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THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS

SEPTEMBER 27, 2017

MEETING MINUTES

I. Introduction

The third meeting of the President's Commission on Combating Drug Addiction and the Opioid Crisis was convened by the Chair of the Commission, New Jersey Governor Chris Christie, at 12:30 PM on September 27, 2017, at the Eisenhower Executive Office Building in Washington, D.C., with Michael Passante, Deputy General Counsel of the White House Office of National Drug Control Policy (ONDCP), as the Designated Federal Officer.

Michael Passante stated that the purpose of this meeting was for the Commission to discuss alternative pain management and new treatments for addiction. Interested parties may contact ONDCP at commission@ondcp.eop.gov with any questions, comments, or concerns regarding these meeting minutes or the Commission more generally, and may find Commission related materials on the Commission page of ONDCP's website.

II. Meeting Participants

The following is a list of participants in the September 27, 2017 meeting.

A. Commission Members in Attendance:

- Governor Chris Christie [Commission Chair]
- Governor Charlie Baker
- Florida Attorney General Pam Bondi
- Governor Roy Cooper
- Congressman Patrick J. Kennedy
- Professor Bertha Madras, Ph.D.

B. Witnesses:

- Stephen J. Ubl, PhRMA
- Dr. James N. Campbell, Cetrexion Therapeutics
- Christian Kopfli, Chromocell Corporation
- David M. Stack, Pacira Pharmaceuticals
- Mike Derkacz, Braeburn Pharmaceuticals
- Dr. George M. Savage, Proteus Digital Health
- Corey McCann, Pear Therapeutics
- Richard Pops, Alkermes
- Dr. Ponni Subbiah, Indivior
- Dr. Roger Crystal, Opiant Pharmaceuticals
- Kristen Gullo, US World Meds

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C. Others in Attendance:

- David Shulkin, Secretary, Veterans Affairs
- Tom Price, Secretary, Health and Human Services
- Kellyanne Conway, Counselor to the President
- Reed Cordish, Assistant to the President for Intragovernmental and Technology Initiatives
- Rachel Brand, Associate Attorney General, Department of Justice
- Jason Botel, Department of Education
- Richard Baum, Acting Director of ONDCP and Executive Director of the Commission
- Dr. Francis Collins, Director, National Institutes of Health
- Michael Passante, Deputy General Counsel of ONDCP and Designated Federal Officer of the Commission
- Other staff from White House and Federal agencies and press

III. Opening Remarks

New Jersey Governor Chris Christie introduced and thanked the President's staff and Cabinet. He thanked the public for the over 8,000 comments that were reviewed and said that they had an impact on the interim report. The focus of the meeting was to talk to leaders in science, across the country, about the issues that confront the opioid epidemic. Counselor Conway, Congressman Kennedy, and Governor Christie discussed the trip to Louis Stokes Veteran's Hospital in Cleveland, Ohio. The rate of opioid based prescription use was decreased by 50% based on alternative methods.

Counselor Kellyanne Conway said that nearly 27 million Americans suffer from chronic pain and over 11 million Americans over the age of 12 abuse opioids. The President has put his full will forward into the effort to help combat the epidemic that spans across the nation. The opioid crisis touches everyone in the country and does not discriminate. Opioids come into the conversation when people open the medicine cabinet and find opioids that are meant to help someone. We must educate and engage Americans regarding the misuse of these otherwise helpful pharmaceuticals. The President has directed many agencies across the cabinet and federal government to chip in on prevention, treatment, and recovery. The White House also wants to destigmatize opioid misuse because of the vast number of Americans who are reluctant to reach out for help.

Reed Cordish thanked the commission for the thoughtful and detailed interim report. The government is making progress and is eagerly waiting the final report. This is a crisis 20 years in the making and it is going to take the full focus and commitment of the entire government and private sector.

