- 1 {York Stenographic Services, Inc.}
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- 4 COMBATING THE OPIOID ABUSE EPIDEMIC: PROFESSIONAL AND
- 5 ACADEMIC PERSPECTIVES
- 6 THURSDAY, APRIL 23, 2015
- 7 House of Representatives,
- 8 Subcommittee on Oversight and Investigations
- 9 Committee on Energy and Commerce
- 10 Washington, D.C.

11 The subcommittee met, pursuant to call, at 10:17 a.m., 12 in Room 2322 of the Rayburn House Office Building, Hon. Tim 13 Murphy [Chairman of the Subcommittee] presiding.

Members present: Representatives Murphy, McKinley,
Burgess, Blackburn, Bucshon, Brooks, Mullin, Hudson, Collins,
Cramer, DeGette, Schakowsky, Tonko, Clarke, Kennedy, and

17 Green.

18 Staff present: Leighton Brown, Press Assistant; Noelle 19 Clemente, Press Secretary; Brittany Havens, Legislative 20 Clerk; Graham Pittman, Staff Assistant; Chris Santini, Policy 21 Coordinator, Oversight and Investigations; Alan Slobodin, 22 Deputy Chief Counsel, Oversight; Sam Spector, Counsel, 23 Oversight; Jean Woodrow, Director, Information Technology; 24 Jeff Carroll, Democratic Staff Director; Ashley Jones, 25 Democratic Director, Outreach and Member Services; Chris 26 Knauer, Democratic Oversight Staff Director; Una Lee, 27 Democratic Chief Oversight Counsel; and Elizabeth Letter, 28 Democratic Professional Staff Member.

Mr. {Murphy.} All right, good morning. We are here at
the Oversight and Investigation Subcommittee hearing on
Combating the Opioid Abuse Epidemic: Professional and
Academic Perspectives. Welcome.

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33 Less than 1 month ago, on March 26, we held the first in 34 a series of hearings to examine the growing problems of 35 prescription drugs and heroin abuse. During that brief span 36 of time, according to the best estimates from the Department of Health and Human Services, at least 3,374 Americans will 37 38 have died from drug overdoses, with opioids being the most 39 common cause. That is 3,374 overdose deaths in less than 1 40 month. Indeed, during the time we spend in this hearing, 41 another 10 lives will be lost.

42 The headlines out of Pittsburgh last week sent 43 shockwaves throughout my district with 10 heroin overdoses in 44 a single 24-hour period. Of the two who died, they were 45 found stamped bags marked either chocolate or 46 ``chicken/waffle.'' And this is what we are up against. 47 This is what is killing our sons and daughters, brothers and 48 sisters, mothers and fathers.

49 Let me state clearly so as to leave no room for doubt. 50 Our current strategy just isn't working, and I am not going 51 to stop until we start moving in the direction of success, 52 defined not just as getting individuals off of street drugs 53 and onto a government-approved opioid, but getting them to be 54 the point--to the point of drug-free living.

55 About 3 weeks ago, on the very same day this committee 56 held our first hearing on this issue, the Department of 57 Health and Human Services released its long-awaited three-58 part plan to reverse this epidemic. Elements of the plan 59 made sense; however, I am puzzled and amazed to read one 60 particular priority included in their press release, and I quote, ``Exploring bipartisan policy changes to increase use 61 62 of buprenorphine and developing the training to assist prescribing.'' 63

We are in desperate need of innovations to reverse the current trend, and not merely maintain it. Why would we focus only a single opioid replacement program rather than the full range of FDA-approved treatments for opioid addiction? Why the fixation on one pharmaceutical product? According to testimony presented to this committee last year

70 by the Director of SAMHSA's Center for Substance Abuse 71 Treatment, nearly 1 million people were prescribed buprenorphine in 2011. We know that number is much higher 72 73 today, probably closer to 1.5 million people or more. Think 74 about that. Success by Federal Government standards for 75 addiction disorders is 1.5 million people prescribed 76 synthetic opioids. Yet, consider the sad fact that states 77 have not seen their investment in prescription clinics 78 reverse this opioid epidemic. States like Maryland, Vermont, 79 Massachusetts and others that have made massive investments 80 in buprenorphine maintenance have not seen reductions in 81 overdose deaths. On the contrary, things have gotten much 82 much worse.

According to the DEA, buprenorphine is the third most 83 84 confiscated drug in law enforcement activities in our country 85 today. More than morphine, more than methadone, more than 86 codeine. Patients are routinely getting buprenorphine 87 prescribed as ``heroin helper'', meaning they get a month's 88 supply of buprenorphine to use whenever they can't get 89 heroin. It tides them over, enabling them to remain in their 90 active addiction. This should more accurately be called

91 addiction maintenance, not just the euphemistically called,

92 opioid maintenance.

93 Some addicted to methamphetamines go to local bupe mills 94 and get a 30-day supply that they promptly sell to buy their 95 drug of choice. In the field of addiction treatment, the 96 enabler is part of the problem. Helping intentionally or 97 unintentionally to keep a family member as an alcohol or drug 98 addict is enabling. Here, the U.S. Government is the biggest 99 enabler of them all.

100 Some clinics operate cash-only businesses for writing 101 30-day supplies of buprenorphine at the highest permissible 102 doses; usually 32 milligrams, knowing full well patients will 103 sell at least of half of the pills in order to pay for their 104 treatment or other illicit drugs.

At our last hearing, Professor Sarah Melton at East Tennessee University noted that that there are methadone clinics operating on a cash basis, handing out methadone without any other treatment, or buprenorphine pill mills. It is not acceptable that federal taxpayer money be used to support programs that hand out these drugs for cash. Worse, Professor Melton testified that there was a dearth of good

112 treatment programs. And what happens after the patient 113 leaves the treatment program? What is being done to followup with patients to prevent relapses and put them on a path 114 115 of real recovery? I fully recognize the importance of medication-assisted treatment as a transition from street 116 117 drugs and to prevent overdose from heroin, but relying on 118 this as the one and only solution shouldn't be the strategy. 119 As I recently heard Dr. McLellan, the former Deputy 120 Director of ONDCP say, while there is an appropriate place 121 for medication-assisted treatment, we should not turn a blind eye to the fact that there is also a tremendous amount of 122 123 medication-assisted addiction. It is not acceptable for 124 federal taxpayer money to be used to support treatment programs that lack evidence of effectiveness, or that define 125 126 success merely as an individual with an addiction disorder 127 using heroin fewer times per week than before treatment. 128 I am calling for a patient-centered initiative with a 129 goal of matching patients with the most appropriate care, 130 coupled with a focus on transition not just off street drugs, 131 but eventual transition from opioids altogether. I hope to modernize our existing opioid addiction treatment system to 132

133 ensure that the right patient gets the right treatment at the 134 right time. It simply isn't true to present buprenorphine 135 and methadone as opioid-free treatment. We do a tremendous 136 disservice to those living with addiction disorders when we 137 advance disingenuous double-talk and not state outright that 138 buprenorphine and methadone are highly potent opioids. 139 We are not going to end this opioid epidemic by

140 increasing the use of opioids. We need an exit strategy that 141 enables Americans to become opioid-free altogether. We can 142 do better than addiction maintenance. We can and we must.

I look forward to working with my colleagues and HHS as 143 144 we explore new innovations for detoxification and treatment 145 models to transition individuals off of all opioids and into 146 evidence-based counseling with non-addictive, non-narcotic 147 behavioral and medication treatments. We don't do enough to help those addiction disorders. I believe in recovery. I 148 149 believe in lives being restored so that every individual may 150 live to their full God-given potential and do so drug free. 151 I consider opioid maintenance as a bridge to cross over in 152 addiction recovery, not a final destination. At this point, the government simply stopped building the bridge. We have 153

154 not yet fully helped move those with addiction disorders 155 beyond opioid maintenance, and I seek to lay out a vision for 156 recovery that includes complete withdrawal from opioids as an 157 option. Once we lay out those goals, we can then move 158 forward with research and clinical efforts, and boldly 159 declare that we are no longer satisfied with the status quo 160 of opioid maintenance only.

161 To assist us today, the subcommittee will hear from some 162 of the nation's foremost professional and academic experts in the field of opioid addiction. Among these questions we hope 163 these experts will address are what can be done to 164 165 incentivize individual compliance with prescribed treatment plans and reduce the risk of relapse? What should be the aim 166 of treatment for opioid addiction, and should--reduce the 167 168 intake of illicit drugs by these individuals to more moderate 169 levels? Or should the aim be to place patients on a path to 170 detoxification and ultimately a full recovery, ending all 171 illicit uses and removing the need for lifelong opioid 172 maintenance recovery? To what extent is the increased prescribing of methadone for pain contributing to more 173 174 overdose deaths? Are Medicaid and Medicare payments for the

175	treatment of pain incentivizing doctors to prescribe the
176	opioids like candy for the treatment of pain?
177	Today we have assembled some of the leading opioid
178	addiction experts. We arewelcome you to get your thoughts
179	on dealing with this epidemic. And I thank you for your
180	expertise and look forward to hearing your testimony.
181	[The prepared statement of Mr. Murphy follows:]

183 Mr. {Murphy.} I now recognize Ms. DeGette for 5 184 minutes.

185 Ms. {DeGette.} Thank you so much, Mr. Chairman. Before I make my opening statement, I want to announce today is Take 186 Your Daughter to Work Day. My daughters tragically have 187 188 grown up, but I have my daughter-for-the-day today, Paula, 189 who is with us. Paula is a student at--sixth-grader. Paula 190 is a sixth-grader at Howard Middle School, and she is going 191 to be with me today. She just told me she thought it would be really boring to come to the Capitol, but actually, so far 192 193 she has found it to be fascinating. So I think she has a 194 career ahead of her in politics, and we are glad to have her. 195 I am also glad, Mr. Chairman, that we are having this 196 hearing today. This is our second hearing in the series on 197 this very important issue.

This is a problem that touches all parts of the country and is growing. In 2013, 50 percent of all drug overdoses in this country were related to prescription pharmaceuticals. In Colorado, my home state, the rate of prescription overdose deaths has guadrupled in the last 10 years.

I am happy to have this distinguished panel today who I hope can actually talk about, Mr. Chairman, what you suggest which is science-based treatments, and the best practices for treating this disease. All of our panelists have years of experience treating patients struggling with addiction, and I want to hear what all of you think is the most effective treatment.

210 In our last hearings, we received considerable testimony 211 from experts which--who told us that medication-assisted 212 treatment, or MAT, can play a vital role in treating opioid addiction. Experts tell us that a combination of MAT and 213 214 behavioral treatment, such as counseling and other supportive 215 services, is the best way of treating opioid addiction. And, 216 of course, there are several FDA-approved medications that 217 have proven effective in treating opioid addiction.

Now, Mr. Chairman, in your opening, you talked about science-based treatments, and I completely support that. You also talked about patient-oriented treatments, and I support that too. But in doing that, we need to recognize that while it is the goal to get everybody off of these drugs if possible, it is not always the case, and we need to look and

224 see at the treatments that should be available for every patient. And so in an ideal world, we would have all the 225 226 options available to every patient, and we should strive for that, but right now, MAT is not an available option for all 227 228 patients. Dr. Bisaga, for example, will testify today that 229 very few patients with opioid addiction receive treatments 230 that have been proven the most effective, which includes 231 access to MAT. What many Americans receive instead is a form 232 of rapid detoxification from the drug, followed by an 233 abstinence-only approach. Dr. Bisaga and others have called 234 this method outdated and mostly ineffective, and even worse, 235 I suppose, it could be dangerous because patients face a significantly elevated risk of dying by overdose if they 236 237 relapse. So I want to ask questions about that today. Is it 238 true that most Americans with opioid addictions don't receive 239 the most effective treatments? Do they and their loved ones 240 understand that? Is it true that many patients receive 241 treatments that some experts suggest may be ineffective or 242 dangerous? And finally, why not--why is not MAT available as an alternative to all patients seeking treatment? 243

244 From the perspective of the Federal Government, it is

important to have science-based policy so that we are expending our resources on efforts that actually have a chance at success. And patients seeking treatment for opioid addiction should be apprised of the benefits and risks of alternative treatment approaches.

250 Now, I understand that we need more study to predict 251 which treatment alternatives will be effective for any given 252 patient, and that is why I look forward to hearing from Dr. 253 Seppala about the work he is doing at the Hazelden Betty Ford 254 to collect data on factors. And by that way, in that vein, I 255 want to recognize our former colleague, Mary Bono, who is 256 here with us today, and a former member of this wonder 257 committee. So we are glad to have you here, Mary.

I also recognize that we need more study regarding how to best treat opioid-addicted patients for the long-term, particularly people who want to taper off of the medications. And I certain understand and support the desire to move toward medication-free recovery, but we also need to make sure that patients understand the risk.

