

Tobacco in Australia

Facts & Issues

Relevant news and research

12B Regulation to disclose or reduce harm from tobacco products

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Research:

Farran, D, Salloum, RG, El Jardali, F, Abla, R, Abu Rmeileh, N, Al Sheyab, N et al (2024). From knowledge production to knowledge translation: Waterpipe tobacco control research in the Eastern Mediterranean Region. *Tob Prev Cessat*, 10. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/38250221>

Morean, ME, Gueorguieva, R, O'Malley, S, & Krishnan-Sarin, S. (2023). Including the term 'tobacco-free nicotine' in the nicotine addiction warning label mandated by the US Food and Drug Administration alters risk perceptions and use intentions. *Tob Control*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/37898544>

Seidenberg, AB, Boynton, MH, Brewer, NT, Lazard, AJ, Sheeran, P, & Ribisl, KM. (2023). Effects of Modified Risk Tobacco Product Claims on Consumer Responses. *Nicotine Tob Res*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/37791605>

Villanti AC, Sterling K, and Rose SW. US Food and Drug Administration Action on Menthol Cigarettes and Flavored Cigars-A Pivotal Moment for Health Equity. *JAMA Netw Open*, 2022; 5(6):e2217150. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35666505>.

van der Eijk Y. Standardised cigarettes: the next step for tobacco policy? *Tobacco Control*, 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35768214>.

Liber AC, Stoklosa M, Levy DT, Sanchez-Romero LM, Cadham CJ, et al. An analysis of cigarette sales during Poland's menthol cigarette sales ban: small effects with large policy implications. *European Journal of Public Health*, 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35679583>.

Kirchner TR, Guttentag A, Vantu A, and Silver D. Documenting the impact potential of a menthol cigarette ban at point-of-sale: A photograph-based analysis of the presence and placement of menthol versus regular cigarette packs on the shelves of tobacco retail outlets in New York City. *Nicotine & Tobacco Research*, 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35657699>.

Issabakhsh M, Meza R, Li Y, Yuan Z, Sanchez-Romero LM, et al. Public health impact of a US menthol cigarette ban on the non-Hispanic black population: a simulation study. *Tobacco Control*, 2022. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35700999>.

Breland AB, Carroll D, Denlinger-Apte R, Ross JC, Soto C, et al. Centering racial justice for Black/African American and indigenous American people in commercial tobacco product regulation. *Preventive Medicine*, 2022:107117. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35716811>.

Voelker R. Rules Finalized for New Tobacco Product Approvals. *JAMA*, 2021; 325(9):816. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/33651076>.

Vansickel A, Baxter S, Sherwood N, Kong M, and Campbell L. Human Abuse Liability Assessment of Tobacco and Nicotine Products: Approaches for Meeting Current Regulatory Recommendations. *Nicotine & Tobacco Research*, 2021. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34498698>.

WHO study group on tobacco product regulation. Report on the scientific basis of tobacco product regulation: Eighth report of a WHO study group. WHO Technical Report Series, Geneva: World

Health Organization, 2021. Available from:

<https://www.who.int/publications/i/item/9789240022720>.

Greenhalgh E and Scollo M. 18.2 Regulation to disclose or reduce harm from tobacco products, in Tobacco in Australia: Facts & issues. Greenhalgh E, Scollo M, and Winstanley M, Editors. Melbourne: Cancer Council Victoria; 2020. Available from: <https://www.tobaccoinaustralia.org.au/chapter-18-harm-reduction/18-2-regulation>.

Regional consultation on novel tobacco products: health effects, research needs and provisional recommended actions for regulators. East Mediterr Health J, 2020; 26(1):129-30. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/32043556>.

World Health Organization. WHO Study Group on Tobacco Product Regulation. Report on the Scientific Basis of Tobacco Product Regulation: Seventh Report of A Who Study Group. Geneva: World Health Organization, 2019. Available from: <https://apps.who.int/iris/handle/10665/329445>.

Studlar D and Cairney P. Multilevel governance, public health and the regulation of food: is tobacco control policy a model? Journal of Public Health Policy, 2019. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30824824>.

Manning CL. Going up in vapour: how does the MHRA regulate so many products. BMJ, 2019; 367:l5781. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31591144>.

Eldridge A, Betson T, Gama MV, Errington G, and McAdam K. Investigation of number of replicate measurements required to meet cigarette smoke chemistry regulatory requirements measured under Canadian intense smoking conditions. Regulatory Toxicology and Pharmacology, 2019; 107:104402. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31199996>.

Bhatnagar A, Whitsel LP, Blaha MJ, Huffman MD, Krishan-Sarin S, et al. New and Emerging Tobacco Products and the Nicotine Endgame: The Role of Robust Regulation and Comprehensive Tobacco Control and Prevention: A Presidential Advisory From the American Heart Association. Circulation, 2019; CIR0000000000000669. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30862181>.

Zeller M. The Future of Nicotine Regulation: Key Questions and Challenges. Nicotine & Tobacco Research, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312450>

https://watermark.silverchair.com/nty200.pdf?token=AQECAHi208BE49Ooan9kkhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwagggI-MIICOGIBADCCAjMGCSqGSib3DQEhATAeBglghkgBZQMEAS4wEQQMpxFlv6cemOl4BirIAGeQgIICBAhGJ-RWaP9hs-MlImOk6RAhGwtulnDZm liFPWTra0oqKqGL OhD6GytJ1_VDXyiS3uJAxPx5m1yaxQoVpB-qJev08_1evYQzo4Mw4XqmcWm ByXeauGh8vgQK082j2-SVeLyux5afGP-Zz2KMKfnxZp3v-iXJpAVDnQoPUxAcP2aHwMrulWrfKtTXm3ocTC-p3inpQYyihTF0ZgBjPn1AFjO4r6ppBqMlaYfx3eDJE3h4P6e3gEJusx8NhTOglpasuik7A7nc286B2bzBRg9uuzt0HF9J9LELhtxK-62NS9hkCeci_aQOLhvDUUrHi6-66-VmfeWwo5bYwl_TjsWDP9BRN1ir51E-e9PciJmZiBoPrso_ttUu19Edw4Fp7waubTj8b4okRXZmLz9XQE-kFm-aoYH3Y0mcVKVynyFCSQ_SPznT033gizw1Wk4zlxq1ggAYogP5UFPuQAYRiHP6rO_x2h4WJbTLXfpL91_QFkcKoTWYbB5LYTHwn96nlzvJlbM_W6AGGETo3KGPptlozqhHHFa0AkYNCdcORwSZ8UYgQVnOdIkoqMc9tCE5TJhQXdd7YW3B50tEDPI9zWdVKVtBEAtOBLyImw9H5kUpPXhiDZ3L0X-KSfPgJeb9tqRewHBpDK_XSnOJQXjVJnnifooXV-LdYv1RbKJp-x4mlrclLkQ

World Health Organization (WHO). Tobacco product regulation: building laboratory testing capacity. World Health Organization, Licence: CC BY-NC-SA 3.0 IGO. Geneva: WHO 2018. Available from: http://www.who.int/tobacco/publications/prod_regulation/building-laboratory-testing-capacity/en/.

West R. The United States is not the World: Response to Zeller et al's Call for Discussion on Nicotine Regulation. *Nicotine & Tobacco Research*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312456>

https://watermark.silverchair.com/nty196.pdf?token=AQECAHi208BE49Ooan9khhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwagggI-MIICOGIBADCCAjMGCSqGSib3DQEHATAeBgIghkgBZQMEAS4wEQQMLHj_AAYO90iZ94mWAgEQgIICBMBBunJ7VIHNB53ha6OM6IZurBkvnSXMb432V_eyrqFCblGa6y3qzp7vtUrUxH0xvQVwMkwvRUu1WILYzJYt7zFcL1t_SdfhPERnz8ycfaxcgmqV4TH59-qcuukCTGS6fG7mloIKUAXmlul9NvK6ptFF3zZzxzrwV_nLSYmMzBzVOU1-K3juvRfs17W9RoD3I_Y31YMPi6EsHVRMJcdeGJGLYWLs_kfYXespBj5ysvU1zVEytcw2pFW1xezP2z80BQWvJRtxVAycBB-a_Gb2btnLo8wZ03QEZNm3I3tlwxVdrUASvoPoLu7ApVTrgMCQFnB0qJ_tdV36Msvomy3Q514ZEzOcN24IT-EE1VFr9I4lu4dWrFHA0AIT3h48aTDJWsHihfoyg7Mwy7SpWCqtVm-TQmclMy38IVY7yO7uj7Lth1iPNbP1I7J-SnXg6X1T536VgX9y-3zIVxQZ1KjmEBQUZD-XO8TJZADoUtMGq12E0luEr7HCaiJ1Xy1UTxUfqx-oS8ZKU0lkKtOTE7DAVIPbnbrLsRqY2AquF2OhM_CXM7UnJketjic0cvtAqe1d-CvByZktomFNZrhhOUMJkEoD-wdejZjlvCax_a043r0nZdDb57_3hKxeivd0xUM7wiC0Y0DZXHydrIga1UP8ujA3yLiZGGoy-1eun0UJiRe3wIw.

Warner KE. The Nicotine Continuum and Regulation: Additional Challenges to Converting an Important Concept into Policy: Commentary on Zeller. *Nicotine & Tobacco Research*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312444>

https://watermark.silverchair.com/nty146.pdf?token=AQECAHi208BE49Ooan9khhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwagggI-MIICOGIBADCCAjMGCSqGSib3DQEHATAeBgIghkgBZQMEAS4wEQQMbUdBjXQgOdVZ1Qb7AgEQgIICBJQLGhookbnMzdaFzGaYFY17HfbbgMmlK7F90NnCYpz1_8Dk-Hj0lhAlBS8vToNA8OKRKIAFly4oV0VzZq0Z9UedieKkv0TUABiUiThLHQEvvh27dZlU5S1GY7U7934eZKPU06bZv2h_YehDyF0yjGzS3v_mCN5SrQtlu0DgDnkJ5GVVkvIAbV2idxuZPsZF0jQd4UI-dsjcq2LfqwGdUFqzXXTzjf0ETcz2v9ktp7YPM9SnhwKKhT6lg-zfNDZO1EUerFYpDc8UHbr1kgxFFmYCdxX28IQNue-3sSdWUBrvThkx3cbPKc3wLoLqvwvtul8jylUekfS5JaUII4gzo2zbe9c8C5whCGuu3ryjvZQeAei4TesCgxYjHhJdlIz8NRG3BASixQLF2kwSZc6TOAuYMjua9ADDlrduEGOWoyHvRrzee4rS-DI52YzTNewEqMg9-6CmzYN2SX7JGrixU17JZJwnRvX7hxSRviES08R6q1tIUZIBFCZdcUKVmEZ9RCwp0hGz2_oM-U2JwryAUtcwNhnmjf1chX9Jzp6eyoFBeLiU-2NGdCn0S0hO1LBXl64MmMRoUCyDqLu18S5xMNKLYaA9eA1kGutrhfPQenKctWOWsdD3oWR1t57g30Rs5oaQdqnkK2EwF6_YYuMub8U3bGCKbfuxDAsbKRF4kDzMbOGZew.

