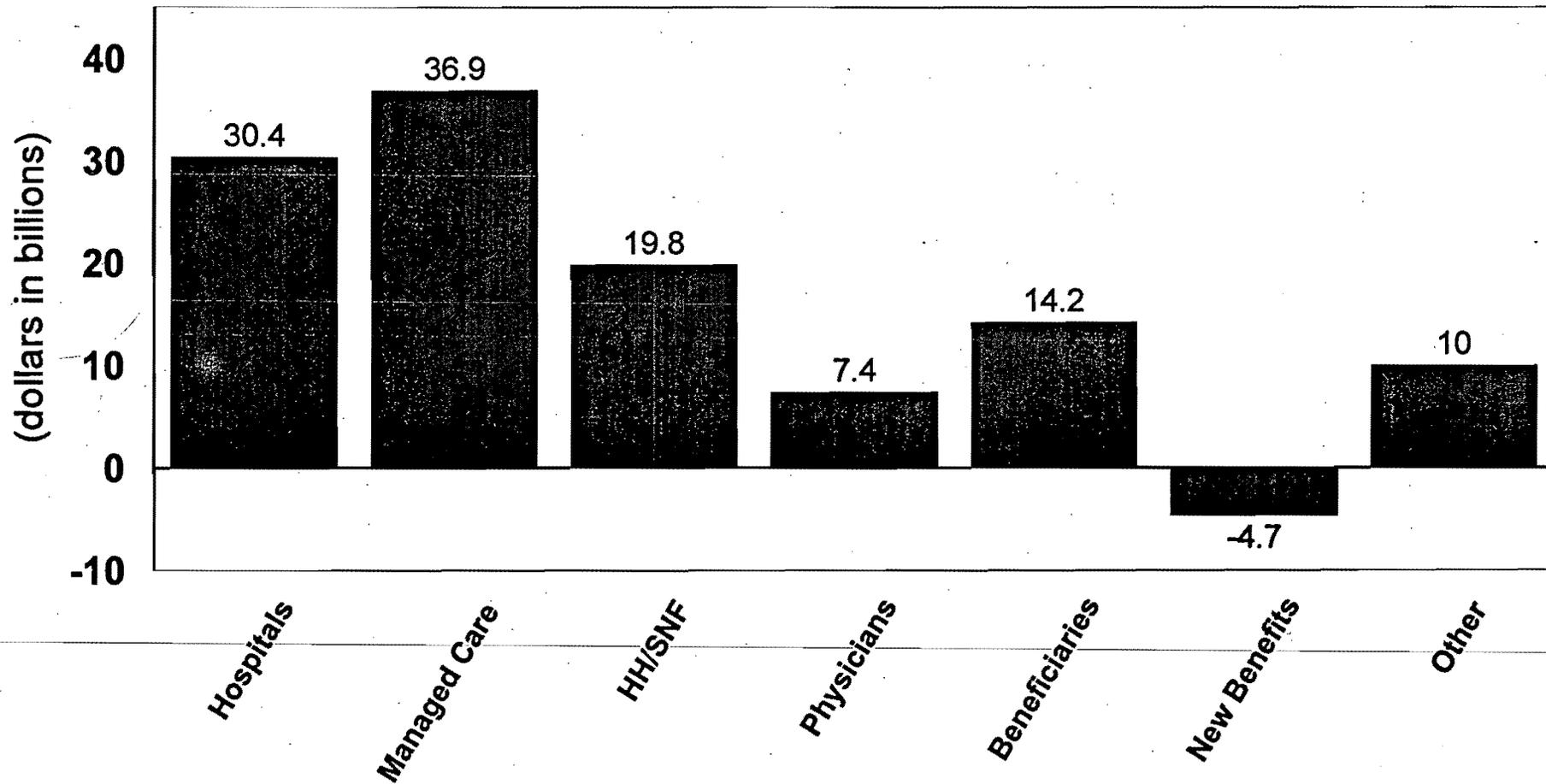
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Recommended FY 1998 Budget Package Savings (con't)

- Competitive bidding for labs and medical equipment
Introduces market forces to determine payment levels
 - Repeals objectionable advisory opinion and anti-kickback provisions from Kassebaum/Kennedy legislation
-

Composition of Savings in Recommended Package (1998-2002)

DRAFT



Contributions to HI Trust Fund Solvency

DRAFT

<u>FY 1997 Budget</u>	<u>1997-2002</u>
Part A savers	\$97
Income-related premium	n.a.
Home health shift	\$69
Total	\$166
<u>FY 1998 Budget</u>	<u>1998-2002</u>
Part A savers	\$81 billion
Income-related premium	\$0 billion
Home health shift	\$79 billion
Total	\$161 billion

* Totals may not add due to rounding

Savings Comparison: 5 and 6 Year Savings

DRAFT

- **Savings in the Recommended Package vs. Republicans: 5-Year Savings.** The recommended Medicare package would save \$114 billion over 5 years (FY98-02), while the most recent detailed Republican plan would have saved \$114 billion over 5 years (FY97-01).
- **Savings in the Recommended Package vs. Republicans: 6-Year Savings.** The recommended Medicare package would save \$157 billion over 6 years (FY98-03), while the most recent detailed Republican plan would have saved \$167 billion over 6 years (FY97-02).

