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COLORADO'S "RIGHT TO TRY" LAW: A LIFELINE OR FALSE HOPE?

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LIST OF PARTICIPANTS

ELLiot GERSON
Executive Vice President
Policy and Public Programs, International Partners,
The Aspen Institute

JOE GARCIA
Lieutenant Governor, Colorado

DIANE E. MEIER
Director, Center to Advance Palliative Care
Co-Director, Patty and Jay Baker National Palliative Care Center, Catherine Gaisman Professor of Medical Ethics, Icahn School of Medicine at Mount Sinai

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MR. GERSON: Am I on? Can people hear me in the back?

SPEAKER: Think you’re on now.

MR. GERSON: Terrific, great. Well, I can only see you if I put my hand over my eyes, but I won’t continue like that, I do trust there is some people out there and I hope you’ve enjoyed your first evening here at Spotlight Health. And I’m thrilled to be able to have this conversation with two very distinguished people.

I’m Elliot Gerson, Executive Vice President of the Institute, and I have no particular expertise in this topic but a fascination in it. And let me say that, you know, the topic as I think all of you know is Colorado’s Right to Try law, lifeline or false hope? And what’s important to know is this is not a parochial issue because we happen to be here in Colorado, and this law, the first of its kind in the country was signed, Governor, about five weeks ago.

MR. GARCIA: That’s right.

MR. GERSON: But this is legislation that is likely to be enacted in many other states. It’s already on the legislative agenda of three or four other states. We’ll probably talk a little bit about the politics of it. As I was discussing it with Governor Garcia earlier, the vote in the legislature in Colorado was actually unanimous in support of this legislation. And I think the politics are really quite interesting. But not only is it legislation that many other states are looking at, but it’s actually of global significance also like our conference today looking not just at U.S. issues but global issues.

Our panelists, Lieutenant Governor Joe Garcia, it’s always a privilege and a pleasure for us here in Aspen to host one of the distinguished leaders of the state that we call home. He is a very distinguished educator before his political career. He is a past president of both a university and a community college. He is passionate about higher education equity issues. And he is also a very respected figure
dealing with K through 12 equity issues.

Diane Meier is the director of the Center to Advance Palliative Care and she is also a nationally respected geriatrician, a medical educator, a medical ethicist. And I think both with her geriatrics perspective and her ethics perspective will be a very important person to hear from about the issues that are raised by this legislation.

The legislation, and I think most of you have a basic idea of what the legislation does, which allows the terminally ill to obtain drugs outside clinical trials, outside the FDA’s own compassionate use guidelines. And the drugs have to have passed phase one of the FDA procedures but not gone beyond that.

Supporters call it hope for the terminally ill, frustrated by what they describe as the red tape relating to the federal guidelines to obtain potentially lifesaving or at least life-extending drugs. Many call it the Dallas Buyers' Club bill or the Dallas Buyers' Club law, of course because of that film and the extraordinary success it had including Matthew McConaughey’s best actor award, gave great currency to some of the issues who – a patient who smuggled treatments from Mexico that were not approved in this country and then distributed them to other people with AIDS in Texas.

So the support is – comes from people who look at it as an extraordinary opportunity to help people who are very desperate and have no alternatives. But there has also been a lot of criticism and skeptics about the bill although you might not see that reflected in the vote in the Colorado legislature. Some have said while saying, you know, perhaps it was a great movie albeit one based on facts that were not in fact accurate about what happened at the time, but not – but actually the source of what some people describe as actually terrible public policy.

Some critics call it empty feel-good legislation that won’t actually help anyone, and others at the extreme call it flat-out cruel or one – I read one commentary, called it a Trojan duck, meaning something that would allow sellers of quack medicine into the state. But most of the people who are critical of it seem to have had very little influence in
Colorado. The Colorado medical societies took essentially no opinion on the bill, the hospitals didn’t take much of – didn’t take an opinion. The health insurers didn’t express an opinion. And the FDA itself has taken, as I understand it – I don’t think Peggy Hamburg is here yet or we could ask her directly, she will be here tomorrow – taken a position but however has noted of course that today patients do get access to experimental treatments either through clinical trials or if the patient doesn’t qualify to apply for access without a trial.

So let me start with you, Governor, and I’ve alluded a couple of times to the politics of it. How did this legislation pass with unanimity?

MR. GARCIA: Well, it’s a really good question and, you know, it’s something that frankly we did not anticipate. Now, want to be real clear, this was not one of the governor’s agenda bill, this kind of came as a surprise to us as well. And it’s important to note that two of the prime sponsors were one senator, one representative in our legislature who are both medical doctors, and they support it, one was a prime sponsor and the other was a supporter. What was interesting is that nobody stepped up to oppose it.

