PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE

MEETING NOTES FOR MAY 9, 2019, 10:00 A.M. – 5:30 P.M.

THE GREAT HALL, HUBERT H. HUMPHREY BUILDING,
200 INDEPENDENCE AVENUE, S.W., WASHINGTON, D.C., 20201

Welcome, Roll Call, and Call to Order 10:00 A.M. – 10:25 A.M.

- **Alicia Richmond Scott, M.S.W., Task Force Designated Federal Officer,** welcomed the public and the Task Force and provided opening remarks on the Federal Advisory Committee Act (FACA).
- **Dr. Vanila Singh, M.D., Task Force Chair**, took roll call, provided opening remarks, took roll call and provided a call to order for the Task Force members and accounted the activities from the past year.
    - May 2018: Inaugural public meeting, established Task Force, and started the one-year clock counting down the Task Force's delivery of their report to Congress
    - September 2018: Second Task Force meeting, Draft Report was voted on.
    - December 31, 2018: Posting of the Draft Report
    - May 2019: Third public meeting, Task Force will vote on Final Report.

Opening Remarks 10:25 A.M – 10:50 A.M.

- **The Honorable Dr. Phil Roe, M.D., Congressman (R – TN)**, provided opening remarks to the Task Force pertaining to current events in pain management, the Task Force's work of the past year, and his past experience in managing pain as a physician. In his remarks, Dr. Roe noted the following key points:
    - Drug overdose deaths claimed 70,000 lives last year; these deaths are preventable.
    - Congressman Roe remarked on a recent tremendous increase in births of opioid-addicted babies at one of his local hospitals in Tennessee.
    - There has also been an increased reliance on opioids for pain management, as compared to past training in pain management.
    - Congressman Roe noted how opioid use, mental health, and drug trafficking are all interrelated, and that he has begun roundtable discussion back in his home state to address these critical issues.

- Congressman Roe applauded the efforts of the Task Force, offering particular practice to the section on Military Active Duty, Reserve Service Members, and Veterans section of the report.

- **ADM. Brett P. Giroir, MD, Assistant Secretary for Health**, then provided his remarks to the Task Force via pre-recorded video message. ADM Giroir was unfortunately, unable to attend this Public Meeting of the Task Force due to a prior commitment.
    - ADM Giroir commended the Task Force for their dedicated and diligent efforts to advance and improve best practices in pain management, and thanked Dr. Vanila Singh, M.D., Task Force Chair, for all her work over the past year as Task Force Chair.

Meeting Purpose and Objective 10:50 A.M. – 11:00 A.M.

- **Dr. Vanila Singh, M.D., Task Force Chair** provided a statement of the purpose to the public and Task Force.
- The Comprehensive Addiction and Recovery Act (CARA) legislation established the Task Force and provided historical data on the Opioid Crisis that contextualized the creation of CARA.
    - The three graphs presented (semi-synthetic opioids; heroin use; synthetic opioids) correspond to the Three Waves of the Opioid Crisis and in part, tell the story of how patients with pain can be forced from licit to illicit pain management arenas.

Public Comment 11:00 A.M. – 11:30 AM

- ***These comments are from the opinions of the public and do not reflect the findings of the Task Force; language and context from the public may be abbreviated throughout the note-taking process; for a full transcript please view the transcripts page.***
- **Speaker 1: Richard Lawhern** – Alliance for the Treatment of Intractable Pain (ATIP): the Task Force has done very constructive work in helping to refocus the treatment on integrative, patient-centered care; CIH modalities are included; alternatives cannot replace analgesia or opioids/anti-inflammatories; reduced rates of opioid prescribing; recent FDA announcement on the risk of sudden withdrawal of opioids – mandatory tapering; doctors will not come back to pain management if they are persecuted; veterans suicide; AMA recently stated that MME dosages are not a medically useful guideline; advocated for the withdrawing of the CDC Guidelines
- **Speaker 2: Megan Wilson** (ATIP) – thank you for the critical work, looking for policies that allow them to receive their medications; chronic pain patients abandonment from forced tapers; heartened by the recent CDC response to the 2016 Guidelines and FDA announcement on forced tapers; chronic pain patients face co-morbidities such as mental health, suicide, trauma, loss of employment, decreased functionality, and loss of family and friends
- **Speaker 3: Benita Talati** – Ehlers Danlos Syndrome; caused by defective collagen; loose joints, stretchy skin and various other co-morbidities; the gold-standard for treatment is physical therapy; for decades, insurance and pharmaceutical companies

have worked together to deny treatment, access to treatment, re-imbursement, and to increase premium; pills can be a part of the treatment plan, but they should be the last resort and not the first; co-pays in the last month and recent year have been incredibly high