Finally, Mr. Chairman, much of what is being done toprevent and treat the opioid epidemic is happing on the state

266 level. I am hoping in one of our future hearings that we can 267 have witnesses come from the states to talk about their 268 approaches. In Colorado, for example, we have the Colorado 269 Consortium for Prescription Drug Abuse Prevention, which is a 270 statewide coalition, and which is designing targeted 271 programs. So when we have our hearing, I would like to have 272 someone from Colorado. 273 I think that this hearing will give us more information, 274 and information and science-based decision making is really 275 what we need to make effective use of our resources to 276 combating this very, very serious problem of opioid abuse. 277 And I yield back. Thank you. [The prepared statement of Ms. DeGette follows:] 278

280 Mr. {Murphy.} Thank you. 281 I now recognize the vice chairman of the full committee, Mrs. Blackburn, for 5 minutes. 282 283 Mrs. {Blackburn.} Thank you, Mr. Chairman. And it is 284 indeed Take Your Daughter to Work Day. And after I get to 285 Nashville this afternoon, my daughter will go to an event 286 with me. But she is an adult and, of course, has two 287 children of her own, and we will not take them to that event. It is so good to see our former colleague, Mary Bono, 288 289 and I appreciate the good work that she continues to do on 290 this issue. 291 And, Mr. Chairman, I thank you for the hearing because this is a critical public health issue, and it does need our 292 293 attention and our best efforts. And we are going to continue 294 to look at this problem if prescription drug and heroin abuse because it has skyrocketed. And since '97, the number of 295 296 Americans seeking treatment for addiction to painkillers has 297 increased by 900 percent. That should give us all pause. Deaths related to heroin abuse increased 39 percent from 2012 298 to '13. That is a 2-year period of time. And while heroin 299

300 use in the general population is still low, the number of 301 people beginning to use it has steadily increased since 2007. 302 And according to the National Institute on Drug Abuse, part 303 of the explanation for the trend is a shift from the abuse of 304 prescription pain relievers to heroin as a more potent, 305 readily available and cheaper alternative to prescription 306 opioids.

307 Addiction and deaths due to overdose are just the tip of 308 the iceberg in terms of medical consequences of this problem. 309 One tragic consequence of the problem is neonatal abstinence syndrome. According to Dr. Stephen Patrick at Vanderbilt, in 310 311 2013, Tennessee became the first state to make NAS a publicly 312 reportable condition to the Department of Health. From 313 information reported to our Tennessee Department of Health, 314 we know the overall rate is 13 cases out of 1,000 births in 315 the State of Tennessee. We can and we must do better for 316 these babies. Our goal is to improve the Federal Government 317 response to this crisis.

318 Recently we heard from witnesses who expressed the state 319 and local perspectives on this issue. Last year, we heard 320 from a federal panel of witnesses, including CDC, DEA,

- 321 SAMHSA, NIH, and the Office of National Drug Control Policy, 322 and today, we are rounding out this focus by hearing from you 323 all who will give us the professional and academic
- 324 perspectives. And we look forward to your testimony today,
- 325 and we welcome you.
- 326 And I yield back.
- 327 [The prepared statement of Mrs. Blackburn follows:]

329 Mr. {Murphy.} And nobody else on this side seeking 330 final 2 minutes, then I will turn towards Ms. Schakowsky for 331 5 minutes.

332 Ms. {Schakowsky.} Thank you, Chairman Murphy and 333 Ranking Member DeGette, for calling this very important 334 hearing on prescription drug and heroin abuse in the United 335 States. Also thanks to our witnesses for coming here today 336 to shed more light on this issue.

This hearing could not be timelier. Increasingly, we are hearing reports of the toll this crisis is taking in communities across the country. And like myself, I am sure that every member of the subcommittee has heard stories from their constituents about the toll of prescription drug abuse and heroin abuse, the toll that it has taken in their districts.

I have mentioned previously before this committee that I have a constituent, Peter Jackson, who tragically lost his 18-year-old daughter, Emily, after she consumed a single Oxycontin tablet that she received from her cousin while visiting family. I look forward to hearing from our

349 witnesses about the most effective ways to combat prescription drug abuse, to learn what additional steps we 350 351 can take together to stop this crisis, and to prevent the 352 further tragic loss of life. 353 I also want to call attention to the impact that 354 reducing discretionary spending will have on access to 355 treatment and research on addiction. Just yesterday, House 356 republicans approved budget allocations that will further cut 357 discretionary spending for vital programs like SAMHSA and the National Institutes of Health. We have already heard--and we 358 359 have already seen devastating cuts to these same programs. 360 For example, the Substance Abuse Prevention and Treatment 361 Block Grant within SAMHSA when adjusted for inflation has actually been cut by 25 percent in the last 10 years. 362

While we are here today to discuss the most effective methods of treating addiction, without federal funding for programs, patients will simply not have access to these services, and research on addiction and treatment of addiction will greatly suffer. That is just a fact. If we are serious about combating the opioid epidemic, it is incumbent that we provide strong federal funding for the

370 programs that patients rely on. 371 And I want to yield the balance of my time to 372 Representative Tonko. 373 [The prepared statement of Ms. Schakowsky follows:]

375 Mr. {Tonko.} I thank the gentlewoman from Illinois for 376 yielding.

377 Each and every year, I have spent Super Bowl Sunday in a soup kitchen, working alongside and serving individuals of 378 379 the addiction recovery community. Why? Because I choose to 380 land myself in the midst of real heroes. The individuals of 381 the addiction recovery community, in my mind, through their 382 courage, determination, and conviction are truly heroes. 383 Bearing witness to the joy and rebirth that recovery has brought to their lives leaves me no doubt that complete 384 recovery to a substance-free life is, and should be, our goal 385 386 for every person who is struggling in the throes of 387 addiction; a disease.

388 While recovery remains the goal, it is nearly impossible 389 to achieve without access to effective treatments. Science 390 tells us that the most effective treatment available for 391 opioid addiction is a combination of medication-assisted 392 treatments, commonly known as MATs, and behavioral therapy. 393 MATs might not be the preferred treatment for everyone, but 394 they constitute a vital tool in our toolbox for treating

395 opiate addiction. Unfortunately, MATs were available in only 9 percent of all substance use facilities nationwide in 2013, 396 397 according to SAMHSA. While I will acknowledge the concerns 398 that a reliance on MATs can raise, the immediate tragedy here 399 isn't that some individuals won't be able to taper off 400 maintenance medications, is that most won't even be able to 401 access an evidence-based treatment modality that has proven 402 to be their best chance of easing the burdens of addiction 403 and saving lives. Across my district, there are hundreds on 404 waitlists to access this treatment. Every minute we delay, needed treatment costs lives. In just the time that we are 405 406 having this hearing today, 5 more people will die from am 407 opioid overdose, and 4 out of 5 addicted to opioids will have no access whatsoever to treatment. This is totally 408 409 unacceptable.

410 No treatment option is perfect, and I strongly support 411 further research that will help us create more effective 412 treatments and cures that can rid us of addiction once and 413 for all. For now though, our focus has got to be on curbing 414 the epidemic, expanding treatment, savings lives, and giving 415 people the stability they truly need to achieve recovery.

416	I look forward to hearing the perspective of our
417	witnesses on these pressing issues. And I yield back, Mr.
418	Chair, the balance of my time.
419	[The prepared statement of Mr. Tonko follows:]

421 Mr. {Murphy.} Thank you. The gentleman yields back.
422 And so we will go right into our witnesses and try and
423 get all your testimony done before we have votes, and we will
424 come back after votes too.

425 We have with us today Dr. Robert DuPont, the President 426 of the Institute for Behavior and Health. Additionally, Dr. 427 DuPont was the first director of the National Institute on 428 Drug Abuse. Welcome. Dr. Marvin Seppala, the Chief Medical Officer at Hazelden Betty Ford Foundation. As acknowledged, 429 Ms. Bono is here with you today. Dr. Westreich is the 430 431 President of the American Academy of Addiction Psychiatry. 432 Dr. Anna Lembke is an Assistant Professor of Psychiatry and 433 Behavioral Science at Stanford University Medical Center. 434 And Dr. Adam Bisaga is an Associate professor of Clinical 435 Psychiatry in the Department of Psychiatry at the College of 436 Physicians and Surgeons of Columbia University, and and a 437 research scientist at the New York State Psychiatric Institute. Finally, Dr. Patrice Harris, Elected Member of 438 439 the American Medical Association, Board of Trustees. Dr. 440 Harris has served on the Board of the American Psychiatric

441 Association, and was an APA delegate to the AMA. I feel like I should get continuing education credits today--442 443 Ms. {DeGette.} I know. Mr. {Murphy.} --for being here. 444 I will now swear in the witnesses. 445 446 You are aware that the committee is holding an 447 investigate hearing, and when doing so, has the practice of 448 taking testimony under oath. Do you have any objections to 449 taking testimony under oath? All the witnesses say they do 450 not object. So the chair then advises you that under the rules of the House and the rules of the committee, you are 451 entitled to be advised by counsel. Do any of you desire to 452 be advised by counsel during testimony today? All the 453 witnesses decline. So in that case, will you all please 454 rise, raise your right hand and I will swear you in. 455 456 [Witnesses sworn.] Mr. {Murphy.} Thank you. All the witnesses have 457 458 answered in the affirmative. So you are now under oath and 459 subject to the penalties set forth in Title XVIII, Section 1001 of the United States Code. I will call upon you each to 460

461 give a 5-minute statement. Just pull the microphone close to

462	you, press the button, and make sure the light is on. And
463	try and keep your comments under 5 minutes.
464	Dr. DuPont, you are recognized first.
465	Dr. {DuPont.} Thank you.
466	Mr. {Murphy.} Make sure your microphone is on and as
467	close to you as possible. Yeah, just pull it real close.
468	No, try again. Well
469	Dr. {DuPont.} There we go.
470	Mr. {Murphy.} There you go.
471	Ms. {DeGette.} There
472	Mr. {Murphy.} Thank you. Okay.
473	Dr. {DuPont.} Thank you very much.
474	Mr. {Murphy.} Okay.

^TESTIMONY OF ROBERT L. DUPONT, M.D., PRESIDENT, INSTITUTE 475 476 FOR BEHAVIOR AND HEALTH; MARVIN D. SEPPALA, M.D., CHIEF 477 MEDICAL OFFICER, HAZELDEN BETTY FORD FOUNDATION; LAURENCE M. WESTREICH, M.D., PRESIDENT, AMERICAN ACADEMY OF ADDICTION 478 479 PSYCHIATRY; ANNA LEMBKE, M.D., ASSISTANT PROFESSOR OF 480 PSYCHIATRY AND BEHAVIORAL SCIENCES, STANFORD UNIVERSITY 481 MEDICAL CENTER PSYCHIATRY DEPARTMENT; ADAM BISAGA, M.D., 482 COLUMBIA UNIVERSITY MEDICAL CENTER, NYS PSYCHIATRIC 483 INSTITUTE; AND PATRICE HARRIS, M.D., AMERICAN MEDICAL 484 ASSOCIATION

485 ^TESTIMONY OF ROBERT DUPONT

486 } Dr. {DuPont.} Thank you, Mr. Chair. It is a privilege 487 for me to be with you.

488 And let me pick up on some of the things that were 489 presented just now. I think one of the most

490 counterproductive approaches to the problem is to pick drug-

491 free against medication-assisted treatment, and I think every

492 time we do that we undermine the--dealing with the problem at

all. We undermine public confidence, and I think it is 493 494 contrary to what the public interest is and public health. And let me be very clear that I believe that full recovery is 495 496 consistent with continuing to take medications for opiate dependence; buprenorphine, methadone, and naltrexone. 497 The 498 issue has--to recovery, to me, is not whether they are taking 499 the medicine, it is are they using drugs, are they using 500 alcohol, are they still involved in drug-dependent behavior. 501 And that is not compatible with recovery. And I am going to 502 talk a little bit more about that issue about drug use in 503 medication-assisted treatment, which I don't think is 504 recovery, and I think that that--but I think that concept is 505 very important, just like these people taking--patients taking psychiatric medicines is fully compatible with 506 507 recovery. So I think that, to me, is a way to bring this 508 together.

And I also point what Dr. Marv Seppala is going to talk about on the Hazelden Program, which brings together medication and the drug-free programs as the way into the future.

513 And the last point I want to make before I really get

514 stated is to think about the elephant in the room when we are talking about recovery, and that is the 12-step programs; AA 515 516 and NA, are an enormous part of what we are talking about, 517 about getting well. We did a study--the first national study 518 of physicians health programs, and we have now followed up 519 with that 5 years after the mandatory monitoring. And 97 520 percent of those physicians were still in recovery 5 years 521 after mandatory--and we asked them what part of the program 522 was most helpful to you, and they were in very high quality treatment and many other services, the--by far the biggest 523 524 percentage was participation in 12-step programs. That was 525 what was most important to them. So I want to make sure at our hearing we understand the importance of that in terms of 526 527 recovery.

Now, my focus is on the users, and I want to make a--one point very clear. Opiate dependence is not like the common cold; it does not go away, it is a lifetime problem. A person who has opiate dependence is going to deal with that problem one way or another for his or her lifetime. If you don't understand that then the concept of treatment is confusing because you think you are going to be confusing

535 because you think you are going to be fixed in treatment. People are not fixed in treatment with opiate dependence. 536 537 Treatment can help them find their path to recovery, but 538 treatment is not recovery, and it is really important that people are not fixed in any treatment, drug-free or 539 540 medication treatment. It is a lifetime struggle, and that is 541 a very important perspective on this. 542 Now, my concern is that treatment would--does not match

543 up with the disease. The treatment is always short-term. 544 Even medication-assisted treatment, which conceptually goes 545 on for a lifetime, has very high drop-out rates, very rapid--546 patients drop out of the program for medication-assisted 547 treatment. And the other thing is a high percentage of people in medication-assisted treatment continue to use 548 549 opiates and other drugs while they are in the program. That 550 is very important to notice that and pay attention to that. But even more important, and the thrust of my testimony, all 551 552 of it is accountability for treatment. What are the results 553 during treatment? What percentage of the patients are 554 continuing to use drugs? How much retention is there? What 555 is the retention curve of the program? How long do they stay

556 in treatment? And when they leave, are they any better off 557 than they were when they came in? Those questions need to be 558 asked and answered in a systematic way.