So I think when it first came up, a lot of us assumed it was not going to get many votes and it was going to die a quick death. But you mentioned it’s a feel-good bill as if that was bad or unusual. Well, maybe bad but it’s certainly not unusual. Lot of what happens in legislatures is we pass bills that make people feel good. I mean, whether we’re talking about things that are innocuous like license plate bills for people who served in Korea or this bill which seems so much more significant, we pass a lot of bills because our constituents come to us and say this is important. And nobody else says, well, we feel strongly – negatively about it.

Now, it’s also important to remember that Colorado is a state that looks very critically on any laws that really infringe on individual rights. We need to be sure that if – before we infringe on a – on an individual right, I won’t say constitutional right, but an individual that there is a good and valid reason for it. That’s why Colorado is in the front not only with this bill but, you know, of course you know about our not just medical marijuana but now recreational marijuana. You know, we are kind of out
front even though I will tell you quite honestly the governor did not want to be, Colorado to be out front on these things. It just happened to us and we are working with it.

But again, the real key here is we’ve got a governing philosophy that says we don’t want to infringe on individual rights unless there is a compelling state interest. And there were – and nobody showed up to say this did that, nobody showed up.

MR. GERSON: Why do you think they didn’t show up?

MR. GARCIA: Because nobody likes to say no to people who are suffering. You know, these are the kind of bills that pass based on very compelling personal stories, very emotional stories, those things carry a lot of weight in front of a legislature and no legislator frankly wants to be the one to say I don’t care that this might have helped your mother live an extra month. I don’t think it’s worth it in terms of what it might mean to public safety overall or to our accepted methodology for confirming that drugs are not only safe but effective. Nobody wants to say to that person we’re going to deny you that right.

MR. GERSON: But it is interesting, these bills are not new. My understanding is that actually many of these bills were drafted by an organization in Arizona, very libertarian organization, and they have been proposed for a decade and they’ve never received this kind of support, they’ve never been enacted. And so in fact many people are saying the Dallas Buyers' Club actually has had a significant effect. Bu, you know, you say it’s feel good for the legislators, but do you think practically speaking it’s going to make any of your constituents actually feel better than they would otherwise, isn’t that the point of the bill?

MR. GARCIA: That is the point of the bill. And first with respect to Dallas Buyers' Club, you’re right, these bills have been introduced before, but this really I think drives home the impact of popular culture on policy decisions. We can’t pretend that that doesn’t have an impact whether we’re talking about civil unions or gay marriage or recreational marijuana or a Right to Try bill. We see that TV shows, whether we’re talking about the Cosbys or Modern Family or the Dallas Buyers Club,
does drive public policy. It makes people think about things in a different way and that’s what happened here.

MR. GERSON: And even if in the Dallas Buyers’ Club the – most of the things brought in from Mexico actually had no positive effect, and ironically the one drug that could have helped people, and this was 30-plus years ago, and it was by the way before the FDA had a compassionate use policy, so the attacking of the FDA in it really was, you know, does not, would not apply today. But the one drug that could have helped, the protagonist actually called toxic and poison, and that was AZT. So in fact the irony is that the facts in that movie, as compelling as it was, were not accurate.

But Diane, what – how do you see the politics of this? I mean, it does seem as if when you have, you know, a dying parent or a dying child and saying why just – why can’t I have a chance, it’s pretty difficult to react against that –

MS. MEIER: Yeah, yeah.

MR. GERSON: – yet many people are responsibly saying that the effects of this either are going to be nil because the FDA still approves these drugs, these drugs are not necessarily going to be safe. And many of these drugs, in fact for people who are seriously ill are likely to shorten their life or cause their last months to be even in greater pain.

MS. MEIER: Well, snake oil sales has a long and valiant history in humanity. I mean, there have always been people proffering false hope to desperate, terrified people. And this is sort of a modern example of that. We also have a very strong anti-government, anti-bureaucracy society these days, so.

MR. GERSON: Yeah, I didn’t know –

MS. MEIER: Yeah, and they’re increasing. So no one is going to tell me not to smoke pot and no one is going to tell me I can’t take experimental treatment when I’m sick. And that I think is behind the politics of this. But for an individual person with a serious illness that is likely to
lead to their death. If it were me, I would want access to whatever might give me a chance. I would want evidence that I wasn't taking poison, and these drugs have to go through phase one clinical trials so that those are safety trials, toxicity trials -

MR. GERSO: Okay, but that's only the first stage, I mean they're still not necessarily safe until -

MS. MEIER: I - believe me, I know.

MR. GERSON: Okay.

MS. MEIER: But I can - it's easy for us to say when we're healthy that we wouldn't want unsafe, untested drugs. Having taken care of a lot of people who are facing death, it's easy to judge the desperation and terror that people feel, and so I'm trying not to do that. But I do think it's important to recognize the opportunity cost because what is the cost of spending the last weeks or months of your life in a desperate search for a miracle cure, what do you not do because you're doing that. And that's what I think doesn't get included in these debates.