Staal YC, van de Nobelen S, Havermans A, and Talhout R. New Tobacco and Tobacco-Related Products: Early Detection of Product Development, Marketing Strategies, and Consumer Interest.

JMIR Public Health Surveill, 2018; 4(2):e55. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/29807884>.

Ranney LM, Jarman KL, Baker HM, Vu M, Noar SM, et al. Factors Influencing Trust in Agencies That Disseminate Tobacco Prevention Information. Journal of Primary Prevention, 2018. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/29397485>.

Proctor RN. Acting Now Is Urgent: Commentary on Zeller. Nicotine & Tobacco Research, 2018.

Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30590816>.

Proctor RN. Acting Now Is Urgent: Commentary on Zeller. Nicotine & Tobacco Research, 2018.

Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312452>

https://watermark.silverchair.com/nty202.pdf?token=AQECAHi208BE49Ooan9kKhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwaggg!-MIICOGIBADCCAjMGCSqGSib3DQEHATAeBglghkgBZQMEAS4wEQQMipYQZx1EO6NcpoUWAgEQgIICBHj9_axaLo7W3t_u8e3qt0qQtIBetKlgL5J6fohJFnsUZ0WSXQDCueImPXb1B6hSBgpMPM9IT5Y8-X4TR_dde_rZHbc5-6Uz6TUDSmh3CpkS1dKN3XMze2pYmf_ak3_MfhU26Sm6ITSffjiZEnV_LUilSdiGQ_vDb6tYoBEa7jd3U1vTWwyoUD5zmSl7KsMUHaAKzBv_gO4uDksUAUCZkmLD_GB83ISXBvBT4xkEvbMrsvJ_yPlxkUIYiJ4LL7ha31RmFg7PUzigFwuMzvCsvT6DV-dXtftTtAaNvqKRHM_ct37jiiPtzPeiGkBDhXeZSpsnpqQ5FRBahBZyydYeaZ6Y9zm9rO3jAgQB54m41cRm_M_YpPRftAvVHHf2P63x8m0fSZmOywrblQ5JxBnX_pvWSPPPCFKjZG440yJfQLy011QjX2c1rjz9IMXz2aZjwr7aPop0pcirwsvzTaT78G9acd3QawmmEmyFmqAOudssRFp8HZHUdz5bInj3KPB_5Y4xC-7SGoxoVvUwSUaNX43HB7_wbyyzuAG_ZDyd2j8g-JjcHd5EwT9MIE8c2Co2Ar2hhREfdVf1fqd0-cXV3rXgoXko7ZeJzxOxixcGNWAKROhZWldJpKwZphAL6ZkfkQ4OMBAtYebW-euVdCZ7KJwXDj000iye1EmgZFKh2pRp_PQ.

Peterson EB, Portnoy DB, Blake K, Willis G, Trundle K, et al. Item development and performance of tobacco product and regulation perception items for the Health Information National Trends Survey. Nicotine & Tobacco Research, 2018. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/30239948>.

Nguyen AB, Henrie J, Slavitt WI, and Kaufman A. Beliefs about FDA tobacco regulation, modifiability of cancer risk, and tobacco product comparative harm perceptions: Findings from the HINTS-FDA 2015. Preventive Medicine, 2018. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/29373819>.

Myers ML. The Debate About Nicotine Regulation: Commentary on Zeller. Nicotine & Tobacco Research, 2018. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/30312468>

https://watermark.silverchair.com/nty198.pdf?token=AQECAHi208BE49Ooan9kKhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwaggg!-MIICOGIBADCCAjMGCSqGSib3DQEHATAeBglghkgBZQMEAS4wEQQMijk_dy59ao58z1jZAgEQgIICBPnlkGXnGMHflbgdaRPIS_DM9kyy1VMA_bvpHsAJCbnQNbYKyEWq47uW3XlfpRuyFkHCePw-gl36S0LE2b1umZ2gRH0F5H3dgYTtT6HEFXb5cV28-RorCaQUU712BixWevCt8obqoTfkOgsfyZDNif3Co7IHopyS9ABO6IXglOwUMiabkGWEKAsko4vsWKn2ylroAvcloHawq8ib1lwzPpWV_E5vJmLA-O6FRlki_ur1kp3Sk3lhLxYW6ROXsrooyuJiiMO00Z2dGpoXvPJ4hrVq5AKR8Z4rU-4pfogsBx727ScIj4ahzUUoXaCLamDy7W2hCjYdtUA_A8j0dGtJqinnXw_DOP2vWaMGdfQnw5f8r1aAzEWhPwgWPXagqBpYB-

[ew62VnCUPubDBD_F1rfe997i_VbTaHn6JoFLXwDFrDkMrAru9mHgbUn7t_LL5M8ZrZQ3e4D4pZ1d-AZQbl_Ee3mn_4ezGz_-bVpotUt3m_l3m1mnoNytesUxktvH6GZRmRyZ0VsuLD_Afgq2GNQ1kKKR56uM8efMLSFxmWfzN855J-QFIg5E7SiE90ACQglxruRjXWOMLypA83Rz7PdkwaebkDE83GpFPv6-RmTQQCZnxGjyGI-hbQUa3bOyVesyCxDSQq872JFnxS2BzdEN9geS-GHYmOISEJp9Xgw-btmyh1LA.](https://www.ncbi.nlm.nih.gov/pubmed/29476766)

MacGregor J. Rapid Review of Nicotine Inhaling Product Compliance with the Tobacco Product and Related Products Regulations : 2017. Chartered Trading Standards Institute, England, UK 2018. Available from: <https://www.tradingstandards.uk/media/documents/news--policy/tobacco-control/rr1-phase-3-final-report-for-dhsc.pdf>.

Lidon-Moyano C, Sampedro-Vida M, Matilla-Santander N, Martin-Sanchez JC, Gonzalez-Marron A, et al. Attitudes towards tobacco product regulations and their relationship with the tobacco control policies. Preventive Medicine, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29476766>.

Levy HG, Norton EC, and Smith JA. Tobacco Regulation and Cost-Benefit Analysis: How Should We Value Foregone Consumer Surplus? Am J Health Econ, 2018; 4(1):1-25. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29404381>.

LeSage MG, Smethells JR, and Harris AC. Status and Future Directions of Preclinical Behavioral Pharmacology in Tobacco Regulatory Science. Behav Anal (Wash D C), 2018; 18(3):252-74. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30214916>.

Kumar A, Bhartiya D, Kaur J, Kumari S, Singh H, et al. Regulation of toxic contents of smokeless tobacco products. Indian J Med Res, 2018; 148(1):14-24. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30264750>.

Hoet P, Rydzynski K, Vermeire T, Nair U, Talhout R, et al. Recommendations to the European Commission implementing a priority list of additives that should have more stringent reporting requirements: the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Tobacco Control, 2018; 27(2):225-8. Available from: <http://tobaccocontrol.bmj.com/content/tobaccocontrol/27/2/225.full.pdf>.

Brown-Johnson CG, Boeckman LM, White AH, Burbank AD, Paulson S, et al. Trust in Health Information Sources: Survey Analysis of Variation by Sociodemographic and Tobacco Use Status in Oklahoma. JMIR Public Health Surveill, 2018; 4(1):e8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29434015>.

Brick C and Spiegelhalter DJ. Winners and Losers: Communicating the Potential Impacts of Policies: Commentary on Zeller. Nicotine & Tobacco Research, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312453>

https://watermark.silverchair.com/nty197.pdf?token=AQECAHi208BE49Ooan9kkhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwagggI-MIICOGIBADCCAjMGCSqGSib3DQEhATAeBglghkgBZQMEAS4wEQQMZGtC4IZIPPHaiKf3AgEQgIICBG7wmViDJHvdv2J5svEzTtnVuwW_v2ldq3ggVlohqdXD5HCdQotd-i9T5NZ29awI5NZMUF0kAocnpnXei-r1XqyoVJeyAFdEMKhDXNrFqeGn3cDkY_PGkXSunM1NMfntTdl0Id9-GVkkCRFeN9s56B5PCzUnp9bXSy-SVxas8KbpO--2mcovtYa8ya6VPOZFiai-CdyHwxVBJlo6O-Wxm70RqgvshELit4tBS3SrZWxj7b12NqbibBPFrZWw17EvRjn42I07gA-L4uCBI-m-1-

[rjuVjGKpa0NE1ItVQ2z0AxLU5XWiXlmx8bErXP-xz6j9tl1UZpzNAx7KwEqXf48X98SgLD41KHGHdVc8-vSmN7B9_q_cV1qaek0luk_UvGB3fEPQDxBFSorKHWRwA5bSpO8TIFHRuYRVPqDSQcQxUk5GsavSubwWUJuhV-DqM944LTeuBVGL1f5S-sO7jkhsrUJ4-gdbRZ4q6ZRIQksmcu8BqK6PJR3-xK8yXrb6JflbK6Nu3ijVFPXDMFteyx-Cbe7FN419dte2KSbFtS2Ye-wtUH67bAemWZTmIK6YPoQdP0jfSJskviLv3_bngunyQM6B-ghsM872HdBTgePRJqxrpeO1tk1QOLIZ6ZbmOwblvRDf359i1V_W7uohEbei8yY7C5iH33aIQcPGWC15AKWhg.](https://www.ncbi.nlm.nih.gov/pubmed/30312458)

Bonevski B. Considerations for High-Risk Populations: Response to Zeller's The Future of Nicotine Regulation: Key Questions and Challenges. *Nicotine & Tobacco Research*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30312458>