559 The other thing I pick up on the chairman's statement 560 about the standard. What we want is recovery. That means no 561 use of alcohol and other drugs, including opiates, not just 562 opiates but all drugs. That is what recovery is. It requires that. And what I am proposing and encouraging the 563 564 committee to do is to look long-term, because the nature of 565 the disorder is long-term. And I use the 5-year recovery standard. Start with a person who enters treatment. Where 566 567 is that person in 5 years? And you can look at any program; drug-free or maintenance--or medication-assisted, and ask the 568 question how good is this program at getting a person into a 569 570 stable recovery. That is one standard for all treatments, 571 and it gets you focused on the long-term. And when we do 572 that in this country, including in the Federal Government, 573 the whole game changes and we have a mechanism to improve 574 treatment. Treatments can all compete on a level playing field to achieve that goal. 575

576 So that is my testimony. Thank you very much.

577 [The prepared statement of Dr. DuPont follows:]

579 Mr. {Murphy.} Thank you. Thank you very much.
580 Dr. Seppala, you are recognized for 5 minutes.

581 ^TESTIMONY OF MARVIN D. SEPPALA

582 } Dr. {Seppala.} Chairman Murphy and Ranking Member 583 DeGette, thank you very much for inviting me to participate 584 in this important hearing, and for your leadership in 585 addressing the crisis of addiction to opioids in this 586 country.

587 My name is Marv Seppala, I am the Chief Medical Officer 588 of the Hazelden Betty Ford Foundation. I attended Mayo 589 Medical School, and have been practicing in the addiction 590 field for 27 years. On a personal note, I have also been in 591 long-term recovery from addiction since age 19.

592 The Hazelden Betty Ford Foundation is the nation's 593 largest nonprofit addiction treatment provider, and we have been around since 1949. We have 16 sites in 9 states. We 594 595 offer prevent and recovery solutions nationwide for youth and 596 adults. At our facilities, we have seen a pronounced 597 increase in the number of patients with opioid use disorders, paralleling the grim stories you have probably been hearing 598 about in your districts for some time now. At our 599

600 residential youth facility, for example, opioid dependence 601 rates increased from 15 percent of patients in 2011 to 42 602 percent in 2014. That is a dramatic rise, and this is an 603 especially difficult addiction to treat. Individuals dependent on prescription pain medications and heroin often 604 605 face unique challenges that can undermine their ability to 606 stay in treatment and ultimately achieve long-term recovery. 607 They are hypersensitive to pain and more vulnerable to 608 stress. Their anxiety, depression, and intense craving for these drugs can continue for months, even years, after 609 getting free from opioid use. They experience a strong 610 611 desire to feel normal again, to escape what seems like a 612 permanent state of euphoria, which puts them at high risk for 613 relapse. They are also at higher risk of accidental overdose 614 during relapse because they no longer have the tolerance to 615 handle the same doses they were taking prior to treatment. 616 In other words, with opioids, unlike other drugs, relapse 617 often means death.

618 In 2012, we launched a new protocol to treat opioid 619 addiction, the Comprehensive Opioid Response with 12 Steps, 620 or COR-12 as we call it. Our approach is grounded in the

621 traditional 12-step facilitation model and based on

abstinence, but it now also utilizes the safest live-saving
medications that keep patients engaged in recovery long
enough to achieve lasting sobriety.

We are not--we don't see a conflict in utilizing medications and pursuing abstinence, just as Bob described. Even when medications are part of our protocol, abstinence is still the objective. In fact, one might call it a third way because it strikes a reasonable commonsense balance between those who see medication assistance and abstinence as

631 diametrically opposed.

Our COR-12 Program includes changes to traditional group therapy, additional patient education about opioids, and the option now of medication assistance. We utilize extended release naltrexone, Vivitrol, as well as

636 buprenorphine/naloxone, or Suboxone, to help engage patients
637 long enough to complete treatment, and then become
638 established in solid 12-step recovery. The highest risk

639 period for relapse is the first 12 to 18 months after

640 treatment, so we prefer to have our patients involved and on

641 medication in outpatient care throughout this extended

642 period. And our goal is to discontinue medication as our patients become established in long-term recovery. 643 644 While our clinicians recommend which medication is 645 appropriate, the final decision is up to the patient, and about 1/3 of our COR-12 patients elect to use no medication. 646 647 Indeed, medication only addresses the biologic aspect of 648 addiction. Our broader measures treat the psychological, 649 social, and spiritual components to improve psychosocial 650 functioning, enrich relationships, and foster a healthier 651 lifestyle. And those are the keys to recovery that last. Our COR-12 Program has resulted in more patients 652 653 completing residential treatment, and a reduction in overdose 654 deaths after treatment. While the research study of COR-12 655 is ongoing, and we do not have full results yet, we do know 656 that COR-12 patients stay in treatment longer. Our atypical 657 discharge rate, those who leave treatment early, for our 658 general population is 13 1/2 percent, and for those with 659 opioid dependence who don't enter this program, it is over 22 660 percent. However, in this program, it is only 7.5 percent. Now, based on our early positive results, we plan to 661 662 continue paving the way for others to use both scientific and

663 spiritual solutions to engage more people in treatment, save 664 lives, and ultimately help more people get into long-term 665 recovery.

I would also like to emphasize the need to educate a 666 wider culture about the dangers of opioid over-prescribing. 667 668 The troubling trends began to emerge in the late '90's after 669 the FDA approved Oxycontin and allowed it to be promoted to 670 primary care physicians for treatment of common aches and 671 pains. Education campaigns often funded by opioid manufacturers minimized risks, especially the risk of 672 673 addiction, and exaggerated benefits to using these opioids 674 long-term for common problems. When prescribing on a shortterm basis to treat moderate to severe acute pain, opioids 675 can be helpful, but when these are highly addictive 676 medications that are taken around the clock for weeks, 677 678 months, and years, they may actually produce more harm than 679 healing. An increasing body of research suggests that for 680 many chronic pain patients, opioids are neither safe nor effective. Over time, patients often develop tolerance, 681 leading them to require higher and higher doses, which 682 ultimately can lead to quality of life issues and functional 683

684 decline.

685 It should be noted that doctors didn't start over-686 prescribing out of malicious intent, but rather out of a 687 desire to relieve pain more compassionately.

688 Now, we have a culture that seeks opioid medication for 689 pain relief, not just for physical pain but also to numb 690 psychic pain. Some of these patients have a significant risk 691 for the development of addiction in a culture that promotes 692 quick fixes, instant gratification, and escapism. Medical professionals need further education about the proper use of 693 opioid medications and their risks. The general public also 694 695 needs such education to prove recognition of risk, and 696 limitations of these powerful, dangerous medications. It is 697 time now to address opioid over-prescribing and overuse 698 without stigmatizing pain. This crisis deserves the 699 attention you are providing today, and requires a substantial 700 response.

701 Thanks again for having me here, and for your
702 leadership. I look forward to answering your questions.
703 [The prepared statement of Dr. Seppala follows:]

705 Mr. {Murphy.} Thank you, Doctor.
706 Now, Dr. Westreich, you are recognized for 5 minutes.

707 ^TESTIMONY OF LAURENCE WESTREICH

708 Dr. {Westreich.} Mr. Chairman, members of the } committee, thank you very much for inviting me to speak to 709 710 you today about treatment for opioid addiction. Dr. Murphy, 711 before I start, I would like to say that as a psychiatrist 712 specializing in addiction, I am particularly appreciative of 713 the clinical awareness you have imparted to the Helping 714 Families in Crisis Act, which will focus resources on helping 715 our patients. I am Board certified in general psychiatry, 716 addiction psychiatry, and forensic psychiatry, and I serve as 717 president of the American Academy of Addiction Psychiatry, 718 which is a professional organization for psychiatrists who 719 specialize in the treatment of addiction and other mental 720 illnesses.

My primary professional focus is on the clinical treatment of addicted people. I trained at Bellevue, where I worked for many years and continue to teach, and I treat people addicted to opioids in my offices in Manhattan and in New Jersey, where I live. I know this committee understands

very well the lethal nature of opioid addiction. You don't 726 727 need us to tell you about that. My main goal in speaking 728 with you today is to underline what you have already heard; 729 opioid-addicted people need access to a broad range of treatments for opioid addiction. This must include access to 730 731 medication-assisted therapy, and treatment for co-occurring 732 psychiatric disorders. I have treated homeless, heroin-733 injecting senior citizens, college students who snort 734 Oxycontin, and practicing attorneys who must take an opioid 735 pill every few hours in order to continue seeing their clients. The death and destruction I have seen due to opioid 736 737 addiction is profoundly disturbing, but thankfully with 738 appropriate treatment, the more common return to health, the 739 workplace, and family, is what keeps most of us doing the 740 clinical work which assisted--which helps addicted people in 741 their search for recovery.

742 Part of that clinical work includes full treatment for 743 what is ailing the addicted person. Research demonstrates 744 that the opioid-using person often has a co-occurring mental 745 illness, like major depression, bipolar disorder, or PTSD. 746 Sometimes the opioid use is self-medicating uncomfortable

747 mood states or anxiety, or just has difficulty soothing him or herself. All these circumstances can increase the risk 748 749 for relapse, and require sophisticated and individualized 750 psychiatric evaluation and treatment. Research makes it clear that prescribing the appropriate effective medication 751 752 to help the patient with craving, along with talk therapy and 753 treatment for a co-occurring psychiatric disorder, gives the 754 addicted person the best possible chance for recovery.

755 That sophisticated treatment system must include access to well-trained clinicians who can select between the 756 757 available psychosocial treatments like relapse prevention 758 therapy, cognitive behavioral therapy, medications like 759 buprenorphine, methadone, and naltrexone, and mutual support groups like Narcotics Anonymous. For many, mutual support 760 761 groups like AA or NA can be extremely helpful, but they are 762 not treatment, nor do they claim to be. They are support groups which can be lifesaving for some, and not so much for 763 764 others. As you have heard, the available research has not 765 provided us with a silver bullet that works for all opioid addiction. Rather, the data tell us that some treatment 766 767 works for some opioid addicts some of the time. Others may

768 respond to a very different approach. That is one reason we
769 clinicians must have all available arrows in our quivers. We
770 must have the skills and training for a broad array of
771 approaches to meet the treatment needs of each patient.
772 Quite often, using a treatment--team approach that includes
773 psychologists, social workers, nurses and counselors, is
774 critical to therapeutic success.

775 The wide variety of personal choices addicted people 776 make about treatment is yet another reason for supporting the 777 full spectrum of treatment possibilities from medicationassisted treatments with buprenorphine and methadone, to 778 opioid blockers like naltrexone, to relapse prevention 779 780 therapy. Some patients demand to be treated without 781 medications, while others clearly want and need medication to control their craving. And they also require more specific 782 psychiatric treatment for any co-occurring disorders. 783 784 Use of buprenorphine and methadone, which are both 785 opioids like heroin, can be controversial. When I talk to 786 opioid-addicted people and their families, I sometimes, but

787 not always, recommend tapering or maintenance with

788 buprenorphine or methadone. The question is not whether the

789 medication has side-effects; all medications do, but whether 790 the risk is worth the benefit. Patients and their families 791 need to know that detoxification treatment and drug-free 792 counseling are associated with a very high risk of relapse. As with other medical conditions, the relevant question about 793 794 whether a medication is worth the risk is the following. 795 Compared to what? Is taking buprenorphine or methadone 796 better than dying from an overdose, better than contracting 797 HIV or Hepatitis, flunking out of school, losing a marriage, 798 losing a job? One-size treatment does not fit all, and different patients may need different treatments. But the 799 800 very good news in this situation is that people who are able 801 to stop their use of illicit drugs, whether through psychotherapeutic interventions, medications, and/or help 802 803 from NA, or most likely some combination of the above, can 804 return to vibrant and productive lives. It is that return to physical and emotional health, which I find so gratifying; it 805 806 empowers me to help my patients to keep trying.

807 Before I stop, let me reiterate my main point, and what 808 I know you have heard from many others. Opioid-addicted 809 people need access to a broad range of treatments for

810	addiction. This must include medication-assisted treatment,
811	and treatment for co-occurring psychiatric disorders.
812	Thank you very much for inviting me today.
813	[The prepared statement of Dr. Westreich follows:]

815 Mr. {Murphy.} Thank you very much.
816 Dr. Lembke, you are recognized for 5 minutes.

817 ^TESTIMONY OF ANNA LEMBKE

818 } Dr. {Lembke.} Thank you for inviting me today to these 819 hearings.

The main point I would like to make today is simple. We don't just have an opioid abuse epidemic or an opioid overdose epidemic, we have an opioid over-prescribing epidemic.

Doctors are a major pipeline of misused and diverted prescription opioids, and contrary to what is commonly believed, doctors who treat addiction are not the main source of the problem.

The methadone that accounts for 40 percent of single 828 829 drug opioid pain reliever death is almost entirely in the 830 form of pills prescribed for the treatment of pain, rather 831 than coming from methadone maintenance clinics that treat 832 heroin-dependent patients. We, thus, need to think broadly 833 about the problem with changing the behavior of all physicians and not just those who treat addicted patients. 834 835 I was pleased to see the education of providers was

836 identified as one of three priority areas in the report issued last month from the Department of Health and Human 837 838 Services, which called prescribers ``the gatekeepers for preventing inappropriate access.'' But providing educational 839 840 material on safe opioid prescribing, even if it is free and 841 readily available, won't be enough. To change doctor 842 prescribing behavior we need first to acknowledge the 843 enormous incentive to prescribe opioids, and the 844 disincentives to stop prescribing. Many doctors are afraid 845 that a patient will sue them or complain about them if they don't prescribe opioids, even when the doctor knows the 846 847 opioid is harming that patient. Also, no insurer questions 848 me when I prescribe Vicodin for pain, but if I want to prescribe Suboxone to help an addicted patient stop taking 849 850 Vicodin, I typically have to spend hours fighting an 851 insurance company to get the prescription approved. Despite 852 the Mental Health Parity and Addiction Equity Act that 853 Congress passed by a huge bipartisan margin in 2008, many 854 insurers still resist reimbursing for addiction treatment. The solution to this problem lies in giving doctors 855 856 tangible incentives to prescribe more judiciously, such that

857 neither pain nor addiction is undertreated.