	Savings		Growth Rate (gross per capita spending)	
	5 years	6-years	FY 97-02	FY 97-03
Recommended Package	\$114 billion	\$157 billion	4.7%	5.1%
Last detailed Congressional Offer ¹	\$114 billion	\$167 billion	4.6%	4.7%

¹These numbers are based on the Senate Chairman's Mark of the FY 1997 Budget Resolution. This is the most recent Congressional plan with sufficient detail to make the required estimates.

Savings Comparison: FY 1998-2003 Savings

DRAFT

- **Savings in the Recommended Package vs. the Republicans: Comparable Periods.** Over the period FY 1998-2003, the Republican plan would have saved over \$200 billion. The recommended package saves \$157 billion over this period.
 - **Savings in the Recommended Package vs. the FY 1997 Budget: Comparable Periods.** Over the period FY 1998-2003, the Medicare savings package in the FY 1997 Budget would have saved \$160 billion. The recommended package saves \$157 billion over this period: slightly *less* than the FY 1997 Budget.
-

B

Composition of FY1997 Budget Package
Structural Reforms

DRAFT

- Common to both plans
 - Prospective payment for HH/SNF
 - Provider-sponsored organizations
 - Reduction in geographic variation in managed care payments

- Policy differences
 - Medigap community rating (1997 PB)
 - Outpatient PPS (1997 PB)
 - Extra billing (GOP)
 - Medical savings accounts (GOP)
 - Income-related premium (GOP)

Composition of FY1997 Budget Package
New Benefits

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- Mammography
- Respite care
- Colorectal and diabetic screening
- Flu shot administration

124
~~138~~
145
over 64

BS

~~Recommended~~ FY 1998 Budget Package
Savings

DRAFT

124

- Achieves \$99 billion in savings over 1998-2002 (\$35 billion in 2002)
- Extends the HI trust fund insolvency date to early FY 2007
- Includes virtually all FY 1997 Budget Proposals (including structural reforms, new benefits and savings) with the following major modifications:
 - Income-related Part B premium
Introduces fairness into Part B financing; revenue transferred to Part A trust fund
 - Managed care payment reform
Corrects systematic overpayment in current methodology
 - Lower magnitude of hospital savings

