

THE BROOKINGS INSTITUTION

POLICY APPROACHES TO THE OPIOID CRISIS,  
FEATURING REMARKS BY  
SIR ANGUS DEATON, REP. ANN McLANE KUSTER,  
AND PROFESSOR BERTHA K. MADRAS

AN EVENT FROM THE USC-BROOKINGS SCHAEFFER  
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**Keynote Remarks:**

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## P R O C E E D I N G S

MR. GINSBURG: Yeah, I'd like to welcome you to today's presentation, "Policy Approaches to the Opioid Crisis." I want to thank you for joining us today.

Before we get started, a few housekeeping announcements. Oh, first of all, I'm Paul Ginsburg and director of the USC Schaeffer Initiative for Health Policy. USC-Brookings Schaeffer Initiative for Health Policy. So if you're on Twitter, our hashtag is #opioidscrisis. It's posted through the room and today's event is hosted by the USC-Brookings Schaeffer for health policy. A collaborative effort that I direct between the Schaeffer Center at the University of Southern California and the Brookings Institution. I'm pleased that among our guests today is Leonard Schaeffer, who is a trustee of both Brookings and USC. And also supported the establishment of this initiative. Mr. Schaeffer will be providing closing remarks later this morning.

Today's program takes on the opioid crisis, which is ravaging almost every corner of the country. The CDC estimates that 91 million Americans -- that 91 Americans die of an opioid overdose each day. We will look at the policy approaches to this epidemic and the underlying issues associated with it. Our keynote speakers are Sir Angus Deaton. Sir Angus is a perfect speaker to help us understand the underlying issues that contributed to the opioid crisis, as well as increased rates of alcoholism and suicide among certain segments of the American population.

Sir Angus is the Dwight D. Eisenhower professor of international affairs emeritus and professor of economics and international affairs emeritus at Princeton University where he's currently a senior scholar. He's also the presidential professor of economics at the University of Southern California. In 2015, Sir Angus was awarded the Nobel Prize in economics. His current research focus is on determinants of health in rich and poor counties in the United States and around the world.

We also will hear from Professor Bertha Madras, who was a member of the

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President's Commission on Combatting Opioid Drug Addiction and the Opioid Crisis and will give us some insight on the Commission's report, which was released on Wednesday.

Professor Madras is a professor of psycho-biology at the Harvard Medical School.

I also wanted to take a minute to introduce today's moderator, Alan Weil, who is editor-in-chief of Health Affairs and the director of the Aspen Health Strategy Group. Alan is the perfect person to shepherd us through this discussion given his extensive work on the opioid process with the Aspen Group. Something I've seen up close as a member of the group and I thank him for being with us with morning.

Now, it is my honor to introduce our first speaker, the Honorable Ann McLane Kuster, congresswoman from the 2nd District in New Hampshire. She also serves as the House's co-chair of the bipartisan heroin task force. This task force has worked hard to increase interagency collaboration to better address addiction and they've successfully helped pass 18 bills that became part of a comprehensive addiction and recovery acts. She has held hearings and events; here in the capitol and at the local level to educate lawmakers and the public about effective ways to address this crisis. I'm grateful for Congress, Honorable Kuster has made time to join us today on her way to the Capitol for some votes this morning.

Congresswoman Kuster?

MS. KUSTER: Thank you, sir.

MR. GINSBURG: Thank you.

MS. KUSTER: Well, good morning. It's great to be with you. I wish I could stay for the entire program. We have votes coming up, but it's a tremendous honor for me to be with you and congratulations on the work that you're doing, both of you and it's -- we need everyone to come together. This is the most complex issue. Every time you try to run down one angle on it thinking -- I keep saying to myself, I want to go upstream, upstream, upstream and then you realize that it's just one big circle where you're dealing with pregnant mothers with babies born with neonatal abstinence syndrome. And you can't get any further up the stream than that and

it just brings together everything. The healthcare delivery system, the economics, the influence of insurance in our lives, the influence of the pharmaceutical industry in our lives and then obviously, all these current economic and cultural issues that are going on in our society right now.

So I'm very pleased to be here with the USC-Schaeffer Initiative and thank you very much for having that on health policy and focus on incredibly important issues, strengthening Medicare, improving the Affordable Care Act, which is high on my list and now focusing on the opioid epidemic. I'm so delighted that you're turning your attention to this because this opioid-heroin epidemic is literally tearing apart our families and our communities from coast-to-coast. It's particularly troublesome right now in rural communities and there's a whole theory behind that of the Mexican drug cartel's targeting rural communities so as not to have to compete with the urban gangs and with law enforcement. And you can literally watch; I've had DEA briefings that are sort of time-lapsed slides and maps and you can literally watch this travel up our interstate.

In my part of the country, this started in Ohio and West Virginia and Kentucky and then, up through Pennsylvania and New York. It came to New England and you can watch over the past five or six years going up I-91. Vermont was hit very hard and the communities in the western part of my district and the Vermont border were hit hard.

The first time I heard about it was a story in a little town called Keene, New Hampshire. There's not a more quiet place on this earth and a beloved high school teacher; mother of three children died of a heroin overdose. And it just -- we were so shocked to hear this story and for that family to have the courage to say that, that's what it was and you'll see death notices now that are much more honest and deliberate about saying what's going on. But then it went up I-91 and then later it came over through Lawrence and Lowell and up I-93. If you've been in the White Mountains and the beautiful lakes of our state, and then eventually up I-95 and all the way up into the farthest reaches of Maine.

And this is spreading throughout the country that way and I talked to my colleagues in West Virginia and Tennessee and Kentucky and now, I'm starting to talk to my colleagues in the Midwest and the northern Midwest and then, finally out on the coast. So I'm really delighted that you're focusing your attention on this. I think it's something that is an epidemic; it is an emergency. We've been urging the president to declare an emergency and now he has, but we need to make sure that we have not only the policy, but the resources behind this to actually make a difference in people's lives.

So the most recent data, 2015, over 50,000 Americans died of drug overdoses. And we know that's growing literally exponentially in some places. A rate that now exceeds automobile deaths. You'll remember back, I said to a group of young staff, I remember automobile deaths before seatbelts. This happened, and we can do this. We can turn the tide on this. Over 30,000 of those drug deaths were due to opioid related overdoses. New Hampshire, my home state, we vie with West Virginia. They're number one for opioid deaths, heroin deaths. We're not number 1 for fentanyl -- fentanyl is this new synthetic substitute and it's even more lethal. And in fact, it's just a lethal cocktail is what happens. People get it in a dose that they are not prepared for. The dealers don't really -- there's no obviously, there's no FDA; nobody's measuring; nobody can tell and so they take what they think is going to be heroin or perhaps some fentanyl -- it will be a hundred percent fentanyl and they're just dead on the bathroom floor. And I met so many families; so many people that this has happened to.

So we're now number one in the nation in per capita fentanyl deaths and we take pride to be first in the nation in many things, the presidential primary and tourism and many others, but this is not the notoriety that we want. And so the complexity of this crisis is well beyond the capacity of any one state or any one community. We need a nationally coordinated response.

It's a crisis that transcends politics. I say to my colleagues all the time, the opioids, the heroin, the fentanyl does not choose Rs and Ds. We have to come together and I

am proud to say it's one of the very rare issues where we have come together. In 2015, I joined my then Republican colleague, Frank Genta from New Hampshire to found what we call, at the time, the bipartisan congressional taskforce to combat the heroin epidemic. Now, we just call it the opioid taskforce. And we now have 100 members of Congress, even split, Rs and Ds, working together on a weekly, daily, monthly basis.

In the spring of 2016, our taskforce helped to push for passage of 18 bills that then became a house version of what was melded in to the Senate Comprehensive Addiction and Recovery Act. And you're probably familiar with that. We called it heroin week and we did all these bills in one week and I want to commend our leadership on both sides of the aisle for the attention and dedication to that.

Last December, we worked hard over the fall to help secure \$1 billion in funding that was a part of the 21st Century Cures Legislation and it was a great honor to come down. I think it was probably the last bill President Obama signed, but it was a great honor to be with my colleagues and to see opioids and the opioid epidemic take that role in the 21st Century Cures Bill. And that some of the funding that you read about, but it's certainly not enough. We continue to raise public awareness through hearings and roundtables. We have presentations by the CDC, the DEA, the NIH and addiction recovery experts. And we'd be happy to talk with you about scheduling different events, but we'd be eager to particularly work with Brookings on future hearings and I'm just going to put in a shameless plug for having a Brookings fellow in my office to work on this issue.

Going forward, we're exploring how we can encourage innovative programs and communities throughout the country to combat this public health crisis and our next hearing coming up is going to be focused on turning out attention to how we move forward. We have an incredible program in New Hampshire called safe stations. You might have heard early on about Gloucester, Massachusetts, but what this is, is that people in addiction, in active crisis can come to our fire stations in National, New Hampshire; Manchester, New Hampshire and other

communities and present themselves with no legal consequence and that's really important. This is so tied up in the law enforcement side and the health -- public health side. And we need to try to work together and we've brought people together so that our hospitals sit at the table with our fire departments and with our police and with our schools and with our business community and with our mayors. Every community has to have their own response because they have local resources that they can draw upon. But when someone comes to the fire station and presents themselves needing help, they will be processed and make sure that they are safe and then they will be immediately transferred into the hands of a non-profit organization that specializes in treatment and addiction recovery. And we can get these people into the resources -- get them access to the resources that they need.

And I've got to say without being partisan, this is -- I'm stating a fact that we could not do this without the Medicaid expansion. That this program would not exist. Of the first hundred people through the door, 90 of them were eligible for Medicaid expansion and they didn't know that they had access to treatment for their health problem and I think that's at the core of what we're dealing with. People don't realize that they can get help. They're not waking up in the morning choosing this, trust me. And so we get them into treatment and long-term recovery. This is the other thing that we need to recognize, a 28-day program does not cut it. It can be a start. We need to detox; we need to get people started down the path to recovery, but nowhere else in the healthcare delivery system would we say to a cancer patient, we're going to give you treatment for 28 days and then you're on your own.

