

Print Format in Direct-to-Consumer Prescription Drug Advertisements on Risk Knowledge and Preference.” *Drug Information Journal*, vol. 36(3), pp. 693–705, 2002.

7. Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs. Revised Draft Guidance. Available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf>.
8. “Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments.” August 21, 2017, 82 FR 39598.
9. Betts, Kevin R., et al., “Serious and Actionable Risks, Plus Disclosure: Investigating an Alternative Approach for Presenting Risk Information in Prescription Drug Television Advertisements.” *Research in Social and Administrative Pharmacy*, 2017.
10. Bhutada, N.S., B.L. Rollins, and M. Perri III, “Impact of Animated Spokes-Characters in Print Direct-to-Consumer Prescription Drug Advertising: An Elaboration Likelihood Model Approach.” *Health Communication*, vol. 32, pp. 391–400, 2017.
11. Zaichkowsky, J.L., “The Personal Involvement inventory: Reduction, Revision, and Application to Advertising.” *Journal of Advertising*, vol. 23, pp. 59–70, 1994.
12. Mackert, M., S.E. Champlin, K.E. Pasch, and B.D. Weiss, “Understanding Health Literacy Measurement Through Eye Tracking.” *Journal of Health Communication*, vol. 18, pp. 185–196, 2013.
13. Chiang, K.P. and A. Jackson, “The Impact of Health Literacy on Involvement and Attitude Toward Pharmaceutical Print Ads.” *International Journal of Healthcare Management*, vol. 9(1), pp. 47–57, 2016.
14. An, S. and N. Muturi, “Subjective Health Literacy and Older Adults’ Assessment of Direct-to Consumer Prescription Drug Ads.” *Journal of Health Communication*, vol. 16(3), pp. 242–255, 2011.
15. Ball, J.G., D. Manika, and P. Stout, “Consumers Young and Old: Segmenting the Target Markets for Direct-to-Consumer Prescription Drug Advertising.” *Health Marketing Quarterly*, vol. 28(4), pp. 337–353, 2011.
16. Christensen, T.P., F.J. Ascione, and R.P. Bagozzi, “Understanding How Elderly Patients Process Drug Information: A Test of a Theory of Information Processing.” *Pharmaceutical Research*, vol. 14, pp. 1589–1596, 1997.
17. Mehta, A. and S.C. Purvis, “Consumer Response to Print Prescription Drug Advertising.” *Journal of Advertising Research*, vol. 43(2), pp. 194–206, 2003.
18. Paulhus, D.L. and S. Vazire, “The Self-Report Method.” *Handbook of Research Methods in Personality Psychology*, vol. 1, pp. 224–239, 2007.

Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17360 Filed 8–13–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Biomedical Advanced Research and Development Authority (BARDA)

AGENCY: Assistant Secretary for Preparedness and Response, HHS.

ACTION: Notice.

SUMMARY: The Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services intends to provide a Single Source Cooperative Agreement to Janssen Research & Development, LLC. The Cooperative Agreement will support QuickFire Challenges to spur innovation in respiratory protection. The total proposed cost of the Single Source Cooperative Agreement is not to exceed \$100,000 for a total of 12 months.

DATES:

Project Period: The period of performance is from July 30, 2018 to June 30, 2019.

Award amount: Estimate \$100,000.

FOR FURTHER INFORMATION CONTACT:

Sherrette.Funn@hhs.gov, 202–795–7714, *Julie.Schafer@hhs.gov*, 202–205–1435.

SUPPLEMENTARY INFORMATION: The Biomedical Advanced Research and Development Authority (BARDA) is the program office for this Cooperative Agreement:

Single Source Justification: Janssen Research & Development, LLC creates global challenges to spur innovation in health care in partnership with JLABS, a global network of open innovation ecosystems designed to support innovators and entrepreneurs in creating and accelerating innovative health care solutions.

Janssen Research & Development, LLC and BARDA will collaborate on a global challenge for reimagined, transformative respiratory protection. Traditional respiratory protective devices used to protect against inhalation of harmful infectious agents were designed for use in occupational settings, to guard against inhalation of dangerous particulates. Disposable versions, such as N95 respirators, are only available for adults, must be fit-tested to ensure proper functioning, and can be uncomfortable to wear. In an outbreak of a novel or newly emerging respiratory

disease, respiratory protection may be the only countermeasure available to protect health care workers and the general public.