- **Speaker 4: Benjamin Goodwin** (PharmedOut) – advances evidence-based prescribing; the Report has appearances of industry bias, the Report invokes opinion pieces and anecdotes rather than evidence-based guidelines to target the CDC Guidelines; the Report fosters unlimited opioid prescribing; this Report will foster, rather than mitigate, the opioid epidemic; issues with opioids and benzodiazepines co-prescribing
- **Speaker 5: Trina Vaughn** (ATIP) – medically orphaned; no treatment for the past 2 years; general practitioners do not treat pain in Tennessee; many do not treat chronic pain patients; rejected from three doctors in the past three months because they do not accept pain patients; thoughts of suicide and hopelessness; stigma of chronic pain; media and political hysteria of the CDC Guidelines; retract and re-write the CDC Guidelines; please take government and DEA out of medicine
- **Speaker 6: Kara Gainer** (American Physical Therapy Association) – physical therapists are integral in the interdisciplinary pain team; felt that the Report placed too little evidence on the use of non-pharmacological treatments including PTs in the early stages of treatment; Task Force membership does not include PTs, cost of treating acute pain is cheaper in early stages than treating chronic pain with medication – found that this will reduce the amount of opioid usage; low re-imbursement rates for acute and chronic pain; advise the use of physical therapy early in the treatment plan; recommend payers revise guidelines for treatment using PT; work with the physician and non-physician community
- **Section 7: Kristen Wheeden** (American Porphyria Foundation) – thanked the Task Force for their time and hard work; four ultra-rare diseases that are triggered by unsafe drug metabolism; there are no other treatments besides opioids; must adhere to a safe and/or unsafe drug list for treatment; to be clear, patients do not want to be treated with medication and/or opioids; needs re-imbursement for treatment
- **Speaker 8: Inga Dawson** – has Ehlers Danlos Syndrome and various co-morbidities associated with the disease; was previously an ICU nurse; tried everything prior to opioids; opioids helped her work for eight years, this would have been only two years otherwise; tried everything prior to opioid treatment; allowed her to marry and have kids – son was born while on opioids and carefully monitored; both pain patients and addicts need treatment
- **Speaker 9: Gabriel Miller** (American Osteopathic Association) – has concerns with mention of osteopathic manipulation in CIH section of the Report; needs its own category; osteopathic manipulative treatment (OMT) is effective in low and chronic back pain; separate section as non-pharmacological, non-opioid therapy; OMT is evidence-based; Report is comprehensive, but AOA is concern with the lack of mention to OMT
- **Speaker 10: Caylee Cresta** – intended versus unintended consequences; stiff person syndrome – causes body spasms; opioids were not a first line; several other therapies were considered; when discussing pain care – we are treating *pain*; cycles of 30-days of terror; doctors are afraid to prescribe; pharmacists are policing physicians

without any knowledge of the patients' history or disease process; many obstacles to prevent the prescribing of medications, but no one can safely prescribe

- **Speaker 11: Scott Faulkner** (Photobiomodulation [PBM] Foundation) PBM therapies – infrared and non-infrared therapies when, directed at the body with the right intensity, stimulates mitochondria to repair and restore cell function and reduce inflammation; discovered in 1967, supported by clinical trials and several hundred resources; approved by the Olympic Committee and several organizations; used in various Veterans hospitals – prudent to include in Section 2.3 Restorative Therapies
- **Speaker 12: Dr. Laura Williams** (Association of American Indian Physicians and the National Hispanic Medical Association) – practicing physician; took care of 300 pain patients; chronic pain patients were targeted using the CDC Guideline, her practice was closed down, no pain doctors would take her patients following her practice closure; ISO suspension that inhibited prescribing; transferred all patients to find doctors who would prescribe opioids; suboxone was not approved at the time, no alternative – had to pay cash; choice of transfer to suboxone was not a choice and therefore patients and Veterans could not take suboxone and had to stay on opioids in California with managed care
- **Speaker 13: Judy Birchfield**; caregiver of her daughter with intractable pain; opioids keep her functioning; have spent years of time and money on alternatives; thankful for opioids and the opportunity to have it as a treatment option

Lunch Break 11:30 A.M. – 12:30 P.M.

Task Force Final Report Recommendations and Discussion 12:30 P.M. – 3:30 P.M.