And nowhere else would we say to a diabetes patient and if you relapse; if you eat cake, we won't treat you anymore. What we say is, this must be a really difficult disease. Eating cake is really tempting and it's not healthy for you and you can't have cake and we're going to help you deal with that and we're going to help your family help you deal with that. But I -- this has become emotional for me. It didn't start out that way, but three years into this, dealing with legislation; dealing with coalitions; dealing with my colleagues; dealing with



education, I learned that my own brother on the West Coast is now in active addiction and I'm happy to say he's in recovery. This happened to him. And I say that because he didn't wake up in the morning choosing this. He had a long series of surgeries, and he was on very potent opioid medication -- oxytocin and oxycodone. Starting last September 11 -- I'll never forget the date, and going all the way to April. And luckily in May, we were able to get him into treatment. And now, he's in recovery, but I say in recovery. This is something that we'll be living with for the rest of our lives. And it's very difficult. It's difficult for his family, it's difficult for his friends and it's difficult in his community. This is a 66-year old man. He's a successful businessman. He has a business of his own. He works hard and he's worked hard his entire life, but I think he probably fits right into your research because he lives in a very small community, way up in the mountains on the West Coast and it's difficult there. Life is hard there. He said to me, "There were mornings I couldn't get out of bed because my body hurt so much, and I took the medicine that the doctor recommended." So that's where we are. We've got a long, long way to go.

I do have staff here that can pass out our legislative agenda or you can find it on my website, [kuster.house.gov](http://kuster.house.gov). This is the second iteration of our agenda. We've got bills such as Jessie's law, helping doctors have access to consenting patients' prior history of addiction in order to make fully informed care and treatment decisions. The Stop OD Act to expand educational efforts to prevent opioid abuse, promote treatment and recovery and encourage understanding that addiction is a chronic disease while providing improved access to naloxone and training in the administration of naloxone and testing for fentanyl.

I want to say everyone is coming together and stepping up. I was on the phone yesterday with Dr. Collins from NIH. They have an incredible program that they're working on, but we need resources and we need funding. Already we've been successful this year in passing the Interdict Act, giving \$15 million to U.S. Customs and Border Protection to fund new screening devices, laboratory equipment, facilities and personnel for the latest in chemical screening devices and scientific to support and intercept fentanyl and other synthetic opioids

because this is a challenge. We've got to work with law enforcement. We had a hearing on synthetic opioids and it was chilling. They're criminal chemists in China that are one step ahead of our DEA every day.

We look forward to working with leadership in both parties. We understand that there is an intention to have another opioid week of legislation, hopefully, between now and the end of the year and we'll look forward to working with them. And again, I have to bring up the issue of funding and resources because we need to make sure that not only do we declare this as an emergency, but that we put the clout behind it. So we're looking forward to a targeted response in New Hampshire on this fentanyl crisis. It's having such a deadly effect and we're working very closely with DEA and coordinating our efforts.

But finally, I just want to close by saying I appreciate your interest; I appreciate the work that you're doing. So many people have to come together to help solve this because of the complexity and if you have suggestions for us on issues we should be tackling, my colleagues are totally open to learning more about this. I think it has helped to have law enforcement come together with the medical and public health community. Every fire chief, every police chief in New Hampshire will tell you, "We will not arrest our way out of this, but do need to work together," and we need to work on where the drugs are coming from. Whether it's legitimate means or illegitimate means -- they're coming from both places. We need to work on education and prevention and then we need to work on treatment, access to treatment, and long-term recovery. And I appreciate all that you're doing and all that you're learning here today. I appreciate Brookings for taking this on and thank you again for the Schaeffer Institute. We're very grateful to you. Thank you.

(Applause)

MR. GINSBURG: He's already been introduced, but it's my pleasure to introduce Sir Angus Deaton to give the keynote address this morning.

MR. DEATON: Thank you. Thank you for the kind introduction and it's wonderful

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to be here again. One of the things if I can echo what Congresswoman Kuster said, I think one of the things that I find most encouraging in what is a very, very bleak landscape, is the extraordinary extent to which people are talking about this and it sort of moved into the public debate in a very, very serious way with it's long-form, short-term everything sort of pouring out on all aspects of this and I think that's the way in the end that we're going to come to terms with this because the community is going to have to come to terms with it locally, nationally and everywhere.

I want to talk about the epidemic in context today. I'm going to leave to Professor Madras to talk about some of the recommendations; the recombining of the task force and the immediate policy things. I just wanted to talk a little bit about some of the background. It's clear that stopping over prescription and better treatment for addiction are absolutely key priorities and Professor Madras will talk about that.

I do just want to emphasize that there are no easy solutions to any of this. There's a lot of political pushback to various forms of control. Many docs and patients believe that pain is undertreated in America, not over treated and there's still a lot of pushback coming from that. Letters in the medical journals; letters in the newspapers; and this is something that we've seen before. I mean, in fact, the history of pain in America over the last 200 years is one of oscillation between not treating it and over treating it and, you know, we can learn from what's happened in the past there.

We should also know that treatment for addiction is not very effective and that's not the counselor of despair. It's just a counselor of realism that you should not expect magic bullets from drugs or treatment or other way of doing it. Many addicts do not believe they're addicted; do not seek treatment or do not adhere once they're treated. There's a high probability of relapse among those who are actually treated and the evidence which is often pushed on us and they say we have evidence-based treatment that work. That evidence is not particularly strong. I mean, it's certainly there. These treatments work for some people. They

work for the people that have been in the clinical trials. They're selected sample and they're still high-relapse rates, so treatment is better than no treatment, but it's not a magic bullet. This is not like if we suddenly get these centers out there and bring everybody into them, this will go away. This is going to be a long, hard road ahead.

Many of us are concerned by turning largely pharmaceutical induced epidemic into another pharmaceutical solved epidemic and that doesn't necessarily mean that pharmaceuticals don't play a role in this, but are dangers there too. So my belief is, before I go into this longer context, that in the end, national and local communities will indeed bring this epidemic under control just as the crack epidemic was brought under control 30 years ago by the communities who'd essentially said, "We've had enough of this. This is not going to have any more." And it's stories and accounts like we just heard from the Congresswoman what will really help on this because once it's your favorite high school teacher who's dying from this, you'll beginning to realize that something's very seriously wrong and we have to do something about it.

Let me talk a little bit about the broader context because I want to move. I'm going to let others and well talk (inaudible) the panel about opioids alone, but I want to talk about some other things that have been happening in the background and a lot of this comes from work that I've been doing, John Clee with my colleague, Ann Case at Princeton. I just want to remind you of what usually happens to mortality rates. These are the mortality rates for white men and women in the United States, age 45 to 54, for the hundred years, from 1900 to the 2000. And this is a sort of very familiar lecture of constant improvement. Mortality rates going down and this is a mixture of science and public health. People quitting tobacco and better tackling of heart disease, a lot of prevention so on, especially in the '70s. You could see there was this sort of flat patch there in the '60s, which was mostly to do with smoking. You can see the flu epidemic the end of the First World War. So nothing smooth here, but this enormous dominant trend over a long period. These are all caused mortality, so this is not just from

opioids or anything else. It's from everything taken together.

And then, if you look at what happened after -- I mean, if you go back to that slide, you'll see that it started at 1,400 per hundred thousand deaths and finishing up at about 400 per hundred thousand deaths. So we're entering the new century, the new millennium with mortality rates at around 400 and you can see them in this picture here in which the redline is U.S. whites, non-Hispanic whites, and the other lines show other selected countries. We just picked those because they looked nice on the graph, but you could pick any other rich country and they all sort of look like this. There's France, Germany, the U.K., Canada, Australia and Sweden. We tend to call those Europe, which is a little odd given Australia's, Canada's in there.

But also look at U.S. Hispanics and U.S. Hispanics have continued for mortality to follow, about 2 percent per year where U.S. non-Hispanic whites have sort of turned around. There are no African-Americans on this picture and the reason I aid it's hard to fit them on the graph, but I can tell you I can tell you what's happening there. The mortality rates for African-Americans in the United States, so this period has fallen quite rapidly, more rapidly than U.S. Hispanics, but even at the end of their period, they're still higher than white non-Hispanics. So there's been a lot of convergence, but Blacks are still doing worse even though they're making more progress in terms of mortality.

The other thing that's happening and it's a very important part to see the opioid crisis within this framework, is that heart disease has stopped falling. And this has been a great driver mortality decline over the last 50 years, is mortality from heart disease and you can see that for U.S. whites, it's continued to fall in the last couple of years. It's flattened out and turned around and it's not because we've already driven it down to lower levels than all other countries, you can see that other countries are continuing to decline and they are doing better than we are. So there's a big problem there and that might be part of the pattern of dust of despair. If this is obesity, which many people think it is, then we've got obesity at over eating is sort of like drug addiction and so on. These are behavioral irregularities that are doing bad things to people's

lives.

So when we find this, we then went -- this is when we discovered about opioids because we came into the opioids this way, so we looked for the things that were driving up mortality rate most rapidly. And the three most rapidly rising causes of death since the turn of the century, which means drug overdoses, suicides and alcohol related liver mortality. So it's drugs, alcohol and suicides. We think of these as all being suicides in some way. I'll show you the relative sizes of these in a minute, but it's sort of like you can do away with yourself quickly with a gun or you can do it more slowly with drugs, but it's still pretty quickly. And you can do it more slowly through alcohol -- excessive alcohol consumption. And what you can see here is it's not just people in middle age. This is happening to all age groups, the 50 to 54 group at the top is the highest, but 55 to 59 is not far behind. And even the elderly are doing pretty well in other respects. This is rising in young people too, so this is happening throughout the distribution.

It's just that all cause mortality is not going up and these other cases that cause of the background of heart disease, for instance. And also, there's not that many deaths in those -- in the younger groups in particular. Here's a crucial slide, which is if you split this up by education group, the people really being affected here. This is true of all these things. People, we do not have a BA and in fact, the blue line for men and women, red line on top are for women and men with a high school degree or less. And people at the bottom, are people in this room who have a BA and that's really not happening to them. These are what we call desolate the spare which are drug, alcohol, and suicide mortality.