Dr. Francis Collins, Director of the National Institutes of Health, thanked Governor Christie and the members of the commission for the recommendations in the interim report. He also thanked Counselor Conway and Reed Cordish for their efforts. More people are dying of opioid overdoses than HIV and AIDs at the peak of that epidemic. There are many partnerships in the private sector. We need to build on these partnerships. Of the 2 million people addicted to opioids, it began with prescription medicines. They are trapped in the rewiring of their brain, and it is almost impossible to recover without medications. There are effective treatments for opioid use disorder (MAT) but they are underutilized and the number of options are limited. Doctors do not even really know how to make these medications work for all patients. Recent neuroscience research has helped understand the pathways involved in addiction and pain. New non-addictive pain medications can be pursued. The goal is to build a partnership with researchers, in academia and industry, the government, and patients to cut in half the time that is needed to make available new and potent non-addictive medications for pain and addiction. In March of this

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year, Dr. Collins proposed a public-private partnership plan to the President. The President charged him to do anything possible to bring this together. In April, Dr. Collins received consensus that such a partnership was needed. There are two themes from the meetings:

- Focus on medications to treat addiction and to reverse overdose. Changes to formulations and combinations of drugs in use could be useful in providing additional options in treatment. New uses for compounds that are not being used for medical treatment that could be used to treat need to be developed. Give the doctors and patients the flexibility in treatment options and increasing the chances in long term recovery.
- The development of potent but non-addictive medication for pain. We cannot walk away from that need, but give them opportunities to receive treatment that do not carry the terrible consequences of opioids.

That means working with industry and partners. Many of the medications being developed for alternatives are still in the development stage. We need biomarkers to predict clinical outcomes and distinguish different types of pain in different populations. We need objective measurements of pain. We need a clinical trial network for testing and rapid assessments for FDA approval.

Stephen J. Ubl, President and CEO of PhRMA, said that he had three points to make. First, he was very excited about having the best and brightest researchers in this new groundbreaking public-private partnership. The two aims of the partnership are to speed patient access to non-opioid alternatives and to modify existing treatments. Second, they support law enforcement capacity in stopping the flow of counterfeit fentanyl and the crackdown on rogue online pharmacies. Third, PhRMA is announcing for the first time the support of limiting of opioids to 7 days for acute pain management. Too often, individuals are given a 30-day supply for minor treatments for short term pain. We can make progress on all the items discussed today, but they can be undermined by insurance coverage barriers. In closing, the researchers and scientists in their companies wake up every day to try to resolve these issues.

IV. Testimony of Invited Organizations

A. Centrexion Therapeutics

Testifying on behalf of the Centrexion Therapeutics, Dr. James N. Campbell made the following recommendations:

Develop new non-therapeutics for chronic pain.

- There are three opportunities to foster the development of new treatments:
 - Business environment. A substantial barrier to the development of novel pain treatments is the perception that this type of drug development has a high risk of failure.
 - Regulatory environment. A barrier in the development of the advancement of new therapies is the lack of an adequately resourced analgesia division in the FDA. A better resourced division will lead to a quicker and efficient review. Create a non-opioid drug priority review voucher to reward sponsors of new non-opioid pain therapies. Allow waivers of FDA filing fees for new non-opioid treatments. Provide significant tax credits to new non-opioid clinical development. Other FDA mechanisms can be used to promote new therapies. Create a non-opioid drug designation. Grant 10-year market exclusivity to new non-opioid treatments. Mandate break through status for new non-opioid treatments.
 - Reimbursement environment.

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B. Chromocell Corporation

Testifying on behalf of the Chromocell Corporation, Christian Kopfli made the following recommendations:

- Long-term solutions. Put a strong focus on the development of sustainable long-term solutions.
- Public-private partnership. Accelerate the development of this non-class of drugs. Make accessible the development of biomarkers and data sharing.
- Regulatory. Support the FDA efforts to enable them to proceed as fast as possible with trials for non-addictive solutions.

C. Pacira Pharmaceuticals

Testifying on behalf of Pacira Pharmaceuticals, David M. Stack made the following recommendations:

- Changing policies that impede and underutilize multi-modal pain strategies.
- Unbundle MEDICARE reimbursements for non-opioid administered drugs administered by health care providers as part of a multi-model post-surgical pain management strategy, while establishing separate recognition and reimbursement for those drugs.
- Establish a new MEDICARE HCPCS code to reimburse healthcare practitioners for additional time needed to provide pre and post-surgical evaluations and educational consultations related to low or no-opioid pain management strategies.
- Adopt expedited development and review pathways for FDA approval of new non-opioid analgesics as well as supplements for approved non-opioid analgesics for acute pain.