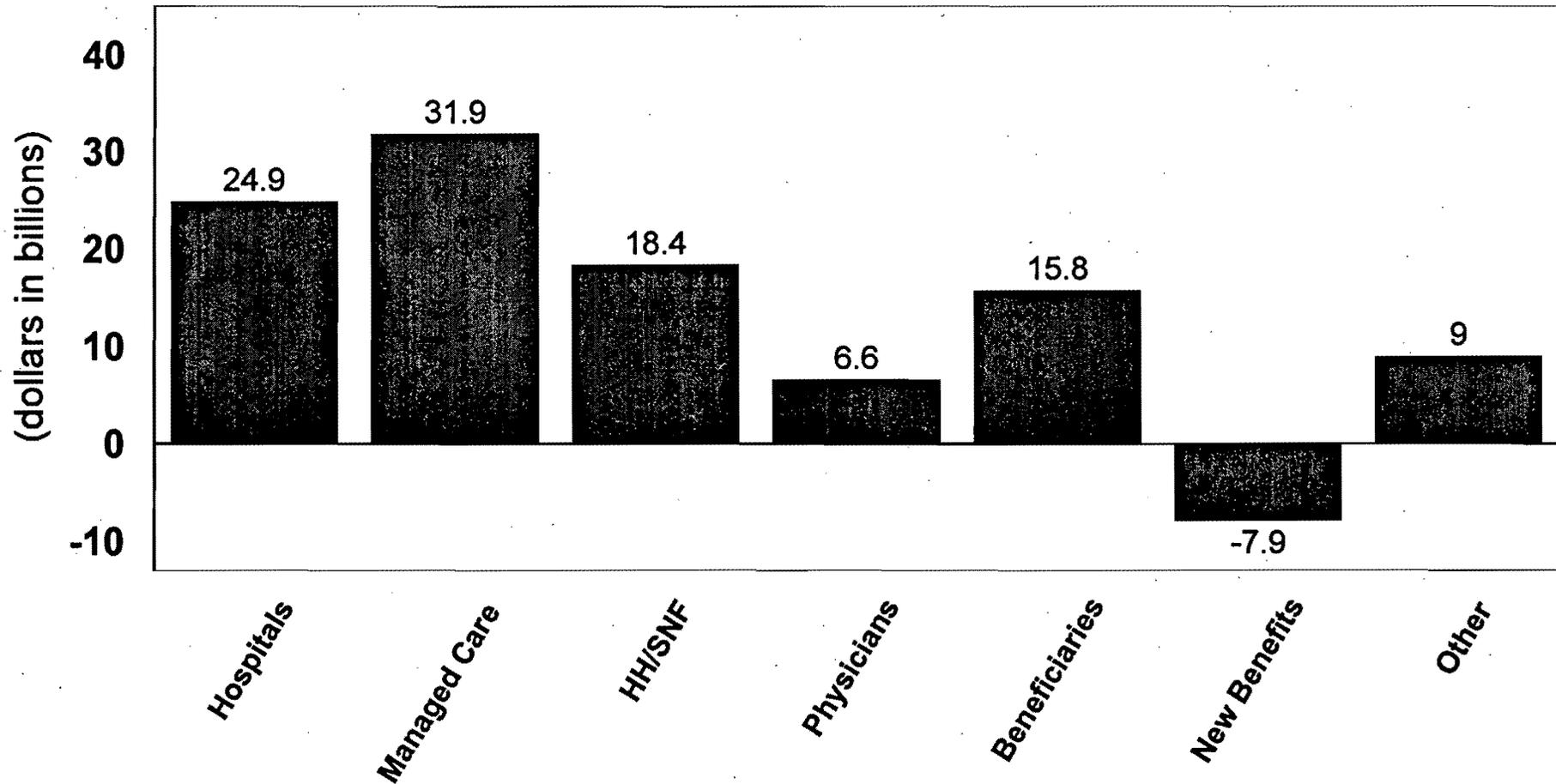
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Recommended FY 1998 Budget Package Savings (con't)

- Competitive bidding for labs and medical equipment
Introduces market forces to determine payment levels
- Repeals objectionable advisory opinion and anti-kickback provisions from Kassebaum/Kennedy legislation
- Earlier start date for respite benefit and higher payment rate for end-stage renal disease facilities

Composition of Savings in Recommended Package (1998-2002)

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Contributions to HI Trust Fund Solvency

<u>FY 1997 Budget</u>	<u>1997-2002</u>
Part A savers	\$97
Income-related premium	n.a.
Home health shift	\$69
Total	\$166

<u>FY 1998 Budget</u>	<u>1998-2002</u>
Part A savers	\$73 billion
Income-related premium	\$5 billion
Home health shift	\$79 billion
Total	\$157 billion

124
Part A
Part B

Part A
- publisher

Part B options
High low
Full time base 17

New to new low

Address
Trust Fund

Savings

Savings Comparison: 5 and 6 Year Savings

DRAFT

- **Savings in the Recommended Package vs. Republicans: 5-Year Savings.** The recommended Medicare package would save \$99 billion over 5 years (FY98-02), while the most recent detailed Republican plan would have saved \$114 billion over 5 years (FY97-01).

- **Savings in the Recommended Package vs. Republicans: 6-Year Savings.** The recommended Medicare package would save \$138 billion over 6 years (FY98-03), while the most recent detailed Republican plan would have saved \$167 billion over 6 years (FY97-02).

	Savings		Growth Rate (gross per capita spending)	
	5 years	6-years	FY 97-02	FY 97-03
Recommended Package	\$ 99 billion	\$138 billion	4.9%	5.3%
Last detailed Congressional Offer ¹	\$114 billion	\$167 billion	4.6%	4.7%

¹These numbers are based on the Senate Chairman's Mark of the FY 1997 Budget Resolution. This is the most recent Congressional plan with sufficient detail to make the required estimates.

Savings Comparison: FY 1998-2003 Savings

DRAFT

- **Savings in the Recommended Package vs. the Republicans: Comparable Periods.** Over the period FY 1998-2003, the Republican plan would have saved over \$200 billion. The recommended package saves \$138 billion over this period.
- **Savings in the Recommended Package vs. the FY 1997 Budget: Comparable Periods.** Over the period FY 1998-2003, the Medicare savings package in the FY 1997 Budget would have saved \$160 billion. The recommended package saves \$138 billion over this period: *less* than the FY 1997 Budget.