Today, I focused on three areas where I believe this Congress can make a positive difference. Number one, require revision of healthcare quality measures. Number two, incentivize use of prescription drugs monitoring programs. And number three, scrutinize accreditation organizations and regulatory agencies.

864 First, require revision of healthcare quality measures. 865 The Centers for Medicare and Medicaid Services and the Joint Commission exert enormous control over how doctors practice 866 medicine today. Their quality measures set the standard of 867 868 care. In the 1990s, they urged doctors to prioritize pain treatment, and that is what we did. Prescriptions for 869 opioids skyrocketed, not always to the benefit of our 870 871 patients.

872 CMS and the Joint Commission need to link quality 873 measures to treatment outcomes for patients with addictions. 874 This will incentivize hospitals and clinics to create an 875 infrastructure to screen for and treat opioid addiction. 876 Quality measures should also limit excessive prescribing

877 of multiple drugs to the same patient, especially of

878 controlled medications. A younger person with no objective 879 evidence of disease should not be on 10 different 880 medications, yet I often see this, and the medications 881 frequently include an assortment of stimulants, sedatives, and opioids. Also, far too many patients are on a 882 883 prescription of benzodiazepines at the same time as opioids, 884 which greatly increases their risk of overdose. 885 Finally, CMS and Joint Commission quality measures 886 should not be linked to patient satisfactions with opioid 887 prescribing. Illness recovery, not patient satisfaction surveys should be the arbiter of quality care. Doctors are 888 889 not waiters, and opioids are not items on a menu. 890 Second, incentivize use of prescription drug monitoring 891 programs. Prescription drug monitoring programs allow 892 doctors to see all the controlled medications prescribed to a 893 patient beyond just the ones that they prescribe. When 894 physicians make use of prescription drug monitoring programs, 895 prescription drug use--misuse decreases. Monitoring programs 896 don't merely limit access to opioids when they should not be 897 prescribed. They allow for patients who really need them to get them. The question how to get more doctors to use these 898

899 databases. By some reports, only 35 percent of prescribers use these databases. Here are some ways to incentivize 900 901 doctors to use prescription drug monitoring programs. Make 902 it a billable medical service. Mandate education on use of 903 PDMPs when physicians apply for DEA licensure. Amend privacy 904 laws such as 42 C.F.R. so that healthcare providers can 905 freely communicate with each other around issues related to 906 prescription drug misuse.

907 Third, scrutinize accreditation organizations and regulatory agencies. The Joint Commission, the accreditation 908 organization which sets standards for hospitals, was 909 910 instrumental in socializing doctors to liberally prescribe 911 opioids for pain. The Joint Commission's campaign on treating pain was funded in part by Purdue Pharma, whose main 912 product is Oxycontin. I do not think Congress should allow a 913 914 major healthcare accreditation body like the Joint Commission 915 to take money from the pharmaceutical industry.

916 In 2012, the Food and Drug Administration wisely 917 rescheduled hydrocodone products to Schedule II, but the very 918 same week, the FDA approved the use of Zohydro, a longer-919 acting opioid with high abuse potential, similar to

920 Oxycontin. The FDA's own advisory panel recommended not to approve Zohydro, yet it was approved anyway. Why? Do we 921 really need one more high-risk opioid medication on the 922 923 market? It seems to me like trying to empty a bathtub with a thimble, while filling it with a firehose. 924 925 Furthermore, the FDA should live up to its commitment to 926 stop approving non-abuse deterrent formulations of opioids, 927 which it did not do when it approved Zohydro. And doctors 928 and patients need to understand that abuse-deterrent 929 formulations make it harder to crush and snort and inject an 930 opioid, but they do not prevent ingesting opioids orally at 931 high doses, becoming physiologically dependent on and 932 addicted to them, and overdosing on them.

To sum up, Congress can push back against the opioid epidemic by requiring revision of healthcare quality measures to reduce over-prescribing, incentivizing use of prescription drug monitoring programs, and scrutinizing accreditation organizations and regulatory agencies. All 3 approaches will save lives and improve the practice of medicine at the same time.

940 Thank you again for this opportunity to testify, and for

- 941 your leadership in addressing this public health epidemic.
- 942 [The prepared statement of Dr. Lembke follows:]

944 Mr. {Murphy.} Thank you, Doctor.
945 Now, Dr. Bisaga, you are recognized for 5 minutes.

| ^TESTIMONY OF ADAM BISAGA

946 ^TESTIMONY OF ADAM BISAGA

947 } Dr. {Bisaga.} Thank you, Chairman Murphy, Ranking 948 Member DeGette, and members of the committee, both for 949 holding this hearing and for inviting me to speak to you 950 today.

My name is Adam Bisaga. I am a scientist, working on developing new medication strategies to treat opioid dependence. I am also educating physicians nationally with regards to safe and effective use of these mediations, and I have been practicing addiction psychiatry for the past 20 years.

957 I would like to speak on the opioid epidemic from the 958 perspective of medical management. And I want to point out how our current treatment--drug treatment system in the 959 United States is outdated; that it does not reflect the 960 961 scientific progress we have made in the past 50 years. Our 962 current system is built on the model for treating patients with alcoholism, and it is not capable of responding to the 963 unfolding opioid epidemic. 964

965 Opioid addiction is manifested by the compulsive use of opioid painkillers or heroin. Patients have abnormal 966 967 activity in several brain regions, and experience powerful 968 urges to use that they find very difficult to control. This abnormal brain activity can persist for months throughout the 969 970 abstinence, driving high relapse rates. Medications can 971 stabilize opioid receptors in the brain; reducing craving, 972 eliminating withdrawal, and blunting the patient's ability to 973 feel the effects of heroin. These medications work best in 974 conjunction with psychosocial therapies to produce long-975 lasting abstinence. This approach has success rates similar 976 to treatments we have for many other medical and psychiatric 977 disorders. However, in stark contrast, the treatment for most other disorders, very few patients with opioid addiction 978 receive evidence-based treatment. 979

980 The traditional approach of a brief detoxification 981 followed by therapy-only approaches has no evidence for 982 treating effectively opioid addiction. This--in addition, 983 this approach can be very dangerous. Patients that do not 984 receive medications are at--to block the effects of relapse 985 face an elevated risk of dying when they relapse. Certainly,

986 all of us have witnessed it on too many occasions.

987 So we have three FDA approved medications; methadone, buprenorphine, and naltrexone. Methadone activates opioid 988 989 receptors in the brain and blocks the effects of heroin or painkillers. Methadone-treated patients use less heroin, 990 991 have fewer medical complications, and have improved social 992 and work functioning. In other words, they are able to lead 993 a normal life. Methadone is the most effective medications 994 we have, however, it is a potent medication, and can cause 995 sedation or even death. Therefore, dispensing of methadone 996 is highly regulated.

997 Buprenorphine works similarly to methadone, but only 998 partially activates opioid receptors. It also protects 999 patients from overdose risk. Because buprenorphine is safer 1000 than methadone, less monitoring is needed and it can be 1001 prescribed by the doctors in their offices.

Naltrexone, the last medication, is available as either a daily tablet or a monthly injection. Naltrexone works differently from methadone and buprenorphine. It completely blocks opioid receptors, and it is used after detoxification to prevent relapse. It has no abuse potential, there is no

1007 withdrawal when it is stopped.

1008 Treatment with medication works best as a maintenance

1009 intervention, without a predefined length of treatment.

1010 There is no scientific evidence showing benefits to limiting

1011 the time someone is treated with medication. Opioid

1012 addiction is a chronic brain disease, and that responds best 1013 to chronic treatment.

1014 Methadone, buprenorphine, and naltrexone have all 1015 different mechanism of action. In this era of personalized 1016 medicine, patients respond best to medication that are 1017 tailored to their individual needs. All of these medications 1018 are needed to adequately address the opioid epidemic. Every 1019 American should have access to these medications, and with 1020 the help of a physician, help make an informed decision about 1021 their path to recovery. Regulations should be put in place 1022 to make buprenorphine and naltrexone available at every 1023 treatment center working with patients addicted to opioids. 1024 More than 100 of individuals, many of them young adults, 1025 die of opioid overdoses every day. Medication-assisted 1026 treatment is the best way to reduce the number of deaths on a 1027 large scale. Addiction is a treatable disorder, and a joint

1028	effort of health professional, community advocates, and
1029	policymakers is urgently needed to reverse this tragic trend.
1030	Thank you for the opportunity to testify.
1031	[The prepared statement of Dr. Bisaga follows:]

1033		Mr. {Murphy.} Thank you. Appreciate it.
1034		We are going to try and get Dr. Harris' testimony in,
1035	then	we are going to run to go vote and come back.
1036		So you are recognized for 5 minutes.

1037 ^TESTIMONY OF PATRICE HARRIS

1038 Dr. {Harris.} Thank you. Good morning, Mr. Chairman } 1039 and Ranking Member, and esteemed members of the subcommittee. I am honored to testify today on behalf of the American 1040 1041 Medical Association. My name is Dr. Patrice Harris. I am 1042 Secretary of the AMA Board of Trustees. I am also the Public 1043 Health Officer for Fulton County, which includes Atlanta, and 1044 I am a practicing psychiatrist with experience in addiction. 1045 We are indeed in the midst of an epidemic. Physicians 1046 are deeply disturbed about the rise in overdoses and 1047 fatalities from prescription opioids, as well as the rapid 1048 increase in deaths from heroin-related overdoses. The 1049 numbers are sobering and unacceptable. 1050 The AMA is working on a number of fronts with many other

1051 groups to develop recommendations and implement specific 1052 strategies to confront this public health crisis. Physicians 1053 are stepping up and taking responsibility to prevent and 1054 reduce abuse, misuse, overdose, and death from prescription 1055 opioids. We also need to make sure that our patients who

1056 experience pain receive the treatment they need. With

1057 opioids, if clinically appropriate, and that patients who

1058 have an opioid use disorder have timely access to affordable,

1059 comprehensive treatment.

1060 These are complex problems and there is no one solution. 1061 A multifaceted, public health strategy is needed. There are 1062 key components to this strategy. First, physicians must 1063 continue to amplify our efforts to train and educate 1064 ourselves to ensure that we are making informed prescribing 1065 decisions, considering all available treatment options for 1066 our patients, and making appropriate referrals for our patients with substance use disorders. As part of the 1067 1068 prescriber clinical support system for opioid therapies 1069 funded by SAMHSA and administered by the American Academy of 1070 Addiction Psychiatry, the AMA is developing new training materials on responsible opioid prescribing, including a 1071 1072 focused educational module on opioid risk management for 1073 resident physicians.

1074 Patients in pain deserve compassionate care, just like 1075 any other patient we treat. The dialogue must change to 1076 reduce the stigma that is associated with pain. We need to

1077 increase insurance coverage for evidence-based alternative, 1078 multidisciplinary, non-drug pain management pain therapies. 1079 At the same time, we need to support access to opioid-based 1080 therapies when clinically appropriate. 1081 Opioid use disorder is a chronic disease that can be 1082 effectively treated, but it does require ongoing management. 1083 Physicians need more resources so that evidence-based 1084 treatments such as medication-assistant treatment in 1085 conjunction with counseling and other behavioral therapies 1086 and interventions are more available and accessible to all of 1087 our patients. There are not enough programs and many are not 1088 affordable. 1089 We strongly support lifting the cap and expanding the 1090 number of patients that office-based physicians can treat 1091 with buprenorphine and Suboxone, which are major tools in 1092 treating opioid use disorder. 1093 Naloxone has saved thousands of lives across the nation, 1094 and we strongly support increasing access to it. We 1095 encourage physicians to prescribe naloxone to their at-risk 1096 patients, but barriers still exist to using this effective

 $1097\,$ drug to prevent overdose deaths.

Now, one way to reduce one of these barriers is passage of good samaritan laws so that healthcare professionals, first responders, friends, family members, and bystanders who see someone who had overdosed can help save a life without fear of liability.

Last, prescription drug monitoring programs can be a helpful clinical tool. However, to be most effective and used more often, PDMPs need to be real time, interoperable, and available at the point of care as part of a physician's workflow. In order to get to this point though, Congress needs to fully fund these programs so that states can modernize and fully fund and staff them.

1110 So in summary, we know that it is up to our profession 1111 to provide the leadership necessary to confront this 1112 epidemic, and we commend this committee's leadership and look 1113 forward to working with you and other stakeholders to promote

1114 evidence-based solutions. Our patients deserve no less.

1115 Thank you.

1116 [The prepared statement of Dr. Harris follows:]

1118 Mr. {Murphy.} Thank you, Dr. Harris. And thank you to 1119 the panel.

1120 We are in the middle of votes, so we are going to break 1121 here. It is going to take us about half an hour or so for 1122 votes. We will come back.

1123 I just wanted to leave one sobering statistic I have 1124 here about this. In North America, the number of deaths from 1125 plane crashes between 1975 and today was 42,495. 1975 1126 through today. For the United States, the number of drug 1127 overdose deaths last year was 43,000. It is--if we were here 1128 having a hearing on plane crashes, we would need an arena to 1129 handle the media. What a sad day it is with 43,000 people died in this country last year. I feel that we need to have 1130 1131 people understand the severity of that.

I thank this panel for your testimony. We will come back and ask you questions in a few minutes. Thank you.

1134 [Recess.]

Mr. {Murphy.} I ran back because I didn't want to waste--get caught up--I want to make sure we are back. Just give us one more minute for the members to return.