There are very important developmental tasks in the last weeks and months of life, and those developmental tasks range from getting your affairs in order to, most importantly, completing important relationships. So your estranged son who you haven't seen in six years, your fight with your black sheep child saying thank you, forgive me, I forgive you, I love you, goodbye, you never get that opportunity back.

MR. GARCIA: Well, but -

MS. MEIER: If someone doesn't say to you this - these are the developmental tasks, these are the things that need to happen, you will be hooked up to an IV in an ICU somewhere and your family will never get that opportunity and you will give up that opportunity. And what my concern is is that people won't know what they're giving up.

MR. GARCIA: That's true, Dr. Meier, but isn't it a rather paternalistic view of government for government to say palliative care is
the better approach and you should take it and you should reach out, you should get your affairs in order. I mean, that is the choice I would make. But I don't believe, you know, it's obviously not the choice everybody makes. And to call it snake oil although I, you know, we - this does not include doctors from the process. A medical doctor has to agree that this is a process that nothing else has worked and this might.

So and it's - we're also not discounting safety because stage one is about demonstrating safety not toxicity but it, granted it doesn't demonstrate efficacy but we're not arguing that it should. I mean, one in fact could pass a law just as easily that says stage one shouldn't even be there. I mean, anything should be in. And so we do need to be thoughtful about what is the benefit to society, for government to intrude on an individual decision about whether they want to pursue a snake oil remedy as opposed to spending their last few weeks in a way that you and I might feel is more appropriate.

MS. MEIER: So I'm not opposed to this legislation because I understand people's desire to try everything and anything. And -

MR. GERSON: But you do see significant risks.

MS. MEIER: I see significant downsides. So if I were making policy on this, I would require that people who pursue this kind of treatment in addition to having a physician recommend it, hopefully a competent physician, and that's not all physicians are competent, I'm sure you're aware of that. So there are plenty of physicians who do things that are not safe, that are ineffective in spite of having a medical license. So let me just say that.

But I would require that people who choose this route are also given concordant simultaneous palliative care that helps focus on their quality of life, their relationships, their pain, their shortness of breath, their depression, their anxiety. So it's not either or, it's both and, both at the same time.

MR. GARCIA: And one of the interesting things about this legislation is it does in fact say that you might be excluded from hospice
care if you choose to pursue an experimental drug, and it does seem that it’s unfortunate that it’s mutually exclusive. I would say we do recognize that not all doctors are good but we have other processes in place to identify those. All of our states have medical boards, all of us look at, you know, appropriate standards of conduct and all of us make decisions about pulling doctor’s licenses. But as we learned with medical marijuana, we have some doctors who will happily prescribe where another doctor might not. I don’t think that’s unique though to this situation.

MS. MEIER: No, no, it’s not.

MR. GERSON: Joe, can you explain how this is going to work practically. As I understand the legislation, pharmaceutical companies are allowed to provide drugs but they’re not required to provide the drugs, and if they wish to provide the drugs they’re even allowed to charge for the drugs, whereas under the FDA compassionate use procedures they cannot charge for the drugs. It’s also my understanding, I may be wrong, that most pharmaceutical companies are opposed to this legislation and have indicated that they don’t expect to be providing drugs. So practically speaking, given the fact that there is an FDA procedure, and the FDA, when people apply for compassionate use, does apparently green light about 99 percent of those requests. So help me understand why this is not just feel good and actually is going to lead to any individuals receiving an effective drug.

MR. GARCIA: May not, there is no question. The way this works is it just allows you to bypass the FDA approval process or the FDA waiver process which the FDA says accurately they grant most of the time. On the other hand, the proponents of this bill say it takes too long, it’s too cumbersome, and most folks don’t pursue it, so let us skip that.

Now, you’re right, the pharmaceutical companies are not required to provide the device or the drug or the treatment that is being sought, not at all, and I don’t know that it will change anything. But on the other hand, one of the things we can look at is it’s not unusual for states to decide, to say to the federal government we want to pass legislation that in some ways is sending a message that is symbolic and
that says to you our citizens are frustrated with this process and you ought to change it.

Now, the FDA process exists frankly because we want it to. I mean, we want to be protected from snake oil, and yet when we look at that snake oil, if we want to call it that, it's the only thing that might save us, most of us would choose to get it any way we could.

MR. GERSON: But what if we thought that it might but on the other hand the likelihood is it could – desperately ill, many of these drugs are extraordinarily potent that it could actually hasten our death and cause much greater suffering in our last months to engage in the kinds of things that you from your experience believe are –

MS. MEIER: It’s not only physical suffering, it’s also the number of families I have seen bankrupted because of a loved one’s desperate search for the miracle cure leaving their wife penniless, leaving their children penniless because individuals are going to have to pay for these drugs, insurers are not going to pay for them. Medicare and Medicaid are not going to pay for them because there is no evidentiary basis and –

MR. GERSON: The pharmaceutical companies are showing that they're not going to provide them.