[Belushkin M, Esposito M, Jaccard G, Jeannet C, Korneliou A, et al. Role of testing standards in smoke-free product assessments. *Regulatory Toxicology and Pharmacology*, 2018; 98:1-8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29983383>.](https://watermark.silverchair.com/nty201.pdf?token=AQECAHi208BE49Ooan9kkhW_Ercy7Dm3ZL_9Cf3qfKAc485ysgAAAEwggJNBgkqhkiG9w0BBwaggl-MIICOglBADCCajMGCSqGSib3DQEHATAeBglghkgBZQMEAS4wEQQMPUC2oMYzseoxctCzAgEQgIICBIFpwEOtykX6sCCuNoagTtYlr5cajB3M-RHnb8z2fTT6SD1OgiCOxpOP6goYDr3OchwW19EPzxi_kfRVw5-d-ApMeaVM2PghF_yJ-akU_sWwXq1fB8lwJdNTDVT7QRLdLIuqelz9LQvfkpGvhXfsc4M97gdINgFHLgmgCuC5EH3fPkM-A3HrauDr7udM0pJnlEBCXBMTmNIJIs1uNYfNwpT69o_jB68_UvVWg1-ymqp3Jr4AZx9nSa70x7fwZSmAiLWDYbR175IQHSAjpf2ogFF1Zluk7-rp0kiuP7ulwW5HwYkjdyu7_zKZy6jScgR2H3OPD17MRISQ1ceg_D7rdAfo8lwWt2z6zvDslpPMIPQWwccFleZ3wJcsze9FPhCrRs7twmTFkDoXpvp8_bf_A1za56kaf6CBYcOCxmawDEYVnmQTJWfviFgf2qQp4kQAIY54ty9xiUxKhtNvi97nas0Chzwf6JbktY_lovW19uAZymEa2RSFjwYjsJ26JXd7xSO9HI7drDkE_VtJ6F03AmMTHRGe1g-gh1xRw-hTmJztfQVrTGiEY2Atc6qTI57_Pjw0q_hXWa_oOWx6dLUBWCqfZLDHV7laITW3yxRnWdTattplBUuwqlgTHPygqJina5pUft-gC1UflqC1IZzUcwTb_gwQd7fIO3E2PexLAVVPjBb5LA.</p></div><div data-bbox=)

Baig SA, Byron MJ, Lazard AJ, and Brewer NT. "Organic," "natural," and "additive-free" cigarettes: Comparing the effects of advertising claims and disclaimers on perceptions of harm. *Nicotine & Tobacco Research*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29529277>.

Arnott D. Why tobacco product regulation is no magic bullet. *Tobacco Control*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30032097>.

Sander LC, Pritchett JS, Daniels YC, Wood LJ, Lang BE, et al. Development of a Cigarette Tobacco Filler Standard Reference Material. *Analytical Chemistry*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28930436>.

Kozlowski LT and Sweanor DT. 'Not harmless' messages without comparisons dissuade consumers, potential consumers, and public health approaches to tobacco/nicotine products. *Addictive Behaviors*, 2017. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28153393>.

Kopel E, Davidovitch N, and Levine H. Using All Means to Protect Public Health in Israel From Emerging Tobacco Products. *American Journal of Public Health*, 2017; 107(10):1599-600. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28902544>.

Hefler M. The changing nicotine products landscape: time to outlaw sales of combustible tobacco products? *Tobacco Control*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28970329>.

Glantz S. Implementing legalized marijuana needs to give protecting public health higher priority. Center for Tobacco Control Research and Education (UCSF), US 2017. Available from: <https://tobacco.ucsf.edu/implementing-legalized-marijuana-needs-give-protecting-public-health-higher-priority>.

Fowler CD, Gipson CD, Kleykamp BA, Rupprecht LE, Harrell PT, et al. Basic Science and Public Policy: Informed Regulation for Nicotine and Tobacco Products. *Nicotine & Tobacco Research*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29065200>.

Czoli CD, Fong GT, Mays D, and Hammond D. How do consumers perceive differences in risk across nicotine products? A review of relative risk perceptions across smokeless tobacco, e-cigarettes, nicotine replacement therapy and combustible cigarettes. *Tobacco Control*, 2017; 26(e1):e49-e58. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27625408>.

Zeller M. The Deeming Rule: Keeping Pace with the Modern Tobacco Marketplace. *Am J Respir Crit Care Med*, 2016; 194(5):538-40. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27585382>.

Yun EH, Park YO, Lim MK, Oh JK, Park EY, et al. Public opinions on disclosure of tobacco components: Results of a nationwide cross-sectional survey in Republic of Korea. *Medicine (Baltimore)*, 2016; 95(27):e3852. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27399063>.

Wright MJ and Valentine G. Advances in Behavioral Laboratory Methods that Inform Tobacco Regulatory Science: A TCORS Working Group Special Issue. *Tob Regul Sci*, 2016; 2(4):294-300. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29152546>.

Wipfli HL, Berman M, Hanson K, Kelder S, Solis A, et al. Defining Tobacco Regulatory Science Competencies. *Nicotine & Tobacco Research*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27613917>.

Weinberger AH. Including Underrepresented Subgroups of Smokers in Tobacco Regulation Research. *Nicotine & Tobacco Research*, 2016; 18(9):1805-6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27613690>.

Velicer C, Aguinaga-Bialous S, and Glantz S. Tobacco companies' efforts to undermine ingredient disclosure: the Massachusetts benchmark study. *Tobacco Control*, 2016; 25(5):575-83. Available from: <http://tobaccocontrol.bmj.com/content/25/5/575.abstract>.

U.S. National Cancer Institute and World Health Organization. Chapter 10: Tobacco Growing and Tobacco Product Manufacturing, in National Cancer Institute Tobacco Control Monograph 21. The Economics of Tobacco and Tobacco Control. Section 5—Policy and Other Influences on the Supply of Tobacco Products. NIH Publication, Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; and Geneva, CH: World Health Organization: 2016. Available from: https://cancercontrol.cancer.gov/brp/tcrb/monographs/21/docs/m21_10.pdf.

Stanton CA, Villanti AC, Watson C, and Delnevo CD. Flavoured tobacco products in the USA: synthesis of recent multidiscipline studies with implications for advancing tobacco regulatory science. *Tobacco Control*, 2016; 25(Suppl 2):ii1-ii3. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27856996>.

Myers ML. Towards more effective FDA premarket review of new tobacco products. *Tobacco Control*, 2016; 25(3):243–4. Available from: <http://tobaccocontrol.bmj.com/content/25/3/243.short>.

Margolis KA, Bernat JK, Keely O'Brien E, and Delahanty JC. Online Information About Harmful Tobacco Constituents: A Content Analysis. *Nicotine & Tobacco Research*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27613931>.

Jenson D, Lester J, and Berman ML. FDA's misplaced priorities: premarket review under the Family Smoking Prevention and Tobacco Control Act. *Tobacco Control*, 2016; 25(3):246–53. Available from: <http://tobaccocontrol.bmj.com/content/25/3/246.abstract>.

World Health O. WHO STUDY GROUP ON TOBACCO PRODUCT REGULATION. Report on the Scientific Basis of Tobacco Product Regulations: Fifth Report of a WHO Study Group. World Health Organization Technical Report Series, 2015; (989):1–234, back cover. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26353746>.

Warner KE. The national and international regulatory environment in tobacco control. *Public Health Res Pract*, 2015; 25(3). Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26243486>.

Travasso C. Indian government outlines plans to tighten tobacco control laws. *BMJ*, 2015; 350:h360. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25609180>.

Song AV and Glantz SA. Assessing tobacco regulation: moving beyond economists. *Tobacco Control*, 2015. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25564284>.

Shepperd CJ, Newland N, Eldridge A, Haswell L, Lowe F, et al. Changes in levels of biomarkers of exposure and biological effect in a controlled study of smokers switched from conventional cigarettes to reduced-toxicant-prototype cigarettes. *Regulatory Toxicology and Pharmacology*, 2015; 72(2):273–91. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25957570>.

Morley CP. The politics of tobacco regulation. *European Journal of Public Health*, 2015; 25(2):186. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25818490>.

Moracco KE, Morgan JC, Mendel J, Teal R, Noar SM, et al. “My first thought was croutons.” Perceptions of cigarettes and cigarette smoke constituents among adult smokers and nonsmokers. *Nicotine & Tobacco Research*, 2015. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26681775>.

Kiviniemi MT and Kozlowski LT. Deficiencies in public understanding about tobacco harm reduction: results from a United States national survey. *Harm Reduct J*, 2015; 12:21. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26135116>.

King B. We need to regulate the contents and construction of cigarettes to discourage initiation and facilitate cessation. *Tobacco Control*, 2015; 24(e4):e232. Available from: <http://tobaccocontrol.bmj.com/content/24/e4/e232.short>.

Appleton S, Liu J, Lipowicz PJ, and Sarkar M. Effect of cigarette design on biomarkers of exposure, puffing topography and respiratory parameters. *Inhalation Toxicology*, 2015:1–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25830813>.

Savell E, Gilmore AB, and Fooks G. How does the tobacco industry attempt to influence marketing regulations? A systematic review. *PloS One*, 2014; 9(2):e87389. Available from: <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0087389>.

Jawad M, El Kadi L, Mugharbil S, and Nakkash R. Waterpipe tobacco smoking legislation and policy enactment: a global analysis. *Tobacco Control*, 2014. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25550418>.

Jawad M. Legislation enforcement of the waterpipe tobacco industry: a qualitative analysis of the London experience. *Nicotine & Tobacco Research*, 2014; 16(7):1000–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24642591>.

Hecht SS. It is time to regulate carcinogenic tobacco-specific nitrosamines in cigarette tobacco. *Cancer Prevention Research (Philadelphia, Pa.)*, 2014; 7(7):639–47. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24806664>.

Freiberg M, Boyle RG, Moilanen M, St Claire AW, and Weisman SR. The land of 10,000 tobacco products: how Minnesota led the way in regulating tobacco products. *American Journal of Public Health*, 2014; 104(2):e10–2. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24328644>.

Edwards R and Wilson N. The need for sustainable regulation of tobacco products. *BMJ*, 2014; 348:g2033. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24614162>.

Levy DT, Huang AT, Currie LM, and Clancy L. The benefits from complying with the framework convention on tobacco control: a SimSmoke analysis of 15 European nations. *Health Policy and Planning*, 2013. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24262281>.

Calo WA and Krasny SE. Environmental determinants of smoking behaviors: The role of policy and environmental interventions in preventing smoking initiation and supporting cessation. *Current Cardiovascular Risk Reports*, 2013; 7(6):446–52. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24634706>.

O'Connor RJ and Hurley PJ. Existing technologies to reduce specific toxicant emissions in cigarette smoke. *Tobacco Control*, 2008; 17 Suppl 1:i39-48. Available from: <https://pubmed.ncbi.nlm.nih.gov/18768458/>.