1138 All right, we are going to return to our hearing here, 1139 and as members come in, we will put them in the queue. 1140 So let me start off here. I want to ask a question 1141 here. Dr. Seppala, a federal policy prohibits Medicaid 1142 matching funds being used at inpatient facilities with more 1143 than 16 beds whose patient roster is more than 51 percent 1144 people with severe mental illness, and for individuals 1145 between the ages of 22 and 64. Does this affect inpatient 1146 substance use disorders clinics as well when they have those 1147 limitations? 1148 Dr. {Seppala.} Sure would, absolutely. Any population 1149 that is restricted in that manner is not going to get 1150 adequate treatment. 1151 Mr. {Murphy.} So again, making sure we have options 1152 available, that is a barrier that we need to eliminate. 1153 Dr. {Seppala.} Yeah, increasing options for addiction 1154 treatment is really necessary in this country. We don't have 1155 adequate treatment to address this problem, but we also have 1156 a public health information problem because, if you look at 1157 the data from SAMHSA, you will see that over 95 percent of the people with addiction don't even know they have it. So 1158

1159 that is where the initial problem lies. And then of that 1160 small group that seeks treatment, the biggest problem is 1161 access. 1162 Mr. {Murphy.} Now, Dr. DuPont, I want to show you a 1163 poster here. According to the National Institute on Drug 1164 Abuse, for patients treated with opioid addiction with 1165 buprenorphine, there is a 92 percent of relapse with an 1166 illicit opiate within 8 weeks after stopping treatment. But 1167 look at the increases here in--this line is buprenorphine in-1168 -from 2003 to 2012, and it has gone up even higher now. 1169 Methadone rates have remained fairly flat, and heroin rates 1170 have increased slightly over this time. So I am wondering, 1171 given these statistics, and given the huge relapse rate with 1172 92 percent, relapse with an illicit opiate within 8 weeks 1173 after stopping treatment, are we doing enough to hold 1174 treatment programs accountable to make sure that they are 1175 getting people the additional treatments to get them on the 1176 road to recovery? 1177 Dr. {DuPont.} Well, I--that is very important 1178 information, absolutely, and I think the--to me, it shows

1179 that buprenorphine or methadone are not magic bullets, but

1180 they are very attractive to many patients and they bring a 1181 lot of people into treatment, and that is a good thing. I 1182 think the question, to me, is what happens to them then? And 1183 if they just go out and leave the program, not--nothing very 1184 good is happening. I am excited about the possibility of 1185 having a longer-term perspective on the buprenorphine 1186 patients, and helping them over a longer period of time. But 1187 the answer is, as you show there, that most stay a very short 1188 time and the outcome when they leave is that they relapse to 1189 the opiates.

Mr. {Murphy.} And I am--I want to make sure we are all on the same page, because what I am pushing for is I want to make sure we have a standard here that has hopes of getting people off of substances. And I recognize, like any other field, we can't reach 100 percent, but our goals should never be less than 100 percent. But there is a big overlap also with people with mental illness.

Dr. Westreich, so people with mental illness and severe mental illness who are actually seeking some substances to numb the effects or self-medicate. I see a lot of these in the military with folks, and of course, it makes a bad

1201 situation worse. But then when you have someone who is now 1202 addicted, and we are trying to wean them off, I would like to 1203 think that this is not just a matter of substituting an 1204 opiate with buprenorphine or methadone as a replacement as a 1205 road of treatment, but really thinking in terms of should 1206 they be on another medication, a psychotropic drug, something 1207 else to treat the underlying mental illness. Is this an 1208 appropriate hypothesis? And two, are we doing this, and if 1209 not, why not?

1210 Dr. {Westreich.} First of all, I think it is absolutely 1211 an appropriate hypothesis, and I don't think we are doing it 1212 enough.

1213 I think the point is that people who have addictive disorders as well as another mental illness need to have very 1214 1215 sophisticated clinicians who are trained in being able to 1216 recognize psychiatric symptoms and what they mean. Do they 1217 mean that the person is simply medicating some uncomfortable 1218 symptoms? Do they mean that the person has got a 1219 freestanding psychiatric illness, which must be trained--1220 treated with psychotropic medications, or some combination of 1221 the above? And so this speaks to the training of

1222 psychiatrists, psychologists, social workers, counselors who 1223 need to be trained to recognize mental illness symptoms and 1224 treat them effectively. 1225 Mr. {Murphy.} And we have heard repeatedly in this 1226 committee that the huge shortage of psychiatrists, 1227 psychologists, especially child/adolescent ones, to deal with 1228 this issue. But another concern we have heard is from states 1229 that there are limitations on--they have funds for substance 1230 abuse, and they have funds for mental illness, and oftentimes 1231 they can't use those together. 1232 Anybody want to comment on that of what we should be 1233 doing to make sure that they have maximum flexibility in the 1234 states? Can anybody comment on that? Dr. Bisaga? 1235 Dr. {Bisaga.} I think those very often is more of a 1236 norm than an exception that they go together. So keeping 1237 them separate, in separate pools of money, doesn't really 1238 make sense from a clinical perspective. I think we are much 1239 more effective when we are integrating treatment for mental 1240 illness and substance abuse by the same provider in the same 1241 setting. This is the way to have better outcomes. Mr. {Murphy.} Thank you. Anybody else want to comment? 1242

1243 Yeah, Dr. Seppala?

1244 Dr. {Seppala.} In our residential settings, in our 1245 youth settings, so it is about age 14 to 24, over 95 percent 1246 of our population enters treatment with a coexisting 1247 diagnosis of a mental illness. In our adult populations, 1248 again, a residential not outpatient setting, it is over 75 1249 percent. So what we are seeing is comorbid psychiatric 1250 illness with addiction in our treatment settings. It is the 1251 norm. We have to treat both. 1252 Mr. {Murphy.} Thank you. 1253 Ms. Schakowsky, you are recognized for 5 minutes. 1254 Ms. {Schakowsky.} So I have never seen that--the chart 1255 before and, you know, you first look at the chart and you 1256 think that buprenorphine is a bad idea. I mean that is how 1257 it looks. So I wondered if anyone--1258 Mr. {Murphy.} Yeah, I am just saying we are doing more of it, but--1259 Ms. {Schakowsky.} So maybe Dr. Bisaga can speak to 1260 1261 that? 1262 Dr. {Bisaga.} Well, you know, obviously, this is a very

1263 complex problem. You know, we see increasing rates of

1264 buprenorphine prescribing because we have an epidemic and we 1265 are trying to expand number of people that are treated with 1266 this medication. So it tells me--tell us a lot of things. 1267 It is true that not every buprenorphine treatment program is 1268 to the best standards, but that shouldn't really stop us from 1269 trying to expand access. We still have a shortage of 1270 providers that are trained to deliver this treatment. But if 1271 this chart had also a number of people addicted to 1272 painkillers, this line would probably go down, which I think 1273 speaks something about at least the beginning of making a--1274 Ms. {Schakowsky.} But it does it mean that methadone is 1275 better, or--1276 Dr. {Bisaga.} Well, you know, when you compare methadone with buprenorphine in a similar situation, 1277 1278 methadone is a little bit more potent as a medication, but 1279 because it is such a, you know, difficult medication to use, it cannot be really widely, you know, as easily disseminated 1280 1281 to the community as buprenorphine, and that is why we are 1282 pushing for the buprenorphine, again, as a first step of 1283 engaging people in treatment, protecting them from overdose, and then engaging them in the long-term psychosocial 1284

- 1285 recovery-oriented treatment.
- 1286 Ms. {Schakowsky.}

Dr. {Lembke.} Yeah, I would just add that this is a really--I just would add a really important difference between buprenorphine and methadone is that the methadone-the overdose risk with methadone is very high, whereas the unique pharmacology of buprenorphine makes it very unlikely for people to overdose on it.

1293 Ms. {Schakowsky.} Right.

Dr. {Lembke.} And so for that reason, there is a huge advantage in using buprenorphine, especially since one of the primary things we are trying to stop is the number of people who are dying due to opioid overdose.

Ms. {Schakowsky.} So also let me understand, on the panel, is there anybody who doesn't think that the combination of meds and psychosocial treatment, that one or the other itself is the way to go? No, okay.

1302So let me ask Dr. Lembke. Unfortunately, there are a1303number of barriers then for people to get medication,

- 1304 assisted treatment, MATs, and one of the barriers is
- 1305 insurance coverage. And according to the American Society of

1306 Addiction Medicine, Medicaid coverage for MAT varies greatly 1307 from state to state, the chairman was talking about that, 1308 with some states not covering all FDA-approved medications, 1309 imposing prior authorization requirements, and fail-first 1310 criteria that require documentation that other therapies were ineffective. I wondered, Dr. Lembke, if you have experienced 1311 1312 these issues in your practice, both of Medicaid and private 1313 insurers? 1314 Dr. {Lembke.} So that is very common with both Medicaid 1315 and private insurers that when you try to get coverage for 1316 addiction treatment, they give you the huge runaround, you 1317 have to talk with somebody on the phone for hours regarding 1318 medical necessity, whereas that is not true if you are prescribing a pharmacologically identical medication, or a 1319 1320 very similar medication, for the treatment of, for example--Ms. {Schakowsky.} So what does that --1321 1322 Dr. {Lembke.} --pain. 1323 Ms. {Schakowsky.} --really mean for patients? 1324 Dr. {Lembke.} Well, what that means is that you want to get addiction treatment for patients who are struggling with 1325 the disease of addiction, and you can't get insurance 1326

1327 companies to pay for it, which means that patients don't 1328 access the treatment. All you are left with is non--you 1329 know, interventions outside of the infrastructure of medical 1330 institutions, which is primarily just the 120-step movements. 1331 So it is a huge problem. 1332 Ms. {Schakowsky.} And so in your opinion, and anybody 1333 else can weigh-in on this too, would increased coverage of 1334 MATs help more individuals to remain in recovery? 1335 Dr. {Lembke.} Well, what happens now is that--what I 1336 see with private insurers is that they say they cover MATs, but then, basically, they have all kinds of loopholes whereby 1337 1338 they can deny that coverage, and they just make it so 1339 incredibly bureaucratically cumbersome in real time, you know, in the trenches, that you end up throwing up your 1340 1341 hands. And once you start somebody on buprenorphine, you 1342 don't want to just suddenly not have it available to them, 1343 but that happens frequently because all of a sudden, you have 1344 been denied coverage. It is insane. 1345

1345Ms. {Schakowsky.}Anybody else want to comment on that?1346Dr. {Seppala.}Yeah, I could speak to it.

1347 Ms. {Schakowsky.} Yes, Dr. Seppala.

1348 Dr. {Seppala.} We have had to increase our own 1349 infrastructure just to have enough people involved to get 1350 these medications approved. 1351 Ms. {Schakowsky.} You are talking about people who 1352 spend time on the phone and--1353 Dr. {Seppala.} Yeah. Yeah. 1354 Ms. {Schakowsky.} Okay. 1355 Dr. {Seppala.} So the--trying to limit our doctors' 1356 involvement and have other people do that, usually nurses, 1357 but it really has required adding FTEs to what we do. So increasing our expenses just to get these medications 1358 1359 approved by insurance companies. 1360 Ms. {Schakowsky.} And eventually you do get them 1361 approved usually? 1362 Dr. {Seppala.} Usually--I would say usually is a good 1363 description. Not always. 1364 Ms. {Schakowsky.} Yeah. Okay. 1365 Dr. {Harris.} And I also would like to add that it is 1366 increasing coverage for MAT, but it is also increasing 1367 coverage for the other interventions; the behavioral interventions, the therapies, cognitive behavioral therapies, 1368

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1369
     the other therapies that we know compliment MAT and work
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     well.
1371
          Ms. {Schakowsky.} And those are hard to--
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          Dr. {Harris.} It is very difficult to--
1373
          Ms. {Schakowsky.} --get approved?
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          Dr. {Harris.} --get coverage for that, yes.
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          Ms. {Schakowsky.} Thank you. Okay, I don't know, can
1376
     Dr.--
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          Dr. {Bisaga.} Can I--yeah, on the other hand, another
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     trend is that insurance companies know that this saves them
1379
     money. Evidence-based treatment saves money. So we also see
     a trend of them declining to pay for the programs that do not
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1381
     offer evidence-based treatment; psychotherapy and the
1382
     medication and on the 12-step. So that is another good
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     trend. So hopefully we, you know, we can use the data to
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      inform how we should invest in the public healthcare.
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          Ms. {Schakowsky.} Thank you so much. Thanks, Mr.
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     Chairman.
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          Mr. {Murphy.} Well, I want to follow up on what she is
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      saying. It is very important, especially in light of the
     mental health parity. So we want to make sure that evidence-
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based care is there. Medication-assisted treatment is there 1390 1391 as part of a protocol, psychosocial therapy is part of a 1392 protocol, using the proper things. Just talk therapy in a 1393 general concept isn't going to work, it has to be very 1394 focused with someone who understands addiction. And part of 1395 our challenge here is, we had previous testimony from some 1396 places just talking about pill mills where doctors are just 1397 cranking out lots of medication, and since 90 percent of 1398 people we found weren't in any kind of treatment--they--other 1399 treatment too, and of those getting treatment, only 10 1400 percent of that were getting the evidence-based treatment. 1401 It sounds like what you are saying the insurance companies 1402 are kind of throwing the baby out with the bathwater here, 1403 responding to Ms. Schakowsky's questions, making it very 1404 difficult to get proper treatment. And since most people aren't getting treatment anyway, shouldn't they be focusing 1405 1406 on something else? Dr. DuPont? 1407 Dr. {DuPont.} A point about that--that the evidence of

1408 what--what is the evidence we are talking about, and the 1409 evidence for evidence-based is what happens to the person 1410 while they are taking the medicine. It is not what happens