Now, this next slide says it's not just drugs, so you can see the drug and alcohol (inaudible) top left, suicide on the right and I'll call it liver disease on the bottom right and cirrhosis on the left. This splits it by high school, some college, which means like an associate degree and people with the BA or more. So that's about a third, a third, a third of the population and those groups have been stable over this period, so it's not like there's big compositional

changes in the educational background of the population. So you see very clearly for all three of these drug and alcohol placing which is basically opioids is what you're looking at here. The BA are more still going up here, but it's nothing like the people who have high school or less. That's one of the reasons why this has been so rural because education depends a lot of rural versus urban. But there's also been a lot of targeting by the pharma companies and by the distributors of where the pain is and a lot of this is pain connected and a lot of it is less educated people who are in jobs where injuries are more serious; where pain is more serious; where life is really much harder. And opioids have been very heavily used in our community.

But you can see from the numbers the drug and alcohol poisoning is about 60; suicide is about 50; and alcohol, liver disease is about 50. So of the three deaths of despair and we're not saying anything about obesity or heart disease here. The -- opioids is the largest part of this, but it's less than half of the total. So that's where -- and we like to see these three things together. It also helps to put the three things together because suicides (inaudible) was clear whether someone intended to kill themselves or not and if you put the opioids and the suicides together, you don't have to make that sharp distinction. The other thing here is urbanization and it's not true that this is primarily rural epidemic. It is true that compared with previous drug epidemics, it is a rural epidemic. But you can see here, these are the various levels of urbanization. The lowest one is large fringe NSAs which is where the well-educated people live up and down the east and west coasts. And then large central NSA, Baltimore City is now the highest -- one of the highest places, not just West Virginia and so on. And you can see it, but it's been rising more or less in parallel in all levels of urbanization.

And then, this is my second to last slide, this is what we call the two Americas slide. And this is, to us, the most troubling slide of them all. These are deaths of despair, so there are three causes of disease together. And what these look at is each line is a birth cohort, so it's the group of people born in a particular year and the older cohorts, the earlier born cohorts are the right of the picture and the younger cohorts are on the left. So you're moving to

younger people as you move from right to left.

The right-hand Graff is for people with a BA or more and the left hand Graff is people for high school or less. So if you look at the right hand one first, you and see that it rises with age over all these cohorts, but these birth cohorts are more or less all on the same track. So the cirrhosis -- it takes a while. You got to drink a lot and that takes years and you get older before you die from that. And drug -- and suicide traditionally all the way back to Durkime rises with age. So we think of this almost as a natural pattern that as people get older, they are more likely to succumb from these deaths of despair. But there's no great difference of later born and younger born cohorts.

But if you go over the left-hand side, there's just this horrendous picture that this pattern, if you look at the ones that (inaudible) born in 1945, 35, 40 -- we have only done every five years here otherwise, the picture gets too messy, but you can see those fairly gentle rise, fairly low level. You get to the birth cohort of 1950. These are people that entered the labor market around 1970 when the world started to come apart for working class people. And you can see it. The level is much higher and not only is the level much higher throughout life, but as you get older, it gets worse and it gets worse faster than the younger people did. So the slopes are getting steeper and look at the one from 1955, that green one. It's way higher and it's tipped up even more and that goes on and on, so for every birth cohort, this progress with age is getting worse and the level is getting worse. This is a profoundly pessimistic picture because elderly people in the U.S. are now doing pretty well, but these people are going to be elderly soon and if you believe this sort of -- what this picture is telling you then there's real trouble ahead.

Here's my last slide, the long-term decline for people without a BA. This is very provocative. Maybe it's not true, but is' this sort of explanation we've been working with.

There's been a breakdown in the implicit social contract between labor and capital that existed from the 1940s through the 1970s with health insurance, minimum wage, the Treaty of Detroit



whereby monopoly profits were sort of shared with labor and that's really sort of happened. The loss of real wages -- real wages have fallen for these people throughout this period. The loss of unions which offered wage and other benefits, better social life, local national influence, huge decline in marriage, rise of cohabitation and out-of-wedlock child bearing, the loss of traditional supported religions in favor of individualistic, evangelical religion, rise in disability, decline in labor force participation, increasing levels of pain, increasing social isolation. All of those have been tracking up together for these less educated people. Ann likes to use the phrase that opioids in the '90s were like taking a loaded gun into a suicide ward. So we think a lot of these tests would have happened without opioids, but have been made much, much, much worse by the opioids. So somehow, if you want to get out of this, we need better economic policies for ordinary Americans. We need to be able to share and not just let it all go to the top. Thank you very much.

(Applause)

MR. WEIL: We have time for a few questions. First, Sir Angus, Stan hold up your hand. Let's get a microphone to you so folks can hear and please introduce yourself as you ask your question. It's coming right behind you.

SPEAKER: Okay, and so as somebody from a union, I really welcome that final analysis which you don't hear. We represent (inaudible) as well as educators who really are on the front lines, but one of the things you said that was most interesting to me, people have talked about big pharma, but you really implied some very direct marketing into poor communities. Can you elaborate on that a little bit?

MR. DEATON: Okay, sorry. The simple answer to that is you can watch it on your television, which I did two days ago. If you look at the 60 minute program on what the distributors did and how they worked with Congress to block the DA and how the marketing was targeted at such areas, but the Congresswoman referred -- she didn't call it that, but Sam Cornones has this terrific book called "Greenland," which draws a parallel between the drug

industry and the Mexican cartels, which is incredibly informative too, but there were pieces in the New Yorker last week and Esquire the week before. There's a torrent of this stuff coming out and I think the deliberate targeting is very, very clear. And in fact, the attorney generals in a bunch of states led by Mike DeLorean from Ohio are going after the pharma companies in the same way they went after the tobacco companies for creating this epidemic.

MR. WEIL: We have a lot of people, so I'm going to hand the mic over there and then we'll come to the aisle here.

MR. DEATON: Sorry, maybe we can talk later, I'd be happy to.

MR. BLANK: Martin Blank with the Institute of for Educational Leadership. Professor, you talked about people recognizing the opioid crisis, but it seems to me nobody's built a bridge that your presentation suggested which is this is part of a very deep economic crisis in the country and opioids are fueling that. We don't seem to be having -- we have these siloed conversations that don't recognize the connection between these issues. Would you comment on that, please?

MR. DEATON: That's the line that's been delivered here in the spring which is available on the Brookings papers for economic (inaudible) website which essentially talks about that. There's a fair amount of push back and it's hard to nail it as to whether it is this broad economic decline, but we're finding that more and more convincing and we think it's not just economic conditions. It's really working through the destruction of a way of life for working class Americans that used to exist. I've been using the analogy of the plains Indians, they had had a life which you might have liked or might not have liked before Europeans came to America and that life was destroyed and was never put back together again. I think we're seeing that for the American working class over the last 40 or 50 years.

MS. O'CONNELL: Yes, good morning. Thank you very much. I'm June O'Connell. I'm originally from Wisconsin and have strong ties to sort of a manufacturing, semi-rural area of the state. And when you hear healthcare -- health policy people, they would say,

"Oh, we're getting healthier. People are living longer and were given healthier," but when I go back to Wisconsin, I have the family members that spend 25 years working in mills, their back hurts. They can't shift to working at Lowes because that's backbreaking too. And so as they've aged, they really haven't gotten healthier. So there's this myth -- I want to ask you about that. Somehow manufacturing jobs were healthy.

MR. DEATON: I think the manufacturing jobs were very tough, but a lot of the jobs that people have taken when they drop out of \$28.00 an hour jobs to \$7.50 an hour are very unhealthy too. This question about whether Americans are getting healthier or not, is very contentious and is divided right and left. If you go back far enough, it's clear that we are healthier now than we were, but you're getting these U-shaped things that I showed you and there's been improvement for a very long time. It's very unusual in any population in the world for mortality rates to go up and for life expectancy to fall. The aids epidemic; what happened in the Soviet Union is one example; the great leap forward, the Holocaust, I mean, you just have to talk about these things to see about how unusual and horrendous and we're talking about these things.

What you focused on is very true too and you see it in the data and then our Brookings paper, we talk about that a lot. There's been a huge increase morbidity, especially middle-age. A lot more pain. There's a lot of controversy as to whether opioids in the long run actually cause pain, make it worse, as opposed to curing it. So, but yes, it's pretty bad out there.

MR. WEIL: So we'll have a panel later and we have time then for only one more question. Get it back here. Mic's coming to you.

MR. MANGINELLO: Hi, my name's Michael Manginello and I work in the health policy field and I noticed over the past two days, I do a lot of work with the FDA and the NIH, that two different drugs by -- I completely agree that the pharmaceutical industry has created a problem, but two different pharmaceutical companies actually advance drugs, Pepanoferin in

different ways to -- for people to take them. I'm just curious about your thoughts about mat and pharma maybe being part of the solution since they caused the problem.

MR. DEATON: I Yeah, I mean, it's obviously a mistake to tie too closely solutions to problems. I also -- I'm deeply distressful of the pharmaceutical company based on their record and the idea that we would turn to them to fix this problem. It bothers me a lot, but that might just be wrong. And I'm sure those drugs (inaudible) and methadone and so on have a place to play, but there's a lot of journalism out there that I find very hard. AA has been wrestling with this problem for a very, very long time and it's almost impossible, we tried to find out, but you just can't document. AA has no one in charge, by their very nature, they will not tell you how many people come in and how many -- you just can't document their success rate, but I suspect AA is about as good as those drugs and there's a lot of journalism out there saying, "We have evidenced-based medicine in favor of pharma and no one has any evidence-based medicine in favor of tall step programs," and I think we ought to be very careful with that too. Thank you.

MR. WEIL: Okay, thank you and as I say, we will have a panel later with some more significant time for our audience engagement. So now, it's my opportunity to introduce to you Bertha Madras, already been introduced by Paul Ginsburg, so I'll turn over the mic.