MS. MEIER: Pharma is not going to give them free, so we're not only feeding this desperate fear as opposed to appropriately taking caring of the seriously ill, we are, you know, allowing, government is allowing people to bankrupt themselves.

MR. GARCIA: It's also –

MS. MEIER: So I think the state does have an interest in protecting people from that.

MR. GARCIA: Right, well, medical care unfortunately has often been allocated based on individual wealth, and one of the criticisms I have of this bill is it does say okay, insurance companies don't have to provide it, the drug companies don't have to provide it for free, hospitals
don’t have to agree to treat you if it does hurt you. And your state can be liable for any expenses you don’t cover. So it can do exactly what you’re talking about.

But people are making that decision knowingly with the advice of a doctor, and there is a very tight informed consent provision of this law that says I’ve been advised, I have to say in writing I’m willing to accept both the physical, medical and economic consequences of my decision, I want to do it. You and I know despite all of these things many people, desperate to stay alive or family members will say do it anyway -

MR. GERSON: Right. Doesn’t the state have a role to actually protect those vulnerable people and how - what is the meaning of informed consent when a drug, you know, may have just passed phase one, may be 20 people involved in it, and all it’s demonstrated is not that it’s extremely toxic at least to those 20 people. Most drugs, I think about 5 percent of cancer drugs that, you know, pass through the whole process, they have found in phase two and phase three that they are highly toxic or that - or not efficacious.

MR. GARCIA: Phase one really may not be again effective but they generally are ruled not toxic. But what you’re asking is for public policymakers, legislators who frankly people don’t trust to make a medical decision that may overrule what a doctor, who people do trust. People trust their doctors. Frankly, they don’t trust their legislators or their governor, especially with a medical decision. So why should you put yourself in a place, my doctor has agreed this treatment might help me or at least that no other treatment will help me. So legislators, get out of the way. And so that is one of the things that legislators and governors have to do all the time.

MS. MEIER: So here is another example of a state legalizing something that one could argue that the state has a strong interest in preventing. Let’s take Oregon and Washington State’s Death with Dignity Act. Also a law that depends critically on the competency of the physician, the competency of the physician to assess the person who says I want to die quickly to make sure that the reason isn’t something that is remediable, like a treatable depression or a feeling of guilt for having
failed the doctor and not responded well to chemotherapy.

Nine out of 10 requests for a hasten death are not actually suicidal, they're actually about something else. I promise you that maybe 1 out of 10 doctors is skilled enough to distinguish those motivations. So I was opposed to those laws not because I don’t believe in people’s right to control the timing of their own death but because I don’t trust the lowest common denominator, a physician, to protect patients from doing things that the doctor could have recognized but failed to recognize could be handled in a different way.

MR. GARCIA: All too true, but again I think the public is really who we are responsive to.

MS. MEIER: Right.

MR. GARCIA: And the laws you’re talking about, we’ve seen some evolution. And who knows, maybe somebody makes a blockbuster movie about that and we end up with a bill that’s entirely possible, I’m not denying that. That is often what shapes the public debate.

MS. MEIER: Yeah.

MR. GARCIA: But we do know – you talked about the lowest common denominator, doctor, that person is still trusted more than the highest common denominator, politician, that’s a sad fact. And so –

MS. MEIER: That’s a sad, sad truth.

MR. GARCIA: But – and politicians like myself who are not medically trained, we don't know, you know, so we would say how can we not defer to the judgment of a trained doctor. And they may be competent but they may not be ethical. And those two things, I think, you know, they’re not always lined up. And we again saw that with medical marijuana which was intended as when it was passed, I thought it would be treating glaucoma and cancer patients, instead the average medical marijuana card holder is a 24-year-old male skateboarder, you know, that's probably not suffering from glaucoma but they got their medical
marijuana card. So that’s a challenge.

MS. MEIER: Right, yeah.

MR. GERSOON: Diane, you talked a minute ago about, you know, the terminally ill person desperate for a miracle.

MS. MEIER: Right.

MR. GERSOON: And I mean isn’t part of what’s going on here a sense that many people have that there are lots of miracle drugs out there that are just being denied to us?

MS. MEIER: Well, and how do think they got that sense that there are lots of miracle drugs out there? Watch TV.

MR. GERSOON: And but the truth is -

MS. MEIER: I mean, you know, there are people making a lot of money selling that perception that we can fix everything.

MR. GERSOON: But sadly that perception is flat-out wrong.