1411 to them later. What--where do they go? And what I am 1412 encouraging is to have evidence-based assessment of what the 1413 consequences are--what the long-term outcome is of all of 1414 these treatments. Which treatments are getting people into 1415 stable recovery, which are not. And that is not what we are 1416 doing now. Our evidence is what happens while they are 1417 there, in the face of the fact that you have very rapid 1418 cycling through these programs. If we are talking about 1419 dealing with an epidemic, we have to deal with those people 1420 as individuals for their lifetimes, for long periods of time. 1421 That is why I say 5 years. So evidence-based of while they 1422 are in the treatment is good, but it is not what we really 1423 want. Is it evidence of getting them into stable recovery or 1424 not--1425 Mr. {Murphy.} Thank--1426 Dr. {DuPont.} --that is the question that has to be 1427 asked. 1428 Mr. {Murphy.} Thank you. 1429 Ms. DeGette, 5 minutes. 1430 Ms. {DeGette.} Thank you very much. 1431 Dr. Lembke, I am listening with interest to this

1432 discussion, and others might have also input on this, but why 1433 is it so difficult to get insurance companies and others to 1434 pay for these appropriate treatments? 1435 Dr. {Lembke.} My believe is that essentially insurance 1436 companies do not want people on their panel who have chronic 1437 lifetime diseases that will need chronic lifetime care, and 1438 they essentially view the addicted population as--wrongly as 1439 folks who cannot get better and will always need lots of 1440 medical care. And it is really an untrue bias that insurance 1441 companies have that mirrors a bias that society has, because 1442 the truth is when you get addicted persons into quality 1443 addiction treatment, they have about 50 percent response 1444 recovery rates, which is on par with recovery rates for 1445 depression and many other chronic illnesses--1446 Ms. {DeGette.} So--1447 Dr. {Lembke.} --with a behavioral component. 1448 Ms. {DeGette.} So you think that they don't want to--1449 they are reluctant to get--pay for a treatment plan if they 1450 think that it could be a chronic long-term plan? 1451 Dr. {Lembke.} Yeah, that those people are going to be--1452 Ms. {DeGette.} Yeah.

1453 Dr. {Lembke.} --costly for them. They don't--1454 Ms. {DeGette.} Right. And--1455 Dr. {Lembke.} They don't want to--1456 Ms. {DeGette.} And you think one of the solutions might be putting more patients on those boards? 1457 1458 Dr. {Lembke.} Patients on--1459 Ms. {DeGette.} People who have dealt with recovery and 1460 so on, is that what I am hearing you saying? 1461 Dr. {Lembke.} On what boards? Ms. {DeGette.} On the insurance review boards. 1462 1463 Dr. {Lembke.} You know, I--it is a weird group thing 1464 that happens even when you have physicians who you have to 1465 talk to who are representing insurance companies, their 1466 mandate is to withhold care. Their mandate is to pay for as 1467 little as humanly possible. I mean I can tell you horror stories about hour-long conversations I have had with 1468 1469 physicians representing insurance companies who then denied 1470 care in cases where care was--1471 Ms. {DeGette.} So--1472 Dr. {Lembke.} --obviously needed. 1473 Ms. {DeGette.} So, Dr. Bisaga, I want to follow up with

1474 that because in your testimony, you said that very few of the 1475 patients with opioid addiction receive treatments that have 1476 been proven to be effective, and you said the treatment most 1477 of them were receiving is outdated and mostly ineffective. 1478 What kind of treatment is that that people are receiving that 1479 is just not working? 1480 Dr. {Bisaga.} So everything--right, so we just had a 1481 wonderful example from Dr. Seppala talking about kind of the 1482 best possible treatment that marriages very efficiently 1483 12-step with the medications. This is really, really 1484 exception. This is 1 of the 1 percent. Majority of people, 1485 the treatment consists of going to the hospital, getting 1486 detoxified, and then trying to be encouraged to go to the 12-1487 step meetings without being told even that there are 1488 evidence-based medications. 1489 Ms. {DeGette.} So it is--what it is, it is kind of a truncated treatment. It is like we are--1490 1491 Ms. {Bisaga.} Again--

1492 Ms. {DeGette.} --we are going to give you some--maybe 1493 we are going to give you some medication, we are going to 1494 make--we are going to tell you to go to this treatment, then

1495 you are on your own.

1496 Ms. {Bisaga.} Right. So we only going to detox you, 1497 and we expect you--that you going to stay abstinent. There 1498 is no information about the evidence-based medications. After detoxification, opiate blocker could be a way to 1499 1500 maintain--1501 Ms. {DeGette.} Okay. So there is not--there is not 1502 even medication involved in most of these. 1503 Ms. {Bisaga.} No. Many inpatient detoxifications do 1504 not put people on medication. It--1505 Ms. {DeGette.} They just detox them--1506 Ms. {Bisaga.} Yes. 1507 Ms. {DeGette.} --and then they--1508 Ms. {Bisaga.} Detox them and sell them to 12-step 1509 groups. Ms. {DeGette.} Okay. 1510 1511 Ms. {Bisaga.} It is changing, but slowly. 1512 Ms. {DeGette.} And do all of the rest of you agree with that, that that is what is going on for the most part? Yes? 1513 1514 Okav. Now, Dr. Westreich, you said in your testimony, patients 1515

and their families need to know that detoxification treatment 1516 1517 and drug-free counseling are associated with a very high risk 1518 of relapse. So it is sort of the same question that I was 1519 asking Dr. Bisaga, do you think that patients enrolling in 1520 programs that employ this approach are being given adequate 1521 information to make informed decisions about their treatment? 1522 Dr. {Westreich.} Well, I think that is exactly the 1523 question. At the middle and end of that treatment episode, 1524 they should be given information about their particular case 1525 and what their likelihood for relapse is, and what possible treatments are, including medications, including abstinence 1526 1527 models, and be able to make an informed decision based on 1528 having those treatments available to them. And my concern is 1529 when they are not available, the person cannot make an 1530 informed decision. Ms. {DeGette.} Right. If you never have MAT offered as 1531

1532 a--as an alternative, you can't have a complete program.

1533 Ms. {Westreich.} Exactly.

Ms. {DeGette.} And this is not just your idea or the other esteemed members of this panel, this is like

1536 scientifically proven, right?

1537 Dr. {Westreich.} Yes.

1538 Ms. {DeGette.} Yeah.

1539 Dr. {Lembke.} Can I just add one thing?

1540 Ms. {DeGette.} Please.

1541 Dr. {Lembke.} You know, MAT works for some people, it

1542 doesn't work for everybody--

1543 Ms. {DeGette.} Right.

1544 Dr. {Lembke.} --and what some people who are in the

1545 acute crisis of the disease of addiction need is to be put

1546 into a hospital so they can--not--detox, and hopefully then

1547 get routed to some kind of behavioral or residential

1548 treatment. And that is also very hard to get insurance

1549 companies to pay for.

1550 Ms. {DeGette.} Right, and if you can find a program to 1551 put them in.

1552 Dr. {Lembke.} Even to put them in the hospital--

1553 Ms. {DeGette.} Exactly.

1554 Dr. {Lembke.} --I mean even to put them in the hospital 1555 for 3 or 4 days is very hard.

1556 Ms. {DeGette.} And, you know, let me just say, Mr.1557 Chairman, I really appreciate this hearing because this is

1558 exactly what I have been trying to say is, it is not a one-1559 size-fits-all solution for these patients, there are 1560 different types of solutions, but if you take out one of the 1561 programs that really works, like MAT, or the MAT plus the 1562 intensive long-term counseling, you are going to have--not 1563 only are you going to have a failure rate but you are also 1564 going to have deaths. So thank you. 1565 Mr. {Murphy.} And even that is difficult for them to 1566 get. 1567 Dr. Burgess, recognized for 5 minutes. Mr. {Burgess.} Thank you, Mr. Chairman. And I do have 1568 a number of questions for Dr. Harris. Thank you for being 1569 1570 here today. I man end up submitting those to you in writing 1571 and ask for a written response because I do want to use part 1572 of the time that I have available to get on my soapbox. That 1573 is what we do here. 1574 This is not quite the appropriate hearing, but this 1575 subcommittee does have jurisdiction over the Food and Drug

1576 Administration, and for--several times, we have had the Food 1577 and Drug Administration in, I have asked the question why we 1578 cannot have the availability of naloxone or Narcan as an

1579 over-the-counter purchase. Why federal law prohibits 1580 dispensing without a prescription, but why? No one is going 1581 to abuse Narcan. Narcan can be a lifesaving measure. Sure, 1582 I want first responders, police departments, EMTs, I want 1583 them to have it available in their armament when they arrive 1584 on the scene of a person who is unconscious. Are there--I 1585 don't think we will be inducing anyone to misbehave by having 1586 a rescue method at their disposal.

So, Mr. Chairman, I just wanted to get that out of the way. I do think the Food and Drug Administration needs to work on this. I think this is one of the things that--I mean you referenced in your opening statement the tragedies that occur happen in my suburban area as well. The tragedies that occur when we lose a young person through what presumably is an unintentional opiate overdose.

And then the other thing that I just feel obligated to talk about, I mean I was in practice for a number of years. Covered for other doctors, as we all do, and I know there were times that I was burned by a patient who was exhibiting drug-seeking behavior and I didn't immediately recognize it. I tried to guard against that. In fact, the latter years

1600 that I was in practice, I would not fill a prescription of a 1601 patient I did not know over the phone, I would go to the 1602 office and look up their chart. If I couldn't find their 1603 chart, yeah, that might be on us because we didn't have 1604 electronic records, we had paper charts, I would offer to 1605 meet that patient in the emergency room and evaluate their 1606 signs and symptoms, and if appropriate, prescribe a 1607 medication. Suffice it to say, most of the time that did not 1608 occur and the patient was not willing to come in and spend 1609 the time required.

1610 But look, we have prescription drug monitoring programs. And I will tell you one time just sticks out in my mind how 1611 1612 frustrated I was. Called in a prescription for a patient 1613 with a very plausible story, and the pharmacist said, you 1614 know, you are about the fifteenth doc that has called in 1615 medicine for that patient this month. And I said, what, that 1616 is crazy. Well, cancel the prescription. He said, you have 1617 already called it in, I will fill it for her when she shows 1618 up, but I just thought you ought to know. And I forget the 1619 number he gave me, but it was an astounding number of Tylenol III that this patient had received during the month. And 1620

1621 forget the codeine part of the prescription; this was a 1622 multiple times lethal dose of acetaminophen that, if somebody had actually ingested it, their liver was long gone and 1623 1624 someone would be paying for a liver transplant. We have 1625 prescription drug monitoring programs. We have one that was 1626 passed by this committee, called NASPER, and President Bush 1627 signed it into law in 2005. There is a competing program 1628 that was done by the appropriators. That is not your 1629 problem, that is our problem. But, Mr. Chairman, it just 1630 underscores how we need to fix that. And now, we ask the 1631 American people with the Stimulus Bill to fund this large 1632 electronic health records, and do we have the 1633 interoperability so a doc in practice would know what that patient is taking? We don't really have the availability of 1634 1635 getting that because of HIPAA, there are some privacy 1636 concerns. Somehow we need to bridge that gap, and I really 1637 would welcome anyone's comments on the panel about the 1638 prescription drug monitoring aspect. 1639 Dr. {Westreich.} I would like to comment--1640 Mr. {Burgess.} Yes, Doctor. 1641 Dr. {Westreich.} --on both. First, I agree 1,000

1642 percent about Narcan, having that available not only to first 1643 responders but to families of people who have members who use 1644 opioids. I agree with you, and I don't see any reason why 1645 that can't happen. 1646 Regarding the prescription monitoring programs, we have 1647 one in New York State where I practice, where I 1648 affirmatively--I am obligated to look at it each time I 1649 prescribe an opioid medication. There is one in New Jersey 1650 which covers Connecticut and Delaware, but there is no 1651 national one. So someone can be getting an opioid medication in the state next-door and I would have no idea from the 1652 1653 pharmacy monitoring program. We need to have a fully 1654 national program, and it would be enormously helpful for 1655 treating our patients. 1656 Mr. {Burgess.} Our other problem is we have to--yes,

1657 Dr. Seppala? I am sorry.

Dr. {Seppala.} I would like to support both of your recommendations, Congressman. We should have over-thecounter naloxone. It is a very innocuous drug, you know that, and there are not much side-effects or problems you could cause with it. It does one thing; it blocks opioid

1663 receptors in a very safe manner.

And as far as the prescription drug monitoring programs, when they are not mandatory, as was described earlier, only about 33 percent of the docs use it, so there is not adequate information on them. We need it to be mandatory and across state lines. So I agree with both.

1669 Mr. {Burgess.} Yes, Dr. Harris?

1670 Dr. {Harris.} Yes, PDMPs are a valuable tool. They 1671 have valuable information, important information for doctors 1672 who are prescribing, however, they have to be easy to use, 1673 available at the point of care. Totally agree with

1674 interoperability.

1675 I do want to say that we have some data, we look across the states, and where they are readily available at the point 1676 1677 of care and have real-time information, doctors are using 1678 them, but where they are more burdensome and don't have real-1679 time information, doctors are not using them as much. And so 1680 I think the AMA is actually--I chair a taskforce looking at 1681 this issue, and one of the things we might come up with is 1682 perhaps what should a model PDMP look like, to give guidance 1683 on that so that doctors increase their use of PDMPs.

1684 Mr. {Burgess.} Thank you.

1685 Mr. Chairman, I will yield back.

Mr. {Murphy.} Yeah, just as a follow-up. So what you are describing here is just to even know when you are prescribing--you know if a patient has already been prescribed opioids by their physician, to be able to follow that up. And then in addition to that--but you are also treating someone with an addiction disorder. That is the 42 C.F.R. Part 2 issue.