MS. MADRAS: This is the first time I've ever had my slides on a Window-gridline. Do you -- can you get (inaudible) no, no, it's because the (inaudible). Thank you very much for having me. The title of my talk is obvious, "It's Been Made in America, Will it Fade in America, this crisis." These are my disclosures which I generally speak of before any presentation. What I'd like to present very quickly today is in the brief time that I have is the national trends on the opioid crisis; the root causes; the solutions; and, lessons learned. And I think all of these are very important. The ancient Greeks had a term called pharmakon. Pharmakon meant medicine and a poison and there's no better application of this terminology than with regard to opioids because opioids can produce profound pain relief. They also

produce profound pleasure in susceptible individuals. And the interaction between the two is what gives rise to this opioid crisis currently.

Pain is the number one self-reported medical reason for using drugs with abuse potential. Pain and pleasure centers in the brain are closely aligned and many forms of pain including psychic pain are relieved by drugs with abuse potential. That's really important to know. The United States leads the world in prescription opioids. It is number one compared to 30 other countries that are the largest prescribers of opioids on our planet.

The average opioid prescribing in the United States is five times higher than most other countries as you can see by this line. The United States leads the world in terms of opioid overdose deaths. If you look at the overdose deaths, only Estonia, which had a problem in 2012 and was cut in half very rapidly, there are other countries that are coming online very quickly now, Canada, Sweden, and certain other countries in Europe are beginning to see what we've seen. The tide wave is moving eastward and also westward because we're getting words from other countries in Asia.

The percent of drug overdose deaths due to specific opioids is also shifting. In 2016, unconfirmed CDC reports are that it's over 64,000. The lion's share are prescription opioids which are declining in terms of cause of death. Heroin, which is still increasing and above all fentanyl, which now accounts in 10 states for the most opioid overdose deaths. To such an extent that police and firemen and other people within the public service community have been recruited in order to reverse the overdose.

So what's happened? We have since 2001, close to 600,000 drug overdose deaths, a three-fold increase in opioid use disorder and it is the addiction to opioids that's driving these deaths. The U.S. death toll is 64,000. The driving force is prescription opioids and the transition from prescription to heroin and fentanyl is a range, but it's approximately 80 percent.

What are the root causes of this particular crisis? Generational forgetting is a

major root cause. For decades, prescription opioids were avoided for chronic pain. The reasons were very simple. Physicians were trained that opioids are addictive; they can produce an overdose; and there's no evidence for effectiveness given chronically until a five-sentence letter was published in the prestigious New England Journal of Medicine that said addiction rare in patients treated with narcotics. They measured the incidence of addiction in hospitalized patients and they concluded that despite widespread use of opioids, narcotic -- the addiction is rare in these patients. Anyone with a science degree or common sense would have known that this is junk science.

Number one, how many doses did they get? How long were they on them? What were the magnitude of the doses? Were they addicted after hospitalization? How long were they used? How do they define addiction? None of these were answered, but the evidence was weak and in spite of that, there were 600 citations, at least, to the single five sentence article in the New England Journal of Medicine. Almost all of them in the dark blue bars were affirmative saying, "This is right. This is accurate."

Low quality science received affirmation. What happened? It began to trigger a shift to the provider. Is that only two minutes left?

MR. WEIL: (off mic)

MS. MADRAS: God (laughs). Tragedy of needless pain. Pharmaceutical companies, one in particular spent millions of dollars in 20,000 events educating physicians on pain patients. The Veterans Administration adopted pain as the vital sign. A number of medical professional organizations bought into it and then became the pressure for assessing pain and using opioids in treating pain, so there was generational forgetting, quality science was forgotten, pain management and opioid prescribing increased dramatically and addictions were disconnected from treatment providers. Rehabilitation centers and that the healthcare system was disconnected. Pain assessment tools were ubiquitous in hospitals, in doctors' offices and clinicians continue to currently prescribe opioids for 90 percent of patients who've overdosed.

Ninety percent and they continue to prescribe high doses and in some cases benzodiazepines which are a lethal combination. Some, who bares the responsibility for this.

I've gone from one to two causes up to over 25 now. The poor science, patient pressure, physician advocates, the pharmaceutical companies, pain societies, the joint commission, Veterans Administration, the media who advocated for pain patients, poor medical education, poor patient education, rogue pharmacies, rogue physicians and so on. I can go into any one of these. Opioid prescribing increased dramatically and we became essentially, a nation awash with opioids.

With 11.8 million people currently misusing them, over 2 million with an opioid use disorder, at least 600,000 to 700,000 of heroin use disorder, the cartels in Mexico took advantage. They raised the purity of heroin. They dropped the price, fentanyl re-emerged and we had a perfect storm, a perfect storm for this. The President's commission on combatting opioid addiction met for the first time in June 16th of this year. I thought of -- I decided, how do we systemize our response to this. We can go into all the factors that are feeding this and then I said, there's another way to look at it and that is to look at what caused this and to reverse engineer the causes and both of these are in part in the report.

There's 65 recommendations including how we address federal funding; including prevention; including prescribing practices, data analytics, barriers to treatment, barriers to rescue, recovery support services and research, and also combatting the stigma and patient education. Many of those are addressed in the report. The areas that bear responsibility are addressed. The lessons learned, I will conclude are to scrutinize low quality evidence, scrutinize marketing evidence suppression, engage all stakeholders, not just advocates. This is so critical. Approval of abuse of all drugs need broader view. Anticipate unintended consequences, medical education needs to be current. Health insurers are a critical component of this issue and apply lessons learned to current movements to legalize and regulate all schedule drugs. The reason I say this is that in the fact of regulatory oversight, tight

scheduling, nothing protected the American people.

Alas, for those who've never seen the die with all the music in them, weep for the voiceless who have known the cross without the crown of glory for those 64,000 deaths. Thank you.

(Applause)

MR. WEIL: So again, we have time for a couple of questions before we move to the panel. I'll take the gentleman here.

MR. HAVACASH: I'm Harry Havacash, retired public health service officer. Have you looked at the medical marijuana and legalizing marijuana and what impact it's had and also, the needle exchange, HIV prevention as far as its impact on drug abuse increase?

MS. MADRAS: You may be aware that I wrote the World Health Organization report on the medical uses of cannabis. So I have looked at this very carefully. The best data we have which is very current, which was published I believe in August of this year in a very high-quality journal is that people that use marijuana have much higher rates of opioid use, as well as opioid use disorder. People who use for pain medications also have higher rates of opioid use and opioid use disorder. The data for long-term outcomes, the suppression of evidence that marijuana is addictive parallels with what's happened in the opioid crisis.

MR. WEIL: The woman right in front of you.

MS. COHEN: Hi, I'm Marguerite Cohen. I'm an OB/GYN physician in Portland, Oregon. In my state, 10 years ago, we were mandated to have eight hours of pain management in order to continue to be licensed in my state because we were undertreating pain and I need to go back and look at why that bill passed. Now, they're telling us, "Well, now we have to educate you the other way." But I think without campaign finance reform and a form of the influence of pharma, we're not going to get to a solution.

MS. MADRAS: We have three issues that are pressuring. The pressure is coming from pharma, clearly. The pressure is coming from pain patients and I think those two



pressure points help to feed the current crisis. The reversal now is really important, but what the Accreditation Council for Continuing Medical Education has found is that mandating training does not necessarily lead to practice change and there has to be far more intricate and obviously finely tuned measures to ensure that overdose -- over prescribing does not continue.

Educated physicians are brilliant to learning things quickly and being able to pass tests. That does not mean that they will absorb and change behavior and there's no question in my mind that it is the nation awash with prescription opioids that fueled this current crisis.

MR. WEIL: Take one last question here and then we'll move to the --

SPEAKER: Hi, (inaudible)

MS. MADRAS: Yes, I can hear -- I'll repeat the question if nobody can hear you.

SPEAKER: I'm a senior at American University and I've been talking a lot about dentist and people of college age individuals that get their wisdom teeth removed and get 30-day supplies of opioid being a huge part of this problem and I wanted to know if you could talk about that at all?

MS. MADRAS: Yes, we're quite aware of the problem with dentists over prescribing and courses have to be taken by them. The DEA and our recommendations in order to be re-registered by the DEA, which requires annual registration, has to show that you've taken a proper course. As I said, that's not good enough.

The solutions seem facile, they're one sentence solutions. Increased treatment, as Sir Deaton said so eloquently, doesn't mean that treatment is going to change the face because a treatment does work in many people, but in do -- 70 percent of people don't show up for treatment. They don't think they have a problem. That's what our (inaudible) studies say. The same with prescribing. The say that you've taken a course and that gives you the right to prescribe schedule two to five drugs doesn't mean that you're going to change practices. There are ways data analytics; there are ways of excavating databases in the country that are being implemented and that we recommend very strongly to find out who is prescribing

pharmacoepidemiologists, absolutely brilliant ones. I suggested this 10 years ago, long before the CDC guidelines. I suggested this while I was ONDCP that we need to recruit pharmacoepidemiologists to understand how many pills for each type of pain that is sensible for a tooth extraction, it may not be more than two or three, instead of 30 to 90.

MR. WEIL: Okay we're going to move to the panel discussion. I'm going to invite my two additional panelists to join up here. Jason Doctor, the Normal Topping Chair in Medicine and Public Policy at the Schaeffer Center for Health Policy and Economics, Price School of Public Policy at the University of Southern California. Rebecca Haffajee, Assistant Professor of Health Management and Policy at the University of Michigan, School of Public Health.

As they take their seats, Paul Ginsburg, at the outset, mentioned some work I've done in the area and I just want to take moment to bring that into the discussion. First of all, at *Health Affairs*, where I'm the editor and chief, just in October we had an article on trends in inpatient and emergency department use associated with opioids. Very important information for addressing the issue. We've had a number of papers on the effectiveness of prescription drug monitoring programs which is a topic that comes up fairly often. We have very powerful narrative matters which is a first person narrative of a person who was trying to get themselves off of opioids in a health care environment that didn't actually seem particular interested in helping them with that. I hope you'll look to some of the work in *Health Affairs* on this topic.

