ABRIDGED TRANSCRIPT

R.D. Sahl, anchor:

Of all the questions of modern medicine, perhaps none is harder than this. When the enemy is deadly cancer, who qualifies for risky unprudent treatment? And when patients take chances, who should pay? Tonight a leukemia victim fights for health and hope in Massachusetts.

Good evening, I'm RD Sahl in for Margie Reedy. This is Newsnight for Friday, September 24.

In the hospitals of Boston, in fact, around the country, the fight to survive cancer is a daily battle. But this week, the story of one leukemia victim has been front-page news. Average citizens and the state's business elite rallied to the cause and the governor threw his weight into the battle. The subject of all the attention is eleven-year-old David Stewart of Cape Cod. The state's Medicaid program does not cover risky treatments that could be his last hope, but others have come through. Greg Wayland has the story.

Greg Wayland reporting:

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Sahl: The fund-raising for David Stewart goes beyond dollars and small bills. The goal of raising one hundred thousand dollars is in reach but there are questions about why private donors had to step in when Medicaid stepped aside. Lorne Matalon takes a look.

Lorne Matalon reporting:

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Matalon: Last year in Massachusetts, the state received twenty-five hundred requests for emergency medical assistance. Eighty-three percent of those requests were approved. Examples of rejections include requests for breast enhancement and cosmetic surgery.

Dr. Alan Sager of Boston University's School of Public Health studies the politics and economics of health care. He says decision makers at the Division of Medical Assistance should never have to be in the position where they must reject any requests. Sager says state government puts unnecessary constraints on the approval process.
Dr. Alan Sager (Boston University School of Public Health): What we need to do is find a fair and adequate way of paying for experimental treatments as parts of clinical protocol, as parts of research instead of asking for individual, ad hoc, case-by-case decisions. The best way to pay for research is to build in the costs of clinical treatment into every research protocol.

Matalon: Before news of David Stewart's predicament prompted a flood of private donations to cover his cost to travel to the West Coast, Massachusetts Governor Paul Cellucci said that whatever happened, David Stewart's costs would ultimately be covered by the state. He, of course, was reacting to intense media scrutiny of a case that was making headlines. He certainly was not making a policy statement that will apply to others in similar situations.

In Boston, Lorne Matalon, New England Cable News.

Sahl: Our first guest tonight is on the front lines of the battle against cancer. Dr. Lawrence Shulman is an oncologist at the Dana Farber Center. Thanks for joining us tonight.

Dr. Lawrence Shulman (Dana Farber Cancer Institute): Thank you for having me.

Sahl: What I'd like to do to begin this--this--this broadcast this evening is--is take a look at some basic definitions here. This little boy has something--has--called acute myeloid leukemia, AML. What is it?

Shulman: AML is a cancer of the white blood cells. It affects the bone marrow in your blood. It's one of two types of acute leukemias. The other type is acute lymphoid leukemia which is the most common type in children and curable on about seventy to eighty percent of children.

Sahl: How do you treat AML?

Shulman: AML is treated generally with standard chemotherapy. In some circumstances, that will be curative. In circumstances where it's not, a bone marrow transplantation is considered as an option. But that also will not cure all the people with acute myeloid leukemia and there are times when we need to turn to new therapies.

Sahl: Now this--this young man, his parents want to take him to Seattle to the Hutchinson Research Center for clinical trials of a drug called CMA-676 which is an anti-body targeted chemotherapy. What does that mean?

Shulman: Well, most of the chemotherapy that we administer to patients now we give intra--into the vein, intravenously and it goes everywhere and you get it in your liver, in your lungs and your bone marrow and all the normal tissues of your body.

Sahl: So in addition to poisoning the cancer cells, you poison everything else?

Shulman: Right, right. There are a number of treatments that are now available, some of which are FDA approved, other of which are investigational
where the toxic substance, whether it's chemotherapy or a radiation molecule, are attached to an antibody that detects the cancer cell specifically and takes whatever that poison is, the chemotherapy or the radioactive molecule, just to the cancer cell and spares the rest of the body.