Janssen Research & Development, LLC will partner with JLABS, which exists to foster innovation in health care products and executes QuickFire Challenges for health care innovation. There is no direct equivalent of the QuickFire Challenge services for innovation specific to health care as is provided by JLABS. Its unique service will directly benefit BARDA’s mission to make available medical countermeasures to address health security threats. Supporting innovation is an authority provided to BARDA under the Public Health Service Act and partnering with a company providing a diverse array of products and leveraging its expertise and infrastructure has the potential to provide solutions to the challenges in developing new respiratory devices.

Reimagined, innovative respiratory protection would contribute directly to ASPR’s mission to save lives and protect Americans against 21st Century health security threats. Respiratory protection is often the first line of defense, and a radically improved approach to protect both health care workers and the general public, including children, would truly improve our ability to respond to public health emergencies. By generating interest and focusing innovation efforts on reimagining respiratory protection, BARDA’s goal for the QuickFire Challenge is for the resulting innovative approaches to be eligible for continued testing and development and eventual regulatory approval, so that these revolutionary products can be widely available and used.

Please submit an inquiry via the ASPR–BARDA Program Contact: Dr. Julie Schafer, *Julie.Schafer@hhs.gov*, 202–205–1435.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2018–17381 Filed 8–13–18; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Pain Management Best Practices Inter-Agency Task Force

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force). The meeting will be open to the public; public comment sessions will be held during the meeting.

DATES: The Task Force meeting will be held on Tuesday, September 25, 2018, from 8:30 a.m. to 4:30 p.m. Eastern Time (ET) and Wednesday, September 26, 2018, from 9:00 a.m. to 12:00 p.m. ET. The agenda will be posted on the Task Force website at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Phone: 240-453-2816. Email: paintaskforce@hhs.gov.

SUPPLEMENTARY INFORMATION: Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) requires the Secretary of Health and Human Services, in cooperation with the Secretaries of Defense and Veterans Affairs, to convene the Task Force no later than two years after the date of the enactment of CARA and develop a report to Congress with updates on best practices and recommendations on addressing gaps or inconsistencies for pain management, including chronic and acute pain. The Task Force is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The Task Force will review clinical guidelines and identify gaps and/or inconsistencies for best practices for pain management, including chronic and acute pain, developed or adopted by federal agencies; propose updates to best practices and recommendations for identified gaps or inconsistencies; provide a 90 day the public comment period on any proposed updates and recommendations; and develop a strategy for disseminating such proposed updates and recommendations

to relevant federal agencies and the general public.

The Task Force will convene its second public meeting, on September 25 and 26, 2018, to discuss updates to existing best practices and recommendations based on gaps and inconsistencies for pain management, including chronic and acute pain. The Task Force will receive presentations from three Task Force subcommittees established at the inaugural Task Force meeting. The Task Force subcommittees will discuss recommendations for updates to best practices and recommendations for chronic and acute pain management and prescribing pain medication based on the components outlined in Section 101 of the CARA statute. The Task Force will deliberate and vote on the draft Task Force recommendations. Information about the final meeting agenda will be posted prior to the meeting on the Task Force website: <https://www.hhs.gov/ash/advisorycommittees/pain/index.html>.

Members of the public are invited to participate in person or by webcast. To join the meeting, individuals must pre-register at the Task Force website at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>. Seating will be provided first to those who have pre-registered. Anyone who has not pre-registered will be accommodated on a first come, first served basis if additional seats are available 10 minutes before the meeting starts. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying the Office of the Assistant Secretary for Health via email at paintaskforce@hhs.gov by September 21, 2018. The subject line of the email should read, "Task Force Meeting Accommodations." Non-U.S. citizens who plan to attend in person are required to provide additional information and must notify the Task Force staff via email at paintaskforce@hhs.gov 10 business days before the meeting, September 11, 2018. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>.

Members of the public can provide oral comments at the Task Force meeting on September 25, 2018, at 9:20 a.m.–9:50 a.m. ET. Please indicate your willingness to provide oral comments on the registration form which can be found at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>.

Individuals who pre-register will be given priority to provide oral public comment within the order they are received. The public comment period will not be extended beyond the allotted time on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Individuals who are not able to provide oral comments are encouraged to submit their written comments. Written comments should not exceed one page in length. Individuals submitting written comments should submit their comments through the Federal eRulemaking Portal at <http://www.regulations.gov>, docket number HHS-OS-2018-0016.

Dated: August 9, 2018.

Vanila M. Singh,

Chief Medical Officer, Chair, Pain Management Task Force, Office of the Assistant Secretary for Health.

[FR Doc. 2018-17446 Filed 8-13-18; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2018-0280]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625-0045

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0045, Adequacy Certification for Reception Facilities and Advance Notice—33 CFR part 158, without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before September 13, 2018.