

deemed products, prior to May 12, 2020, or during the one-year review period.

Since issuing the August 2017 Compliance Policy, FDA has received information underscoring the problem of youth use of ENDS products, as well as evidence of other new and continued public health concerns related to ENDS products. For example, data from the 2018 National Youth Tobacco Survey (NYTS), as described throughout the guidance, documented a significant increase in youth use of ENDS products and revealed the magnitude of the problem. These data prompted FDA to issue a draft guidance regarding the continued marketing of deemed tobacco products that had not obtained premarket authorization, and to call on industry to do more to keep their products out of the hands of minors. In March 2019, FDA published a draft guidance entitled “Modifications to Compliance Policy for Certain Deemed Tobacco Products” (“March 2019 Draft Guidance”), which discussed the Agency’s plan to modify the August 2017 Compliance Policy and prioritize enforcement of the premarket authorization requirements for certain deemed tobacco products.

Recent data show a second consecutive year with an alarming increase in youth use of ENDS products. In 2019, two of the largest surveys of tobacco use among youth found that e-cigarette use has reached the highest levels ever recorded. The 2019 Monitoring the Future Study shows that e-cigarette use among 8th, 10th, and 12th graders who had used ENDS products during the previous 12 months and those who had ever used ENDS products significantly increased from 2018 to 2019. Data from the 2019 NYTS also show that 2019 was the second consecutive year in which current (past 30-day) e-cigarette use among youth reached unprecedented levels. Evidence from the 2016–2017 (Wave 4) Population Assessment of Tobacco and Health Study and other studies, as described in the guidance, further confirms these trends, including that youth are particularly attracted to flavored ENDS products.

Moreover, recent data indicate that youth overwhelmingly prefer cartridge-based ENDS products, which FDA has found are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. The 2019 NYTS survey instrument included a measure for the “usual brand” of e-cigarette used in the past 30 days, and the majority of youth who were current e-cigarette users reported a cartridge-based e-cigarette as their usual brand.

Finally, FDA remains concerned about health and safety issues connected to ENDS products—e.g., cases of lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that all of these products have been marketed without premarket authorization. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. For example, FDA review of premarket tobacco product applications considers the risks and benefits of the product to the population as a whole, including tobacco product users and non-users. In reviewing premarket tobacco product applications, FDA will consider, among other things: The product’s components, ingredients, additives, and properties; manufacturing practices; and any studies or investigations into the health risks of the tobacco product.

The Agency views the dramatic increase in youth use of these products as a problem that requires an urgent response. Accordingly, FDA is issuing this final guidance to communicate its enforcement priorities with respect to ENDS products. FDA would adopt these enforcement priorities for ENDS regardless of the decision of the U.S. District Court for the District of Maryland in *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*<sup>3</sup> Additionally, as described in the guidance, consistent with the court’s order, manufacturers of other deemed new tobacco products will be required to submit marketing applications for those products by May 12, 2020.<sup>4</sup>

## II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of the Agency’s enforcement priorities for premarket review requirements for certain deemed tobacco products and describes how the Agency intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization. It does not establish any rights for any person and is not binding

<sup>3</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, 379 F. Supp. 3d 461, 496 (D. Md. 2019).

<sup>4</sup> *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18–cv–883 (PWG), 2019 WL 3067492, at \*7 (D. Md. July 12, 2019) (Dkt. No. 127).

on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This final guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1107.1(b) and (c) have been approved under OMB control number 0910–0684; the collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910–0768. The collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673.

## IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either <https://www.regulations.gov> or <https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance>.

Dated: December 31, 2019.