THE WHITE HOUSE
WASHINGTON

August 16, 1996

MEMORANDUM TO THE PRESIDENT

FROM: Carol Rasco and Laura Tyson

SUBJECT: Health Care Policy Achievement and Initiatives Update

You may want to highlight health care reform achievements and unveil "next-step" initiatives concurrent with, or soon after, the signing of the Kennedy-Kassebaum bill and the Democratic Convention. This memo outlines: **Health Reform Achievements, Pending Proposals, and New Reform Options.** These could be highlighted as part of any major health message.

I. Health Reform Achievements: Because the Health Security Act was not enacted, there has been a perception that the Administration has had few health care achievements. As the following summary attests, this perception is a mistaken one. The enactment of the Kennedy-Kassebaum bill and a more forceful effort to highlight our achievements will help turn this perception around. In the first term, you have:

- **Passed portability, guarantee issue and guarantee renewal insurance reforms.** In response to your State of the Union challenge, the Congress finally passed long-overdue insurance reforms that will benefit as many as 25 million Americans. As a result, workers will no longer be locked into "second-choice" jobs because their (or their families') pre-existing condition make them live in fear of losing health insurance. Similar insurance reform provisions were included in the Health Security Act and your balanced budget proposals.
- **Eliminated the discriminatory tax treatment of the self-employed.** You have advocated eliminating or reducing the 100 percent vs. 30 percent disparity between large employers and the self-employed for years (the 1992 Campaign, the Health Security Act, and your two balanced budget proposals). The Kennedy-Kassebaum bill increases the deduction to 80 percent for the 3 million self-employed Americans now purchasing health care, (which is close to parity since most employers do not pay for more than 80 percent of their employees' premiums).

- **Strengthened fraud and abuse prevention and enforcement initiatives.** The Kennedy-Kassebaum legislation included provisions long sought by Secretary Shalala that strengthen our ability to target and prosecute "bad apple" health providers who are bilking the system of billions of dollars from Medicare, Medicaid, and private insurance. The bill expands penalties and provides for permanent funding to build on our already successful efforts to combat fraud. The Congressional Budget Office conservatively estimates that these provisions will save over \$3 billion.
- **Provided tax incentives for private long-term care policies and consumer protections to go along with them.** The Kennedy-Kassebaum bill included the tax clarifications for private long-term care policies and many of the basic consumer protections that were in the Health Security Act. These provisions should increase the sales of private long-term care policies, which should reduce future financial burdens on our public programs caused by an fast aging population.
- **Provided the tools to simplify the health care system and reduce paperwork, while still protecting the privacy of patient records.** The Kennedy-Kassebaum bill included provisions you have long called for that would modernize, streamline and cut the costs of insurance paperwork by providing standards for a common electronic system for paying health claims that most private insurers would use. The bill also provides the Secretary the authority to establish Federal privacy protections that would prohibit inappropriate disclosure of information.
- **Strengthened Medicare Trust Fund by 3 years.** Your 1993 economic package included policy and structural changes that extended the life of the Trust Fund by three years and were enacted without one Republican vote.
- **Preserved and protected the Medicaid guarantee of health coverage, while providing more flexibility to states to expand coverage.** You successfully defeated the Republican Leadership's proposal to block grant the Medicaid program, thus assuring that millions of vulnerable Americans would not lose guaranteed health care coverage or benefits. At the same time, you presided over the rapid approval of 12 thoughtful Medicaid waivers that, when completely implemented, will provide health coverage to 2.2 million previously uninsured Americans.
- **Contributed to getting health care inflation under control.** Your efforts to assure that all Americans have affordable, quality health care focused the nation's attention on the problem of health costs. This attention expedited the private sector's interest in implementing approaches to slow cost growth. This, along with the improvements in the economy, helped slow medical inflation to 3.9 percent in 1995 -- the lowest rate in 23 years. In the first 6 months of 1996, medical inflation is running at less than 2 percent and may actually grow below the general inflation rate for the year.
- **Increased investment in biomedical research at the National Institutes of Health (NIH) by an impressive 16 percent at a time when many other programs were being cut.** Funding for breast cancer research at NIH has increased by 76 percent and support for AIDS research funding has increased by 25 percent.

