From: Kolodny, Andrew
Sent: 8 May 2015 17:21:46 +0000
To: Porter, Linda (NIH/NINDS) [E];'NPSPublicComments@NIH.gov'
Cc: 'Jane C. Ballantyne';Frank, Richard (HHS/ASPE);Manocchio, Teresa (HHS/ASPE);Frieden, Thomas (Tom) (CDC/OD);Dowell, Deborah (Debbie) (CDC/ONDIEH/NCIPC);Houry, Debra E. (CDC/ONDIEH/NCIPC);Baldwin, Grant (CDC/ONDIEH/NCIPC)
Subject: PROP comment on the draft National Pain Strategy
Attachments: PROP Comment on draft National Pain Strategy 5.8.2015.pdf

Dear Dr. Porter,
Thank you for the opportunity to offer feedback on the draft National Pain Strategy. Our formal comment is attached.
Although there are elements in the draft that PROP strongly supports, we have serious concerns about the proposed "safe use campaign" for opioid analgesics. We believe that it would perpetuate failed tactics for reducing adverse outcomes. A more effective educational campaign would encourage rational use and discourage use for conditions where opioid risks are likely to outweigh benefits.
Thank you for considering PROP's comment.
Sincerely,
Andrew Kolodny, MD
Executive Director,
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Chief Medical Officer,
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PROP
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Jane Ballantyne, M.D., F.R.C.A.
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Linda Porter, Ph.D.,
NINDS/NIH, 31 Center Drive
Room 8A31
Bethesda, MD 20892

Dear Dr. Porter,

Physicians for Responsible Opioid Prescribing (PROP) appreciates the opportunity to offer the following comment on the draft National Pain Strategy:

***PROP recommends against a "safe use" campaign for opioid analgesics* -** PROP strongly endorses many key recommendations of the National Pain Strategy (NPS). However, while we encourage use of an educational campaign, we recommend against terming this a "safe use" campaign. There is no scientific evidence that commonly used risk mitigation strategies (e.g. risk stratification, treatment agreements, and urine drug testing) are effective in reducing opioid-related adverse outcomes. On the other hand, there is strong evidence that increased prescribing for chronic pain has produced increases in dependence, overdose and death without improving pain relief, function or quality of life for many individuals with common chronic pain diagnoses. We would therefore urge that an educational campaign is aimed at best practice, and not focused solely on risk mitigation or "safe use".

***PROP endorses key NPS recommendations* –** PROP supports many key recommendations of the NPS which, when implemented, could help reduce inappropriate use of opioids for common chronic pain conditions such as fibromyalgia, chronic headache, and chronic low back pain. Key NPS findings and recommendations that PROP supports are:

- Employing self management programs to improve patient quality of life as an important component of acute and chronic pain prevention and management
- Use of integrated, multimodal and interdisciplinary treatment approaches
- Reducing incentives for treatments with little absolute benefit or a limited benefits relative to risks
- Increasing incentives and reimbursement strategies to promote high-quality coordinated pain care through an integrated biopsychosocial approach

Why PROP opposes use of the term "safe use". - PROP strongly opposes the wording of the call for "a national educational campaign encouraging safe medication use, especially opioid use,

among patients with chronic pain." We believe this recommendation should be struck from the NPS or modified for the following reasons:

(1) NPS recommendations for chronic pain should be based on scientific evidence establishing interventions as safe, effective and cost-effective. There is no such evidence for long-term use of opioids for common chronic pain conditions, or for a "safe use" campaign for opioids intended to reduce their harms. The evidence review on long-term opioid use carried out for the NIH Pathways to Prevention conference offered numerous conclusions that argue against the use of a "safe use" educational campaign[1]:

> *"This systematic review found scant and insufficient evidence that long-term opioid therapy for chronic pain improves function, quality of life, or pain outcomes. Serious harms of long-term therapy, such as risk for overdose and abuse and fractures, seemed to be dose-dependent"*
>
> "*No study evaluated the effectiveness of risk mitigation strategies for improving outcomes related to overdose, addiction, abuse, or misuse."*
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> *"More evidence is available on harms of opioid therapy. Controlled observational studies published after our prior review suggest that, compared with no opioid use, opioid therapy for chronic pain is associated with increased risk for overdose, opioid abuse and dependence, fractures, myocardial infarction, and use of medications to treat sexual dysfunction. For fractures, 1 study found that the risk was highest shortly after the start of opioid therapy. For some harms, studies suggest that higher opioid doses are associated with increased risk."*
>
> "*Evidence on benefits and harms of methods for initiating opioid therapy and titrating doses, use of short- versus long-acting opioids, scheduled and continuous versus as-needed dosing, use of opioid rotation, and methods for tapering doses or discontinuing long-term therapy was insufficient to reach reliable conclusions.*"
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> *"Evidence on the accuracy and effectiveness of risk assessment instruments for predicting opioid abuse or misuse in patients before initiation of long-term opioid therapy was sparse and was characterized by methodological limitations and inconsistent findings, which precluded reliable conclusions. No study evaluated the effectiveness of risk mitigation strategies, such as the use of urine drug screening, prescription drug monitoring program data, or abuse-deterrent formulations, in reducing harms."*
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> *"Reliable conclusions about the effectiveness of long-term opioid therapy for chronic pain are not possible due to the paucity of research to date. Accumulating evidence supports the increased risk for serious harms associated with long-term opioid therapy, including overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction; for some harms, the risk seems to be dose-dependent. Research is needed to understand long-term patient outcomes, the risks for opioid abuse and related problems, and the effects of different opioid prescription methods and risk mitigation strategies."*

(2) The safety of opioids will not be improved by risk mitigation alone. Risk mitigation strategies have been recommended by guidelines for over a decade, yet rates of misuse, abuse, overdose and death continued to rise in the United States. This rise is directly correlated with increased prescribing for chronic pain. While risk mitigation strategies are common sense measures designed to improve safety for users and the community, there is no evidence to support their effectiveness in preventing opioid overdose, addiction, abuse or misuse. It is clearly important that research efforts continue to assess the value of risk mitigation strategies, but reliance on risk mitigation alone to improve safety has not been

effective to date, and such reliance has led to overprescribing based on the likely false premise that opioids can be used safely provided precautions are in place.

(3) At the beginning of the movement to prescribe opioids for chronic pain, many were convinced that opioid addiction rates would be extremely low (some claimed rates of less than 1 percent). After several decades of increased use and greater experience, it is becoming evident that the initial estimates of dependence and addiction were artificially low, partly related to difficulties in defining dependence and addiction and partly due to research conducted in unrepresentative samples without systematic assessment of opioid addiction. Current evidence, which includes some studies published after the most recent AHRQ evidence synthesis[1], indicate that at least 20% of treated patients will develop a prescription opioid use disorder defined by DSM-5 criteria, and if opioid dependence is included in the definition, opioid use disorder may occur in 30% or more.[2-8] It is becoming clear that we can no longer assume that most problematic use is limited to so called "drug abusers", but that problematic use is often a significant problem for individuals using medically prescribed opioids for the treatment of pain.

(4) The effectiveness of long-term opioid therapy must also be taken into account, since the only reasonable basis for prescribing medications with inherently high risk is that the benefits exceed the risks. There is a growing recognition that for many common chronic pain conditions, benefit is not as great as once believed, and alterative treatments, particularly behavioral and physical treatments, have greater likelihood of improving function and quality of life. One known effective strategy for reducing risk is to refrain from prescribing for all cases where risk generally exceeds benefit, including chronic headache, most chronic musculoskeletal pain, and central pain states such as fibromyalgia. Since these conditions occur commonly, population safety would be markedly improved by a change in recommended practice dictating avoidance of long-term opioids in patients with these conditions.

An educational campaign that PROP could endorse. We strongly urge that rather than a "safe use campaign" that would likely perpetuate failed tactics for reducing adverse outcomes, a more effective educational campaign would encourage rational use and discourage use for conditions where risks likely outweigh benefits. Rational use would encompass careful patient selection, limits on dosing and duration (including dose and duration for acute pain), and common sense safety precautions. The latter would emphasize mandatory use of prescription monitoring data, non-sharing, safe-keeping and safe return policies. For patients, education would emphasize the limited benefits of opioids for common chronic pain conditions, the significant risks, and the value of alternative treatments, engagement and self-management. Non-industry funded programs are in development and several are already in use that present a broader approach to improving treatment outcomes than existing industry sponsored programs that have tended to

focus on risk mitigation. These newer educational programs emphasize the limitations of chronic opioid therapy as well as the value of alternative approaches. We would advise that any educational program concerning opioid use be developed along the lines of excellent programs such as the California Worker's Compensation on-line program[9] and the AHRQ interactive videos[10] that teach responsible prescribing and evidence-based management of chronic pain.