**Stephen M. Hahn,**

*Commissioner of Food and Drugs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Update to the Women’s Preventive Services Guidelines

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** On December 17, 2019, HRSA approved an update to the HRSA-supported Women’s Preventive Services Guidelines (Guidelines) that addresses health needs specific to women. The Guidelines are based on clinical recommendations from the Women’s Preventive Services Initiative. Preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA are required to be covered without cost-sharing by non-grandfathered group health plans and health insurance

issuers offering non-grandfathered group or individual health insurance coverage. This 2019 update adds one additional service—Screening for Anxiety—to the HRSA-supported Women's Preventive Services Guidelines to the 11 preventive services that were last updated in 2017. The 11 services included in the 2017 update are: Breast Cancer Screening for Average Risk Women, Breastfeeding Services and Supplies, Screening for Cervical Cancer, Contraception, Screening for Gestational Diabetes Mellitus, Screening for Human Immunodeficiency Virus Infection, Screening for Interpersonal and Domestic Violence, Counseling for Sexually Transmitted Infections, Well-Woman Preventive Visits, Screening for Diabetes Mellitus after Pregnancy, and Screening for Urinary Incontinence. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see <https://www.hrsa.gov/womens-guidelines/index.html> for additional information.

**FOR FURTHER INFORMATION CONTACT:** Ada Determan, Maternal and Child Health Bureau at email: [wellwomancare@hrsa.gov](mailto:wellwomancare@hrsa.gov) or (301) 945-3057.

**SUPPLEMENTARY INFORMATION:** The updated 2019 HRSA-supported Women's Preventive Services Guidelines and information related to guideline development and implementation can be found on <https://www.hrsa.gov/womens-guidelines-2019/index.html>. Information regarding the new preventive service approved by the HRSA Administrator for inclusion in the comprehensive guidelines is set out below:

### Screening for Anxiety

The Women's Preventive Services Initiative recommends screening for anxiety in adolescent and adult women, including those who are pregnant or postpartum. Optimal screening intervals are unknown and clinical judgement should be used to determine screening frequency. Given the high prevalence of anxiety disorders, lack of recognition in clinical practice, and multiple problems associated with untreated anxiety, clinicians should consider screening women who have not been recently screened.

### *HRSA-Supported Women's Preventive Services Guidelines*

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from the Institute of Medicine, now known as the National Academy of Medicine (NAM), developed under a contract with HHS.

Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, HRSA awarded a 5-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust*. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative to perform this work.

Under section 2713 of the Public Health Service Act, 42 U.S.C. 300gg-13, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage (generally plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing for preventive services listed in the updated HRSA-supported guidelines (which include the 11 preventive services last updated in 2017 as well as the one new service added in this update) beginning with the first plan year (in the individual market, policy year) that begins on or after December 17, 2020.

Dated: December 30, 2019.

**Thomas J. Engels,**  
Administrator.

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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Findings of Research Misconduct

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** Findings of research misconduct have been made against Alexander Neumeister, M.D. (Respondent), who was a Professor of Psychiatry and Radiology, Department of Psychiatry, New York University School of Medicine, Langone Medical Center (NYUSOM). Dr. Neumeister engaged in research misconduct in psychiatric clinical research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH096876, R01 MH102566, R21 MH094763, R21 MH096105, R21 MH102035, and R34 MH102871. The administrative actions, including debarment for a period of two (2) years, followed by supervision for a period of two (2) years, were implemented beginning on December 13, 2019, and are detailed below.

**FOR FURTHER INFORMATION CONTACT:** Elisabeth A. Handley, Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453-8200.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

*Alexander Neumeister, M.D., New York University School of Medicine, Langone Medical Center:* Based on the report of an investigation conducted by NYUSOM and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Alexander Neumeister, Professor of Psychiatry and Radiology, Department of Psychiatry, NYUSOM, engaged in research misconduct in psychiatric clinical research supported by NIMH, NIH, grants R01 MH096876, R01 MH102566, R21 MH094763, R21 MH096105, R21 MH102035, and R34 MH102871.

Respondent neither admits nor denies ORI's findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent. The parties entered into a Voluntary Exclusion Agreement (Agreement) to conclude this matter without further expenditure of time, finances, or other resources.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating data in the clinical records of research supported by six (6) NIMH grants, resulting in the inclusion of falsified and/or fabricated research methods and results in four (4) published papers:

- Association of in vivo k-opioid receptor availability and the transdiagnostic dimensional expression of trauma-related psychopathology. *JAMA Psychiatry* 2014