- **Funding for AIDS prevention and treatment has been increased to historic levels.** Support for AIDS prevention programs has increased by 19 percent, and support for treatment programs, primarily through the Ryan White Care Act, has increased by an extraordinary 95 percent. In addition, earlier this year, the Congress responded to your request to increase the Federal commitment to the State AIDS drug assistance programs (ADAP) by \$52 million. This funding will be used to help AIDS patients buy expensive, new protease inhibitor drugs. Combined with the increases in our AIDS research investment, total funding for HIV/AIDS programs in fiscal year 1996 was \$2.86 billion; this represents a nearly 40 percent increase since you took office.
- **Established a comprehensive childhood immunization initiative to ensure vaccinations and healthy futures for all children.** The proposal includes: a major community-based outreach effort to educate parents and providers about the need for vaccination; better detection of vaccination levels and outbreaks of infection; and a standardized immunization schedule to make it easier for parents to know when vaccinations are due. This program contributed to the immunization rate of 75 percent of 2-year old children in 1995 -- an historic high.
- **Expedited the FDA review and approval of new drug products.** U.S. drug approvals are now as fast or faster than in any other industrialized nation. Average drug approval times have dropped since the beginning of the Administration from almost three years to just over one year. In 1997, virtually all breakthrough drugs will be approved within 6 months.
- **Protected kids from tobacco products and advertising.** Issued a proposed regulation to eliminate easy access to tobacco products by children and to prohibit companies from advertising to make tobacco appealing to kids. The goal is to reduce smoking by children by 50 percent within seven years after the plan goes into effect.
- **Increased funding for the VA health system by nearly two billion dollars.** This support will provide the resources necessary for the treatment of 94,000 more veterans.
- **Significantly reduced the regulatory burden of the Department of Health and Human Services for providers and consumers.** The Vice President's reinventing government initiative has resulted in the elimination of 1,600 pages of regulations, a 23 percent reduction.

II. Currently Pending Health Care Proposals: Unnoticed by much of the public, you unveiled an extraordinary number of substantive health reform proposals which in any other Congress would have been viewed as aggressive and quite ambitious. No other President has put as many public (Medicare and Medicaid) health savings dollars on the table, and no other President has proposed to so significantly alter and modernize the Medicare and Medicaid programs. However, relative to the Republican proposals, your proposals have been mistakenly viewed by the media (and thus the general public) as modest. Despite the fact that anyone who knows these programs knows better, the media has either ignored your proposals or has chosen to classify them as protecting the status quo.

We have never strongly promoted the private insurance reform initiatives you advocated that go beyond the Kennedy-Kassebaum bill because we feared they had the potential to undermine our Hill negotiations on the bill. The good news about this is that these initiatives will appear to be new to the public and the media, and -- with the exception of the \$1 billion over seven years mental health parity initiative -- they are paid for in the context of your previous omnibus balanced budget proposals. Your major currently pending proposals include:

- **Extending the life of the Medicare Trust Fund until 2006.** Your Medicare savings (\$124 billion/CBO estimates it to be \$116 billion), combined with the home health care expenditure transfer (previously passed by the House), extends the Trust Fund for ten years from today while also making a significant deficit reduction contribution. It is a responsible savings package that would hold the Medicare per person growth rate just under what CBO numbers assume is equivalent to the private sector growth rate. [NOTE: Because the Medicare baseline is increasing, we may be able to squeeze more savings from the program in next year's budget.]
- **Modernizing the Medicare program and beginning to prepare it for the retirement of the baby boom population.** Your Medicare plan would increase choice of plans for beneficiaries (by adding a new Medicare Preferred Provider Organization option, a new Provider Sponsored Organization alternative, and a new HMO with a point-of-service option). It also would add important and potentially cost-effective preventive benefits (by providing for full coverage of mammography screenings, adding a colorectal screening benefit, and providing for diabetes case management.) It takes the first step toward providing for a long-term care benefit by establishing a respite benefit for families of Medicare beneficiaries afflicted with Alzheimer's Disease. Lastly, it includes a number of market-reform-oriented "competitive-bidding" initiatives that would make Medicare a more prudent and effective purchaser of health care services.
- **Liberating the states in their desire to have more flexibility to manage Medicaid.** Your Medicaid proposal (which provides for \$59 billion/CBO estimates \$54 billion in deficit reduction through a per person cap) would eliminate the burdensome waiver process for managed care, eliminate the waiver process for home and community-based care alternatives to institutionalization, and eliminate the Boren requirement. It would also make it easier for states to spend money in an attempt to expand coverage. [NOTE: Because the Medicaid baseline is declining, the fiscally aggressive policy we are now advocating would likely be scored lower on both the CBO and OMB baseline next year; in other words, it will be difficult to get the same deficit contribution from Medicaid next year.]
- **Building on Kennedy-Kassebaum by providing for a "Workers' Transition Insurance" benefit.** This proposal would help assure that previously insured people who are looking for a new job could afford to keep their health insurance and thus retain their portability protections. It would cost about \$2 billion a year, would annually help approximately 3 million temporarily unemployed Americans, and would illustrate our resolve to still expand coverage within a balanced budget context.