World Health Organization. WHO Framework convention on tobacco control. Geneva: WHO, 2003. Available from: <http://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=8D28335A9D60D63D78BE79F59EA44809?sequence=1>.

12B.1 FDA regulation

Fairman, RT, Cho, YJ, Popova, L, Cummings, KM, Smith, TT, Fong, GT et al. (2023). Support for nicotine reduction in cigarettes: findings from the 2016 and 2020 ITC Four Country Smoking and Vaping Surveys. *Tob Control*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/38071523>

Benowitz, NL, Warner, KE, Myers, ML, Hatsukami, D, Berman, ML, Vallone, D, & Cohen, JE. (2023). How the FDA Can Improve Public Health - Helping People Stop Smoking. *N Engl J Med*, 388(17), 1540-1542. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/37092791>

Wu, J, Origi, JM, Ranker, LR, Bhatnagar, A, Robertson, RM, Xuan, Z et al. (2023). Compliance With the US Food and Drug Administration's Guidelines for Health Warning Labels and Engagement in Little Cigar and Cigarillo Content: Computer Vision Analysis of Instagram Posts. *JMIR Infodemiology*, 3, e41969. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/37113379>

Glantz, S, & Lempert, LK. (2023). Vuse Solo e-cigarettes do not provide net benefits to public health: a scientific analysis of FDA's marketing authorisation. *Tob Control*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/36764683>

Lindblom, EN. (2023). How might FDA fix this e-cigarette PMTA mess? Commentary on Glantz and Lempert and Meshnick et al. *Tob Control*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/36764684>

Silvis L, Axelrad J, Flanagan K, Frizzera C, and Gutierrez A. Operational Evaluation of Certain Components of FDA's Tobacco Program: A Report of the Tobacco Independent Expert Panel. Reagan-Udall Foundation (RUF), 2022. Available from: <https://reaganudall.org/sites/default/files/2022-12/Tobacco%20report%2010pm.pdf>.

Liu ST, Loomis BR, Kinsey SH, Nagler CF, Chen P, et al. Development of a panel of U.S. adult tobacco users to inform tobacco regulatory science. *Prev Med Rep*, 2022; 28:101898. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35845822>.

Jenson D. Success from failure: US federal commercial tobacco regulation. *Tobacco Control*, 2022; 31(2):212-5. Available from: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/31/2/212.full.pdf>.

Wackowski OA, Gratale SK, Rashid MT, Greene K, and O'Connor RJ. Exploring the implications of modified risk claim placement in tobacco advertising. *Prev Med Rep*, 2021; 24:101608. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/34976664>.

Sutfin EL, Lazard AJ, Soule EK, Kimes CM, King J, et al. Health Claims, Marketing Appeals, and Warnings on Popular Brands of Waterpipe Tobacco Packaging Sold in the U.S. *Nicotine & Tobacco Research*, 2021. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/33406241>.

Food and Drug Administration and HHS. Premarket Tobacco Product Applications and Recordkeeping Requirements. *Federal Register*, 2021; 86(190). Available from: <https://www.govinfo.gov/content/pkg/FR-2021-10-05/pdf/2021-21011.pdf>.

Spinner JR, Araujo R, and Zeller M. Changing the Tobacco Landscape: FDA's Role in Addressing Tobacco and Nicotine Use. *Health Promot Pract*, 2020; 21(1_suppl):5S-8S. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31908199>.

Lindblom EN, Mays D, Schroth KRJ, and Delnevo C. Has FDA abandoned its efforts to make fake-cigar cigarettes comply with federal tobacco control laws that apply to cigarettes but not cigars? *Tobacco Control*, 2020. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/32102908>.

GBD 2019 Tobacco Collaborators. 7. Global health metrics: Tobacco—level 2 risk. *Lancet*, 2020. Available from: <https://www.thelancet.com/pb-assets/Lancet/gbd/summaries/risks/tobacco-smoke.pdf>.

Fagan P, Eissenberg T, Jones DM, Cohen JE, Nez Henderson P, et al. The First 10 Years: Reflecting on Opportunities and Challenges of the Tobacco Products Scientific Advisory Committee of the United States Food and Drug Administration. *Journal of Legal Medicine*, 2020; 40(3-4):293-320. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/33797324>.

Berg CJ, Barker DC, Sussman S, Getachew B, Pulvers K, et al. Vape shop owners/managers' opinions about FDA regulation of e-cigarettes. *Nicotine & Tobacco Research*, 2020. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/32722808>.

Perry CL, Creamer MR, Chaffee BW, Unger JB, Sutfin EL, et al. Research on Youth and Young Adult Tobacco Use, 2013-2018, From the Food and Drug Administration-National Institutes of Health Tobacco Centers of Regulatory Science. *Nicotine & Tobacco Research*, 2019. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31127298>.

Jacob M. Looking Back and Ahead: The Food and Drug Administration's Regulation of the Tobacco Industry and Next-Generation Products. *Advances in Dental Research*, 2019; 30(1):22-5. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31538803>.

Center for Tobacco Products. Modifications to Compliance Policy for Certain Deemed Tobacco Products. US Food and Drug Administration, 2019. Available from: <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/Draft%20guidance%20-%20modifications%20to%20compliance%20policy%20-%20March%202019.pdf>.

Yang YT. FDA's regulatory shift on tobacco control. *Preventive Medicine*, 2018; 113:153-5. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29866276>.

Tsoh J, Apollonio D, Hall S, Vijayaraghavan M, Ramo D, et al. FDA's Nicotine Steering Committee should develop policies, regulations, and procedures that promote cessation and increase the use of proven therapies. Comment for Nicotine Steering Committee, Docket No. FDA-2018-N-0128. Tobacco Center for Regulatory Science University of California San Francisco 2018. Available from: <https://tobacco.ucsf.edu/fda%E2%80%99s-nicotine-steering-committee-should-develop-policies-regulations-and-procedures-promote-cessation-and-increase-use-proven-therapies>.

Sutfin EL, Soule EK, McKelvey K, and Jenson D. Implications and challenges for implementation of the FDA's final deeming rule for waterpipe tobacco. *Tobacco Control*, 2018; 27(3):347-51. Available from: <http://tobaccocontrol.bmj.com/content/tobaccocontrol/27/3/347.full.pdf>.

Smiley SL, Blackman KCA, Bluthenthal RN, Rodriguez YL, Barahona R, et al. "Who's Really Regulating? Who's Benefiting?" Exploring Black Stakeholders' Awareness and Trust in the Food and Drug Administration's Role as a Tobacco Regulator. *Tob Regul Sci*, 2018; 4(4):41-9. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31440525>.

Osman A, Kowitt SD, Sheeran P, Jarman KL, Ranney LM, et al. Information to Improve Public Perceptions of the Food and Drug Administration (FDA's) Tobacco Regulatory Role. *Int J Environ Res Public Health*, 2018; 15(4). Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29661991>.

Food and Drug Administration. Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights. Center for Tobacco Products, 3 August 2018. 2018. Available from: <https://www.fda.gov/downloads/TobaccoProducts/PublicHealthScienceResearch/UCM613046.pdf>.

Food & Drug Administration. Tobacco Regulatory Science Research Program at FDA's Center for Tobacco Products: Summary and Highlights. Centre for Tobacco Products: Office of Science, Maryland, USA 2018. Available from: <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-tob-home/documents/document/ucm613046.pdf>.

Farber HJ, Neptune E, and Ewart G. FDA Regulation of Tobacco Products: Time for a Course Correction. *Ann Am Thorac Soc*, 2018. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30407839>.

Berman ML and Hatsukami DK. Reducing tobacco-related harm: FDA's proposed product standard for smokeless tobacco. *Tobacco Control*, 2018; 27(3):352-4. Available from: <http://tobaccocontrol.bmj.com/content/tobaccocontrol/27/3/352.full.pdf>.

Warner KE and Schroeder SA. FDA's Innovative Plan to Address the Enormous Toll of Smoking. *JAMA*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28885641>.

Sutfin EL, Soule EK, McKelvey K, and Jenson D. Implications and challenges for implementation of the FDA's final deeming rule for waterpipe tobacco. *Tobacco Control*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28667092>.

Schmidt AM, Jarman K, Ranney LM, Queen T, Noar SM, et al. Public Knowledge and Credibility Perceptions of the FDA as a Tobacco Regulator. *Nicotine & Tobacco Research*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29059369>.

Rubin R. Will the FDA's New Tobacco Strategy Be a Game Changer? *JAMA*, 2017; 318(24):2413-5. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29214315>.

Overlay J. New FDA enforcement stats show shifting targets. *Law 360*, 2017. Available from: <https://www.law360.com/articles/831637/new-fda-enforcement-stats-show-shifting-targets>.

No authors listed. The United States must act quickly to control the use of e-cigarettes. *Nature*, 2017; 545(7654). Available from: <http://www.nature.com/news/the-united-states-must-act-quickly-to-control-the-use-of-e-cigarettes-1.21987>.

No authors listed. Proposed Bill Removes Vapor Products From Deeming Rule. *Convenience Store News*, 2017. Available from: <http://www.csnews.com/product-categories/tobacco/proposed-bill-removes-vapor-products-deeming-rule>.

Kowitt SD, Goldstein AO, Schmidt AM, Hall MG, and Brewer NT. Attitudes Toward FDA Regulation of Newly Deemed Tobacco Products. *Tob Regul Sci*, 2017; 3(4):504-15. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29450218>.

Jarman KL, Ranney LM, Baker HM, Vallejos QM, and Goldstein AO. Perceptions of the Food and Drug Administration as a Tobacco Regulator. *Tob Regul Sci*, 2017; 3(2):239-47. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29051917>.

Berman ML, Byron MJ, Hemmerich N, Lindblom EN, Lazard AJ, et al. Communicating Tobacco Product Information to the Public. *Food Drug Law J*, 2017; 72(3):386-405. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29398886>.

Berman ML, Bickel WK, Harris AC, LeSage MG, O'Connor RJ, et al. Consortium on Methods Evaluating Tobacco: Research Tools to Inform FDA Regulation of Snus. *Nicotine & Tobacco Research*, 2017. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29059363>.

Berman M and Hatsukami D. Reducing tobacco-related harm: FDA's proposed product standard for smokeless tobacco. *Tobacco Control*, 2017. Available from: <http://tobaccocontrol.bmj.com/content/early/2017/08/22/tobaccocontrol-2016-053612?papetoc>

<http://www.ncbi.nlm.nih.gov/pubmed/28634163>.