Sincerely,

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REFERENCES

1. Agency for Healthcare Research and Quality. The effectiveness and risks of long-term opioid treatment of chronic pain. Evidence Report/Technology Assessment Number 218, AHRQ Pulication No 14-E005-EF, Rockville MD 20850 2014.
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5. Ballantyne JC. What can the POINT study tell us? Pain 2015;156:201-2.
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9. California State Compensation Insurance Fund wwwhealthcare-coursecom/statefund 2015.
10. Pathways to Safer Opioid Use http://healthgov/hcq/trainingasp - pathways 2015.

From: Frieden, Thomas (Tom) (CDC/OD)
Sent: 8 May 2015 17:42:14 +0000
To: Ikeda, Robin (CDC/ONDIEH/OD);Arias, Ileana (CDC/OD);Foti, Kathryn (CDC/OD/OCS);Daniel, Katherine Lyon (CDC/OD/OADC)
Subject: FW: PROP comment on the draft National Pain Strategy
Attachments: PROP Comment on draft National Pain Strategy 5.8.2015.pdf

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From: Kolodny, Andrew [mailto:AKolodny@phoenixhouse.org]
Sent: Friday, May 08, 2015 1:22 PM
To: Porter, Linda (NIH/NINDS) [E]; 'NPSPublicComments@NIH.gov'
Cc: 'Jane C. Ballantyne'; Frank, Richard (HHS/ASPE); Manocchio, Teresa (HHS/ASPE); Frieden, Thomas (Tom) (CDC/OD); Dowell, Deborah (Debbie) (CDC/ONDIEH/NCIPC); Houry, Debra E. (CDC/ONDIEH/NCIPC); Baldwin, Grant (CDC/ONDIEH/NCIPC)
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9. California State Compensation Insurance Fund wwwhealthcare-coursecom/statefund 2015.
10. Pathways to Safer Opioid Use http://healthgov/hcq/trainingasp - pathways 2015.

From: akolodny@supportprop.org
Sent: 30 Sep 2015 13:15:30 -0700
To: Dowell, Deborah (Debbie) (CDC/ONDIEH/NCIPC);cdcopioidguidelines (CDC)
Cc: Frieden, Thomas (Tom) (CDC/OD);Houry, Debra E. (CDC/ONDIEH/NCIPC);Akolodny@phoenixhouse.org
Subject: PROP Feedback on Opioid Guideline
Attachments: PROP letter to CDC 9 30 15.pdf, Stakeholder Comment PROP 9-30-2015.xlsx

Dear Debbie,
PROP's feedback on the opioid guideline is attached. We hope you'll find our suggested changes to be consistent with your intent to offer practical, evidence-based approaches that improve prescribing practices.
If you or any member of your team have questions about our feedback please contact me.
Regards,
Andrew

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September 30, 2015

Deborah Dowell, MD, MPH
Senior Medical Advisor,
Division of Unintentional Injury Prevention
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Dear Dr. Dowell,

Physicians for Responsible Opioid Prescribing (PROP) appreciates the opportunity to provide a stakeholder review of the CDC Guideline for Prescribing Opioids for Chronic Pain. Distinguished members of PROP with expertise in pain medicine, primary care, rheumatology, addiction medicine, anesthesiology, physical medicine and rehabilitation, and pharmacoepidemiology have contributed to the feedback we submitted on the spreadsheet provided. The purpose of this letter is to help clarify the changes we are suggesting to the draft recommendations.

Recommendation 1: *Non-pharmacological therapy and non-opioid pharmacological therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.*

> Our view: This recommendation should explicitly state that opioids <u>should be avoided for fibromyalgia, chronic headache and chronic low back pain</u>.
>
> We are suggesting this change because evidence-based reviews and expert consensus have found that long-term use of opioids is likely to be counter-productive for fibromyalgia[1], chronic headache[2-3], and chronic axial low back pain,[4] apart from the considerable risks of addiction and overdose imposed on patients by long-term use of opioids.

Recommendation 2: *Before starting long term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.*

Recommendation 3: *Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.*

> Our view: Recommendations 2 and 3 will be difficult to operationalize without setting a specific time period for completion of the suggested precautions. We recommend specifying 30 days from the initial opioid prescription for patients transitioning to long-term use.
>
> We believe this suggested change will help guide primary care clinic policies for monitoring quality of care. There is evidence that recommended precautions for chronic opioid therapy are usually not implemented in community practice.[5-8] Specifying a time frame will help increase compliance with these recommendations.