Sahl: Thus the word targeted. So this is a phase one clinical trial. What does that mean?

Shulman: Well, the way we develop new treatments for any disease is we develop a molecule or a new chemical in the laboratory. We test it against tumors in the laboratory, first in mice, then often in other animals. We test its safety in other animals, but eventually we need to bring it into the clinic and try it in human beings. And we've learned from our experience that not everything occurs in the clinic as it does in the laboratory...

Sahl: Right.

Shulman: ...that sometimes medicines have toxicities we didn't anticipate. Some medicines we thought would work very well don't work and vice versa. We do phase one trials to determine really how to safely give the medicine. A medicine we hope will be effective for a particular disease but we don't yet know how human beings will tolerate it.

Sahl: All right.

Shulman: That's—that's the first stage of developing new medicine.

Sahl: There we have some basic definitions. Stay—stay with us, Dr. Shulman. Let's bring in Dr. Alan Sager. We saw you in one of our set-up pieces this evening. Dr. Sager's a health policy analyst with the BU School of Public Health. So is a substance that is used in a clinical trial an experiment or is it a treatment?

Sager: I would call it an experimental treatment without quibbling about it. The question is if we're going to make medical advances, all the different clinical trials and therapeutic experiments have to be evaluated. We have to learn whether the new way is better than the old way. Someone has to pay for it. And the only question is which pocket do we take the money out of? Do we take the money out of the National Institutes of Health pocket, the Medicare pocket, the Medicaid pocket, the Blue Cross, the Harvard Pilgrim, the Tufts pockets? Or do we have—or we do establish a new pocket?

Either way, the best method of paying for the clinical trial is the one that gives us the least pain, gives families a fair shot at experimental treatments and avoids the kind of process we've seen over the last week of turning a family's human difficulty and personal tragedy into soap opera on television.

Sahl: Dr. Shulman, in—in a clinical trial, the drug company that wants to test whatever substance it is, picks up a lot of the cost here, does it not?

Shulman: Yes, that's correct?
Sahl: And pays for the drug, the administration of the drug.

Shulman: Yes.

Sahl: And as I understand it, the--the nearly one hundred thousand dollars we're talking about in this case was basically for the likelihood of post-treatment possibilities, hospitalization, additional drugs and so on.

Shulman: I think one of the important things to understand is that this boy, as the case with all of our patients, has their disease whether they get this treatment or not. There are lots of standard medical costs that they will incur because of their illness. They'll have some treatment and what we need to do is to find the most effective treatments and develop new treatments.

But there's a lot of standard costs involved in the care of anybody with cancer as well as this boy and that, I think, should be covered by standard insurers.

Sahl: Now, by comparison, I was told today that a bone marrow transplant--the costs can run two hundred to three hundred thousand dollars.

Shulman: It depends on the type of transplant and, you know, whether there are complications or not, but certainly most of the bone marrow transplants we do for leukemia probably run between a hundred and two hundred thousand dollars.

Sahl: Dr. Sager, the--this--this notion of--of who pays here. If--if we pay for experimental treatments, is there somebody else who suffers by not being able to get an established treatment?

Sager: Well, not necessarily. It depends on how we do it. Right now in the United States, we're spending 1.2 trillion dollars on health care. In Massachusetts, thirty-six billion dollars. That's six thousand dollars per person every year for health care. We can find the most money to--inside the--we can find the money in dollars we're already spending to pay for evaluation of new treatments. If we don't evaluate new treatments, we're flying blind and health care becomes some huge dinosaur with a tiny little brain and huge body wandering around the countryside tossing money recklessly. We can't have that. We have to find out what works and we have to invest in that. We probably don't spend enough, measuring what care really works, for whom and whether it's worth the money.

Sahl: Need to take a break here--a lot more to talk about. For example, how are these decisions made? How should that decision-making process be changed? We'll talk about some proposed legislation (unintelligible). This is Newsnight.

(commercial break)

Sahl: The story of eleven-year-old David Stewart's fight against leukemia could have implications for a bill at the Massachusetts Statehouse. The legislation is backed by the American Cancer Society. Here to talk about it
is Lori Fresina, the Cancer Society's director of governmental affairs. Thanks for coming by tonight.