In addition, Paul is a member of the Aspen Health Strategy Group where I'm the director. The Aspen Health Strategy Group is only two years old. It's a program of the Aspen Institute. It brings together CEO's from a broad range of organizations. Aetna, the Robert Johnson Foundation, the National Academy of Medicine, Epic, Merck, Marriot, Consumer Reports and the like. Each year, the group takes on an issue. It is chaired by two former HHS secretaries and governors, Kathleen Savillas and Tommy Thompson. Our second year which is the year that is coming to a close, the topic was, the opioid epidemic, and the group spent a few

days discussing it with background papers prepared by experts in June.

The groups were in the final process of finalizing the report but it's framed around some findings that I think will be familiar, if you've been here this morning, and some recommendations as well. The complex origins of the crisis as we definitely heard a lot about this morning, the multiple roles of the healthcare system in creating and addressing the crisis, the significant gap in treatment availability and the significant gaps in our knowledge about the nature of the crisis. As well as the need to find partial successes and learn from them and spread them.

That led the group to propose suggestions in five areas. The first around over prescription. Again, you saw the data just moments ago about how we're a global outlier and the need to bring rates of prescribing down. The need to treat addiction as a public health issue. This doesn't mean there is no role for the criminal justice system but it does mean that addressing the problem has to primarily be viewed through the lens of public health. The imperative of stopping the deaths. Overdose is reversible. That doesn't solve the problem long term but it does prevent deaths and create an opportunity for treatment. The importance of guaranteeing access to treatment where we have a tremendous gap in availability. And finally, to increase our investment in data and knowledge so that we can improve treatment of pain as well as treatment of addiction itself. This is a report that will come out from the Aspen Health Strategy Group later this year.

With that, what I'm going to do is ask our two new panelists who work in this area to describe just briefly what their work is and to give a little context to some issues that haven't been brought up as much in the morning sessions. And then I'll ask some questions of the panel and we'll open it up to you. So, let's start with you, Jason.

MR. DOCTOR: Thank you. My work is in the area of physician decision making and encouraging better prescribing. A lot of what we've been talking about today, fits in with that. I think some of the comments by Sir Deaton and also Dr. Madras, relate to this type of

work. Some of the big issues are around the fact that something Dr. Madras brought up, clinicians are good at learning clinical facts but to be an expert in decision making is an entirely different thing. What we've seen is that there has been this breakdown there with regard to opioid prescribing and how do we address that.

One way to address that is through reversing the social pressure that was brought on to increase prescribing by having doctors be more accountable for their prescribing and also to know what their peers are doing and to understand who are the top performers and who are the top performing physicians in their practice and to incentivize prescribing that is safe and effective rather than perhaps unsafe. That's going to require data. It is also going to require closing the loop on death which is that doctors don't understand or they don't know. They don't learn of when their patients die because we have a fragmented healthcare system. So, these large clinical data networks and databases, PDMPs, this data needs to come together along with medical examiner data so that doctors can understand, what are the effects of the prescribing that they're doing. Also, as they scale back on prescribing, what are the effects on illicit drug deaths as well.

The third thing that I'm interested in is non-pharmacologic treatments for pain. These were actually quite common up until the mid-90s. They fell away. Partly that was economic. The economic model behind them wasn't very sustainable. But there has been a lot of work since then on those treatments and there's ways to deliver them that are much more cost effective. Physicians need training in that and we need an infrastructure for supporting that and also reimbursement for those treatments.

Those are kind of the issues that I'm interested in working on around the crisis. I agree with the committee's recommendations and report that this crisis is not easily characterized medically, it's not easily characterized legally. We have to think outside the box, bring together new ways of addressing the problem that will tighten the hold on opioids so that we can reduce exposures because that is what's driving new addiction and dependence on

these drugs.

MR. WEIL: Thank you. Rebecca.

MS. HAFFAJEE: Thank you. Thank you so much for the opportunity to participate in this panel and for the excellent comments you've heard thus far. I'd like to emphasize three policy recommendations based upon my work which is as a lawyer and a health policy researcher around wise policy response at the state and the federal level to this epidemic.

First, as a matter of procedure, the imperative that we distinguish, public health emergency actions from those that are non-emergency. Second, the need to nationalize policy, in my opinion, around prescription drug monitoring programs, something that I study closely. Third, key mechanisms to increase the provision of affective opioid use disorder treatments. I'll focus my comments on Buprenorphine.

First, in terms of recommendations, we've had a lot now. 56 from the commission, we've had a National Academy of Sciences report, we've heard President Trump's comments last week. So, the question is, all of these things are important, where do we start. Given the public health emergency declaration a week ago, and to make this more than just a symbolic act, we need to think about what the best use of those powers are. Really that's for acute imminent public health threats. What can we do in the 90 days of this order to really make a dent in these opioid overdose deaths, 91 happening every day? So, we need to be thinking about allocating money and funds in the public health emergency fund which currently is almost empty and having Congress appropriate money towards that and think about particularly increasing a Naloxone and medication assisted treatment therapies using that money. Increasing the provision of that at the state level and in a Naloxone to EMT's to other community workers to prisons and potentially friends and family. So, we can really make a dent in that particular outcome in the very short term. And then think about many of these other recommendations over the longer term that are more structural. And that money is going to

need to be appropriated, even just for the public health emergency in my mind, in the billions.

Second, the federal government has an increasing role to play in prescription drug monitoring programs or PTMPs. These are state based databases that aggregate controlled substance prescribing. They are very rich databases. They've been around for a while and 49 states have them. From a policy perspective, they are very heterogeneous and we've now tested a number of different features in the laboratories of the states. The federal government has been funding a lot of this and currently there is an act, the PDMA of 2017 proposed in the Senate. I think that gets us part way there to nationalizing some standardized metrics and features of the program. It would condition funds of PDMPs on data sharing at a federal DOJ hub and also daily updates of the data. I think we can go further because we know other mechanisms that are effective with these programs. The Commission did recommend mandating use of the systems. I think also mandating registration for controlled substance prescribers, allowing delegate access, integrating the data into EHRs, actually using these databases as referral centers. So, being able to search and find treatment providers in your locality using the databases. These are all best practices, many of which are very evidence based at this point. The federal government has a role to step in and really standardize these systems.

Finally, and increasing the access to medication assisted treatment therapy, or MAT, in my mind is an imperative. The treatment gap is substantial. We have almost about 3 million people with opioid use disorders. By best estimates we think like less than a million of those are getting treatment or some say 25 percent. Of those, some are not even getting the evidence based treatment. So, medication assisted treatment therapy, it does actually have quite a strong evidence base. I agree with Sir. Deaton that we haven't been able to test some of the other alternatives but we do know that these medications, especially when supplemented with behavioral health counseling and other support services, are quite effective.

Buprenorphine, in particular, I think has great potential and maybe Naloxone although the

evidence base isn't quite as strong for that drug yet. Because they can be provided in primary care settings and we can get that access from a primary care provider and not having to go to addiction specialist of which there is a supply also.

So, things to be thinking about, some of which the Commission recommended but some of which they didn't, include eliminating the waiver process for Buprenorphine prescribing and instead, training more broadly in medical school and CME education. Reimbursing better for counseling and support services so we're getting the full panoply of support services here and reducing the costs. Some of these drugs are very expensive and the federal government could play a role there so that insurers can cover them robustly and prescribers can choose which therapy is best for their patient. Finally, things like loan forgiveness and other financial incentives for providers to actually get out into those areas, those rural and underserved areas where there aren't providers providing these services. As much as we can reduce stigma and get patients to try to access these services, and those are very important, if there aren't providers to actually provide these services which right now there is a lack of supply, then we're not going to get very far. Thank you.

MR. WEIL: Great. I'm going to start with a couple of questions to the panelists here. I want to set aside the broader economic structure of the American economy which is probably a little more than we can take on. I did promise we wouldn't talk tax policy this morning. And setting aside even the question of how many dollars need to be added to responding to this problem, I'd like to try to get a sense of how much consensus we have. It's been commented repeatedly that we're having more conversations. It has moved up on the agenda, those are all true. But is there really consensus, where do we have consensus about either the nature of the problem or the response to the problem. Where is there still significant disagreement?

DR. MADRAS: I think there is very strong consensus on increasing access to treatment, increasing access to rescue, increasing healthcare insurers responsibility in this

because they have an enormous impact. They approved prescription opioids indiscriminately, yet they put roadblocks in terms of approval for medication assisted treatment and they put roadblocks in approval for treatment itself. I would say that almost every one of the recommendations you have is in our report in terms of the entire spectrum. What is controversial, I think, and which most people who have these, what I call, facile solutions because they're almost chapter headings, is once you start to think about reducing to practice, it's far more complicated. Educate physicians. Will they listen? How do you get medical schools, 125 or so, to incorporate pain management, opioid prescribing and addictions recognition and treatment into the curriculum? I've tried for 20 years on this one. There are so many issues that have resistance to change from many sectors of our society and the buy in can easily be accorded to the federal government. Because the federal government has regulatory, legal, statutory oversight and also finances.

But getting people to be interested, physicians to be interested in taking care of people who have an opioid use disorder, is difficult. You can give them waivers for Buprenorphine, you can teach them how to administer and yet the number who have waivers and actually have patients who are eligible, is a fraction. Recruiting people into this area is not that easy. So, the big topic headlines are quite facile and they are logical and there is tremendous buy in from all sectors. Reduction to practice has another layer of analysis that is far more difficult and the Commission tried to do that.

MR. WEIL: Anyone else want to take this on? Sir Angus.