We believe that Recommendation 3 should explicitly mention the risk of addiction and that physiological dependence can result in difficulty discontinuing use. Many clinicians underestimate the addiction potential of opioids as well as the difficulty patients can experience when discontinuing use. If not explicitly mentioned in the recommendation, clinicians may fail to discuss these risks with patients prior to initiating treatment. Rates of opioid discontinuation are low once patients have used opioids for more than 90 days, and discontinuation rates are lowest for high risk patients and those on high opioid doses.[9-11]

Recommendation 8: *Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related harms are present.*

Our view: An assessment of risk factors for opioid-related harms should include an effort at early identification of an opioid use disorder. Patients should be asked about craving, difficulty controlling use, persistent desire and inability to stop or cut down, and work/family problems due to opioids. We recommend this change because recent research has found that at least 20% of long-term opioid users meet DSM-5 criteria for prescription opioid use disorder.[12-13] While it seems self-evident that clinicians should directly assess early indicators of opioid use disorder, there is little evidence that community physicians routinely ask direct questions about behaviors and experiences that suggest that patients may be developing an opioid use disorder. In contrast, many chronic opioid therapy patients participating in survey research interviews readily self-report these problems.

We would also like Recommendation 8 to add gradual tapering to the options for risk mitigation strategies when risks of opioid related harms or early indicators of an opioid use disorder are present. We recommend this change in light of evidence that a significant percentage of patients using opioids long-term have mild to moderate opioid use disorders or are otherwise engaging in hazardous misuse of medically prescribed opioids.[12-13] For such patients, gradual tapering is an important option to mitigate risks of overdose and to prevent opioid addiction from becoming more severe and difficult to treat.

Recommendation 11: *Providers should avoid prescribing of opioid pain medication and benzodiazepines concurrently whenever possible.*

Our view: We suggest expanding Recommendation 11 to include mention that opioids should be avoided for patients who frequently consume two or more drinks of alcohol per day as well as for patients frequently using sedatives or muscle-relaxants, not only benzodiazepines.

This change is recommended based on evidence that heavy drinking concurrent with opioid use is a common problem as is chronic use of sedatives and muscle-relaxants (not only benzodiazepines),[14] which can result in fatal effects of drug-drug interactions between opioids and CNS depressants.[15-16]

Recommendation 12: *Providers should offer or arrange evidence-based treatment (usually opioid agonist treatment in combination with behavioral therapies) for patients with opioid use disorder.*

Our view: We believe that Recommendation 12 (opioid agonist treatment in combination with behavioral therapies) should be expanded to include patients who suffer from complicated physiological dependence but who may not meet criteria for an opioid use disorder.

This change is recommended based on evidence that patients with complicated physiological dependence on opioids can experience significant opioid-related harms even though diagnostic criteria for a prescription opioid use disorder may not be met, or are difficult to evaluate.[17-18] There is considerable ambiguity in distinguishing between addiction and complicated physiological dependence on opioids in some patients using opioids long-term for chronic pain.

We greatly appreciate the opportunity to offer CDC feedback on its draft guideline. We hope you will find our suggested changes to be consistent with your intent to offer practical, evidence-based approaches that improve safety and effectiveness of chronic pain care.

Sincerely,

Paul Coelho, MD
Physical Medicine and Rehabilitation
Pain Medicine

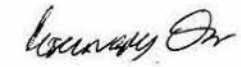
Irfan Dhalla, M.D., MSc, FRCPC
General Internal Medicine
Population Health

Stephen Gelfand, MD, FACP
Internal Medicine
Rheumatology

Andrew Kolodny, MD
General Psychiatry
Addiction Medicine

Elinore McCance-Katz, MD, PhD
General Psychiatry
Addiction Psychiatry

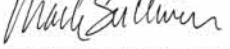
Danesh Mazloomdoost, MD
Anesthesiology
Pain Medicine



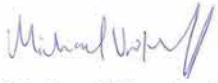
Rosemary Orr, MD
Anesthesiology
Pain Medicine