- **Dr. Vanila Singh, M.D., Task Force Chair, provided an overview of the key concepts within the Task Force Final Report based on feedback from the 90 day public comment period, followed by a discussion with the Task Force on areas that needed further clarification.**
- **T**he Task Force's five broad treatment categories by four major cross-cutting themes, which outlines the components of the Task Force's individualized, patient-centered approach to acute and chronic pain management were discussed.
- **T**he members of each Subcommittee, along with the Subcommittee Chairs (Drs. Rutherford, Gallagher, and Zaafran), were thanked for the tremendous effort devoted to all facets of the Final Report development each member contributed over the past year.
- Major updates and key points Subcommittee One contributed to the final report were covered. Subcommittee One sections were approaches to pain management, medications, interventional procedures, restorative therapies, and special populations.
- The Task Force discussed Subcommittee One's focus areas. Highlights of the suggested Task Force changes to the Final Report are as follows:
    - Delete the second sentence of Recommendation 8a in Review of CDC Guideline
    - Change "compound" to "product" in the Opioid Medications section in Medications (pg. 31)

- Delete the word “more” preceding “potent synthetic opioid” in Introduction (pg. 16)
- Replace “as a result of” with “there is a growing concern that there may be” in Introduction (pg. 16)

- Major updates and key points to the Review of CDC Guideline section of the Final Report were presented.
- The Task Force then discussed the updates and provided suggested Task Force changes to the Final Report, which are as follows:
  - Insert “risk mitigation strategies and counseling” (between “benzodiazepines” and “collaboration”) into Recommendation 6a in Review of CDC Guideline
  - Revise sentence in Review of CDC Guideline section (pg. 73) to read: “The CDC Guideline for Prescribing Opioids for Chronic Pain is not intended for patients who are in active cancer treatment, palliative care, end-of-life care, acute trauma, or surgery.” (i.e., adding “acute trauma” and “surgery”)
  - Revise sentence in CDC Guideline section (pg. 74) to read: “The authors highlight that the dose recommendations in the Guideline do not address or suggest discontinuation of opioids prescribed at higher dosages.”
- Major updates and key points on the topics within Subcommittees Two and Three were presented. Subcommittee Two topics were behavioral health approaches, risk assessment, and complementary and integrative health. Subcommittee Three topics were stigma, education, and access to care.
- The Task Force discussed the focus areas of Subcommittees Two and Three. Highlights of the suggested Task Force changes to the Final Report are as follows:
  - Recommendation 1a (pg. 45), replace “alternative” with “the full range of treatment”; replace “traditional and non-traditional” with “full range of” in recommendation 1c (pg. 45)
  - Insert “body awareness such as yoga, behavioral changes, and” (between “through” and “intensive” (pg. 39)
  - Delete Harold Rogers and NASPER from Recommendation 1j (pg. 59); leave as “Encourage funding programs to link interstate PDMP programs …”
  - Dr. Lynch noted edits needed to the Poison Center Figure (pg. 34): insert “of” after “treatment”; delete “1” after ‘effective’; capitalize “Geriatric”

Remarks: A Review of Task Force Effort 3:40 p.m. – 4:00 p.m.

- **Dr. Vanila Singh, M.D., Task Force Chair**, reviewed major Task Force milestones from the past year. This included the following:
  - Thanking all Members of Congress, Government Dignitaries, Agency Officials, and pain management experts and stakeholders through the public and private sectors
  - Discussing, in detail, the results of the 90-day Public Comment Period, as well as the process by which the Task Force implemented their findings into the Final Report

- Thanking medical organization stakeholders for their support and feedback submitted to the Task Force during the 90-day public comment period
- Reading of select comments from medical organizations and the public that supported the Task Force's Draft Report and efforts to improve pain management best practices

Pain Management Patient Testimonials 4:00 p.m. – 5:00 p.m.