1693 Dr. Lembke, can you comment on that about how we need to 1694 make modifications to that? I am thinking that our former 1695 colleague, Patrick Kennedy, is always on me saying we have to 1696 fix this problem too, that someone has--getting addiction 1697 treatment, they are not even going doctor shopping, they are actually trying to get help, and they go see another doctor, 1698 1699 the doctor doesn't know they are getting addiction treatment 1700 and he says, here, take this Percocet, take this. Can you

1701 comment on that, Dr. Lembke?

1702 Dr. {Lembke.} Yeah, so the phenomenon we essentially 1703 have today is that on one side of the aisle in a medical 1704 institution you have people prescribing Vicodin, on the other

1705 side of the aisle you have people trying to get them off of 1706 it, and each other doesn't know what the other is doing 1707 because, according to 42 C.F.R., we cannot--it is a higher 1708 burden of privacy than even HIPAA, if someone is getting 1709 substance use treatment, we cannot communicate without their 1710 expressed consent to another provider that they are getting 1711 that treatment.

1712 This Code of Federal Regulations was implemented more 1713 than 2 decades ago with good reason. What was happening was 1714 that police were going into methadone maintenance clinics and essentially arresting people who were trying to get treatment 1715 1716 for their addiction. And so it was a higher burden on 1717 privacy so that people wouldn't resist going into treatment 1718 because they were afraid of being exposed around their 1719 addiction. But in this day and age of electronic medical records, and this day and age of prescription drug misuse, 1720 1721 most importantly, as well as just the fact that we are trying 1722 to advocate for addiction being a disease, and we can't 1723 advocate for addiction being a disease if we treat it 1724 differently from other diseases. So I believe we have to 1725 amend 42 C.F.R. so that doctors can communicate openly about

1726 which patients are possibly misusing the drugs that they are 1727 prescribing to other providers caring for those patients. 1728 Mr. {Murphy.} You--other people agree with that? 1729 Okay, Mr. Tonko, you are recognized for 5 minutes. Mr. {Tonko.} Thank you, Mr. Chair. 1730 1731 All of us on this dais are seeing the toll that 1732 addiction can have on our communities, and--however, with 1733 that in mind, insufficient data are available in the field of 1734 opioid addiction treatment. I would like to better 1735 understand from our panelists just how we should move forward 1736 with investments in research. How should those efforts be 1737 utilized to improve recovery outcomes? 1738 Dr. DuPont, you have been treating opioid addiction for 1739 a long time. How would you advise us in terms of research 1740 dollars--we obviously need to do more in research, I would 1741 hope that would be an agree across the board here, but how 1742 should those dollars be invested, in what ways are they most 1743 beneficial? 1744 Dr. {DuPont.} Evaluations of outcomes over a longer 1745 period of time. But I want to bring up something that I 1746 don't think has been clear here, and that is no matter what

1747 happens with prescription drugs, there is a robust heroin 1748 market and it is getting bigger all the time, and I think it 1749 will be a huge mistake for us to think that the only problem 1750 we have is prescription drugs. That is contributing to it, 1751 that has kicked it off, but now it has taken off in an 1752 entirely different direction and it is huge, and I think we 1753 underestimate the power of heroin distribution in the country 1754 that produce high quality products at low cost, and that is 1755 just going to get worse. So I think that is something to 1756 keep in mind.

1757 The other thing is--

1758 Mr. {Tonko.} But that supply and demand equation is 1759 something we hear about all the time. I hear about it all 1760 the time in the district. People are very concerned.

Dr. {DuPont.} It is a--well, it is a very, very serious problem, and it drives me nuts that people who want to solve the drug problem by legalizing drugs. I say let's start with heroin. We are going to solve that problem by legalizing it? Give me a break. But it is a very serious problem for us to deal with.

1767 But the other point is, most people who have this

1768 problem do not see that they have a problem. They do not 1769 want treatment. When they go to treatment, they drop out of 1770 treatment. To get good long-term outcomes the answer is not 1771 just in the treatment. You can improve treatment and improve 1772 treatment and improve treatment, and you are still going to have tremendous frustrations getting people in, and keeping 1773 1774 them in and keeping them clean when they leave. And that is 1775 why I studied the physicians health programs, because what 1776 those programs do is monitor the people for 5 years. And the 1777 physicians don't have a choice of getting out once they are 1778 diagnosed, and it is interesting how positive they are about 1779 that. I think one of the things this committee could do is 1780 look at the environment in which the choice is made to use 1781 and not to use, and think about what can be done to change 1782 that equation.

One area of tremendous potential is the criminal justice system, where there is the kind of leverage that you have. You have 5 million people on probation and parole in this country, many of whom are opiate dependent, but I think also for families to understand that they have to be concerned about somebody who has an opiate problem, and not--and

1789 essentially manage that environment for that person, because 1790 that person's judgment is changed by the addiction and they 1791 are helpless on their own without somebody intervening. So I 1792 would suggest 2 things. One is look long-term, and the other 1793 is think about the environment in which that is going on, and 1794 think about ways of using the environment to promote 1795 recovery. 1796 Mr. {Tonko.} And to our other panelists, are there ways 1797 that research can be connected into positive treatment 1798 outcomes? Dr. {Seppala.} Absolutely. It should be one of the 1799 1800 focuses of most research to look at positive treatment 1801 outcomes, and actually negative treatment outcomes, to define 1802 both for the rest of the field so we know what we are doing, 1803 and we can individualize care in a much better way. Right 1804 now, there is no research that shows who should be on 1805 buprenorphine versus who should be on Vivitrol. Can't--it 1806 has not been defined. Our field is limited in regard to the 1807 type of research to make those decisions. We need a great 1808 deal more research in this field.

1809 Mr. {Tonko.} Is there anything that has been planted as

1810 a seed that needs to be grown to a bigger program of 1811 research, or is it just being avoided in general? 1812 Dr. {Seppala.} I think research dollars are so limited 1813 across medicine right now that it is really hard to get--1814 Mr. {Tonko.} Well, there is a theme around here at 1815 times to cut research, which I oppose. I think it is the 1816 wrong path, but--1817 Dr. {Seppala.} Our--we have a huge system, we are in 16 1818 states, and we don't even have the infrastructure to gain 1819 grants from NIH. We can't do that, we have to partner with 1820 people to get research dollars. The research we are doing on 1821 this program I described is self-funded. We can't get the 1822 money we need to do the research in our setting. 1823 Mr. {Tonko.} Anyone else on the panel? Yes, Doctor. 1824 Dr. {Bisaga.} Well, I mean, you know, the most of the rest of the medicine is moving towards personalized medicine 1825 1826 or precision medicine, but we are trying to find out which 1827 treatments work best for which patients so we can avoid 1828 wasting time giving ineffective treatments. And this is very 1829 relevant to this hearing because we have four methods of treatment; three medication and maybe some people will even 1830

1831 respond to no-medication treatment. And we have a lot of 1832 people affected by the illness. So investing in pursuing, 1833 again, research, which patients should be treated with which 1834 medications, which can be done probably, would be the very 1835 smart way to use the research dollars to address this, you 1836 know, huge problem. 1837 Mr. {Tonko.} I, with that, yield back. 1838 Mr. {Murphy.} Thank you. Excellent questions. 1839 Ms. Brooks, 5 minutes. 1840 Mrs. {Brooks.} Thank you, Mr. Chairman, and thank you so much for holding this critical hearing. 1841 1842 Last year in Indianapolis, an area that I represent, and 1843 to the north, we saw massive spikes, and I heard from our 1844 public safety officials, and I a former United States 1845 Attorney, about the increased use of heroin in our communities. I met with law enforcement officials first 1846 1847 before meeting with treatment providers to see what they were 1848 seeing, and one of the greatest frustrations some of the law 1849 enforcement officials in Indianapolis had, who have now been 1850 trained in the use of Narcan, it is a pilot project being used in the city, they would save someone, and about 2 weeks 1851

1852 later save them again. Same person who they have saved their 1853 life, they are now getting saved once again by even the same 1854 officer. And what they were so frustrated about is, where 1855 are the treatment providers. You know, we are saving them, 1856 you know, they are taken to the hospital, where is the 1857 system, what are we doing.

1858 Then when I met with treatment providers, obviously, as 1859 we have learned, I mean it is very, very difficult, A, to get 1860 people to stay in treatment, to realize they need the 1861 treatment. Drug courts sometimes work, and not enough communities have drug courts, although I have recently heard 1862 1863 that drug courts--some drug courts are not allowing Medicaid-1864 assisted treatment. I am curious what your thoughts are about that, because we fund drug courts. Much of their 1865 1866 funding comes from federal grants. And so I think that is 1867 something that we ought to realize that when these patients 1868 are going in to the drug courts, which can save their lives, 1869 there is no question about it, would like your comments on 1870 that. And then finally, I just would ask all of you, because 1871 physicians, whether they are in the ER, whether they are part of treatment providers, or whether they are treating them for 1872

1873 something else, what more should we be doing to educate our 1874 physicians, because I have also prosecuted physicians who 1875 became pill mills for communities, this was back in the Oxy 1876 days--Oxycontin days, but what do we need to do to better 1877 educate physicians and psychiatrists about how to treat 1878 addictions but I--we are not there, we are not even close to 1879 being there. And I applaud all of you for your work. And 1880 just--I guess I would start with the drug treatment courts 1881 that we actually may have some leverage over. I don't know 1882 who would like to comment about drug treatment courts.

1883 Dr. {Bisaga.} If I may. You know, I have a lot to say on the issue of these topics, but this is very important 1884 1885 topic because a lot of people who are under criminal justice 1886 system custody really are there because they have a disease 1887 that affects their functioning and may cause them to do 1888 criminal things, and the way to help them get out of the 1889 custody is to treat their medical illness, which is an 1890 addiction. However, the drug courts and the judges still, I 1891 think, tend to think in the old days, thinking that the way 1892 to treat them is to send them to the drug--medication-free treatment, not medication-assisted treatment. So we are 1893

1894 working with the Bureau of Prisons, and hopefully you guys 1895 can help with that tool, to encourage them to use evidence-1896 based treatment when they are making decisions about the 1897 medical treatments. It can be done in combination with the 1898 decision about the, you know, criminal justice with ability. 1899 So--

Mrs. {Brooks.} Because, you are right, our prisons, which we also fund, obviously, as people are coming out of prison, probably one of the top reasons they recidivate and are back within a short period of time is they didn't have their addiction dealt with, and they are--anyone else like to comment--

1906 Dr. {Westreich.} Yeah, as--

1907 Mrs. {Brooks.} --or all of--

Dr. {Westreich.} As to drug courts, I mean I would say on both of your questions, education is the key. I think drug courts are great. I think judges and lawmakers need to be educated about addiction itself and not practice medicine. In the same way, we clinicians need to be educated about law and about the necessity for a holding structure of people who are addicted. So I think drug courts work well when everyone

1915 is educated about what they are doing, about therapeutic 1916 jurisprudence, which is what that is. 1917 Secondly, as far as educating doctors, I agree 100 1918 percent. I think we need to have much better efforts both 1919 through the auspices of groups like mine, and organized 1920 medicine in general, to educate not only psychiatry but 1921 primary care doctors and all physicians about prescribing 1922 practices, about--and then about recognizing and treating 1923 addiction in an evidence-based manner. So education in both 1924 spheres I think.

1925 Dr. {Lembke.} We give a lot of lip service to addiction being a chronic medical illness, but we don't actually treat 1926 1927 it like one, either in the medical system or in the criminal 1928 justice system. I cannot imagine a judge working with 1929 someone in the criminal justice system saying you have to go off your diabetes or your hypertension meds, otherwise you 1930 can't be in this court system. We wouldn't accept that, and 1931 1932 yet we accept them saying to these individuals you can't be 1933 on Suboxone.

1934 So obviously, we don't regard it as an illness. Even 1935 within the medical system, doctors do not treat it like a

1936 medical illness. So we need a huge frame shift. And I think 1937 education is really important, but unless, again, you 1938 incentivize doctors and judges, and whoever it is, to really 1939 treat it like an illness and create the infrastructure to 1940 treat it like an illness, you are not going to make any 1941 headway. 1942 Mrs. {Brooks.} And while my time is up, Mr. Chairman, I 1943 believe Dr. Seppala would like to address that question as 1944 well, if that is okay. Thank you. 1945 Dr. {Seppala.} I would. We have had a couple of leaders of the drug court system come and look at our 1946 1947 program, and they have held a fairly conservative stance in 1948 regard to the use of Suboxone and other maintenance 1949 medications for opioid dependence over time, but I think they 1950 are shifting. So I believe that you could play a huge role 1951 in pushing them along in this direction. They need to go 1952 there. 1953 Mrs. {Brooks.} And their education. 1954 Dr. {DuPont.} Could I just make one quick comment about 1955 this? In the physicians health programs, about 1/3 of the

1956 $\,$ physicians in those programs are opiate addicts, about 1/2

1957 are alcoholics, and the rest are other drugs. We looked at 1958 what happened to the opiate addicts' physicians, none of them 1959 were given Suboxone or methadone, and they did as well as the 1960 alcoholics in their long-term outcomes. They did very, very 1961 well without medication. Now, that is a specialized 1962 population, I don't want to generalize it, but I just want to 1963 get that clear.

1964 I would suggest that -- in the drug courts that the 1965 committee encourage the drug courts to actually look at the 1966 question, like they are doing in Hazelden, and see for 1967 themselves, do they get better results when they offer that 1968 as an option. I think that is a researchable question. I think it could go either way. I don't know what would 1969 1970 happen, but I think that would be the way to talk about it 1971 with them, and I think they would be receptive to that. 1972 Mrs. {Brooks.} I want to thank you, Mr. Chairman, for 1973 that. And I think with respect to educating judges and 1974 lawyers, while you are focused on physician addicts, there 1975 are plenty of judges and lawyers who also could share their 1976 knowledge and experience, and maybe help better educate our 1977 judges and lawyers.