Jon Streltzer, MD
Addiction Psychiatry
Pain Medicine

Betts Tully
Patient Advocate



Mark Sullivan, MD, PhD
General Psychiatry
Pain Medicine



Michael Von Korff Sc.D.
Pharmacoepidemiology
Primary Care Management/Chronic Pain

cc: Thomas R. Frieden, MD ,MPH
Debra Houry, MD, MPH

Section or Recommendation #	Page # and Paragraph #	Comment
General	NA	It is essential to provide guidance for operationalizing "before starting long-term opioid treatment" so that primary care clinic policies can be developed to monitor compliance with guideline recommendations. If left entirely to clinical judgment, research suggests that recommended precautions will often not be taken until patients have been using opioids for many months, if at all. We recommend supplementing the CDC guideline definition of initiation of long-term use (when the expected duration of acute treatment is exceeded) with specific guidance regarding when precautions should be completed, to guide clinic efforts to monitor quality of care. This does not obviate the need for precautions that need to be taken every time opioids are prescribed (e.g. checking the PDMP and advising patients of risks of overdose and addiction). We recommend "within 30 days of the initial opioid prescription" for purposes of monitoring quality of care.
Recommendation 1	Page 13 Paragraph 4. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks. ***Opioids should be avoided for patients with fibromyalgia, chronic headache and chronic axial low back pain as risks are likely to exceed limited benefits for these chronic pain conditions.*** --- **Fibromyalgia evidence:** Carville SF1, Arendt-Nielsen L, Bliddal H, Blotman F, Branco JC, Buskila D, Da Silva JA, Danneskiold-Samsøe B, Dincer F, Henriksson C, Henriksson KG, Kosek E, Longley K, McCarthy GM, Perrot S, Puszczewicz M, Sarzi-Puttini P, Silman A, Späth M, Choy EH; EULAR. EULAR evidence-based recommendations for the management of fibromyalgia syndrome. Ann Rheum Dis. 2008 Apr;67(4):536-41. **Headache evidence:** Loder E1, Weizenbaum E, Frishberg B, Silberstein S; American Headache Society Choosing Wisely Task Force. Choosing wisely in headache medicine: the American Headache Society's list of five things physicians and patients should question. Headache. 2013 Nov-Dec;53(10):1651-9. doi: 10.1111/head.12233. Epub 2013 Oct 29. Buse DC1, Pearlman SH, Reed ML, Serrano D, Ng-Mak DS, Lipton RB. Opioid use and dependence among persons with migraine: results of the AMPP study. AMPP Headache. 2012 Jan;52(1):18-36. doi: 10.1111/j.1526-4610.2011.02050.x. **Chronic back pain evidence**: Deyo RA, VonKorff M, Duhrkoop D. Opioids for Low Back Pain: State of the Art Rreview. BMJ 2015;350:g6380 doi: 10.1136/bmj.g6380.
Recommendation 2	Page 14 Paragraph 3. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	Before starting long-term opioid therapy providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should only continue opioid therapy if there is clinically meaningful improvement in pain and function that exceeds risks to patient safety. ***In monitoring guideline adherence, treatment goals should be established within 30 days of the initial opioid prescription for patients transitioning to long-term use.*** ---------- ----------**References on**
Recommendation 3	Page 15 Paragraph 1. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	3. Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy. ***Potential difficulties discontinuing opioids due to physiological dependence on opioids or opioid addiction should be disclosed. In monitoring guideline adherence, patient and provider responsibilities for managing long-term opioid therapy should be discussed within 30 days of the initial opioid prescription for patients transitioning to long-term use.*** --- **References on low rates of opioid discontinuation:** Martin BC, Fan MY, Edlund MJ, et al. Long-term chronic opioid therapy discontinuation rates from the TROUP Study. J Gen Int Med. 2011;26:1450–1457. Vanderlip ER, Sullivan MD, Edlund MJ, Martin BC, Fortney J, Austen M, Williams JS, Hudson T. National study of opioid discontinuation among veterans. PAIN 2014; 155: 2673-9. Thielke S, Turner JA, Shortreed S, Saunders K, LeResche L, Campbell CI, Weisner CC, VonKorff M. Do patient perceived pros and cons of opioids predict sustained higher dose use? Clin J Pain 2014; 30:93-101.
Recommendation 8	Page 20 Paragraph 1. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid related harms ***and assess early indicators of prescription opioid use disorder (craving, difficulty controlling use, persistent desire and inability to stop or cut down, work/family problems due to opioids)***. Providers should incorporate into the management plan strategies to mitigate risk, ***including gradual tapering*** and offering naloxone, when ***there are early indicators of an opioid use disorder or other*** factors that increase risks of opioid-related harms are present. --- **References indicating that DSM5 prescription opioid use disorder is found in 20% or more of primary care chronic opioid therapy patients:** Boscarino JA, Rukstalis MR, Hoffman SN, Han JJ, Erlich PM, Ross S, Gerhard GS, Stewart WF. Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria. J Addict Dis. 2011 ;30:185-94. Degenhardt L, Bruno R, Lintzeris N, Hall W, Nielsen S, Larance B, Cohen M, Campbell G.. Agreement between definitions of pharmaceutical opioid use disorders and dependence in people taking opioids for chronic non-cancer pain (POINT): a cohort study. Lancet Psychiatry. 2015 Apr;2(4):314-22.

Recommendation 11	Page 24, Paragraph 4. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	Providers should avoid prescribing opioids to patients who ***frequently consume two or more drinks of alcohol per day or*** who ***frequently use sedative-hypnotics or muscle relaxants.*** --- **References:** Saunders K, Von Korff M, Campbell CI, Banta-Green CJ, Sullivan MD, Merrill JO, Weisner C.Concurrent use of alcohol and sedatives among persons prescribed chronic opioid therapy: prevalence and risk factors. J Pain. 2012;13:266-75. Overholser BR, Foster DR. Opioid pharmacokinetic drug-drug interactions. AM J Managed Care 2011; 17:S276-287. Smith H, Bruckenthal P. Implications of opioid analgesia for medically complicated patients. Drugs Aging 2010; 27:417-22. Pergolizzi
Recommendation 12	Page 25, Paragraph 2. ***Proposed changes to the CDC recommendation are highlighted and underlined.***	Providers should offer or arrange evidence-based treatment (usually opioid agonist treatment in combination with behavioral therapies) for patients with an opioid use disorder ***or with complicated physiologic dependence on opioids causing harms that exceed benefits of opioid treatment.*** --- **References on the clinical significance of complex opioid dependence and addiction among chronic opioid therapy patients:** Ballantyne JC, Sullivan MD, Kolodny A.. Opioid Dependence vs Addiction: a distinction without a difference? Arch Int Med 2012;172:1342-3. Ballantyne JC1, LaForge KS. Opioid dependence and addiction during opioid treatment of chronic pain. Pain 2007;129:235-55.

A COALITION TO END THE OPIOID* EPIDEMIC
*Opioids are narcotic painkillers & heroin

August 23, 2016

Thomas R. Frieden, Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Frieden:

On behalf of the FED UP! Coalition, a coalition of organizations representing hundreds of thousands of families and individuals impacted by the epidemic of opioid addiction and overdose deaths, I would like to invite you to participate as a special guest and speaker at the 4th annual FED UP! Rally. The event will be held at 1:00 p.m. on Sunday, September 18th at the Sylvan Theater on the Washington Monument Grounds in Washington, D.C.

Your efforts to address the opioid addiction epidemic, which is devastating communities across the country, are greatly appreciated. In particular, we would like to thank you for your efforts to reduce the overprescribing of opioids and to expand access to opioid addiction treatment.

At this year's Rally, we will be calling for a more forceful federal response to the opioid addiction epidemic and we will call on Congress to approve President Obama's $1.1 billion funding request. We are expecting thousands to join us in our call for immediate action, and we would be greatly honored to have you with us.

For more details, please call me at 612-865-1754 and/or visit our website at http://www.feduprally.org.

Thank you for considering our invitation. I look forward to your reply.

Sincerely,

Judy Rummler

Judy Rummler, Chair
FED UP! Coalition to End the Opioid Epidemic
www.feduprally.org
feduprally@gmail.com
612-865-1754 (cell)

From: Kolodny, Andrew
Sent: 7 Sep 2016 00:56:27 +0000
To: Frieden, Thomas (Tom) (CDC/OD)
Subject: Opioid Crisis Speaking Request - Washington, DC on 9/18
Attachments: Frieden invitation.pdf

Dear Dr. Frieden,

Attached is an invitation to speak at a rally on the National Mall on Sunday 9/18. The event is organized by a coalition of organizations that have been calling for a federal response to the prescription opioid and heroin crisis. More information is available at feduprally.org. Director Michael Botticelli is a confirmed speaker at the event.