■ **Empowering small businesses to gain market-leverage to access more affordable insurance through the use of voluntary health purchasing cooperatives (HPCs) by providing access to FEHBP plans, overriding restrictive state laws, and giving financial assistance for the establishment and operation of HPCs.** We have been studying a series of options about how best to use the FEHBP and the limited political and financial resources we have available to empower voluntary HPCs to purchase more affordable, accessible health insurance for small businesses.

Based on extensive conversations with public and private sector insurance analysts, we continue to believe that, in the absence of universal coverage, the potential for serious risk selection is too great to recommend that FEHBP's current insurance pool be opened to other purchasers. Since the Kennedy-Kassebaum bill does not include rating/price bands, there will continue to be significant premium price variation in the insurance market. As a result, a health plan that charges average premiums for larger populations -- like FEHBP -- would become a magnet for poor risk employers who are currently charged higher than average premiums in the market place. This would increase FEHBP plan costs as well as Federal employee hostility towards us. If we held Federal employees harmless, this could significantly increase the Federal costs of running FEHBP. Whether the Government picked up these costs or not, opening up the FEHBP insurance pool would attract extremely loud Government union opposition.

The risk selection issue could be addressed by requiring OPM to administer a separate insurance pool in FEHBP for the non-Government employees. While this could be done, we are hesitant to recommend this option primarily because we are skeptical that OPM could administer an effective FEHBP alternative without a significant and politically risky infusion of money and talent. Second, based on what people in the field are telling us about what is actually happening in the marketplace, it seems much more likely that private, locally-administered HPCs (perhaps certified by the state) are better positioned to negotiate more effectively than an OPM employee who has little knowledge of plan rates within a particular geographic area. And finally, without a large number of small group enrollees in a particular geographic area, it is highly unlikely that FEHBP would negotiate attractive arrangements with insurers.

Having said this, using FEHBP and other changes to the law to empower small businesses can and should be done. We would suggest that you strongly promote a proposal that would give private or state-run HPCs the ability to require that health plans participating in FEHBP (who also operate in the small market) must also offer coverage (in a separate risk pool) in HPCs. In addition, since one of the greatest hurdles HPCs face in becoming viable is their difficulty in attracting capital for their formation and operation, Federal grants would be made available to either state or private run HPCs who met certain standards (including that they are regulated by the state.) This proposal also would incorporate the Kennedy-Kassebaum purchasing cooperative provisions, which were dropped in conference, that: (1) Override state "fictitious group" laws (which prevent non-associated employers from purchasing insurance together), (2) Allow HPCs to negotiate price reductions even in states where community rating laws would preclude them from doing so, and (3) Allow HPCs to offer the same insurance packages for small businesses that bypass state benefit mandates that the state has authorized other insurers to sell.

- **Providing mental health parity across health insurance products.** The Republican Leadership rejected all attempts by Senator Domenici to come up with a compromise on the mental health parity issue and dropped it from the Kennedy-Kassebaum conference. They would not even support an Administration-endorsed Domenici alternative that dropped all parity provisions other than those related to lifetime and annual caps. This approach reduced the proposal's costs by 90 percent and would have assured that premium increases to pay for this benefit would not exceed .4 percent. This issue may come before the floor of the Senate again this Fall.
- **Protecting mothers and their newborn babies from premature discharges from hospitals.** You endorsed this proposal in your Mothers' Day Radio Address. Similar to legislation sponsored by Senator Bradley, it requires health care plans to allow mothers to remain in the hospital for at least 48 hours. There have been cases where plans have required a discharge within 8 hours of birth. Premature discharge can lead to serious health consequences for both mothers and children. Like the mental health parity provision, this popular initiative may come up for a vote in September.
- **Expanding health care options for older veterans.** This summer you proposed the "Veterans Medicare Reimbursement Project of 1996," a proposal to open the VA system to Medicare-eligible veterans at a number of cities. This measure, sometimes known as Medicare "subvention," would allow VA to receive reimbursement from Medicare, improving access to care for older veterans while lowering VA costs.
- **Contributing to the World Health Organization's initiative to eradicate global Polio by the Year 2000.** This proposal -- advocated strongly by Rotary International -- would increase spending on global polio eradication efforts by \$20 million. The Centers for Disease Control (CDC) has estimated that adequate funding and intervention could achieve the goal of eradication within one or two years. If successful, the United States alone could save more than \$230 million per year after polio eradication is achieved and vaccinations are no longer needed. It appears that your request may well be included in the FY '97 Appropriations bill.

III. Options for New Health Reform Initiatives: There are three additional health care reform issues that we believe merit particular consideration for possible future Administration involvement. The initiatives are: (1) Appropriate oversight over managed care and other health plans; (2) Proposals aimed at providing children with greater access to affordable insurance; and (3) Initiatives designed to provide more independence for people with disabilities. With the exception of the managed care/health care delivery oversight issues, these proposals are quite preliminary and have yet to be formally scored and fully reviewed through normal interdepartmental process.