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses.” Final rule. Federal Register, 2017; 82(5):2193-217. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28071877>.

Tidey JW, Cassidy RN, Miller ME, and Smith TT. Behavioral Economic Laboratory Research in Tobacco Regulatory Science. *Tob Regul Sci*, 2016; 2(4):440-51. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/28580378>.

Stone A. FDA Claims Jurisdiction Over Premarket Tobacco Product Applications. *ONS Connect*, 2016; 31(1):27. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26887106>.

Retzky SS. FDA Encourages Reporting of Tobacco Product Adverse Experiences. *Chest*, 2016; 150(6):1169-70. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27938736>.

McCarthy M. US is to regulate all tobacco products, including e-cigarettes and hookah tobacco. *BMJ*, 2016; 353:i2594. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27154555>.

Kamerow D. Finally the US regulates e-cigarettes as tobacco. *BMJ*, 2016; 353:i2596. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27154900>.

Food and Drug Administration HHS. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Final rule. Federal Register, 2016; 81(90):28973–9106. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27192730>.

Delnevo CD, Hrywna M, Giovenco DP, Miller Lo EJ, and O’Connor RJ. Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation. *Tobacco Control*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27220622>.

Chatterjee K, Alzghoul B, Innabi A, and Meena N. Is vaping a gateway to smoking: a review of the longitudinal studies. *International Journal of Adolescent Medicine and Health*, 2016; 30(3). Available from: <https://pubmed.ncbi.nlm.nih.gov/27505084/>.

Carpenter D, Connolly GN, and Lempert LK. Substantial Equivalence Standards in Tobacco Governance: Statutory Clarity and Regulatory Precedent for the FSPTCA. *J Health Polit Policy Law*, 2016. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27864349>.

Cagney H. E-cigarettes classified as tobacco products in the USA. *Lancet Respir Med*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27198669>.

Boynton MH, Agans RP, Bowling JM, Brewer NT, Sutfin EL, et al. Understanding how perceptions of tobacco constituents and the FDA relate to effective and credible tobacco risk messaging: A national phone survey of US adults, 2014-2015. *BMC Public Health*, 2016; 16(1):516. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27333921>.

Berman ML and Yang YT. E-Cigarettes, Youth, and the US Food and Drug Administration’s “Deeming” Regulation. *JAMA Pediatr*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27668949>.

FDA Announces Limits on Electronic Cigarettes. *Cancer Discovery*, 2016. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27234476>.

Weitkunat R, Lee PN, Baker G, Sponsiello-Wang Z, Gonzalez-Zuloeta Ladd AM, et al. A novel approach to assess the population health impact of introducing a Modified Risk Tobacco Product. *Regulatory Toxicology and Pharmacology*, 2015; 72(1):87–93. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25819932>.

Wackowski O and Delnevo C. Young adults' risk perceptions of various tobacco products relative to cigarettes: results from the National Young Adult Health survey. *Health Education & Behavior*, 2015. Available from: <http://heb.sagepub.com/content/early/2015/08/21/1090198115599988.full.pdf+html>
<http://www.ncbi.nlm.nih.gov/pubmed/26304709>.

Ray AP. Treading Lightly: Why The FDA Should Use Its New Authority To Regulate Electronic Cigarettes Sparingly. *Journal of Legal Medicine*, 2015; 36(2):215–31. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/27128338>.

Myers ML. FDA errs in removing highly qualified scientists from Tobacco Advisory Committee – decision is based on misguided court ruling. Campaign for Tobacco-Free Kids, 2015. Available from: http://www.tobaccofreekids.org/press_releases/post/2015_03_05_fda.

Kaufman AR, Finney Rutten LJ, Parascandola M, Blake KD, and Augustson EM. Food and drug administration tobacco regulation and product judgments. *American Journal of Preventive Medicine*, 2015; 48(4):445–51. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25726094>.

Donny EC, Denlinger RL, Tidey JW, Koopmeiners JS, Benowitz NL, et al. Randomized Trial of Reduced-Nicotine Standards for Cigarettes. *The New England Journal of Medicine*, 2015; 373(14):1340-9. Available from: <https://pubmed.ncbi.nlm.nih.gov/26422724/>.

Combes RD and Balls M. A critical assessment of the scientific basis, and implementation, of regulations for the safety assessment and marketing of innovative tobacco-related products. *Altern Lab Anim*, 2015; 43(4):251–90. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/26375889>.

Bolcic-Jankovic D and Biener L. Public opinion about FDA regulation of menthol and nicotine. *Tobacco Control*, 2015; 24(e4):e241–e5. Available from: <http://tobaccocontrol.bmj.com/content/24/e4/e241.abstract>.

Baker HM, Lee JG, Ranney LM, and Goldstein AO. Single Cigarette Sales: State Differences in FDA Advertising and Labeling Violations, 2014, United States. *Nicotine & Tobacco Research*, 2015. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25744967>.

Zeller M and Rose S. Q&A: Mitchell Zeller on the FDA and tobacco. *Cancer Discovery*, 2014; 4(1):10–1. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24402930>.

European Commission. Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC., Document 32014L0040. Brussels, Belgium: European Commission, 2014. Available from: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014L0040>.

Mitka M. NIH, FDA setting up research centers to generate evidence base to inform tobacco regulation. *JAMA*, 2013; 310(15):1550. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24129450>.

Chapman S. Benefits and risks in ending regulatory exceptionalism for tobacco. *Tobacco Control*, 2008; 17(2):73-4. Available from: <https://pubmed.ncbi.nlm.nih.gov/18375727/>.

Burns DM, Dybing E, Gray N, Hecht S, Anderson C, et al. Mandated lowering of toxicants in cigarette smoke: a description of the World Health Organization TobReg proposal. *Tobacco Control*, 2008; 17(2):132-41. Available from: <https://pubmed.ncbi.nlm.nih.gov/18375736/>.

National Academies of Sciences Engineering and Medicine. Public health consequences of e-cigarettes., Washington, DC Available from: <https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes>.

12B.2 EU regulation

Vardavas CI. European Tobacco Products Directive (TPD): current impact and future steps. *Tobacco Control*, 2022; 31(2):198-201. Available from: <https://tobaccocontrol.bmj.com/content/tobaccocontrol/31/2/198.full.pdf>.

Carnicer-Pont D, Tigova O, Havermans A, Remue E, Ferech M, et al. Tobacco products in the European Union Common Entry Gate (EU-CEG): A tool for monitoring the EU tobacco products directive. *Tob Prev Cessat*, 2022; 8:10. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/35330752>.

Thompson ME, Driezen P, Boudreau C, Becuwe N, Agar TK, et al. Methods of the International Tobacco Control (ITC) EUREST-PLUS ITC Europe Surveys. *European Journal of Public Health*, 2020. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/32053183>.

Talhout R, Duarte-Davidson R, Hoet P, Nair U, Rydzynski K, et al. Advice to the European Commission as Regards Type and Criteria for Comprehensive Studies to Be Requested From Manufacturers: The Opinion of the Scientific Committee on Health, Environmental, and Emerging Risks (SCHEER). *Nicotine & Tobacco Research*, 2019. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31329942>.

Liam S, Anna C, Thilo P, Andrew M, James M, et al. Assessment of priority tobacco additives per the requirements of the EU Tobacco Products Directive (2014/40/EU) part 1: Background, approach, and summary of findings. *Regulatory Toxicology and Pharmacology*, 2019. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/30797887>.

Farsalinos K and Lagoumintzis G. Toxicity classification of e-cigarette flavouring compounds based on European Union regulation: analysis of findings from a recent study. *Harm Reduct J*, 2019; 16(1):48. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31345235>.

Vardavas CI, Becuwe N, Demjen T, Fernandez E, McNeill A, et al. Study Protocol of European Regulatory Science on Tobacco (EUREST-PLUS): Policy implementation to reduce lung disease. *Tobacco induced diseases Tob Induc Dis*, 2018; 16:A2. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/31516458>.

Peeters S, Costa H, Stuckler D, McKee M, and Gilmore AB. The revision of the 2014 European tobacco products directive: an analysis of the tobacco industry's attempts to 'break the health silo'.

Tobacco Control, 2016; 25(1):108–17. Available from:
<http://tobaccocontrol.bmj.com/content/25/1/108.abstract>.

Berteletti F, King J, Burch J, and Toma Friedlaender A. Campaign for a revised Tobacco Products Directive in the European Union: lessons learnt. Tobacco Control, 2016. Available from:
<http://www.ncbi.nlm.nih.gov/pubmed/27432913>.

Peeters S, Costa H, Stuckler D, McKee M, and Gilmore AB. The revision of the 2014 European tobacco products directive: an analysis of the tobacco industry's attempts to 'break the health silo'. Tobacco Control, 2015. Available from:
<http://tobaccocontrol.bmj.com/content/early/2015/02/06/tobaccocontrol-2014-051919>.

Watson R. EU brings in new tobacco rules to deter young smokers. BMJ, 2014; 348:g1895. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24589431>.

Watson R. Priority for EU commissioner is implementing tighter rules on tobacco. BMJ, 2014; 349:g5977. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25274029>.

Maurice J. European Union adds teeth to its anti-tobacco legislation. Lancet, 2014; 383(9920):857–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24616916>.

Bagley JH. EU Tobacco Products Directive trumps debate on regulation of electronic cigarettes. BMJ, 2014; 349:g5897. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25270422>.

Tanday S. European Parliament votes to tighten tobacco regulations. Lancet Respir Med, 2013; 1(9):678. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24429266>.

12B.4 Regulation of the contents and emissions of tobacco products

Denlinger-Apte, RL, Cassidy, RN, Donny, EC, Godin, J, Hatsukami, DK, Strahley, AE et al (2023). Qualitative reactions to a low nicotine product standard for cigarettes from adolescents and young adults living in the United States who smoke. *Prev Med Rep*, 32, 102163.

News reports:

Therapeutic Goods Administration. Listed complementary medicines, in *Australian Government Department of Health* 2019. Available from: <https://www.tga.gov.au/listed-complementary-medicines>.

No authors listed. Tobacco Centers of Regulatory Science (TCORS), in *U.S. Food and Drug Administration (FDA)* 2018. Available from:
<https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm369005.htm>.

Minato C. D.C. Court Rules in Favor of FDA in Cigar Regulation Lawsuit, in *Half Wheel* 2018. Available from: <https://halfwheel.com/d-c-court-rules-favor-fda-cigar-regulation-lawsuit/264346>.