We are especially interested in having you join us because of your efforts to address the crisis. If you are able to make it we'll have an opportunity to acknowledge you and CDC for the work you've been doing to promote more cautious opioid prescribing and expand access to treatment for the millions suffering from opioid addiction.

This year our advocacy is focused on approval by Congress of the President's request for $1.1 billion in new mandatory funding for the opioid crisis. Several thousand people, mostly affected family members, are expected to attend the rally which will be followed by a march to Congress.

If you or your staff have any questions about this invitation please let me know. I can be reached at the number below or on my cell at 917 582-9005.

Thank you for considering this request.

Regards,

-Andrew

Andrew Kolodny, MD
Chief Medical Officer,
Phoenix House Foundation

Executive Director,
Physicians for Responsible Opioid Prescribing

Senior Scientist,
Heller School for Social Policy & Management,
Brandeis University

164 W. 74th Street
New York, NY 10023
(T) 347 396-0369

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Sincerely,

Judy Rummler

Judy Rummler, Chair
FED UP! Coalition to End the Opioid Epidemic
www.feduprally.org
feduprally@gmail.com
612-865-1754 (cell)

From: Frieden, Thomas (Tom) (CDC/OD)
Sent: 7 Sep 2016 01:13:19 +0000
To: Scales, Scott L. (CDC/OD/OCS)
Cc: Villar, Carmen S. (CDC/OD/OCS)
Subject: FW: Opioid Crisis Speaking Request - Washington, DC on 9/18
Attachments: Frieden invitation.pdf

regrets

-----Original Message-----
From: Kolodny, Andrew [mailto:AKolodny@phoenixhouse.org]
Sent: Tuesday, September 06, 2016 8:56 PM
To: Frieden, Thomas (Tom) (CDC/OD) <txf2@cdc.gov>
Subject: Opioid Crisis Speaking Request - Washington, DC on 9/18

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Thank you for considering this request.

Regards,

-Andrew

Andrew Kolodny, MD
Chief Medical Officer,
Phoenix House Foundation

Executive Director,
Physicians for Responsible Opioid Prescribing

Senior Scientist,
Heller School for Social Policy & Management, Brandeis University

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Phoenix House is committed to helping individuals, families, and communities affected by substance abuse and dependence.

Visit www.phoenixhouse.org to get help or make a donation.

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August 23, 2016

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Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

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Sincerely,

Judy Rummler

Judy Rummler, Chair
FED UP! Coalition to End the Opioid Epidemic
www.feduprally.org
feduprally@gmail.com
612-865-1754 (cell)

From: CDCExecSec (CDC)
Sent: 7 Sep 2016 14:40:28 -0400
To: AKolodny@phoenixhouse.org (b)(6)
Subject: FED UP! Rally Invitation

Dear Dr. Kolodny and Ms. Rummler:

Thank you for inviting Dr. Thomas Frieden to speak at the 4th annual FED UP! Rally on September 18 in Washington, D.C. He is truly honored by the invitation; however, his fully committed schedule will not permit him to participate.

The Centers for Disease Control and Prevention (CDC) commends the FED UP! Coalition for its commitment to addressing opioid addiction and overdose deaths in the Unites States.

Thank you again for the invitation. Please accept our very best wishes for a successful event.

Sincerely,

Sandra Cashman, MS
Executive Secretary
Office of the Chief of Staff, CDC

From: Bell, Beth (CDC/OID/NCEZID)
Sent: 25 Oct 2016 18:20:54 -0400
To: Houry, Debra E. (CDC/ONDIEH/NCIPC);Frieden, Thomas (Tom) (CDC/OD)
Subject: RE: PROP/Kognito: Simulation for PCPs about Opioid Pain Relievers

Thanks, yes. I believe we received a similar email from these folks.

From: Houry, Debra E. (CDC/ONDIEH/NCIPC)
Sent: Tuesday, October 25, 2016 6:17 PM
To: Bell, Beth (CDC/OID/NCEZID) ; Frieden, Thomas (Tom) (CDC/OD)
Subject: FW: PROP/Kognito: Simulation for PCPs about Opioid Pain Relievers

Didn't know if you had seen this AR simulation resource
Our program will follow up re the PDO sim for more info

From: Ron Goldman (b)(6)
Sent: Tuesday, October 25, 2016 3:23 PM
To: Houry, Debra E. (CDC/ONDIEH/NCIPC) <vjz7@cdc.gov>
Cc: Kolodny, Andrew <AKolodny@phoenixhouse.org>; Chu-Hsu, Jean <jchuhsu@phoenixhouse.org>
Subject: PROP/Kognito: Simulation for PCPs about Opioid Pain Relievers

Dear Dr. Debra Houry,

I am writing to you at the suggestion of Dr. Andrew Kolodny, Executive Director of Physicians for Responsible Opioid Prescribing (PROP). I lead Kognito, a health simulation company founded in 2003 and based in NYC. We develop role-play simulations that prepare physicians, patients, and caregivers to lead real-life conversations that improve physical, social and emotional health.