The public, consumer advocates, health care providers (academic health centers in particular) are increasingly fearing that the cost containment successes of managed care are the result of cuts in quality care, research and training, and questionable financial incentives between insurers and providers. The trick for developing politically viable policy alternatives is to strike the balance between the desire to enhance consumer protections with the need to avoid micromanagement of the health care system. What follows is a package of proposals that we believe achieves the appropriate balance.

Because the House Democratic Leadership and a number of health policy advocates are very interested in children's insurance coverage initiatives, we are also including a range of potential policy options. And finally, we believe that there are a couple of disability empowerment initiatives that are worth seriously considering. As you know, people with disabilities have a heavy reliance on public health programs, particularly Medicare and Medicaid. As a result, since the only way to retain benefits is to stay eligible for SSI and/or SSDI cash benefits, they have overwhelming incentives to not seek gainful employment. In addition, there is a growing frustration within the disability community that the institutional bias of the Medicare and Medicaid programs are also undermining the potential for people with disabilities to be more independent.

- **Building on your managed care/health care insurance oversight record** (mental health parity provisions, 48-hour rule and a recent Medicare/Medicaid regulation to monitor excessive financial incentives for physicians to underutilize health care), **consider becoming active on three visible fronts: (1) sign the "gag" rule; (2) further define the appropriate role of the Federal government in regulating managed care; and (3) develop approaches to protect the academic health center community in this period of unprecedented changes in health care delivery.**

- (1) **Push for and sign the "gag" rule into law.** Consider immediately calling on the Congress to move to pass the "Patient Right to Know Act." In response to concerns about health care plans prohibiting physicians from advising their patients about alternative treatments, Congressman Ganske (R-IA) and Congressman Markey (D-MA) introduced legislation prohibiting any health plan from restricting medical communications, oral or in writing, between health care providers and their patients. This bill was unanimously reported out of the Commerce Committee in late July and may well pass the House prior to adjournment. If you push the Congress, you may ensure that they pass the bill before they leave. OMB and HHS support this provision.

The only possible downside of endorsing the bill is that it will strain our relationship with the managed care community, but even they are now beginning to accept the fact that this bill and the 48 hour rule proposal will likely pass with little to no opposition.

- (2) **Establish an advisory board to make recommendations about the appropriate Federal role in monitoring managed care, assuring quality, and protecting consumers.** Consider establishing a bipartisan working group of public and private appointees (with representatives of consumers, unions, providers, insurers, businesses, and the government) to evaluate the shortcomings of consumer/quality protections/access in managed care and other health delivery systems, and to make recommendations about the appropriate role of government in regulating these plans. You may recall that you and the Vice President discussed a similar initiative with John Sweeney and Gerry McEntee earlier this year. (They are particularly concerned about the impact of managed care on the workforce and would strongly support this proposal.) The Vice President, OMB, HHS and Labor support this initiative.

There are a number of advantages of this route. First, it would be an initiative that illustrates you want to act, but act thoughtfully in this area. Second, if controversial recommendations were made from the perspective of the insurer, managed care, and business community, there would be policy and political cover for proceeding. Third, the fact is we need better information to make thoughtful recommendations that do not unintentionally hurt the positive elements of managed care. And finally, if we are visibly associated with the "gag" rule bill and the 48-hour protection measure, we will have shown our commitment in this area without having to go further at this time.

The disadvantage of this approach is that it may appear we are either ganging up on the industry or, conversely, delaying necessary action. Some proponents of intervention would probably suggest that the delay in the report was nothing more than a stalling mechanism designed to stop necessary intervention.

- (3) **Host a Presidential forum on the impact of managed care on the declining private sector financial contributions for research and training at academic health care centers and on possible approaches to reverse this trend.** The managed care community is being (fairly) charged with not adequately supporting its share of the new health care research that is necessary to sustain the nation's overwhelming lead in health care technology/research. We propose that you consider hosting a "challenge" event to get the managed care and the research community together to engage in constructive conversations about an issue that neither is effectively addressing. The event would be designed to discuss how centers of excellence can produce the type of research HMOs and other managed care plans are interested in seeing and, conversely, how these health plans can better financially support the work academic health centers are undertaking.

There are no disadvantages to this proposal as long as it is not the only managed care oversight initiative you pursue. (If that were the case, it might seem too insignificant a step relative to the perception of problems with managed care.)