SIR DEATON: Just very briefly, it's worth noting that these things are not prescribed in Europe, by enlarge. In Britain for instance, opioids are rarely prescribed outside of hospitals. If you had a hip replaced, they'll give you some when you're in the hospital but you don't get any to take home and we could move towards that. I would point out that in Dr. Madras's slides, you do see this drop. The doctors are in some sense, getting a hold of this and the prescription opioids are going down. You really do worry about the Heroine dealers and the



Fentanyl dealers who are standing outside the pain clinics waiting to take over the patients who have been told by their docs that they can't have that anymore. That, we can deal with to some extent, because we've dealt with drug epidemics before, but that will not be particularly easy.

Just to raise another point, I worry a lot about this term, evidence based, which always comes with a positive connotation. Evidence based is good, not evidence based is not good. Evidence based usually means a randomized controlled trial, at best. Remember what a randomized control trial does. It tells you it works on average so that more people benefit than are hurt. But it is quite consistent with very few people actually benefiting from a particular treatment. So, we just need a richer structure. Remember, the FDA is an evidence based agency and it approved Oxycontin. If you read the report in which they licensed it, they talk about it being safe because physicians know who is likely to be addicted and who is not likely to be addicted. I don't think physicians know any such thing. If I swallow an Oxycontin, I throw up, so I'm probably not going to get addicted from Oxycontin. Apart from that, I don't think my physician has a clue as to whether I'm an addictive personality or not. If the FDA is an evidence based thing, it got this very, very badly wrong. I presume there are recommendations in the report which I've read and the National Academy of Sciences said that too. But the FDA didn't come out of this covered with glory nor did evidence based procedures for approving pharmaceuticals.

DR. MADRAS: The FDA is actually hit very hard in this report. In one of the lessons learned, I can read it. I wrote it so I should not have to read it. The approval process of medications with abuse liability should not be restricted to drug safety and efficacy in short term clinical trials. It should expand its oversight and consider the number of doses, duration of a prescription and the possibility of misuse, diversion and tampering and other consequences not traditionally a component of evidence required in the approval process.

MR. DOCTOR: Just on that point, I personally went back and read a lot of the FDA commentary from those meetings when they approved reformulations of Oxycontin and

when they approved Oxycontin. What was interesting to me was that the idea of the FDA for getting an expert panel together was to get people who had experience using opioids. Those generally were palliative care doctors and some pain doctors. Those doctors are using massive amounts of opioids at the end of life and their patients are on deaths door anyway. So, they don't really understand the notion of addiction or the notion of a life being shortened by addiction or the effect these drugs can have. I think that is also part of the problem. We should have people who have suffered addiction on those FDA panels. We should have addiction experts and extend who it is that approves these drugs not just people who have had experience prescribing them.

MR. WEIL: It does seem to me that the question of whether we view treatment as effective, Sir Angus, I think I heard you say treatment is not very effective. We also have places where we don't have good evidence because we don't have the trials. Then you commented on the limitations even of those. The congresswoman spoke about how we have very different expectations for other chronic conditions and we don't say, well one try and you're out and one failure and you're out. I guess I'm curious again. I'm always looking for where there is consensus but also want to hear where there is disagreement. What do we really think about the effectiveness at this point? Is this a matter of shifting expectations to be more realistic or are we very far away from even understanding what the right modalities of treatment are.

DR. MADRAS: Well, I think it's an excellent question. Number one is that, this is a work in progress. We heard from insurance companies and from the Department of Labor on the difficulties of reimbursing because there are algorithms for treating almost every medical condition except for addiction. For chemotherapy, there are so many rigorous standards that are being used and applied for most medical conditions. In this case, it's an open field day in terms of what goes. I have been to many treatment centers in the country, some of which are excellent and others which are bizarre and so out of kilter with what we consider standard of care, that it shocked me that the federal government would reimburse for this.

So, there is the American Society of Addiction Medicine, the American Academy of Addiction Psychiatrists. Both organizations are trying to develop a set of care standards that would be applicable across the board. The Commission clearly understands that this is a problem and also understands that treatment is not a one size fits all for this condition compared to many others. If you have an infection, there is a standard way of dealing with or diabetes or cardiovascular disease. With addiction, think about Lee Robbins study of Vietnam War veterans, 20 percent of whom had returned from Vietnam with a heroin addiction. Of those, less than 5 percent remained addicted and the vast majority never entered a treatment center.

So, there are clearly cultural, sociological, family factors that deal in. On the other hand, the other extreme, 80 percent of people who are addicted to opioids and who do not have medications assisted treatment relapse very quickly. So, we have very different populations with different genetic platforms that are, in fact, in need of help and we have to understand how to tailor the help depending on the individual. At this point, we have certain principles of addiction treatment that, I think, are clear. It is a long term chronic disease that requires continuum of care for the duration just like diabetes.

Medications assisted treatment helps the vast majority of people. Other people don't want an agonist and an antagonist may serve the purpose. There are so many considerations on an individual basis. There are certain subcultures that would be treated differently than others.

SIR DEATON: A tiny remark. I worry about statements like 80 percent of people who are in medically assisted treatment. That is a form of the population who will go into that program. So, you've got a very large number of people who will not go into those programs. The congresswoman talked about people not admitting they're addicted. That's a huge problem in alcohol as well as opioids. People just don't say they have a problem. There are people who run hedge funds while addicted to heroin. It's amazing what you can do.

We tried very hard to spend time at AA meetings finding out what goes on there.

It is clear that AA, even though it is impossible to study systematically, works for a lot of people who are in there or they believe it works. I see no particular reason to doubt that simply because it is impossible to do a randomized controlled trial. I think there has been a lot of difficulty with courts mandating people go to 12 step programs which leads to all sorts of abuse. For people who believe in markets, most of those AA treatment centers or 12 step treatment centers are financing themselves out of money that people pay for the treatment.

MR. WEIL: I want to focus on the A in MAT because we talk about the M, the medication but the assistance side. A and I'm thinking, Jason, you talked about the non-pharmacological treatments which is a different kind of A but gets at this question of what is the non-medication side of this. Rebecca, you talked about treatment gaps. I just wonder, it seems like there is a lot of attention to, what are the drugs, what are their affects. What do we know about the non-medication element of the treatments?

MS. HAFFAJEE: Well, the study suggests that the medication assisted treatment therapies on the treatment side, particularly Buprenorphine and Methadone. I agree that those are short term trials, typically for specific populations. In my reading of the literature, a strong evidence based for reductions in opioid overdoses, opioid use and misuse, spread of infectious diseases, many important outcomes. It is quite strong as compared to other areas in levels of evidence we have in other areas of healthcare and health policy.

I do agree, we haven't been able to study as well. Generally, the study suggests when we think about MAT, it actually includes not just the medication but also the behavioral health therapies which can include counseling and other forms of support. Generally, the evidence suggests that adding those other components, the counseling, for example, the evidence says that it does not increase the return of these therapies above what you would get with just the medications. That's what the evidence says. But, I think, we know that the best practices are to actually include those counseling and we haven't been able to study the effects of adding on those other therapies on top of the medications. Also, we don't know the effects of

the medications and that combination of therapies over the longer term. So, we really need to have better evidence generated in that regard. I agree, I just worry that I don't want us to go back to this philosophy that absent are as effective as the medications because the evidence does not say that.

MR. WEIL: I've got another question and then I'll open it up to you all. We've still got a good bit of time. I want to ask about, Sir Angus, you showed the racial ethnic breakdowns and there is, I think, a broadly held belief that this is a rural problem. You mentioned that what makes it unique is not that it's rural but it's more equally rural than some others. There is also, I think, a lot of publicity around those who are newly addicted and affected by the crisis who are white. I'm interested in how any of you think these beliefs, to the extent that they are or aren't rooted in data, affect how we're responding to the crisis.

SIR DEATON: Well, you get into a lot of trouble talking about that. If you listen to politicians talking about the crack epidemic, white politicians, there is a famous speech from Ed Koch in New York talked about. Which was, I have no sympathy for these people at all, they should be thrown in jail in they've addicted themselves, they deserve everything that's coming to them. That was the democratic mayor of New York City talking about black people. And now you have Chris Christie who is the poster child for the way that even Republican politicians now talk about this epidemic which is largely an epidemic of white people. And that is certainly not been lost on the African American community who are very sensitive to the differences in tone. Epidemic used to be a criminal behavior when it was done by blacks, when it's done by whites it's a disease.

That's horrifying and we have to live with that and we have to sort of atone for that somehow. It doesn't mean that the disease approach is incorrect. I don't think, I haven't heard anyone who says, because of this history that we can arrest our way out of this epidemic, that we can throw addicts in jail and that will really fix things. So, there is this disgraceful history behind us and it's very hard from a sociological point of view. There is a famous old book by

Cortold, I think, about the opioid history in America. He makes the point that over 200 years, the treatment of opioid addiction has always depended on who it was who was consuming the drugs. Not necessarily across the racial and ethnic lines but across socioeconomic lines and whether it was man or whether it was women and so on. The history of American medicine has a lot to answer for in that regard.

I'm not sure how much that affects what we should do now. We should be behaving well now and I think most of what people believe is that this is a disease, that addiction is a disease. It is a very difficult to treat disease and it should be treated not punished and that punishing doesn't really help very much. That said, I think social sanctions against this could be very important. So, that was why I emphasized the very beginning of my talks, that communities knowing that this demon is out there and trying to stop it. The people, when a doctor gives you some Oxycontin, you say is that Oxycontin, I'm not taking that. Think of some other way of treating me. So, there is just a lot you can do by knowing about this and people knowing about this and shying away from this.

MR. DOCTOR: I was just going to say, on the prescribing side, and we know a lot of this from research published in your journal, with regard to health disparities, there is a tendency to overtreat whites and a tendency to undertreat minorities. This is an example of that. It's possible, we don't know, but it is possible that there is implicit bias happening on the prescribing side that doctors are more concerned about addiction with minorities and not at all concerned with whites. And that could have potentially have driven this high level of prescribing willingness to become more liberal with opiates given the pressures with the fifth vital sign and other factors.

So, just in general and to think about health disparities in that way, I think, is useful because it does affect all sorts of racial and ethnic groups in different ways. This is one example of that.