PROP and Kognito are joining forces to develop, disseminate, and evaluate a *professional development simulation* for primary care professionals (PCPs) on the appropriate and inappropriate uses of opioid pain relievers. The online and mobile simulation, aligned with the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, will help PCPs build their competency in leading real-life conversations with patients around:

- Appropriate prescribing of opioids for acute pain
- Non-opioid treatment for chronic pain conditions such as lower back pain
- Talking with chronic pain patients already taking opioids about alternative treatment options, tapering opioids, and substance abuse treatment.

Together with Andrew, we are interested in setting up a time for a phone call with you to discuss and demo our past work and share more information on the Kognito-PROP proposed initiatives (attached is a brief description). Any advice you could provide as we explore potential partners and funders for this important initiative would be much appreciated as well. Below are available dates in the next two weeks. Please let us know if it will be possible to speak during one of these time frames.

You can view a recent example of our work at www.conversationsforhealth.com. This simulation, developed with funding from the Robert Wood Johnson Foundation, allows PCPs to learn through role-play conversations with emotionallty resposnsive virtual patients how to build trust, collaborate on a treatment plan, and address the patient's request for antibiotics. You can learn more about Kognito at www.kognito.com

Available Dates:

10/27 Thursday - 9-11am and 3-5pm ET
10/28 Friday - 9am-5pm ET
10/31 Monday - 9am-3pm ET
11/1 Tuesday - 9am-2pm ET
11/3 Thursday - 9am-5pm ET
11/4 Friday - 9-12pm or 2-3pm ET

Thank you for your consideration, and I look forward to our conversation.

Sincerely,

Ron Goldman
Co-Founder & CEO
Kognito
135 W. 26th St |12th Fl | NY, NY 10001
Tel: 212-675-9234 | Fax: 646.217.3677

Join us for the upcoming webinar:
Innovations in Supporting Student Veterans on Campus
Connect with us!
Twitter I Linkedin I Facebook I Vimeo

From: Kolodny, Andrew
Sent: 16 Nov 2016 21:48:50 +0000
To: 'akolodny@brandeis.edu'
Subject: New Contact Info

Dear Friends and Colleagues,
Please note that I have left Phoenix House.
My new contact info is:
Andrew Kolodny, MD
Co-Director, Opioid Policy Research
Institute for Behavioral Health
Schneider Institutes for Health Policy,
Heller School for Social Policy & Management
Brandeis University
415 South Street
Waltham, MA 02453-2728
akolodny@brandeis.edu
781-736-4542

From: txf2@cdc.gov
Sent: 16 Nov 2016 17:03:06 -0500
To: Davis, Carma L. (CDC/OD/OCS)
Subject: Fwd: New Contact Info

Discuss

Begin forwarded message:

From: "Kolodny, Andrew" <AKolodny@phoenixhouse.org>
Date: November 16, 2016 at 4:51:10 PM EST
To: "'akolodny@brandeis.edu'" <akolodny@brandeis.edu>
Subject: New Contact Info

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Please note that I have left Phoenix House.
My new contact info is:
Andrew Kolodny, MD
Co-Director, Opioid Policy Research
Institute for Behavioral Health
Schneider Institutes for Health Policy,
Heller School for Social Policy & Management
Brandeis University
415 South Street
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akolodny@brandeis.edu
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From: Kolodny, Andrew
Sent: 16 Nov 2016 21:51:10 +0000
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akolodny@brandeis.edu
781-736-4542

From: Frieden, Thomas (Tom) (CDC/OD)
Sent: 16 Nov 2016 22:03:07 +0000
To: Davis, Carma L. (CDC/OD/OCS)
Subject: Fwd: New Contact Info

Discuss

Begin forwarded message:

From: "Kolodny, Andrew" <AKolodny@phoenixhouse.org>
Date: November 16, 2016 at 4:51:10 PM EST
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Subject: New Contact Info

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