● **Consider options that assist children in terms of access, affordability and/or coverage.** We are looking at four options: (1) investments in community health centers and school-based health centers; (2) health care financial assistance through the tax code; (3) premium subsidies; and (4) empowerment of states to design kid coverage programs. Cost and coverage estimates are unavailable, but are expected in short order. However, while all four options would increase access to care and -- to some extent -- affordability, it is clear that only the last two options would significantly increase coverage. Most importantly, with the exception of the modest public health investment outlined in option one, they all will require significant investments -- probably in excess of \$15-\$20 billion over 7 years. Unless we drop some other priority, it is difficult to see "credibly" financing any significant proposal in the context of a balanced budget.

- (1) **Introduce legislation to invest in public health initiatives to expand access to children.** This proposal could be pursued on its own or in addition to any of the other three options. Targeted investments would be made to community health centers and school-based clinics to provide preventive and other services to children. Health centers participating would aggressively undertake outreach activities aimed at signing up eligible children for Medicaid.

The advantages of this proposal are: it builds on an existing system that serves many of the most difficult to reach children; it is cost effective to provide health services in these settings; and it could be achieved with a relatively modest investment. The disadvantages are: it does not significantly increase health insurance coverage; school-based clinics have been controversial because they often provide family planning services, (but any proposal could be targeted at clinics in elementary schools); and States may oppose circumventing their own outreach efforts and undermining the control of their program.

- (2) **Provide tax relief for families purchasing health insurance for their kids.** This proposal, fathered by the House Democratic Leadership, would require all health plans doing business with the Federal government to offer health insurance policies for uninsured children. Working families with incomes below a certain level would be given premium assistance through a tax deduction or credit if their employer does not contribute toward dependent coverage. To keep costs low and to prevent substitution of tax subsidized coverage for employer-sponsored coverage, the subsidy would be set at a low percentage of the premium. As a result, the primary benefactors of this option would be those who already have insurance. Therefore, this proposal can be best described as addressing affordability more than coverage problems.

The advantages of this proposal are: it is easy to administer because it uses the existing structure of the tax system and middle-class families will benefit the most. The primary disadvantage of the proposal is that initial estimates show that few uninsured children would gain coverage.

- (3) **Provide Federal premium subsidy assistance.** This proposal would subsidize families below certain income levels (on a sliding scale) to purchase health insurance for their children. Eligible populations include uninsured and state optional Medicaid children. Because they would receive a full subsidy, the primary benefactors of this program would be lower-income children.

The advantage of this proposal is that it would significantly expand coverage for children. Old estimates projected that 6 million children would receive benefits, although only 2 million children would have been previously uninsured. The disadvantages of this proposal are that it would be costly, inefficient, difficult to administer, duplicative of Medicaid, and would create incentives for employers to drop children who currently have coverage.

- (4) **Empower states to design an innovative program that supplements Medicaid to expand coverage for children.** This proposal would give states a Medicaid per capita amount to expand coverage to children. This could be done by: (a) giving states more flexibility to use different delivery systems, including managed care, without seeking waivers but leaving current benefit rules in place; or (b) allowing even more flexibility by permitting states to require contributions from higher income Medicaid eligibles. Using savings from these premium and cost-sharing requirements, states could expand coverage to additional populations of children. Populations eligible to receive benefits would be uninsured children in low-income working families.

The advantages of this proposals are: it builds on existing state structures; it limits Federal cost to the Medicaid matching amount versus a full premium subsidy; and it gives Governors much desired flexibility to increase coverage for children in working families.

The disadvantages of this proposal are: Although limited to lower-income populations, it will still likely induce some employer dropping of coverage; its cost-sharing requirements would impose burdens on some beneficiaries that have none now.

● **Consider options that increase the independence of people with disabilities,** including breaking the health coverage link to public cash assistance programs and creating more incentives to use home- and community-based services in lieu of institutional care.

- (1) **Unveil a proposal to allow people with disabilities the opportunity to retain, or in return for a sliding scale premium, purchase Medicare or Medicaid.** Because private insurance is often not available or affordable to people with disabilities, many people choose to remain on the rolls rather than take the risk of working and losing coverage. This proposal, which we are designing with the Social Security Administration, would allow disabled social security clients the opportunity to purchase Medicaid or Medicare on a sliding scale as their income from employment rises. The primary potential downside is that this option might create unintended consequences of attracting many more people with disabilities to the subsidized Medicare/Medicaid programs than are currently being served. We are still waiting for final OMB estimates and will obviously rethink this option if it is cost prohibitive.

- (2) **Consider additional ways to reorient the Medicaid program towards home- and community-based care and away from its institutional bias.** The disability community hates the fact that nursing home coverage within Medicaid is defined as a mandatory service, while home- and community-based care services are optional. We are currently evaluating options (that go even beyond your current proposal to eliminate the waiver process for States who wish to implement a home- and community-based service option). We will keep you informed of developments.