DR. MADRAS: There are a number of issues that I would just like to point out

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and also ask Sir Deaton some questions, if I may. If you look at the NSDUH survey, the National Survey on Drug Use and Health, it is the largest database we have in terms of substance abuse disorders in the country. It surveys annually, about 70,000 people. In terms of the prevalence of opioid use disorders, it is highest among whites, 72 percent and it is about 13 percent among Hispanics, 9 percent of African American's. Over represented are 18 to 35 year olds, 56 percent males, 57 percent low income, 67 percent residents of large metropolitan areas, 50 percent and about 40.1 percent have private insurance. So, the demographics are quite -- they are not simple. There are a lot of people in metropolitan areas, there are a lot of people who are non-white that are using. But what I found interesting in your data is the upsurge in deaths of people who were born from 1960 onward. One of the factors, there are two factors that I really would love to interrogate with regard to that.

Number one, that was the period in which chemical coping and chemical rewards became a national philosophical approach to life. Drug use surged in the 60s and 70s and has not abated really, since that time. The only dramatic fall we saw was when Len Bias died in 1986, first pick for the Boston Celtics. Right after that, cocaine use just went straight down because he had one dose and he died. The concept of chemical coping and chemical reward, with regard to these demographics, I think, has to be interrogated.

The second issue that I think is really interesting, is doing longitudinal studies on individuals starting from pre adolescence all the way through into their 60's. George Valiant at Harvard has inherited a project that began in the 1940s. Interrogating what happens to individuals throughout their lifespan and using alcohol and depression and other cope factors. What he found is that in many cases, the use of drugs preceded unemployment, depression and all these other consequences. So, that some people have said, well alcohol is used to cope. And what his data showed is that alcohol is the precondition factor that gives rise to a loss of employment, a loss of motivation, a loss of hope, depression and all that. I think that unless we have individual longitudinal studies that look at what are causes and what are affects as well as

understanding the genetic platform. I don't think we can sort out whether or not unemployment is the cause or drug use give rise to unemployment.

The other thing that I think has not even begun to penetrate our collective conscience is the concept of epigenetics. Epigenetic changes that give rise to multi-generational drug use, there are pre-clinical studies in animals that show that if an animal is exposed to drugs during adolescence and then they never see the drug again and then they mate as adults, their children, their offspring, in fact, have a predisposition to liking drugs at higher rates and their brains are different than the brains of animals whose parents were not exposed. I don't know how far the research will get, whether or not it is applicable to humans but I think that this is an area that requires some in-depth scrutiny going forward.

MR. WEIL: (No audio) leaves you all without questions or maybe there are enough questions on the table, it's hard to add anymore. We'll go to the center here.

QUESTIONER: I wanted to get back to what you were talking about medication assisted treatment and if you could expound a little more on the biological basis of the disease. The difference between addition and dependence. Partly I ask the question because, in working with some governors, I know there has been some frustration about the court systems and judges who sometimes view medication assisted treatment as, you're still an addict, you're still using a substance, you need to go to jail, you can only go into therapy if you're off of treatment. And then also, Professor Madras, the epigenetics is a fascinating area. I don't know if you've looked into epigenetic changes from chronic pain or untreated pain as well, the flip side of epigenetic changes from opioid use.

DR. MADRAS: That's a wonderful question. Our report does recommend that medications assisted treatment be offered to prisoners, to parolees, to everyone and judges have to back off and give rise to modern medicine instead of personal points of view.

DR. WEIL: I realize when I asked my first question about consensus, there is, if you will, elite consensus and then there is broad consensus. I fear that part of what you



captured in terms of consensus was sort of an elite consensus. I don't have another word for it.

DR. MADRAS: I think that we need to inject science into opinions. There is so much misinformation about drugs in our communities, in our legislatures, in our valid initiatives that don't match the science. In this case, the science says that medications assisted treatment, as my colleague so eloquently stated, reduces HIV/AIDS, reduces reversion to using heroin, keeps people in treatment, reduces a lot of the consequences of heroin and other types of illegally obtained drugs. And the reason is, the biology is different. When you inject heroin, you get a surge, an absolute surge of, I won't use dopamine but dopamine is the common vernacular. You get a surge in the reward system. That surge and then the serenity and all that persists for quite a long time. With medications assisted treatment such as Methadone, Buprenorphine, you don't get the surge. The surge comes with heroin, IV or insufflation or smoking. With medications that are oral, you just get this even steven sense of peace, your opioid receptors are not screaming for high doses and that's what enables a person to have a relatively stable affect during that period of time.

The antagonist like Naltrexone block the receptors so that if you're tempted to use heroin, you don't feel it because the sights are occupied. It's like having a key in the door and you try to use a fake key, that key is not going to work because there is already one in the door.

MR. WEIL: There's a question over here.

MS. SILAR: Hi, thank you. My name is Naomi Silar and I teach health law and policy over at GW. My question is regarding insurance status. I know we're not talking tax policy but it is hard not to talk about health policy a little more broadly. With the consensus that there needs to be increased access to MAT, increased access to alternate modalities for pain treatment, there is an assumption that someone will be paying for that. But particularly, some of the populations that Sir Deaton showed was at risk are most likely to be uninsured, middle aged men, poorer men, et cetera. So, I was curious, Sir Deaton, if your data included any information

about insurance status with regard to deaths of despair. Not necessarily as a causative factor but just if there is even a route towards payment for these kinds of services for those populations. And then, just if others have comments about what is going on with attempts to increase or decrease access to insurance for these populations.

SIR DEATON: We don't know the insurance data's. Most of the evidence you've seen there comes off the death certificate so if it's not on the death certificate, we don't know. The one thing we haven't done as much on as we should is marital status which I think is a huge cross cutting thing here. I'm sure it's important. I should say though that pain treatment is almost as hard as addiction treatment. The reason that Ann and I got involved in this is, she suffers very badly from lower back pain and docs have no idea how to treat lower back pain for a very large number of patients. So, you can see why that created a huge opening for drugs like this. She also, like me, throws up when given opioids so not even they work for her. That's a real problem.

MS. HAFFAJEE: I think just as to your question about the uninsured, I think that is a huge problem. I think back to Representative Kuster's comments, that kind of is a reason that we need to maintain these Medicaid expansions, include insurance on the exchanges but there will still be a significant portion of the population that is affected by this epidemic that are uninsured. That's where a lot of these community level interventions, providing funds and block grants to states to be able to provide more in a lock zone, provide more medication assisted treatment therapy, putting infrastructure in to more housing, more unemployment assistance, those sorts of things need to come into play. That population is going to be harder to reach.

MR. WEIL: Towards the back.

QUESTIONER: (off mic) of Baltimore. I have a pretty -- and I've done that long enough to see the pendulum swing from providers not wanting to treat pain to perhaps overtreating pain. But obviously as somebody who sees people who often have advanced illness and terminal illness, the population for whom these drugs were intended and who, in

many cases, do take them appropriately if you can manage the potential from abuse from family members and neighbors. I'm concerned that the knee jerk reaction certainly among clinicians right now is, no one is going to get these drugs. I'm just asking, how is that being factored into the national dialogue because they are appropriate for some people under hospice using these medications is generally very effective and appropriate. So, how are we going to handle that to make sure that they continue to have access to these drugs?

MR. DOCTOR: That's a great question. So, we know that opioids are useful at the end of life, we know they're useful for cancer pain. You mention that there is still issues with addiction in some cases, particularly with cancer, and that is true. However, we also know that these drugs are not effective long term for chronic low back pain, for example, for migraine headache, for fibromyalgia and yet we have inordinate prescribing for those disorders. I think part of the issue is around making sure that the conversation always includes acknowledging that at the end of life, opioids are appropriate. But also, that they're not appropriate if you have a chronic, long term condition. One issue with prescribing and why it increased, has to do with the fact that people treating patients at the end of life thought it might be a good idea to extend palliative care to others who had longer to live and chronic conditions. That was partly based on that information from the Porter and Jick article and other articles that said addiction was rare. So, I think the pendulum does still have to swing back to less prescribing but it doesn't have to do so for all conditions.

DR. MADRAS: I completely agree but I think one of the unintended consequences of an overreaction with tamper proof medications, with cutting down patients precipitously was that there was no attempt to think through what will happen to patients who are precipitously removed from drugs. One of the questions that went unanswered, what is the difference between addiction and dependence. Dependence is becoming more and more of an obsolete term because it used to imply both addiction as well as physical dependence. And physical dependence can happen to every single person in this room on chronic opioids. If you

are given them for a few days or a few weeks, you will go into withdraw, most of you will. And that has nothing to do with addiction. It's just that the body neuro adapts to the opioids and you end up with cold sweats and nausea and what have you. Nobody considered once you remove an individual that they could go into withdraw and they were addicted and they were going to go to heroin, they were going to go to the street because it is less expensive and you don't need a prescription. That kind of scenario is something that we addressed in the report as one of the unintended consequences as well because medical education now has to include screening of patients for addiction. An alert system that says, if a patient has developed an addiction to opioids, there has to be an algorithm on what to do about it rather than just say, this is enough, there is no evidence for it, goodbye. That's a drastic step that was taken that has really caused some of the problem we see now.

SIR DEATON: Just one quick remark, in Britain they've used heroin end of life forever and it has never resulted in this problem. I agree with what Bertha just said which is incredibly important that getting there is the hard place but there is certainly a solution in which opiates are used at the end of life without generating the crisis that we've got here. That doesn't help you get from here to there.

MS. HAFFAJEE: And just one last comment, I think to the different conditions, there is a lot of work we can still do and the Commission comments on this also on the acute prescribing side also. We have the CDC guidelines for prescribing for chronic pain but we know that a number of people do get addicted upon the exposure in the acute pain context but opioids are quite effective for treating post-surgical pain and things like that. Coming up with, and then we know people, if they get more than 5, more than 9, more than 30 days of a prescription, they are more likely to become long term users. I think doing some more work around, what are the acute prescribing guidelines and there are some places like there is an initiative at M Open in Michigan where they have come up with some of these prescribing guidelines and maybe we want to ramp those up to a national level. But thinking about, what are recommended best

practices for acute prescribing. Some states limit it to 5 or 7 days and things like that. Giving those prescriptions and then having the patient come back and if they need additional pills, give them at that time instead of initially giving the 30 day prescription. So, there are some other levers that we can use, it's not all about either giving the drug or not giving the drug.