MS. MEIER: Of course it’s wrong. But actually if you’ve got -

MR. GERSOON: I mean, everyone thinks this, you know, GLEEVEC was the exception.

MS. MEIER: Right. Well, I mean the fact is it depends on the patient population. Most people understand that ever life ends in death and that the mortality rate news flash remains at 100 percent. And it’s actually very few older people who pursue wildly experimental desperate things, it’s more typically younger - middle-aged or younger people.

And in my experience, and I’ve taken care of many patients who want that miracle cure, a skilled clinician can get at what is behind the terror, can ask the person to say more about what they are afraid of. And that requires training, it requires skill, it requires time which doctors
don't have. They don't have the training, the skill or the time. But a doctor who has those things can very often make that last phase of life the most precious and valuable that person ever had. But it requires skill not quick fixes and not, oh, I'll just order another PET scan and order some more chemo and get you out of my office because I don't have time.

MR. GERSON: Governor, why wouldn't the same logic apply to people who have chronic diseases and suffer great pain? Why shouldn't they be able to take whatever they want, you know, who cares whether the FDA has said it's actually efficacious. It's my right to take something that I think is going to reduce my pain even if it might kill me.

MR. GARCIA: It's precisely people of our generation, the baby boomers who are reluctant to age, who are struggling hard to hold on to our imagined youth. I mean, if there was something out there that would re-grow my hair, I would pay for it.

(Laughter)

MR. GARCIA: But think about -

MS. MEIER: There is, there is.

MR. GARCIA: you know, the low testosterone, how many ads have we see now that would suggest that every man of my age suffers from low T and that can be treated. And then following that within a year you see all the ads from lawyers suggesting if you received low T treatment and you had this side effect, come to us, and we'll sue that provider of testosterone treatment.

You know, it is about money, but it's also about providing what people want, and what people want is to delay in some cases death and in some cases simply aging. We don't want to be wrinkled, we don't want to be old, we don't want to be able to - we don't want to have to admit we can't do what we could do 20 years ago.

MR. GERSON: Governor, I - you're I think a lawyer or you -
MR. GARCIA: I am a lawyer by training.

MR. GERSON: All right, does the state expect that there may be a challenge to this on federal preemption grounds, or do you think that the FDA and the federal government is afraid of those ads about dying babies and dying parents doesn’t want to come in and just say, look, the FDA, you know, preempts this. I mean, one possibility is that no responsible pharmaceutical company is going to provide a drug, they have a process already. And the only ones that might are in fact peddling quack cures or in-state Colorado pharmaceutical company that is not – that does not operate outside of Colorado and thereby may not be preempt.

MR. GARCIA: Well, remember, there is a requirement that it has to have passed the stage one FDA trial, so that is still a requirement.

Now, you’re right, I mean even the bill’s sponsors, when I talk to the sponsors, including those who are doctors, they said you’re right, the practical effect may be nil, it may be that not a single pharmaceutical company out there is willing to do it despite all the things we’ve put into the bill to kind of encourage them to do so, you know, why is it in their interest.

And certainly we saw – again –

MR. GERSON: Why don’t they not want to do it, it’s not because their cruel, it’s not because they don’t want to save this dying baby or dying 32-year-old mother of twins.

MR. GARCIA: No, they don’t. They want to be sure again that they don’t do anything that interferes with their ability to get to stage two and stage thee and stage four approval and ultimately on the market. They do worry that whatever is written into state law that somebody could still legally challenge and say we still think because of the FDA and the federal requirements you’re still liable.

But you’re right, federal preemption is an issue, it was the issue with passage of both medical marijuana and recreational marijuana as
well. So far the feds have kind of taken a cautious approach, they haven’t stormed in. But we’ve seen that because of other federal prohibitions, you know, the marijuana industry, for example, is not advanced as far as it could because banks won’t their money because of federal law. So, you know, there are other things that get in the way and the feds still having a prohibition might make it, might make this law absolutely ineffective other than to the extent that it sends a message to the federal government and the FDA that we want you to ease up on those approval processes and not require a 100-page application that will take months for approval because I might be dead by then.

MR. GERSON: So you seem ambivalent about this if – so if –

MS. MEIER: I am. I think any rational person would be ambivalent about it.

MR. GERSON: Arizona, Missouri, I mean if they asked you to come and testify, you would say no because, you know, on the one hand on the other hand do what you want.

MS. MEIER: Well, I mean, this is a democracy, right, and the people’s will determines the law. And I understand why this is a popular law and why all the legislators voted for it because it feels like why not. It’s a desperately ill terminally ill person –

MR. GERSON: Why didn’t they go for it five years ago, seven years ago, one movie?

MS. MEIER: Maybe the movie, maybe the success of recreational marijuana, maybe a sense that the public is going to hold them to this and no reelect them if they don’t do it.