D. Braeburn Pharmaceuticals

Testifying on behalf of the Braeburn Pharmaceuticals, Mike Derkacz made the following recommendations:

- Regulatory bodies need to create space that does not include barriers to patients seeking treatment.
- Tear down barriers for patients to receive treatment.
- Include policies that help ensure patients can receive care and access treatments when and where they need it.
- Advocates for the Commission's recommendation for mental health parity.
- Insurance companies that reduce the pre-approval requirements will increase treatment.

E. Proteus Digital Health

Testifying on behalf of the Proteus Digital Health, Dr. George M. Savage made the following recommendations:

- FDA leadership should clarify whether new innovations fall within the existing definition of abuse deterrent formulation, which is essential in approval.
- FDA should consider priority review to novel opioid and non-opioid solutions that are designed to reduce and deter abuse.
- CMS and private payers should swiftly create and value codes to reimburse physicians for the resources they need to expend to realize the benefits to these technologies.

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F. Pear Therapeutics

Testifying on behalf of Pear Therapeutics, Corey McCann made the following recommendations:

- Wants the Commission's willingness and partnership in generating awareness among clinicians within the VA healthcare system that digital therapeutics as a new standard in efficacy for this set of patients.
- Engage the Commission in getting mental health and addiction conditions on par with physical health conditions and driving towards reimbursement for those conditions in accordance with the Mental Health Parity Act.
- Bring these technologies to patients by means of reimbursement components.

G. Alkermes

Testifying on behalf of Alkermes, Richard Pops made the following recommendations:

- The Commission can address insurance plans that treat long-acting injectables in a way that makes reimbursement cumbersome and difficult for the average physician.
- Ensure that patients are aware that they have access to all FDA approved medication. No medication is right for every person.
- All healthcare providers need to have access to all available drugs for treatment.

H. Indivior

Testifying on behalf of the Indivior, Dr. Ponni Subbiah made the following recommendations:

- End the stigma of addiction.
- Accelerate access to all evidence based treatments.
- Continue to enforce and comply with the Mental Health and Substance Use Disorder Parity Act and require plans to demonstrate compliance as a basis for approval. Ensure that patients and their families understand their rights under the act.
- No one with an overdose should leave an emergency room without treatment and a pathway for a recovery plan for the disease.

I. Opiant Pharmaceuticals

Testifying on behalf of Opiant Pharmaceuticals, Dr. Roger Crystal made the following recommendations:

- Escalate from lower addictive medications such as acetaminophen, ibuprofen, and perhaps escalate up to an opioid if the pain wasn't well managed.
- Increase the public-private partnership.
- Relentless focus on the addiction as a disease. There should be more access to medical treatment. Medical treatment should be a supplemental means of therapy.
- Drug development timelines need to decrease to only a few years rather than several years.

J. US World Meds

Testifying on behalf of the US World Meds, Kristen Gullo made the following recommendations:

- Educate about all risks of opioid use, to include withdrawal symptoms. Consider federally funding and expand the CDC's campaign on opioid misuse.

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- Include withdrawal strategies and opioid based pain management strategies to minimize unnecessary opioid use.
- Encourage addiction and recovery intervention strategies for both mental and physical components of opioid use disorder.
- Be more thoughtful about the consequences of delaying evidence based treatments.

V. Open Dialogue Between Commission Members and Invited Guests

Professor Madras asked Dr. Savage if the sensor technology could be applied to naloxone to monitor and alert a first responder of use, report, and document. Dr. Savage said that the current technology is aimed at oral and ingestible. It can be adapted to injectable but has not been adapted to that technology yet.

Governor Christie asked Richard Pops about Section 303 in CARA and what the real effect is on patients who have to go to several facilities to receive treatment. Mr. Pops said that Section 303 of CARA allows the physician to prescribe all the drugs that may be required for treatment. Governor Christie asked a follow up question to Richard Pops about what the government can do to make sure the Section 303 of CARA is being enforced because the Commission wants to make a recommendation to agencies to ensure enforcement. Mr. Pops stated that the government has done a good job with training and ongoing certifications through SAMHSA in methadone clinics. This has established a baseline in which we can expand treatment. Governor Christie asked if the training and prerequisites for administering methadone and Vivitrol were adequate. Mr. Pops explained that the administration is very different between drugs because for some, detox happens after the administration of some drugs where it does not in others. Some doctors have not had to deal with this and do not realize the additional time that is required to treat the ensuing detox.