Lori Fresina (American Cancer Society): Thanks for having me.

Sahl: Tell us about this bill. What does it do?

Fresina: House Bill 2916 will require private insurers to pay for routine patient care costs for patients who are part of a clinical trial. Studies...

Sahl: Exactly the costs that are being talked about in this case.

Fresina: Actually, the bill as it was written would not include Medicaid but the sponsor of the bill, John Stefanini, who's a representative from Framingham, is speaking with House leadership right now to amend that. It was a technical decision in the beginning to wait and do the Medicaid coverage after the fact because getting--getting managed care sort of in line on this was a priority and then moving to Medicaid where we would have some evidence to bring to the Medicaid board seemed like the--the best strategy at this point.

Sahl: But, as initially written, the--the--the scope of this was limited to private insurers, not...

Fresina: Right, that's correct.

Sahl: And, specifically, because in the age of managed care, they were covering these sorts of things less and less.

Fresina: Less and less with every year. It's become--there's become just a obviously greater strain on the dollars in managed care. I think we see it every day and Medicaid ti--typically tends to be the last to fall in line in terms of coverage of--of most of the benefits that we're dealing with and that was just a strategic decision, although in light of David Stewart's case, there seems to be great energy on Beacon Hill to revisit that and have it amended.

Sahl: Any models for this legislation in place...

Fresina: There actually--the Massachusetts bill is based on the Maryland law which became effective in January of 1999 which is considered the gold standard in the country which is why we stole it and basically translated it into Massachusetts vernacular. It's considered the best and we want it here. I think five other states also have clinical trial legislation.

Sahl: And then there's federal legislation pending as well.

Fresina: There's federal legislation pending having to do with Medicare and clinical trails coverage and that's another bill that the American Cancer Society on a national level is sponsoring. Again, it remains to be seen whether that's going to pass and we didn't want to wait here, particularly with such a rich research community, for the federal government to step in and
Sahl: Now, Alan Sager, what—what is the case here for state-mandated coverage of clinical trials?

Sager: Well, if the federal government isn’t going to act, and in most parts of health care, the federal government is largely paralyzed, why not try it at the states? Just as Brandeis always called the states the laboratories of democracy and let’s try different things in different states to see what works. On the downside, if the state passes legislation, it doesn’t cover more than half the working people in the state because the federal government preempts certain state decisions and prohibits the state from acting, similar to the way the—the state was not able to compel HMOs to provide unlimited prescription drug benefits to seniors.

Sahl: Dr. Shulman, certainly one of the things that makes this story so compelling and so troubling is—is the conflict inherited. I mean, what parent would not want to do whatever you thought you could do to try and save your child’s life? And—and yet you’ve—it becomes a public policy issue. The state says that the initial no ruling in this case was made by a doctor, was not an issue of money, was, in fact, a medical determination.

Shulman: Well, I would have to take—I would have to disagree with that and I disagree with it for a couple of reasons. The program that’s in question here is a program that’s been well thought out. It’s been—it’s being run by one of the premiere research institutions in the world. It’s a place where we’ve developed many of our curative treatments for leukemias and other diseases in the past and this is another chance to be able to cure people who today we can’t cure. I think it gives the patient the opportunity to have state-of-the-art care. It gives the medical facility the chance to develop new and more curative therapies. And I think those both are really key.

Sahl: Does it raise the cost of health care and health care insurance, Lori Fresina?

Fresina: Actually, though, the studies that have been done, including a large one out of the Mayo Clinic, shows that—that legislation like this would make it cost substitutive and not cost additive. The incremental increase in terms of total health care in—cost increase to the insurer is nominal, if at all. Some—some studies have shown there’s absolutely no increase in cost.

Sahl: And I suppose part of the argument here as well is that if—if the treatment actually works, then potentially you reduce the cost for other patients down the road.

Fresina: Exactly.

Shulman: And you return somebody to—as a healthy member to the society and there’s nothing more important than that.