MR. GERSON: – an increasing sense that people don’t trust government.

MS. MEIER: Which is certainly true. But as I said, I think there are real costs. I think pharmaceutical companies would be crazy to provide these drugs because all they have to do is kill somebody. And,
you know, that's it, they could easily be sued by the family, the surviving family for giving a toxic drug that had only been through phase one testing. The family could say you hastened my loved one's death.

MR. GERSON: So why support it if you're convinced that no responsible pharmaceutical company is going to provide a drug.

MS. MEIER: I don't - it's not a matter of support or not support. I understand -

MR. GERSON: You understand -

MS. MEIER: - the fears and the public desire for those.

MR. GERSON: What about other issues where you got emotion on one side and science on the other?

MS. MEIER: This is why I was opposed to the Death with Dignity Act because public policy has to protect the public from the lowest common denominator. I believe it is a public policy responsibility to protect the public from predictable risk.

MR. GERSON: What about physician assistance, what's different about that and this. What are -

MS. MEIER: They're very similar, I think.

MR. GERSON: Yeah, what if - if the logic applies here why shouldn't it apply to me if I'm ill and I don't want to suffer and I want to die and who is to tell met that I can't die.

MS. MEIER: No one is to tell you that you can't die, you can.

MR. GERSON: But the way I want to die, with -

MS. MEIER: You can.

MR. GERSON: With a physician helping me commit suicide.
Is it different?

MS. MEIER: Well, okay, so you’re talking to someone who wrote, after Kevorkian, an article in the New England Journal called morals and moralism in the debate on physician-assisted suicide and euthanasia, arguing that the medical profession’s excessive scrupulosity was ignoring the real expressed needs of patients and families. Then I started taking care of people who were asking me for help committing suicide. And one after another were depressed, very guilty about having abused a child, you know, and thought they deserve to die because as a punishment for their sins.

Someone else felt guilty because she had failed her oncologist by having her cancer progress. It took me learning to be a better doctor to understand that it wasn’t a settled rational conviction, it was about something else that could be handled in a different way. And I learned how hard it is to do that and how hard it is to really understand that. We’re talking about life and death here. This is the ultimate kind of obligation of government, to protect.

MR. GARCIA: But we are talking about individual decisions, and that is not the ultimate obligation of the government.

MS. MEIER: But they have to be informed, but they have to be informed.

MR. GARCIA: But someone who comes here and says my life is worthless and I don’t want to live a day longer and I want your help, you can provide it or choose not to but that individual is going to make a decision one way or another about whether they want to end their life. And I’m not sure that government, we can say suicide is illegal, I’m not sure that changes things much. How many of you out there think motorcycle riders should be required to wear a helmet and that law should require that, why? Because it’s dangerous.

MS. MEIER: Because taxpayers pay for their crash in the ER.

MR. GARCIA: Okay, I’m a motorcyclist, I should admit. Now,
first. So how many of you – recognizing that motorcyclists even with a helmet are far more likely to be injured and cost taxpayers money, how many think we should outlaw motorcycles. I mean, it’s really – it’s a line-drawing question we face all the time, right? Cars, seatbelts, motorcycles, helmets, experimental drugs that have passed stage one, we really do - I mean, that’s what government is about, it’s about line drawing, and trying to figure out what’s the right balance of interest. And I’m ambivalent about this law too, I would not have voted for it, but on the other hand I see why the legislators were, even those who were ambivalent, were not willing to publicly vote against it.

MS. MEIER: Yeah, no, I see that too if they want to be -

MR. GERSON: All right, well, now that all of you are used to raising your hands, I am going to turn things over to the audience. Do we have microphones that we can because all of this is being videotaped so do we have microphones ready?

MR. GARCIA: Yes. There is a question back there in the middle.

MR. GERSON: Okay. And I – there is a question in the middle, in the back, and then I will move around the room. Yeah, that green sweater, I think.

MR. SHIN: Thanks. Hi. Andy Shin. So I just want to put a finer point on Diane and Elliot’s point about informed consent. And I think that if you think about informed consent and its origins, I think even back to the Hippocratic Oath in terms of beneficence, you know, is really where its origins were, it was something that the U.S. court system created to protect patients, actually to empower patients in holding providers liable because there is no way that a patient would ever know as much as a provider knows.

So in a world of Right to Try, you know, recognizing Diane’s point that not all providers are going to have all the information and even those that think they might have all the information may not have all the information and they even have less information than they would if the – it
was completely cleared by the FDA. So in that case, are we now creating an environment where providers are under even more risk for medical liability, and in fact aren’t we also putting patients in a position that’s almost backwards in terms of their – I’ll use the word liberty, in terms of their ability to have all the facts and have as much of an informed opinion about medical decision making as possible.