- ***The following testimonials come from select patients living with chronic pain; language and context from the patient testimonials may be abbreviated throughout the note-taking process; for a full transcript please view the transcripts page.***
- **Lieutenant (Ret.) Morgan Luttrell:** 2009 broke back in six different places, damaged nerves from waist down. 15 days in hospital with a cast. Five different opioids- discovered an allergy to opioids after a diaphragm seizure. Hasn't taken anything again since 2009. Once out of his body cast, he was able to manage the pain acutely. Started to travel across country and visit several specialists, took a holistic approach to managing his pain. Cognitive rehabilitation in combination with physical rehabilitation regimen. In his opinion, it takes a multidisciplinary approach consisting of multiple therapeutic modalities to recover.
- **Sarah Whitlock**: "Know pain, know gain"; numerous victories and challenges in managing her pain; suffers from severe spastic cerebral palsy and Chron's disease. Acute pain has been really difficult to manage. Three areas that have helped in recovery or pain management: 1.) experiences voicing her desire consistently, exploring alternative methods have been key- Physical therapy, meditation. 2.) Facilitating an open dialog with entire treatment team; explore educational materials of acute vs chronic pain 3.) Collaboration and continuity of care is key. Support is necessary to help patients navigate pain management.
- **Amy Partridge:** Worked for two decades in the health insurance industry. Chronic low-back pain; received 6 epidurals, the sixth, in fall 2015. In February 2016, Amy had to stop working- even resting her laptop on her leg caused too much pain. Amy then saw 6-8 doctors in a 6-month span. In May 2016, Amy was diagnosed with Adhesive Arachnoiditis. Amy saw a pain management doctor in the fall of 2016 doctor on the West Coast, after which, she walked without pain for the first time in a year. Amy uses a combination of opioid and non-opioid therapies. Last year, stigma almost killed her: and ER doctor stigmatized her as a drug-seeker, missing a perforated colon that nearly killed her. Amy recently traveled alone for the first time in years. Amy accepts she will never again work full-time; medication will never help reduce pain completely. Amy notes individualized, patient-centered care is key to her improvement in quality-of-life. Consider three things: 1.) we are individual 2.) we need providers to provide individualized care 3.) providers need protections to treat patients with pain.
- **Mark Zobrosky**: Had a successful career, loved working, 3 successful ventures – he and his family had a good life. He sustained severe back injuries, went to a great neurosurgeon, had surgery, went back to work and got injured again; destroyed by back; no fault of surgeon; finally, surgeons said "we have done everything we can"; Tried 2-3 different opioids, found 1 that works. Decided on anti-inflammatories, short-term opioids, long-term opioids, and muscle relaxant. Hasn't changed medical treatment (medication combo + spinal stimulator) in years, got back 65% of function.

Reason why I am able to function is because I have a physician that cares about me and my medications, family support, and spiritual support. Has independent pharmacist who is very involved, communicates regularly with his Pain Management Physician and Primary Care Provider. Is in a higher opioid dose group and is blessed with great physician. Every month, his physician counts medication, and his wife keeps his medication in a lock box. Worried about insurance appeals process for prescriptions and how physicians managing pain are being treat.

- **Katie Golden:** Chronic migraine headaches, light is a trigger. I am what chronic pain looks like, it doesn't discriminate by age. Traveling and even Activities of Daily Living (ADL) are exhausting; today, she had to take a nap after she showered. Has not had a pain free moment in 8 years. Was getting a Master's degree at Georgetown University. Takes three-times as long to perform tasks (ADLs); short term memory loss has increased, now has to carry notebook to record and remember ADLs and tasks. Always needs to be alert of exit strategies in case pain becomes unbearable. Patients should be treated equally and should have easily accessible treatment options – multimodal treatment approaches should be the standard of care and should be fully covered by insurance. Opioids are part of her pain management plan – has maintained the same stable dose for 6 years. Lost a loved-one to the Opioid Crisis. Notes that pain management reform should be treated as a "movement not a moment".

Vote on Task Force Final Report
5:00 p.m. – 5:15 p.m.

- **Dr. Vanila Singh, M.D., Task Force Chair, concluded the meeting by calling for a vote to approve the final report and its release to the federal agencies, Congress, and the public. A ten-minute deliberation was given prior to calling for the final motion to vote.**
    - The Task Force was reminded that a majority vote of approval (i.e., 'Aye') will carry the motion presented.
- Multiple Task Force members (**Dr. McGraw, Dr. Rosenberg, Dr. Zaafran, Dr. Griffith, Rene Campos, and others**) voiced their support of the report and thanked Dr. Singh and the Task Force for their tremendous in developing the Final Report.
- **Dr. Gallagher and Cindy Steinberg** echoed their support for the report but also noted that the major challenge to come will be implementing the Final Report and its recommendations in pain management practice.
- **Dr. Cecilia Spitznas** noted that the Final Report is not consistent with ONDCP findings and requested edits; she noted that she will not be voting to approve the report.
- After the 10-minute deliberation period passed, **Dr. Vanila Singh, M.D., Task Force Chair,** referred back to her previous motion, calling for a vote to approve the Final Report, which was seconded.
    - **Dr. Cecilia Spitznas** voted 'Nay' – i.e., not in support of approving the Final Report for release to the federal agencies, Congress, and the public
    - **Dr. Jan Losby** abstained from voting.

- A majority vote of 'Aye' was reached amongst the remaining members of the Task Force; no other Task Force members voted 'Nay'

- With a majority vote of support (i.e., 'Aye') the motion carried; the Final Report was approved for release to the federal agencies, Congress, and the public, by the Task Force
- **Ms. Alicia Richmond Scott, M.S.W., DFO,** moved to adjourn the meeting, which was seconded, concluding Day 1 of the meeting.

Participants*

PMTF Members

Sondra M. Adkinson, PharmD
Amanda Brandow, DO, MS
Commander René Campos, MBA
Jianguo Cheng, MD, PhD (*phone*)
Daniel Clauw, MD (*phone*)
Jonathan C. Fellers, MD
Howard L. Fields, MD, PhD
Rollin M. Gallagher, MD
Halena M. Gazelka, MD
Scott Griffith, MD
Nicholas Hagemeier, PharmD, Ph.D. (*phone*)
Sharon Hertz, MD
Jan Losby, Ph.D.
Michael J. Lynch, MD
John McGraw, MD
Mary W. Meagher, PhD
Linda Porter, PhD
John V. Prunskis, MD
Mark Rosenberg, DO
Molly Rutherford, MD
Friedhelm Sandbrink, MD (*phone first day*)
Bruce A. Schoneboom, PhD
Vanila M. Singh, MD
Cecelia Spitznas, PhD
Cindy Steinberg
Andrea Trescot, MD
Harold K. Tu, MD
Sherif Zaafran, MD

Guest Speakers

LT. Morgan Luttrell (Ret.) *(Day 1)*
Sarah Whitlock *(Day 1)*
Amy Partridge *(Day 1)*
Mark Zobrosky *(Day 1)*
Katie Golden *(Day 1)*
Patrice Harris, M.D., M.A. (President-Elect and Chair of AMA Opioid Task Force, American Medical Association) *(Day 2)*
Kris Held, M.D., President-Elect, Association of American Physicians and Surgeons *(Day 2)*
Jason M. Schwalb, M.D., FAANS, FACS, Chairman of AANS/CNS Section on Pain, American Association of Neurological Surgeons *(Day 2) (phone)*

Government Attendees

Vanila M. Singh, MD, HHS, PMTF Chair
Alicia Richmond Scott, MSW, HHS, DFO
ADM Brett P. Giroir, MD, Assistant Secretary for Health, U.S. Department of Health and Human Services *(Day 1) (Video)*
The Honorable Phil Roe, MD, Congressman (R-TN) *(Day 1)*
The Honorable Bill Cassidy, MD, Senator (R-LA) *(Day 2)*
RADM Michael Toedt, MD, Chief Medical Officer, Indian Health Services *(Day 2)*
Shari M. Ling, M.D., Deputy Chief Medical Officer, CMS, HHS *(Day 2)*

***** *Day 1 = Spoke Day 1 only; Day 2 = Spoke Day 2 Only; Video = Remarks provided via video; Phone = Joined via phone*

Registered Public Comment Attendees

Richard Lawhern *(Day 1)*
Megan Wilson *(Day 1)*
Benita Talati *(Day 1)*
Benjamin Goodwin *(Day 1)*
Trina Vaughn *(Day 1)*
Kara Gainer *(Day 1)*
Kristen Wheeden *(Day 1)*
Inga Dawson *(Day 1)*
Gabriel Miller *(Day 1)*
Caylee Cresta *(Day 1)*
Scott Faulkner *(Day 1)*
Laura Williams, MD *(Day 1)*
Judy Birchfield *(Day 1)*

Support Staff

Vanila M. Singh, MD, HHS, PMTF Chair
Alicia Richmond Scott, HHS, DFO
Morgan Courbois, HHS
Karen Foster, HHS
Rachel Katonak, HHS
Chanya Liv, HHS
Rachel McCoy, HHS
Monica Stevenson, HHS
Ashley Watkins, HHS
Diane Epperson, Booz Allen Hamilton
Matt Aldag, Booz Allen Hamilton
Jeffery Saeling, Booz Allen Hamilton
Brendan Dolan, Booz Allen Hamilton
Diana Castiblanco, Booz Allen Hamilton

Certification

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Dr. Vanila Singh, MD

Pain Management Best Practices Inter-Agency Task Force, Chair