MR. WEIL: Right behind the person who just asked the question out towards the window.

MS. CHA: Hello, I'm Gi Yong Cha. I'm working in Health Policy for the federal government. When I actually think about the opioid crisis, I can't help but thinking about the pain management issue. As the person who just asked the question, there are people who actually need this kind of medication but at the same time, pain is a very personalized experience and it is also both physical and psychological. We have tons of scientific evidence nowadays saying that pain sensitivity and pain catastrophizing actually affects the usage of the opioids. Also, there are people who are prone to more depression, they are also prone to more addiction and utilizing the opioids. So, it seems like if we really want to talk about the prevention, we probably need to talk about the more (audio dropped).

DR. MADRAS: Just very quickly, in our commission report, we have, by the way, 65 recommendations, which includes the interim report. One of this that we do comprehensive mental health screening as well as addiction screening as well as physical screening of all patients. So, that we can understand where along the spectrum they lie with regard to anyone of these three converging issues that could give rise to pain as well as opioid prescribing as well as addiction.

MR. DOCTOR: That was a great question. I was just going to comment is the way that we've been thinking about pain is in terms of driving down numeric pain ratings with opioids. That has led to building up a tolerance dependence, addiction. As you describe pain, there are really psychological and social elements as well. You may be out of a job, you may be having problems in your family life that are making the pain more apparent to you. Once we can

reconceptualize how we treat pain and to see it as an issue that extends beyond just a neurologic event, then we'll be able to address it in a better way and in a way that does not necessarily require opioids.

MR. WEIL: I'm going to interject a question and then we'll take a couple more and we'll be at the end of our time. I want to talk about leverage points for change. I'm just struck by how much we're hearing needs to happen. Those of us who work in healthcare know and Bertha, you went into some detail about this. The translation of good ideas into overcoming all the resistance both intentional and often unintentional just because people are busy, that transition is very difficult, very slow. This is a problem that we don't want to sit on and let it go fester. The downward turn in prescribing does seem like a good data point. I'm interested in some other thoughts around leverage points. You went quickly over the slide where you showed the separation of the addiction treatment system from the rest of the healthcare system. That seems like a potential leverage point because we're doing all kinds of things, supposedly, to change delivery of care in healthcare and hold health systems accountable for outcomes. If we could push this into the stream, that seems like a stream that might give us more force behind us. Rebecca, you talked about the Emergency Declaration, the potential of federal authority to move things along. The congresswoman spoke a lot about local action necessary. I want to move a little bit away, not that they aren't important, but the questions of what we need to do to the how and where do we get some movement. What moves this agenda forward more quickly.

DR. MADRAS: Well, the first thing is, the federal government has full leverage of CMS, the Centers for Medicaid and Medicare because they reimburse hundreds and hundreds of billions of dollars in healthcare in the country. And they are very linked to commercial insurers. So, the leverage that we have, not we but the federal government has, I'm a special government employee only until December 1<sup>st</sup> and then I'm back to private citizenship, is quite profound. One of the things we recommend is improving the quality of treatment with regard to

reimbursements. Improving the road blocks to providing treatment as well as medications for treatment and disincentivising just slate of hand approval for opioids. There is tremendous leverage at that level.

The second issue that we have leverage in terms of the federal government is using pain as an assessment score for physicians, hospitals and other healthcare organizations which has been a primary pressure on physicians. Because when patient pain assessment and patient satisfaction scores are scored in, there is a financial disincentive not -- there is a financial incentive to use opioids. Because is a patient says, you didn't satisfy my pain by giving me opioids, that physician, that hospital can be financially penalized for not doing it. The federal government has leverage, tremendous leverage, in disincentivising pain and patient assessment with regard to those factors. There are many others, I won't hog the time but there are many other leverages the federal government can use in terms of regulations that can be enormously helpful in beginning to dampen this.

MS. HAFFAJEE: One other place we haven't discussed too much but some of the costs for some of these -- some of it is reimbursement but also the cost for some of these drugs are quite high. One that I think it very promising is Probuphine which is an injectable Buprenorphine. It lasts for six months and it is less susceptible to diversion concerns. Really expensive, \$5000, I think, per administration. So, thinking about ways that the federal government can leverage some of its purchasing power and then negotiate on behalf of Medicaid to actually bring these drugs down and get them covered by insurance get them in more circulation. Naltrexone also is quite expensive. There are things, because the government is such a huge purchaser that we could do to try to get those drugs down that don't rely on the private sector quite as much.

MR. WEIL: Okay, we have time for a few more questions.

MS. RIVLIN: Alice Rivlin, Brookings. I wanted to ask about the role of the drug industry and the pharmacy industry. It has been mentioned, Sir Angus mentioned and others,

but we always seem to just retreat and say we can't do anything about that because they are so politically powerful. One of the previous questioners mentioned campaign finance reform but that's a very general solution to a specific problem. So, if you could do something to reign in the industry and the distribution, what would it be?

DR. MADRAS: The FDA and the DEA could do enormous amounts. The DEA has done a lot. The 60 Minutes program that featured a bill that prevented them from going after rogue pharmacies because the clause said, an immediate danger, and that's difficult to approve. That was only 2016. This problem has festered for 15 years. The FDA, there are 50 applications now for opioids from the pharmaceutical industry. There are so many parameters that one can insist on that could make it prohibitive for approval. I can think of five off the top of my head. The FDA could do a massive amount. They were asleep at the wheel for a decade and that's quite sad. Now, I do think that they're committed to trying to alleviate this problem. But they are a key and there are many keys. As I said, there are 25 keys in this but they are a federal regulatory key that is critical. The DEA, their hands have to be untied from that bill that passed last year.

SIR DEATON: The FDA is funded by the pharmaceutical industry right? I mean that's one point. The 60 Minute thing made it very clear as to how it wasn't the DEA stopping it was Congress people who tried to stop them. It is hard for me to believe that that investigative journalism, which in the past, has done a lot of good. If you think of the muck raking in the '30s and what happened a hundred years ago, that can generate public pressure that makes it very hard for Congress to do those things.

The shaming of the Sackler family which seems to me, long overdue, has managed to disassociate itself from Perdue Pharmaceutical and will never testify and has never appeared in public or even tried to admit that they have anything to do with it. While taking the family, by some accounts, has earned \$13 billion over the past few years. And Perdue, up until last summer, had earned \$32 billion from selling Oxycontin. Those facts need to be much more



publically known and the National Academy of Sciences and the Metropolitan Museum and other institutions, need to stop whitewashing families who are making money on the backs of people who are dying. I think, if that's out there much more publically then it will do a lot of good because there will be public demands to stop this sort of stuff. Congressman Marino looks like he'd be reelected in the district he represents in Pennsylvania even though his constituents are dying as a result of this thing that he engineered.

MR. DOCTOR: So, one thing I'm concerned about that no one is really talking about is that there are very close ties between these private claims databases and the pharmaceutical industry. It was just mentioned in the New Yorker article that the Sackler family were cofounders of the IMS data system. There are lots of other private claims databases that have consulting arrangements with pharmaceutical companies around opioids and other addictive drugs. So, one issue, that helps them direct conversations so when they become stakeholders with research institutions like Pecora and NIH, that helps direct the conversation in ways that benefits the pharmaceutical industry. It is sort of a type of regulatory capture in a way so they can talk about misusers and non-misusers, people who may be benefiting and it sort of mucks things up. We can't really get to a place where there is less prescribing and more appropriate prescribing.

I think something needs to be done along those lines in terms of regulation and making sure that we have access to these databases and that we can feed that information back for quality measurement in the right way to physicians.

MS. HAFFAJEE: I also want to just make one point. I agree, the FDA could have done more and it seems like they're moving in the right direction also through their REMS program. I want to mention the role for litigation also here. I'm sure many of you have heard about the increasing numbers of suits that are being brought by, originally it was patients and then class actions and now it is really governments, local, state and even, Trump says that we're going to have some federal suits coming out way and a number of settlements. The

settlement amounts are paltry compared to the profits that these companies are making but I do think there is a role for, I think, we could be looking along the lines of maybe a potentially the big tobacco settlement here when all of the suits are aggregated. That is a way for not captured, not disinterested consumers and their lawyer representors to tackle the problem from a different angle and actually hold many of these manufacturers, distributors and even pharmacies accountable. It becomes hard when you can, through discovery, get some of these documents that show that a manufacturer, how could they not have known that they were shipping this amount of opioids to this locality and that that was way more than could possibly be medically used. They are looking at these data and that is another way that we can try to hold these actors accountable.

MR. WEIL: I know there are a lot of questions still, but we are at time. We're going to have some closing remarks in a moment from Leonard Schaeffer who as, Paul Ginsburg mentioned at the outset, is a trustee at the University of Southern California and at the Brookings Institution. As he comes up, please join me in thanking Sir Angus Deaton, Bertha Madras, Rebecca Haffajee and Jason Doctor for their comments.

MR. SCHAEFFER: I wanted to begin by thanking everyone who is here for taking the time to learn more about this very important issue. I am going to give some concluding remarks because my name is on the wall, not because I have anything to add. I will be very brief so do not worry. I'd also like to thank our excellent keynote speakers who helped us get a better understanding of this national crisis and I want to thank all of our panelists. I thought that was a very interesting discussion.

Now, the paid political announcement, I'm a trustee both of USC and Brookings. I want to note for the record that this conference was a perfect fit with the USC Brookings initiative which is to use data and analysis to influence policy and to have impact in the real world. I hope that all of us are committed to encouraging policy makers to become familiar with the information that was presented today and to support programs that address opioid use.

Especially now, it seems to me we should all reinforce the need for looking at the facts and developing solutions that are based on evidence. Facts are important and should inform public policy whenever they are relevant. Thank you and we are adjourned.

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