MR. GARCIA: I’ll answer that. I mean, first, there is no point at which we can say a patient has all the information or a doctor has all the information, they have the information that’s available given the current state of the science. But that may not be complete. Certainly when we used to use bloodletting and leeches, I mean, people were making decisions based on what they thought worked. This informed consent isn’t something that’s entirely up to the patient, it does require a doctor to consult with a patient and to inform the patient among other things that the use of the drug might in fact hasten their death or might make the remaining weeks or months of life even more unpleasant, but a patient may still say I’m going to take my chances, thank you for telling me all that, I don’t want to die. And that is ultimately a liberty decision, it may not be a sound decision but it’s an individual choice.

MR. FAUST: Hi, I’m Jeremy Faust from Mount Sinai. Dr. Meier, hello.

MS. MEIER: Hi.

MR. FAUST: First, the only – I’m the person who said I would ban motorcycles because I’m an emergency doctor and this particular disease seems to create a lot of single families and so that’s why I speak to that.

MR. GARCIA: Yes.

MR. FAUST: But my question is about research. Does this law actually undercut equipoise, the idea if someone with end-stage cancer says I want the drug, we – currently we randomize them to get a placebo or the current practice and then the new drug, and that’s how leukemia rates have gone and children death rates being high to very low. Does
this law undercut that? So if someone says I want this drug, I don't want the placebo, I don't want to risk it, I want the right to this medication so get me out of the trail. Are we going to end up with no progress? Will research be undercut is my question.

MR. GARCIA: Well, the two things are mutually exclusive. I mean, you could have a patient who says, yeah, I don't want the placebo, give me this thing whether it works or not, I want to try it. And then of course that doesn't interfere with the drug company's right, in fact, obligation to go forward with those randomized studies that we see in stage two, three and four. So I don't think the – again, the two are mutually exclusive.

MS. MEIER: This is a tension between the right of the individual and what's in the best interests of society and you can't have it both ways. I mean, the best interest of society is to properly test drugs. That means the week before a drug is released to the market somebody can't get it, right, because we have processes that serve the greater good, and that's the ethical tension, the rights of the whole versus the right of the individual.

MR. GARCIA: Doctor, don't we now have breast cancer patients who survive at a much higher rate than they did 20 years go, being treated, and I'm not a doctor, so I'm just speculating, treated with drugs that had gone through stage one but hadn't advanced through the process through full FDA approval, but had they been available to some of those patients earlier, some of those patients might have survived. I mean, it's a hard thing to know but we certainly don't know that's not the case.

MS. MEIER: Yeah, no, we can't know that. But you know, probably 99 to 1 are the drugs that get through phase one but are found to be completely ineffective in phases two, three and four in terms of the number of drugs that don't make it to market because they either turn out to be very toxic or ineffective after phase one trials far outnumber the effective drugs that make it to market. That's why – drugs cost so much because it costs so much to develop them.

MR. GERSON: Question in the front. Microphone.
SPEAKER: Thank you. I have first a comment and then a question. So from what I understand of your explanation of the Right to Try law, it's similar to compassionate use. The voters have identified the particular problem as the rate of FDA approval on compassionate use and the duration of time the FDA takes to come up with their decision in compassionate use. First of all, is that correct?

MR. GARCIA: It's mostly correct. I will say the advocates for it I think probably don't have such a nuanced view. They don't want to go through the FDA, they want less government. And it's that simple, they want less government involved.

SPEAKER: So the problem with that position though is that the FDA isn't the problem. As you know, FDA accepts 95 percent of all compassionate use requests that are accepted by companies and the FDA has a process to review a request within 24 hours and uses it very frequently. I know this because my organization has been involved in several compassionate use requests and we have seen it occur. So the real problem is not the FDA, the problem is companies that decline compassionate use requests from terminally ill patients. So I basically disagree, Diane, with your paradigm, why do patients request compassionate use? There may be some folks looking at snake oil, but oftentimes the issue is that the patients who are seeking compassionate use are patients who can't get on trail because there are no trails for them.

For example, in the area of cancer drug development there are almost zero pediatric trials on approved drugs. Kids only get trials after drugs are approved, which is a problem for terminally ill kids, right, because we know there are some unapproved drugs that are very promising and we're seeing exciting results and we know these drugs won't be approved for 5 or 10 years and all these kids are going to die, they won't have a chance to have these drugs. So that's the reality. The problem is not the FDA, the problem is companies who elect not to share these drugs with, for example, children because it doesn't comport with their fiduciary responsibilities to their shareholders.

MR. GARCIA: And because of liability. I mean -
SPEAKER: And because of liability because they worry that a
dead kid is going to slow down the FDA approval process on the adult
indication. So I guess my question is two-fold then. If companies are
concerned about putting, opening pediatric trails, for example, in the
cancer space, what company would ever under the Right to Try law agree
to provide a drug to terminally ill patient when they don’t even have FDA
consent to this particular patient’s access to the drug? It’s riskier for the
company in going under compassionate use. That’s my first question.