Governor Cooper asked Dr. Collins and Mr. Ubl how the Commission can further the public-private partnership. Dr. Collins said that the Commission has already made some interim recommendations that has furthered the partnership. From the NIH perspective, they do not have any special appropriations that will fulfill the needs of the crisis based on the speed necessary to combat it. They will redirect funds to address the issue, but they will not fulfill the requirement. Specifically, setting up rigorous clinical trial networks focused on patients that have a high need for pain relief and a homogenous kind of pain syndrome. It is difficult to test a high pain medicine because a patient may have multiple pain symptoms. Ultimately, we need to speed the FDA approval process and reimbursement issues with additional resources. If we come up with multiple powerful non-addictive pain medicines but the third-parties will not pay for them, then we haven't achieved very much. Mr. Ubl said that we have critical mass and enthusiasm coming out of the Trenton meeting. Developing a work plan with Dr. Collins, with resources associated with the work plan, will enable the partnership. Industry has a role to play in the partnership.

Governor Baker asked Dr. Crystal what people do in the U.K. that is done differently in the U.S. to treat pain. Dr. Crystal said that they begin pain management at the lowest dose and incrementally escalate the dose and medication. If that low dose, for example ibuprofen, does not work then they consider an opioid but a milder opioid, like codeine. Limiting to seven day prescriptions of the milder opioids would be the next step in escalation. Governor Baker asked if there is pain management and therapy as part of medical school. Dr. Crystal said that they do, but things may have changed because the more extreme and potent opioid medications were not as prevalent in the world at the time he went through medical school.

Governor Baker stated that he could not understand why if the rest of the world are using protocols that work, why not start with the examples of down-sized risks that are being used in other parts of the world.

Dr. Collins said that we need to carefully examine these practices to see what we can learn from them. The medical profession was part of a terrible mistake in the early 1990s in the U.S. by stating that pain is not something that a patient should be going through and pain became part of the vital signs and should

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be zero. The notion was that opioid prescriptions for patients with physical pain could not lead to addiction. The rest of the world did not make that mistake, so we are trying to recover from this misunderstanding. Governor Baker said that there are two schools of thought: 1. Detox/blocking and 2. Change in the delivery model. Governor Baker distinguished between the two strategies and asked what the different thoughts were on the two types of strategies. Richard Pops said that if you know someone, like I do, sourcing the street for fentanyl with the risk of dying, getting that person onto replacement therapy could save their life. The person may not be ready for Vivitrol and may want to look at other alternatives for treatment until they are ready to make the full commitment to break the addiction. We need multiple options and the options need to be known to everyone. Mike Derkacz stated that there need to be multiple solutions to the vast number of people addicted to opioids. The ability for patients to make the right decision for their lives and to save lives. We need to enforce the Mental Health and Substance Abuse Parity Act. Dr. Subbiah said that there is no “one stop shop.” That is why we need a health care treatment congregation package for different patients at different phases. It is not all about the physical symptoms, but instead the mental aspects are important as well. We will never be able to fully support a patient in their recovery without those multi-factor approaches. Governor Baker responded, “Get a lot more aggressive on the front end and maybe people will get a little more aggressive on the back side, too.” David Stack said that the European medical system has more aggressive post-surgery protocols. They have stricter and more aggressive protocols, which the U.S. medical system has not followed. The problem is that the pure additional cost from the MEDICARE bundle systems in place creates a disincentive for hospitals to employ these European protocols. We are asking the hospitals to take on the additional costs to fall in line with the protocols. We need to level the playing field. Dr. Collins stated that the more options we have on the table to offer patients, the more issues we will be able to address. We need additional precision medical options for people that have pain where opioids have proved to be ineffective, similar to how we addressed precision medicine for cancer.

Professor Madras asked how long the drugs in the pipeline for FDA approval should be evaluated, especially opioids that have abuse or long-term adverse effects. The opioids were only evaluated for a few months. What is a reasonable process for evaluation or post-marketing surveillance? Dr. Campbell said that a real tragedy with the opioid crisis is that we do not do a good job at managing pain. The opioids do not always work, so we need to come up with innovative therapies. There can be improvements in the timeline of review and addressing simple issues with guidance from the FDA. Professor Madras asked how long the outcomes should be monitored by the FDA before approval. Dr. Campbell stated that the ICH guidelines require that safety must be demonstrated for one-year before approval. The FDA does a good job at answering safety issues. It does take a long time to develop the drugs. He directed the Commission toward the approval rates of pain drugs over the past five years. There have been thirteen new drugs approved. Eleven of them dealt with opioid variants and two dealt with aspirin type drugs. In five years, we have had no new chemicals approved for pain.

Congressman Kennedy said depression is rampant and that it is clearly in line with the opioid crisis. Suicide is getting “up there to the height of the AIDS epidemic itself.” We have a combined problem here, and he stated that we need to have segmented treatments for each of the problems. There is a need for parity and to enforce the Act. He put an “ask” out to the individuals testifying to get stories of patients that were denied access to medications. We should take these stories to the Attorney Generals of each state and have them confront the insurance companies. Because the illness is so stigmatized, the advocacy is anemic. Nobody is “shaking the trees, like HIV and AIDS.” The Commission needs to take into account the mental health aspect that is not reimbursed as well. Governor Christie made a comment last week that New Jersey would be spending the equivalent of half the national budget on this. Governor Christie said that we need the federal Department of Labor to enforce the Parity Act as well.

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Middle-class citizens are paying for insurance, but are not getting the benefits they deserve. But, “if they had cancer, they would be getting those benefits. I don’t understand what the difference is between the two because they are killing our citizens, both of them are.”

Florida Attorney General Bondi said that we are getting mental health and drug addiction merged when we don’t have to. AG Bondi thanked the creators of Narcan, stating how the drug has saved many first responders from her state. She asked all the individuals at the meeting to look for other “Narcan” type drugs to treat our addicts and first responders. We have to drive the price of them down. We need to hear more about “what an addict goes through.” She asked if the drug discussed by Mike Derkacz could be administered to pregnant women. Mr. Derkacz said that they are currently in the process of exploring the administration of the drug for that. It is going to take a while to get there, but it is a goal.

Professor Madras asked if we are able to generate an over-the-counter naloxone, how are we going to identify and help the people that are currently dying? Dr. Subbiah said that the use of different technologies needs to marry the treatment options available. Congressman Kennedy said that he would like to get follow up information and recommendations regarding the telehealth and digital health world.

Congressman Kennedy asked the panelists to comment on the Ryan Haight Act, particularly prescribing through telemedicine. This is important for the people who do not have the adequate service to get the proper prescribed treatments and medications. Dr. Subbiah said that because the laws regarding telemedicine change from state to state, the Commission could help make them consistent. The distribution laws in rural areas need to allow patients to get information and consultations from the urban areas. Because of the rural laws, the patient is thus forced to drive hours away to get treatment. Governor Christie noted that “recovery coaches” have been used and expanded to every hospital in New Jersey. The coach is there to help the patients during the process. Eighty percent of the patients have become recovered addicts. Governor Christie told a story about how an addict had threatened suicide just to stay in the hospital and receive treatment. Having a person there, the coach, to direct those patients has proved very beneficial. Corey McCann stated that prescribing medication is not alone sufficient to treat opioid use disorder. Instead, a multi-modal treatment therapy is the standard of care. Patients need more than medication, but they also need to be provided access to very dedicated support services and cognitive behavioral therapy. Whether that is adequately trained face-to-face therapists or pieces of software, it is incredibly important for the Commission to not lose sight of this.

Governor Baker said that his state attempted to pass legislation that allowed an overdose patient, who was “brought back,” to receive the same treatment as someone who would be brought in for a three-day treatment. This was to get the overdose patient the opportunity to get their “head clear” and have a conversation about further treatment. The legislation was not passed. That is as good of an opportunity to help somebody get treatment, clear their head, and help them make that decision to get treatment.

VI. Closing Remarks

Governor Christie thanked all the panelists. If there is additional information that you wish to be considered, please submit it for consideration in the final report. The Commission will be getting together soon to deal with the insurance issues before issuing the final report. There may be two more meetings before issuing the final report. Governor Christie thanked Congressman Kennedy, Governor Cooper, Governor Baker, Professor Madras, and Attorney General Bondi for their hard work. He thanked the support from the ONDCP, NIH, and PhRMA.

VII. Adjournment

The meeting adjourned at 2:45 PM.