Lempert LK, Schick S, Hendlin YH, Benowitz NL, Jacob P, et al. FDA should revise its new guidance on listing of ingredients in tobacco products to require disclosure of all ingredients that can become toxic during normal use, in *Comment on FDA's revision of tobacco products ingredients list* 2018. Available from:
<https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/UCSF%20comment%20on%20FDA%207s%20April%202018%20revised%20guidance%20on%20listing%20of%20ingredients.pdf>.

Kaplan S. Citing Deaths of Lab Monkeys, F.D.A. Ends an Addiction Study, in *NY Times* 2018. Available from: https://www.nytimes.com/2018/01/26/health/fda-monkeys-nicotine.html?emc=edit_tnt_20180126&nliid=60534081&tntemail0=y.

No authors listed. How to regulate lower-risk smoking products, in *The Economist* 2017. Available from: <https://www.economist.com/news/leaders/21732809-it-hard-trust-big-tobacco-anything-reduces-harm-should-be-welcomed-how>.

De Graaf M. Medical marijuana has NO public health risks and should not be withheld from patients, WHO declares after months of deliberation. *Daily Mail (Aus)*, 2017. Available from: <http://www.dailymail.co.uk/health/article-5175825/Medical-marijuana-NO-public-health-risks-declares.html>

No authors listed. Do you know what you're smoking? Research suggests that you don't, in *Medical XPress* 2016. Available from: <http://medicalxpress.com/news/2016-06-youre-dont.html>.

Australian Government and Department of Health. Tobacco advertising, 2014. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-advert>.

12B.1 FDA regulation

King, B. CTP's Progress Addressing Recommendations from the Reagan-Udall Evaluation. *Center for Tobacco Products*, 2023. June 29, 2023. Retrieved from <https://www.fda.gov/tobacco-products/ctp-newsroom/ctps-progress-addressing-recommendations-reagan-udall-evaluation>

U.S. Food and Drug Administration. Actions to Address Recommendations from the Reagan-Udall Evaluation of CTP, in *FDA* 2023. Available from: <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/actions-address-recommendations-reagan-udall-evaluation-ctp>.

World Health Organization. 4. WHO Framework Convention on Tobacco Control. Parties to the convention. Geneva: WHO, 2022. Last update: Viewed Available from: https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IX-4&chapter=9&clang=en.

U.S. Food & Drug Administration. FDA Marks Historic Public Health Milestone with Finalization of Two Key Rules for Companies Seeking to Market New Tobacco Products, 2021. Available from: https://www.fda.gov/news-events/press-announcements/fda-marks-historic-public-health-milestone-finalization-two-key-rules-companies-seeking-market-new?utm_campaign=ctp-pmtase&utm_content=pressrelease&utm_medium=email&utm_source=govdelivery&utm_term=stratcomms.

Truth Initiative. Public Health Groups Call on FDA to Deny Authorization of Sale For JUUL E-Cigarette Products, 2021. Available from: <https://truthinitiative.org/press/press-release/public-health-groups-call-fda-deny-authorization-sale-juul-e-cigarette-products>.

Ministry of Health MH. Smokefree Aotearoa 2025 Action Plan. 2021. Last update: Viewed Available from: <https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-aotearoa-2025-action-plan>.

McKinney W and Olson CK. Filling the gaps: The FDA gifted you a PMTA deficiency letter...what's your strategy?, in *Tobacco Reporter Magazine*2021: Raleigh, NC, U.S. Available from: <https://www.tobaccoreporter.com/digital/july21/>.

Australian Institute of Health and Welfare. Australian Burden of Disease Study: Impact and causes of illness and death in Australia 2018. Canberra: AIHW, 2021. Last update: Viewed Available from: <https://www.aihw.gov.au/reports/burden-of-disease/abds-impact-and-causes-of-illness-and-death-in-aus/summary>.

Australian Government Department of Health. Smoking and tobacco laws in Australia. 2021. Last update: Viewed Available from: <https://www.health.gov.au/health-topics/smoking-and-tobacco/about-smoking-and-tobacco/smoking-and-tobacco-laws-in-australia#:~:text=about%20advertising%20bans.-,Tobacco%20packaging%20laws,on%20how%20brand%20names%20appear>.

US Food and Drug Administration. Tobacco Product Marketing Orders, in *FDA*2020. Available from: <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders>.

U.S. Food and Drug Administration. FDA Submits Request to Court to Extend Premarket Application Deadline for Certain Deemed Products, in *FDA*2020. Available from: <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-submits-request-court-extend-premarket-application-deadline-certain-deemed-products>.

No authors listed. Last Call: Vapor Industry Braces for Impact of PMTAs, in *Vapor Voice*2020. Available from: <https://vaporvoice.net/2020/09/02/last-call-vapor-industry-braces-for-impact-of-pmtas/>.

No authors listed. Vaping: Companies feel burn from US lawmakers, in *BBC News*2020. Available from: <https://www.bbc.com/news/business-51392571>.

Minato C. 12 thoughts: FDA wants to reevaluate how to regulate premium cigars, in *Halfwheel*2020. Available from: <https://halfwheel.com/12-thoughts-fda-wants-to-reevaluate-how-to-regulate-premium-cigars/379873/>.

Leonard K. Trump calls for ending FDA authority for regulating tobacco, in *Washington Examiner*2020. Available from: <https://www.washingtonexaminer.com/policy/healthcare/trump-calls-for-ending-fda-authority-for-regulating-tobacco>.

LaVito A. Altria Asks FDA to Delay Regulatory Deadline Due to Coronavirus, in *Bloomberg Law*2020. Available from: <https://news.bloomberglaw.com/pharma-and-life-sciences/altria-asks-fda-to-delay-regulatory-deadline-due-to-coronavirus>.

Craver R. Federal court approves extending premarket application deadline for e-cigarettes, in *Winston-Salem Journal*2020. Available from: https://www.journalnow.com/business/federal-court-approves-extending-premarket-application-deadline-for-e-cigarettes/article_a4fa39af-3ddb-59c3-9490-918d18753356.html.

Australian Government Department of Health. Tobacco control legislation review. 2020. Last update: Viewed Available from: <https://www.health.gov.au/health-topics/smoking-and-tobacco/tobacco-control/tobacco-control-legislation-review>.

American Lung Association. State of Tobacco Control 2020: Proven Policies to Prevent and Reduce Tobacco Use, in *American Lung Association*2020. Available from: <https://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/>.

US Food and Drug Administration. Premarket Tobacco Product Applications and Recordkeeping Requirements, in *Federal Register*2019. Available from: <https://www.federalregister.gov/documents/2019/09/25/2019-20315/premarket-tobacco-product-applications-and-recordkeeping-requirements>.

Sharpless N and Zeller M. Achievements in Tobacco Regulation Over the Past Decade and Beyond, in *U.S. Food and Drug Administration*2019. Available from: <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/achievements-tobacco-regulation-over-past-decade-and-beyond?>

No authors listed. FDA In Brief: FDA seeks comment on proposed additions to list of harmful and potentially harmful constituents found in tobacco products, including electronic nicotine delivery systems such as e-cigarettes and e-liquids, in *Food and Drug Administration*2019. Available from: <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-seeks-comment-proposed-additions-list-harmful-and-potentially-harmful-constituents>.

No authors listed. Safety Reporting Portal for Tobacco Products, in *US Food & Drug Administration* 2019. Available from: <https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/ucm377563.htm>.

Marimow A. FDA can regulate e-cigarettes just like conventional cigarettes, appeals court says, in *The Washington Post*2019. Available from: https://www.washingtonpost.com/local/legal-issues/fda-can-regulate-e-cigarettes-just-like-conventional-cigarettes-appeals-court-says/2019/12/10/e4c28836-cffc-11e9-b29b-a528dc82154a_story.html.

Halpern-Felsher B. FDA must use its existing authority to combat the youth e-cigarette use epidemic by preventing addiction now, rather than by seeking to treat it after the fact, in *Center for Tobacco Control Research and Education*2019. Available from: <https://tobacco.ucsf.edu/fda-must-use-its-existing-authority-combat-youth-e-cigarette-use-epidemic-preventing-addiction-now-rather-seeking-treat-it-after-fact>.

Glantz S. UCSF TCORS public comment on expansion of FDA HPHC list, in *Center for Tobacco Control Research and Education*2019. Available from: <https://tobacco.ucsf.edu/ucsf-tcors-public-comment-expansion-fda-hphc-list>.

Glantz S. Federal Court Sets 10-Month Deadline for E-Cigarette Makers to Apply to FDA to Keep Products on the Market, in *Center for Tobacco Control Research and Education*2019. Available from: <https://tobacco.ucsf.edu/federal-court-sets-10-month-deadline-e-cigarette-makers-apply-fda-keep-products-market>.

ALM Media. FDA Issues Draft Guidance on Tobacco Products, in *Yahoo Finance*2019. Available from: <https://finance.yahoo.com/news/fda-issues-draft-guidance-tobacco-053917453.html>.

U.S. Food and Drug Administration. Tobacco Registration and Product Listing (TRLM) Instructions, in *FDA*2018. Available from: https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm386651.htm?utm_source=Eloqua&utm_medium=email&utm_term=stratcomms&utm_content=

[landingpage&utm_campaign=CTP%20News%3A%20Annual%20R%20and%20L%20Updates%20Remi
nder%20-%20121318.](#)

Perrone M. Anti-smoking plan may kill cigarettes—and save Big Tobacco, in *The Fresno Bee* 2018. Available from: <http://www.fresnobee.com/news/article195512184.html>.

No authors listed. Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce tobacco use, especially among youth, by exploring options to address the role of flavors – including menthol – in tobacco products, in *U.S. Food & Drug Administration* 2018. Available from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601690.htm>.

No authors listed. Statement from FDA Commissioner Scott Gottlieb, M.D., on agency’s ongoing commitment to improving efficiency, transparency of tobacco product application review process as part of FDA’s comprehensive framework to reduce tobacco-related disease and death, in *FDA U.S Food & Drug Administration* 2018. Available from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm623949.htm>.

No authors listed. AMA, 10 Other Medical Nonprofits Tell Court FDA Is Abdicating Its Obligations, in *Lexis Legal News* 2018. Available from: <https://www.lexislegalnews.com/articles/28867/ama-10-other-medical-nonprofits-tell-court-fda-is-abdicating-its-obligations>.

No authors listed. FDA to support development of nicotine replacement therapies, in *Pharmaceutical Technology* 2018. Available from: <https://www.pharmaceutical-technology.com/news/fda-nicotine-replacement-therapies/>.