But my second question, which is really the one I’m more
interested in is is Colorado talking about ways to push companies to give
patients opportunity to try drugs? And are you looking at that question that
companies really say no too often, are you asking companies to track how
often they say no, are you thinking about a third-party institution to review
compassionate use requests instead of companies or are you looking at
other mechanisms to address this really serious problem which is
companies keep on saying no when maybe we as a society might say yes.

MR. GARCIA: Very good question. First, right, as a practical
matter it may not change anything because if I ran a drug company I
would say, no, as long as the FDA requires this I’m not going to, so we
don’t know. And even as I said before, the proponents of this bill don’t
know if it’s going to lead to any practical change. We pass laws all the
time. We know that does not lead to practical change. But then what
you’re asking, the second part of your question is are you asking us to
respond to - belief that there is too much government involvement in this
decision and answer it by requiring more government involvement. That is
government saying to drug companies we want to incentivize you, coerce
you, do something to get you to provide it. And I think those two things
become again completely inconsistent. If the philosophy is less
government intervention then that would not suggest that we ought to do
and so far no one I know is suggesting that we do something, try to force
or encourage drug companies to provide those.

MS. MEIER: You know, many deaths are tragedies, especially
when they happen to children, but we can’t protect, we cannot prevent all
of them, it’s just not given to us as a species. I think there is a lot of
marketing of that belief in this country that with enough research death itself
can be defeated I would say is not hyperbolic in terms of how people feel in this country. But it's not true, it's not true. So there are children who are going to die, diseases we don't have treatment for, there are adults who are going to die of diseases we don't have effective treatment for. And eventually every one of us is going to die no matter how much of our budget we put into research. So is it good public policy to feed that fantasy, I don't know. There are many other public goods that are also important.

MR. GERSON: Do we have any other questions? Right here.

SPEAKER: I'm sorry, I feel compelled to respond to that. We're not trying to prevent death, we're trying to prevent cancer death in children. There is a big difference between a child looking for some kind of answer to survive or a 25-year-old or, as you mentioned, a 32-year-old with three kids, there is not really a sense here that this program is to keep people alive forever, it's more a sense of dying a different way or a less painful way or having options to have a life worth living.

MS. MEIER: Absolutely, I am totally in favor of all of those things and work every day to achieve that. Giving people things that are untested and unproven, I'm not sure is an example of that. If it's something that has promise in adults but hasn't been approved in children, I'd be all for that. But something that's never been tested in anyone of any age, I think that's dangerous, I think that's snake oil.

MR. GERSON: In the middle. David.

SPEAKER: Hi, thank you. This is a great conversation. It strikes me that the whole point of setting up an FDA or regulatory body is to protect those, protect the public's interest. And in particular in this case what strikes me as interesting is that the terminally ill are some of our most vulnerable members of society. We're dealing with some of the things that you've mentioned. And it strikes me that this is one of the time that you actually want the most regulatory support and defense to prevent them from being taken advantage of in some way, or their families.

And it strikes me that the vulnerability, you know, if we allow
this to our very vulnerable members of society that we should allow it for everybody in Colorado, right, so that everybody should be able to try whatever they want. It strikes me that why not let anybody take any medicines they want outside of the bureaucratic regulatory -

MR. GARCIA: Well -

MR. GERSON: Well, there are actually some people who say that the foundation in Arizona that supports this legislation, that that in fact is their aim.

MR. GARCIA: And there are plenty of people not in that foundation but Coloradoans who think, yeah, I don't want government telling me what I can ingest or not if I think it will either prolong my life or just make me feel better. You know, there is certainly that argument. I do agree that there is an appropriate point for government regulation and in fact government intrusion. If we have a child who is suffering whether from a terminal disease like leukemia or maybe that's been diagnosed with type one diabetes, we don't let the patient, the parent say we're going to treat this child with prayer because that's what we believe in, we don't want to provide a drug that we know will work or that you think will work because we have something that we think will work just as well. We do get involved.

So we're not - I don't think anyone is, at least I'm not arguing that we should not have some ability to protect those who are most vulnerable, like children. We do need to protect them.

And the whole question again comes down to the matter of degree and line-drawing, how many stages, how much time, how much testing is enough. Some would argue we have way too much and some would say we still don't have enough because some drugs get through that process and still cause harm and still lead to costly litigation.

MR. GERSON: We have a few more minutes if there is another question, but we don't. It's - I think this has been a terrific conversation though.
All right. Well, I would like to thank our panelists. And we look forward to seeing you all tomorrow including many conversations that I think will be more cheerful than this one. Thank you very much.

(Laughter)

(Applause)

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