1978 I yield back.

1979 Mr. {Murphy.} Thank you.

1980 I now recognize Mr. Kennedy for 5 minutes.

Mr. {Kennedy.} Thank you, Mr.--thank you, Chairman. I want to thank the chairman and the ranking member. I want to also thank an extraordinary group of panelists for your dedication to this issue, which is really--it is a preeminent group that we have here. So thank you for your testimony today. It has been a big help, I think, as we try to think through these issues.

And, Chairman, I also want to thank your kind comments about my cousin, Patrick, as well. This has obviously been an issue that has been very close to his professional life's work, and I appreciate your recognition of those efforts.

A number of you have talked about incentives over the course of the testimony today. And, Dr. DuPont, you also mentioned the impact of heroin and the heroin trade. I like my colleague, Ms. Brooks, was a prosecutor--I was a state prosecutor. I ended up prosecuting an awful lot of property crimes; breaking and entering cases, that were more--it was kids, 18, 20, 22 years old, that were breaking into 15 cars

1999 in a night to try to feed an Oxycontin addiction. I--2000 Massachusetts has been struggling with this for years now. I 2001 met recently with the DEA and, you know, rough numbers, but 2002 they describe the drug trade with Mexico alone to be in the 2003 order of \$30 billion a year. So--and a big percentage of 2004 that is heroin. So until we kind of wrap our minds around 2005 the fact that, as the street market for Oxycontin is 80--or 2006 essentially, a buck a milligram, so \$80 a pill, but you can 2007 get heroin for \$3 or \$4 a bag, there is a very strong 2008 economic incentive to push you into heroin. And I think I 2009 have said this before at these hearings, meeting with local 2010 law enforcement, meeting with federal law enforcement back 2011 home, a widespread recognition, we will not arrest our way 2012 out of this problem. So the question becomes, if it is a 2013 demand-based epidemic, because you people are addicted and 2014 that is fueling either because of over-prescription, because 2015 of easy access, and then a migration towards heroin, how do 2016 we make sure that we don't even get there in the first place? 2017 So, one, I wanted to get some thoughts from you, Dr. 2018 DuPont and Dr. Lembke, as to what we can be doing to make 2019 sure that your efforts here hopefully one day aren't

2020 necessary, but then two, we have touched on this a little 2021 bit, in my study of the--people will follow incentives, and 2022 is--the Federal Government has systematically underinvested 2023 in substance abuse treatment and in mental health now for 2024 decades. I hear from our hospitals, our doctors, our patient 2025 groups, everybody, our judges, our court system, there are 2026 not beds for people to get treatment. So if we start 2027 reimbursing for--if you start to put the economic incentives 2028 in for doctors to get compensated adequately for their time 2029 for there to be actually treatment facilities, you will see 2030 more beds, you will see more treatment facilities, you will 2031 see more wraparound services. So I was hoping to get both of 2032 you to comment on that as well, and what--I guess bifurcated 2033 question to start, what should we be doing to--hopefully to 2034 make sure we actually one day don't need all of these 2035 services you are talking about, and in the meantime, what 2036 incentives -- where should we be really focused on these 2037 incentives to build up and flush out so that people can get 2038 the continuum of care that they need?

2039 Dr. {DuPont.} Well, I think one thing to focus on is 2040 the drug problem is not just about heroin or opiates; we have

2041 a very serious drug problem across a very broad spectrum to 2042 deal with. But I also want to just say it has been my 2043 privilege to work with Patrick often, and he is a genuine 2044 hero of our field and a hero to me. An extraordinary guy who 2045 is making a tremendous contribution.

2046 And I want to go back to those young men you were 2047 arresting and prosecuting. One of my preoccupations is the 2048 use of the criminal justice system in what was described as 2049 therapeutic jurisprudence. When that person is arrested, 2050 there is an opportunity to change his life direction in a very positive way. And one of the most striking programs 2051 about this is called Hope Probation from Hawaii, which uses 2052 2053 the leverage of the criminal justice system to promote 2054 recovery. I visited out there, and let me tell you 2055 something, the treatment programs love the people that they 2056 get from Hope probation because they do stay, they do pay 2057 attention, they do get better, because they are required to 2058 be drug-tested for their probation. And so it makes 2059 treatment work like that. And I think that there is a real 2060 opportunity to use that as an engine for recovery that should not be overlooked when a person is out of control. But I 2061

2062 don't think we are going to treat our way out of this either. 2063 We have to deal in an integrated way with a very complex 2064 problem, and the problem is the drugs really work. People do not understand the potential. They think somehow there is--2065 some small percentage of the population is vulnerable to drug 2066 2067 addiction. That is not correct. It is a human phenomenon, 2068 it is a mammalian phenomenon. And when there is access to 2069 these drugs, an awful lot of people are going to use them, 2070 and a lot of the people who use them are going to be stuck 2071 with that problem for the rest of their lives. This is a 2072 very big problem, of which this is a very important part. 2073 Mr. {Kennedy.} I am already over time, but if I could 2074 ask you to ask--just answer as briefly as you can. 2075 Dr. {Lembke.} Just briefly. I really appreciate your 2076 emphasis on incentives, particularly in changing doctors' 2077 behavior and creating the infrastructure to treat the 2078 illness. Even if you don't believe addiction is a chronic 2079 illness, we need to pretend like it is because, from a practical perspective, if we don't, we will just make people 2080 2081 sicker, we won't make them well.

2082 And then what is really driving the recent heroin

2083 increase is young people, so I absolutely agree that we need 2084 to put our resources toward youth, and not just for the short 2085 term, but they need to learn how to live differently in the 2086 world and whatever that takes, changing the structure of their lives and their friendship groups, giving them jobs, 2087 2088 socializing them in a better way to adapt to contemporary 2089 culture is, I think, you know, where it is, not just short-2090 term and long-term.

2091 Mr. {Kennedy.} Thank you.

2092 Thank you, Mr. Chairman.

2093 Mr. {Murphy.} And, Ms. Clarke, you are recognized for 5 2094 minutes.

2095 Ms. {Clarke.} Thank you, Mr. Chairman. And I want to 2096 thank all of our witnesses for giving this committee the 2097 benefit of your expertise and experience today.

I would like to focus my questions on the prevention side of the equation. I know we have discussed the array of access points to heroin and opiates, and I would like to focus us back to the universe of prescribed opiates.

2102 According to the National Institutes on Drug Abuse, the 2103 number of prescriptions for opiates in the United States

escalated from 76 million in 1991, to about 207 million in 2105 2013. Between 2000 and 2010, there was a fourfold increase 2106 in the use of prescription opiates for the treatment of pain. 2107 The uptake in prescriptions for opiates has been accompanied 2108 by a corresponding increase in the number of opiate-related 2109 overdose deaths.

2110 So let me start with Dr. Seppala. My question to you 2111 is, are opiates being over-prescribed, and I want to get to 2112 the why if that is the case?

2113 Dr. {Seppala.} Yes, they are being over-prescribed, and 2114 they are being used for purposes that they are not

2115 necessarily proven to be effective for, and particularly when 2116 it comes to chronic pain.

2117 Opioids are the best, most powerful painkillers on the 2118 planet. They are necessary for the practice of medicine and 2119 for relief of suffering, but primarily, in an acute pain 2120 situation. Chronic pain studies are not long-term and don't 2121 show over the long-term the effective relief of chronic pain. 2122 Opioids just don't work that well, and yet they are being 2123 prescribed readily for that, so people are taking them for 2124 months and years.

2125 Ms. {Clarke.} So is there a standard of care as to when 2126 it is appropriate to prescribe opiates for the management of 2127 pain?

2128 Dr. {Seppala.} Yes, there are standards of care defined 2129 for the prescription of opioids for pain, for acute pain and 2130 for chronic pain, and the -- there has been a shift in how that 2131 is viewed, and the standards have shifted over the last 10 2132 years, first to increase the prescribing of opioids for 2133 chronic pain, and now to decrease and go back to a more 2134 conservative approach. So it is being understood in medicine 2135 but, you know, I am reading the literature right out of the 2136 pain folks who understand this, and the primary care docs 2137 don't necessarily follow suit for years--

2138 Ms. {Clarke.} Um-hum.

2139 Dr. {Seppala.} --they still have to kind of catch up, 2140 so we do need to educate our physician population.

2141 Ms. {Clarke.} So the--Dr. Lembke, I would like to get 2142 your thoughts on that as well.

2143 Dr. {Lembke.} Well, there is a long story to why we 2144 over-prescribe prescription opioids, which we do, and 2145 basically, it started in the 1980s when there was this

2146 recognition that we were not doing enough to treat pain. It 2147 also coincided with the hospice movement. And there was a big push to use opioids more liberally for the treatment of 2148 2149 pain, so doctors did that. What happened was that the 2150 evidence that showed the use of opioids was indicated for 2151 people who were dying was then turned over to the use of 2152 opioids in those who have chronic pain conditions. And 2153 Purdue Pharma and others aggressively marketed to doctors to 2154 use opioids for chronic pain, although there is no evidence 2155 to show that they are effective for chronic pain. And now 2156 reports are coming out that the risks far exceed any benefits 2157 that you might have for an individual patient. So now there 2158 has been a big seat change in that regard. Nonetheless, it 2159 is hard to get doctors to catch up with that seat change. 2160 Ms. {Clarke.} So are physicians not getting the appropriate level of training and education in pain 2161 2162 management, and how to identify patients who may be at risk 2163 for addiction? And I don't know what that universe looks 2164 like. It sounds to me, just in hearing the dialogue, that 2165 just about everyone can be a candidate for addiction under 2166 that construct.

2167 Dr. {Lembke.} They are now getting that education, and 2168 there are standards. The problem is that a doctor gets paid 2169 twice as much for a 5-minute medication management visit as 2170 they do for 1 hour talking to patients, so there is, again, 2171 no infrastructure to incentivize doctors to not prescribe 2172 pills. There is a lot of incentive for them to prescribe. 2173 Ms. {Clarke.} Dr. Harris, would the AMA support 2174 mandatory CME or responsible opioid prescribing practices in 2175 addiction tied to the DEA registration of controlled 2176 substances?

2177 Dr. {Harris.} So I think the mandatory is the issue, and I think the AMA would like to offer an alternative 2178 2179 approach because mandatory CME just feels like sort of a one-2180 size-fits-all. You have many psychiatrists here on the 2181 panel, and the education that we may need might be different 2182 than the education of our primary care colleagues, and so 2183 certainly more education is the key. We are right now 2184 cataloging best practices. Each of the specialties are looking at how should they educate their own colleagues. 2185 And 2186 so really it is about the right education at the right level, for the right specialty. So education is key, but certainly 2187

not mandatory. Feels like that is a one-size-fits-all--2188 2189 Ms. {Clarke.} I am over time but, Dr. Lembke, do you 2190 agree, should we be mandating or do you think that it should 2191 be left to the field to make--2192 Dr. {Lembke.} Yeah, so I respectfully disagree with Dr. 2193 Harris. I think that when doctors get their DEA license to 2194 prescribe controlled and potentially addictive medications, 2195 they should mandatory be taught how to use a prescription 2196 drug monitoring system, that that just simply should be the 2197 standard of care, independent of their subspecialty. 2198 Ms. {Clarke.} Mr. Chairman, I thank you for your 2199 indulgence. I yield back. 2200 Mr. {Murphy.} Thank you. This has been quite an 2201 enlightening panel. I have been writing down some of your 2202 recommendations. I have a number of things here. Change the 42 C.F.R. program to bring us up to 2015 standards of 2203 2204 integrating physical and behavioral medicine so that we can 2205 know who is getting addiction treatments, and help the 2206 practices. Improve the intra and interstate communication 2207 between pharmacies and physicians so they can distinguish between patients who truly need a medication, versus those 2208

2209 who are involved with addiction shopping. Better define 2210 recovery. Dr. DuPont, you had said not in terms of just today if they are off medication, but recovery as a longer 2211 2212 term. And many of you have used the word chronic. And we need to be paying attention to longer-term data. We need 2213 2214 more education to monitor physicians, and more education of 2215 monitoring for physicians so they understand prescription 2216 drug use here, and what treatment from pain is. We also have 2217 to make sure we do have insurance parity to truly deal with 2218 this treatment, something we have been dealing with on this 2219 committee for 6 or 7 years now. We need more providers who 2220 are trained and experienced with mental illness, severe 2221 mental illness, and addiction. More inpatient beds for 2222 treatment for detox, for in-depth treatments that meets the 2223 needs of the patients. And understanding that medication-2224 assisted therapy and psychosocial therapy are not enough; we 2225 have to make sure that we have this spectrum, the pallet of 2226 treatments available to people to meet their needs.

I think now as we look at that sobering number of 43,000 overdose deaths, and 1-1/2 million on some of these medications as treatments, we have our marching orders. This

2230 is not something that is simple, but it is something that I 2231 think is doable. And the good news is this is the committee that can do it, so we will get our work together. 2232 2233 Again, I want to thank this very distinguished panel. 2234 Remind members that they have a few days to get to us their--2235 what is it? 2236 {Voice.} Ten business days. 2237 Mr. {Murphy.} Ten business days to submit questions for 2238 the record. And ask all the witnesses if you would respond 2239 promptly to this. Again, thank you so very much. We have 2240 our work cut out for us. 2241 This is--committee is adjourned. 2242 [Whereupon, at 1:03 p.m., the Subcommittee was 2243 adjourned.]