No authors listed. FDA Releases Draft Guidance on Inhaled Nicotine Replacement Therapies, in *Occupational Health and Safety* 2018. Available from: <https://ohsonline.com/articles/2018/08/06/fda-draft-guidance.aspx?admgarea=news>.

No authors listed. AAFP Responds to FDA Nicotine Steering Committee in *American Academy of Family Physicians* 2018. Available from: <https://www.aafp.org/news/health-of-the-public/20180417nicotineltr.html>.

No authors listed. Health Groups File Suit to Expedite FDA Review of E-Cigarettes, Cigars, in *Truth Initiative* 2018. Available from: <https://truthinitiative.org/news/health-groups-file-suit-expedite-fda-review-e-cigarettes-cigars>.

No authors listed. FDA to re-examine premium cigars as it overhauls tobacco regulation, in *CNBC* 2018. Available from: <https://www.cnbc.com/2018/03/23/fda-seeks-guidance-on-regulating-premium-cigars.html>.

Myers ML. FDA Decision to Leave Thousands of Tobacco Products on Market without Review Raises Troubling Questions, in *Tobacco Free Kids* 2018. Available from: https://www.tobaccofreekids.org/press-releases/2018_04_06_fda.

Henry T. FDA pulled into federal court on delay in regulating e-cigarettes, in *AMA Wire* 2018. Available from: <https://wire.ama-assn.org/practice-management/fda-pulled-federal-court-delay-regulating-e-cigarettes>.

Gottlieb S and Zeller M. Advancing Tobacco Regulation to Protect Children and Families: Updates and New Initiatives from the FDA on the Anniversary of the Tobacco Control Act and FDA’s Comprehensive Plan for Nicotine, in *Food & Drug Administration* 2018. Available from:

<https://blogs.fda.gov/fdavoices/index.php/2018/08/advancing-tobacco-regulation-to-protect-children-and-families-updates-and-new-initiatives-from-the-fda-on-the-anniversary-of-the-tobacco-control-act-and-fdas-comprehensive-plan-for-nicotine/>.

Food and Drug Administration (FDA). Regulation of Premium Cigars. 2018. Last update: 21 March 2018; Viewed 11 May 2018. Available from: <https://www.regulations.gov/document?D=FDA-2017-N-6107-0001>.

Food & Drug Administration. Tobacco Centers of Regulatory Science (TCORS), in *Tobacco products* 2018. Available from: <https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm369005.htm>.

Food & Drug Administration. Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Deemed Tobacco Products. 2018. Last update: 8 August 2018; Viewed 3 September 2018. Available from: <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm500778.htm>.

Food & Drug Administration. Compliance Policy for Certain Labeling and Warning Statement Requirements for Cigars and Pipe Tobacco. 2018. Last update: 9 August 2018; Viewed 3 September 2018. Available from: <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm615968.htm>.

Food & Drug Administration. Labeling and Warning Statements for Tobacco Products. 2018. Last update: 13 August 2018; Viewed 3 September 2018. Available from: <https://www.fda.gov/TobaccoProducts/Labeling/Labeling/default.htm>.

Food & Drug Administration. FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, in *Newsroom* 2018. Available from: <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm>.

Clarke T. FDA moves to speed nicotine replacement product development, in *Reuters* 2018. Available from: <https://uk.reuters.com/article/us-fda-smoking-proposal/fda-moves-to-speed-nicotine-replacement-product-development-idUKKBN1DT33P>.

Chowdhury A and Wolf BK. FDA Publishes Revised Ingredient Listing Guidance for Tobacco Products, Exempts Non-Consumable Product Hardware and Components and Parts, in *The National Law Review* 2018. Available from: <https://www.natlawreview.com/article/fda-publishes-revised-ingredient-listing-guidance-tobacco-products-exempts-non>.

Apollonio D, Stanton A, Glantz, Sharon Hall, Lauren Lempert, Gideon St. Helen, et al. The FDA should not adopt the nicotine "harm reduction" paradigm because doing so is likely to increase the amount of smoking-caused disease and death, in *University of California, San Francisco* 2018. Available from: <https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/wysiwyg/UCSF%20comment%20on%20FDA%207s%20approach%20to%20NRTs%20-%20final.pdf>.

Adney A. E-Cigarettes, Snus Get a Wary Reception as Alternatives to Smoking, in *Bloomberg* 2018. Available from: <https://www.bloomberg.com/news/articles/2018-09-14/e-cigarettes-snus-get-wary-reception-as-alternatives-to-smoking>.

Tozzi J. The FDA's Consumer Protection Warnings Are Falling Under Trump, in *Bloomberg* 2017. Available from: <https://www.bloomberg.com/news/articles/2017-08-28/fda-warnings-meant-to-protect-consumers-fall-under-trump>.

Philip Morris International. Philip Morris International (PMI) files premarket tobacco product application for its Electronically Heated Tobacco Product (EHTP) with the US Food and Drug Administration (FDA). Switzerland 2017. Last update: Viewed Available from: <https://www.pmi.com/media-center/press-releases/press-release-details/?newsId=2257952>.

No authors listed. Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Guidance for Industry; Availability. US 2017. Available from: <https://www.federalregister.gov/documents/2017/12/08/2017-26469/registration-and-product-listing-for-owners-and-operators-of-domestic-tobacco-product-establishments>.

No authors listed. Population Assessment of Tobacco and Health: An FDA and NIH Study. US 2017. Available from: <https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm337005.htm>.

No authors listed. CASAA - FDA's New Vision for Nicotine and Tobacco Regulation is an Important Step Forward for Public Health in *PR Newswire* 2017. Available from: <http://www.prnewswire.com/news-releases/casaa---fdas-new-vision-for-nicotine-and-tobacco-regulation-is-an-important-step-forward-for-public-health-300496182.html>.

No authors listed. FDA's move to lower nicotine and examine flavoring a promising step, but Deeming Rule delay disappointing, says American Heart Association in *American Heart Association (AHA)* 2017. Available from: <http://newsroom.heart.org/news/fdas-move-to-lower-nicotine-and-examine-flavoring-a-promising-step-but-deeming-rule-delay-disappointing-says-american-heart-association>.

No authors listed. 51 Health Groups Urge Administration to Defend and Enforce FDA Rule for E-Cigarettes, Cigars. Campaign for Tobacco-Free Kids (CTFK), 2017. Available from: http://www.tobaccofreekids.org/press_releases/post/2017_05_17_fda

Minato C. Cigar Groups File for Injunction Against Deeming Rules, in *HalfWheel* 2017. Available from: <http://halfwheel.com/cigar-groups-file-injunction-deeming-rules/179303>.

McKeganey N. E-cigarettes should be marketed as smoking cessation products, in *The Hill* 2017. Available from: <http://thehill.com/opinion/healthcare/362672-e-cigarettes-should-be-marketed-as-smoking-cessation-products>.

Lag Reid P. FDA News 2 FDA center for tobacco products names science director, in *HalfWheel* 2017. Available from: <http://halfwheel.com/fda-center-tobacco-products-names-dr-matthew-holman-new-office-science-director>.

Gottlieb S. Looking ahead: Some of FDA's major policy goals for 2018. US 2017. Available from: <https://blogs.fda.gov/fdavoices/index.php/2017/12/looking-ahead-some-of-fdas-major-policy-goals-for-2018/>.

Glantz S. UCSF TCORS public comment on FDA proposed NNN standard, in *Center for Tobacco Control Research and Education (UCSF)* 2017. Available from: <https://tobacco.ucsf.edu/ucsf-tcors-public-comment-fda-proposed-nnn-standard>.

Glantz S. New report does not necessarily reflect “the views of 120 leaders in tobacco control”, in *Center for Tobacco Control Research and Education (UCSF)* 2017. Available from: <https://tobacco.ucsf.edu/new-report-does-not-necessarity-reflect-views-120-leaders-tobacco-control>.

Geller M. Philip Morris asks for FDA nod to sell heated tobacco device, in *Reuters* 2017. Available from: <http://www.reuters.com/article/us-pmi-fda-idUSKBN172275>.

Eilperin J. FDA delays enforcement of stricter standards for e-cigarette, cigar industry. The Washington Post, 2017. Available from: https://www.washingtonpost.com/politics/fda-suspends-enforcement-of-stricter-standards-for-e-cigarette-cigar-industry/2017/05/02/be7e557a-2ed6-11e7-9534-00e4656c22aa_story.html?utm_term=.48ed95ca7ec5

Boyles S. FDA to Shift Tobacco Regulatory Focus
Basing decisions on ‘continuum of risk’ from different products in *MedPage Today* 2017. Available from: <https://www.medpagetoday.com/primarycare/smoking/66942>.

Bates C, Lehrer E, and Sweanor D. Eight Tobacco harm reduction proposals for the Federal Government, in *R Street Institute | Free Markets. Real Solutions.* 2017. Available from: <http://www.rstreet.org/wp-content/uploads/2017/01/81.pdf>.

U.S Food and drug Administration. The facts on the FDA’s new tobacco rule. US 2016. Available from: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>.

No authors listed. Perspective: Lessons learned from the first review of Modified Risk Tobacco Product (MRTP) applications. US 2016. Available from: http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533753.htm?source=govdelivery&utm_campaign=ctp-sos&utm_content=20161220-button-mrtp&utm_medium=email&utm_source=govdelivery.

No authors listed. FDA makes statements on synthetic nicotine, in *Convenience Store Decisions* 2016. Available from: <http://www.cstoredecisions.com/2016/12/15/fda-makes-statements-synthetic-nicotine/>.

No authors listed. US public largely unaware that cigarette smoke much more harmful than additives, in *Medical News Today* 2016. Available from: <http://www.medicalnewstoday.com/releases/314587.php>.

No authors listed. Big Tobacco loses legal challenge to FDA report on menthol cigarettes in *Bullfax.com* 2016. Available from: <http://www.bullfax.com/?q=node-big-tobacco-loses-legal-challenge-fda-report-menthol-ci>.

Glantz S. FDA should regulate the manufacturing and marketing of hookah tobacco to prevent misperceptions of harm and widespread use in *Center for Tobacco Control Research and Education* 2016. Available from: <https://tobacco.ucsf.edu/fda-should-regulate-manufacturing-and-marketing-hookah-tobacco-prevent-misperceptions-harm-and-widespread-use>.

Food & Drug Administration. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products.: FDA, 2016. Last update: Viewed Available from:

<https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>.