Sahl: Yeah. Alan, you were saying or about to.
Sager: If you're a gardener—if you're a gardener, you have to spend time getting the weeds out with a hoe or on your hands and knees. In health care, we have to go through all of the old treatments that have never been evaluated and find out whether they really work. If we discredit some of those, we'll save lives and we'll save money at the same time. We have to invest more in health care. When you're spending 1.2 trillion dollars, you've got to invest more in finding out what really works.

Sahl: Where do you--where do you draw the line here or--or do you draw a line? What is--how far do you take this? If--if someone comes up and says, look, the traditional therapy hasn't worked in--in your particular case, but I have good reason to believe that I know of a place where they're doing some trials, that if you--sort of a pyramid under bright lights, that everything will be all right. Where--where do you draw the line?

Shulman: Well, I think that the legislation that's been passed in other states and is pending here in Massachusetts, regulates the types of clinical trials that will be covered. Not any clinical trial done by anybody anywhere in the state will be covered. They have to be trials that are done under the auspices of research institutions which are working with the National Cancer Institute or the National Institutes of Health under careful scrutiny. So there is good intellectual and patient safety control of which trials would be covered.

Sahl: Lori Fresina.

Fresina: I--I agree. I think that's it. It's--it's actually a very conservative bill that we're pursuing here in Massachusetts and it would actually give insurers the permission to deny covering certain fly-by-night clinical trials that they--they are afraid that they might have to cover if a mandate went through. This--this bill would not do that. It's really quite rigid.

Sahl: But there would be an appeals process presumably in--in cases like that, would there not, such as there was in this case?

Fresina: I would assume--I would assume so. It's not written into the bill but I think the normal contract would--would include an appeals process anyway.

Sahl: Are we running the risk of creating an institutional nightmare here? I don't know.

Shulman: I think we're actually running the risk of taking away an institutional nightmare here and allowing the patients of the Commonwealth to have access to well-thought out, well-conceived, well-regulated clinical trials and giving us the ability to advance health care and help our citizens.

Sahl: All right. Some final thoughts coming up. This is Newsnight. We'll be right back.

(Commercial break)
Sahl: Welcome back to Newsnight as we continue to take a look at the case of little David Stewart. Dr. Lawrence Shulman, you work on clinical trials. What an awesome responsibility when you think that you are giving patients untried drugs.

Shulman: It is. It's very frightening for all of us to give medicines to patients that have never been given to human beings before. And in spite of giving them to many, many laboratory animals and trying to be as careful as we can, we really don't know what's going to happen. But I do know one thing and that is that every day I watch many of my patients die because we don't have the effective treatments to save them and we've got to develop new therapies. There's no question about it.

Sahl: Lori Fresina, what do we do about the--well, in this case, this--this story has come to public attention because of--of news coverage. Not every case is going to motivate that kind of coverage or generate that kind of coverage. How do we get it out of the press so we're not making decisions the way they're--they're made in very high profile cases?

Fresina: Well, certainly, our preference and I would think the Stewart family's preference, would be not to have had to play this out in the media, but the family had gone through proper channels. His physicians had gone through proper channels with the government and weren't getting anywhere and felt like that was really their last resort was to go to the media. I think--I--this legislation would take care of a lot of that. Passing legislation like this that puts in the right safeguards and creates equal access to quality clinical trials will make a difference. Until then, this type of a story will continue to occur in the media and we're going to have reactionary efforts, major fund-raising efforts, for things like this when really there's--there's a better solution.

Sahl: Alan Sager, we'll give you the last word here. The goal is to find some--is--is to take away the highs and the lows and find some stability in this process, right?

Sager: Health care is about safety, security and trust, not about raising people's anxieties and parading problems like this through the press. We can find a way to cover people for clinical trials. We can also find a way to get the free market out of health care because we don't have a free market and stop having all these crazy incentives that lead different payors to deny services for financial reasons. We've got enough money to provide the cure that works.

Sahl: Thanks to all of you, Lori Fresina, Alan Sager, Lawrence Shulman. I'm RD Sahl. This is Newsnight.

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