FDA - U.S. Government. Now available: New "Reference cigarette" to help measure properties of U.S. cigarettes. U.S. 2016. Available from:

http://www.fda.gov/TobaccoProducts/NewsEvents/ucm500766.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Devaney T. FDA unveils tobacco ingredients guidelines, in *The Hill* 2016. Available from:

<http://thehill.com/regulation/healthcare/303089-fda-unveils-tobacco-ingredient-guidelines>.

Campaign for Tobacco Free Kids. FDA regulation of tobacco products: A common sense law to protect kids and save lives. Washington DC 2016. Last update: Viewed Available from:

<https://www.tobaccofreekids.org/assets/factsheets/0352.pdf>.

Boehm E. Animal rights group: FDA's e-cigarette regulations will kill critters, in *Watchdog.org (Franklin Center for Government & Public Integrity)* 2016. Available from:

<http://watchdog.org/266194/fda-e-cigarette-regs-animals/>.

Verleur J. How the FDA is helping Big Tobacco, in *Business Wire* 2015 Available from:

<http://dailycaller.com/2015/09/08/how-the-fda-is-helping-big-tobacco/>.

Tavernise S. Cardiologist nominated to be head of F.D.A. The New York Times, 2015 Available from:

http://www.nytimes.com/2015/09/16/health/cardiologist-nominated-to-be-head-of-fda.html?emc=edit_tnt_20150915&nlid=60534081&ntemail0=y&r=1

No authors listed. Use of investigational tobacco products. US 2015 Available from:

http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm463951.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Haag A and Redington T. 22nd century group receives order for nearly 5 million SPECTRUM® U.S. government research cigarettes, in *Business Wire* 2015 Available from:

<http://www.businesswire.com/news/home/20150909006273/en/22nd-Century-Group-Receives-Order-5-Million#.Vhw7pCuFmu->.

Frieden J. Calif nomination for FDA chief gets mostly high marks - but ties with industry may be an issue in *Med Page Today* 2015 Available from:

http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/53594?xid=nl_mpt_DHE_2015-09-17&eun=g220600dOr.

Voss G and Collins K. National Environmental Policy Act; environmental assessments for tobacco products; categorical exclusions. US 2015. Available from:

<https://www.federalregister.gov/articles/2015/09/24/2015-24219/national-environmental-policy-act-environmental-assessments-for-tobacco-products-categorical>.

Vonder Haar M. Insights abound at smoker friendly conference, in *Convenience Store* 2015. Available from: <http://www.cspnet.com/category-news/tobacco/articles/insights-abound-smoker-friendly-conference>.

Tillman Z. Tobacco companies bring new fight with Feds over labels, in *Legal Times* 2015. Available from: <http://www.nationallawjournal.com/legaltimes/home/id=1202723452050/Tobacco->

[Companies-Bring-New-Fight-with-Feds-Over-Labels?mcode=1202615432600&curindex=0&back=NLJ&slreturn=20150420025800.](#)

Sifferlin A. FDA panel votes against smokeless tobacco safety claims. Time, 2015. Available from: <http://time.com/3817902/fda-snus-smokeless-tobacco/>

No authors listed. Roundup of recent tobacco product review actions. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm451086.htm>.

No authors listed. Tobacco product marketing orders. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm>.

No authors listed. FDA panel opposes dropping warnings from tobacco pouch. Daily Mail 2015. Available from: <http://www.dailymail.co.uk/wires/ap/article-3034118/FDA-panel-wary-dropping-warnings-tobacco-pouch.html>

No authors listed. FDA questions evidence for lower-risk tobacco product. Mail on Sunday 2015. Available from: <http://www.mailonsunday.co.uk/wires/ap/article-3029030/FDA-questions-evidence-lower-risk-tobacco-product.html>

No authors listed. Clarification of when products made or derived from tobacco are regulated as drugs, devices, or combination products; amendments to regulations regarding “intended uses”. US 2015. Available from: https://www.federalregister.gov/articles/2015/09/25/2015-24313/clarification-of-when-products-made-or-derived-from-tobacco-are-regulated-as-drugs-devices-or?source=govdelivery&utm_medium=email&utm_source=govdelivery.

No authors listed. FDA proposes rule to clarify when products made or derived from tobacco are regulated as drugs and/or devices. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm464281.htm>.

No authors listed. FDA extends comment period for nicotine exposure warnings and child-resistant packaging ANPRM. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm459378.htm>.

No authors listed. Uruguay slams Big Tobacco, defends marijuana policy, in *teleSUR* 2015. Available from: <http://www.telesurtv.net/english/news/Uruguay-Slams-Big-Tobacco-Defends-Marijuana-Policy-20150929-0025.html>.

No authors listed. Technical Project Lead (TPL) Review: SE0000276,SE0000277,SE0000278,SE0000281 2015. Available from: <http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM462402.pdf>.

No authors listed. Demonstrating the substantial equivalence of a new tobacco product: responses to frequently asked questions. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm436462.htm>.

No authors listed. Tobacco regulatory science in action: in the researchers’ own words. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/ucm436335.htm>.

No authors listed. Statement from Mitch Zeller. US 2015. Available from: <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm436783.htm>.

Minato C. Senate Bill to exempt premium cigars from FDA introduced, in *Half Wheel* 2015. Available from: <http://halfwheel.com/senate-bill-exempt-premium-cigars-fda-introduced>.

Itkowitz C. Democrats accuse GOP of siding with tobacco industry over children's health. The Washington Post 2015. Available from: <http://www.washingtonpost.com/news/powerpost/wp/2015/07/09/democrats-accuse-gop-of-siding-with-tobacco-industry-over-childrens-health/>

Howard D. R.J. Reynolds Tobacco Company disagrees with FDA ruling on four of its cigarette brands, in *Reynolds American* 2015. Available from: http://www.reynoldsamerican.com/files/doc_news/2015/2015-06-RJRT-disagrees-with-FDA-ruling-on-4-cig-brands.pdf.

Godoy J. FDA says rebranded tobacco products get faster review, in *Law 360* 2015. Available from: <https://www.law360.com/articles/699683/fda-says-rebranded-tobacco-products-get-faster-review>.

Food and Drug Administration (FDA). Tobacco product marketing orders. US 2015. Available from: http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Food and Drug Administration. Guidance for industry. Demonstrating the substantial equivalence of a new tobacco product: responses to frequently asked questions. US 2015. Available from: <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM436468.pdf>.

Felberbraum M. 4 members on FDA tobacco advisory panel leave following court ruling on conflicts of interest, in *US News* 2015. Available from: <http://www.usnews.com/news/business/articles/2015/03/06/4-members-of-fda-tobacco-panel-leave-after-court-ruling>.

Dye J. 3-Tobacco companies sue U.S. FDA over label approvals, in *Reuters* 2015. Available from: <http://www.reuters.com/article/2015/04/14/fda-tobacco-lawsuit-idUSL2N0XB1R220150414>.

Craver R. FDA issues interim policy on tobacco labeling Winston-Salem Journal 2015. Available from: http://www.journalnow.com/business/business_news/local/fda-issues-interim-policy-on-tobacco-labeling/article_a1625ea9-83c0-584a-bade-14cae4a61c3d.htm

Campbell T. FDA bans sale of Four Reynolds tobacco brands, in *Maine News Online* 2015. Available from: <http://mainenewsonline.com/content/15095862-fda-bans-sale-four-reynolds-tobacco-brands>.

Adams DG. Tobacco product substantial equivalence guidance — Take 2, in *Law 360* 2015. Available from: <https://www.law360.com/articles/710674/take-2-of-the-tobacco-product-substantial-equivalence-rule>.

Campaign for Tobacco-Free Kids. FDA regulation of tobacco products: a common sense law to protect kids and save lives, 2010. Available from: <http://www.tobaccofreekids.org/research/factsheets/pdf/0352.pdf>.

Food & Drug Administration. Family smoking prevention and tobacco control and federal retirement reform.: FDA, 2009. Last update: Viewed Available from: <https://www.govinfo.gov/content/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>.

Family Smoking Prevention and Tobacco Control Act. No. 111-31 2009. Available from:
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf>.

World Health Organization. WHO Tobacco Laboratory Network (TobLabNet): About us.: WHO, Last update: Viewed Available from: <https://www.who.int/groups/who-tobacco-laboratory-network/about>.

World Health Organization. WHO Study Group on Tobacco Product Regulation (TobReg). About us.: WHO, Last update: Viewed Available from: <https://www.who.int/groups/who-study-group-on-tobacco-product-regulation/about>.

European Commission. Revision of the Tobacco Products Directive. Last update: Viewed Available from: https://ec.europa.eu/health/tobacco/product-regulation/implementing-tobacco-products-directive-directive-201440eu/revision-tobacco-products-directive_en.

12B.2 EU regulation

UK Government. The Tobacco Products and Nicotine Inhaling Products (Amendment etc.) (EU Exit) Regulations 2018, in *EXITING THE EUROPEAN UNION CONSUMER PROTECTION PUBLIC HEALTH*2018. Available from:
http://www.legislation.gov.uk/ukdsi/2018/9780111174203/pdfs/ukdsi_9780111174203_en.pdf.

Orlowski A. Vaping on the NHS? Don't hold your breath, in *The Register (UK)*2018. Available from:
http://www.theregister.co.uk/2018/02/28/vaping_on_the_nhs/.

Michalopoulos S. Swedish snus wants place in EU tobacco directive, in *Euractiv.com*2017. Available from: http://www.euractiv.com/section/health-consumers/news/swedens-snus-seeks-room-in-the-eu-tobacco-directive/?utm_term=Autofeed&utm_campaign=Echobox&utm_medium=Social&utm_source=Twitter#link_time=1506403696.

Orlowski A. Peer tables motion to kill vaping rules, in *The Register*2016. Available from:
http://www.theregister.co.uk/2016/05/19/peer_tables_motion_to_kill_vaping_rules/.

Oppel P and Geller M. EU's highest court upholds restrictive new law on cigarettes, in *EuroNews*2016. Available from: <http://www.euronews.com/newswires/3188945-eus-highest-court-upholds-new-restrictive-law-on-cigarettes/>.

No authors listed. Blu launches EUTPD retailer guide, in *Talking Retail* 2016. Available from:
<http://www.talkingretail.com/category-news/independent-news/blu-launches-eutpd-retailer-guide/>.

Tobacco Tactics. EU Tobacco Products Directive Revision, 2015. Available from:
http://www.tobaccotactics.org/index.php/EU_Tobacco_Products_Directive_Revision#cite_note-0.

EU Tobacco Products Directive (2014/40/EU). 2014. Available from:
http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf.