

In addition, there are also concerns about a history of anticompetitive conduct.⁸ Expansive investigation for mergers like these is time well spent.

Again, with a few exceptions,⁹ many FTC Commissioners have primarily scrutinized pharmaceutical mergers based on an examination of whether there are any product overlaps between the merging corporations, or where there may be clear-cut incentives to foreclose rivals with the ability to compete.¹⁰ When there are no obvious overlaps or foreclosure possibilities, the Commission typically does not challenge any aspect of the transaction.¹¹

deal, Reuters (Feb. 28, 2019, 6:59 a.m.), <https://www.reuters.com/article/us-celgene-m-a-bristol-myers-wellington/starboard-joins-opposition-to-bristol-myers-74-billion-celgene-deal-idUSKCN1QH1K7>.

⁸ For example, last year, the Food & Drug Administration published a list of drug makers that were the subject of complaints that they had restricted generic drug companies from accessing drug samples, which enable generic firms to develop viable alternatives. Celgene was a top recipient of these complaints. Alison Kodjak, *How a Drugmaker Gamed The System To Keep Generic Competition Away*, NPR (May 17, 2018; 5:00 a.m.), <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>.

⁹ See, e.g., Statement of the Federal Trade Commission, *In the Matter of Teva Pharmaceuticals Industries Ltd. and Allergan plc* (July 27, 2016), <https://www.ftc.gov/public-statements/2016/07/statement-federal-trade-commission-matter-teva-pharmaceuticals-industries>; cf. Concurring Statement of Commissioner J. Thomas Rosch, Federal Trade Commission v. Ovation Pharmaceuticals, Inc. (Dec. 16, 2008), <https://www.ftc.gov/public-statements/2008/12/concurring-statement-commissioner-j-thomas-rosch-federal-trade-commission>.

¹⁰ In this matter, the Analysis of Agreement Containing Consent Orders to Aid Public Comment focuses primarily on a specific product market overlap. This is similar to many past analyses contained in public notices seeking comment on proposed consent orders in the FTC's pharmaceutical merger actions. See, e.g., Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Boston Scientific Corporation*, File No. 191-0039, https://www.ftc.gov/system/files/documents/cases/191_0039_boston_scientific_aapc.pdf; Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Impax Laboratories, Inc., and Impax Laboratories, LLC*, File No. 181-0017, https://www.ftc.gov/system/files/documents/cases/1810017_amneal_impx_analysis_4-27-18.pdf. See also Markus Meier et al., Fed. Trade Comm'n, *Overview of FTC Actions In Pharmaceutical Products and Distribution* (2019), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf.

¹¹ For example, in January 2015 the Commission granted early termination of the Hart-Scott-Rodino waiting period and took no enforcement action against the proposed \$66 billion merger between Actavis plc and Allergan, Inc. See Fed. Trade Comm'n, *Early Termination Notices, 20150313: Actavis plc; Allergan, Inc.* (Jan. 9, 2015), <https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices/20150313>.

I am deeply skeptical that this approach can unearth the complete set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today's pharmaceutical industry when it comes to innovation. Will the merger facilitate a capital structure that magnifies incentives to engage in anticompetitive conduct or abuse of intellectual property? Will the merger deter formation of biotechnology firms that fuel much of the industry's innovation? How can we know the effects on competition if we do not rigorously study or investigate these and other critical questions? Given our approach, I am not confident that the Commission has sufficient information to determine the full scope of potential harms to competition of this massive merger.

Conclusion

The financial crisis and the Great Recession taught our country a tough lesson: When watchdogs wear blindfolds or fail to evolve with the marketplace, millions of American families can suffer the consequences. The regulators and enforcers of the mortgage industry failed to stop the widespread abuses that plagued the marketplace. And there are many more examples every year, from the opioid crisis to the failures of the Boeing 737 Max, where blindfolded regulators and the absence of rigorous investigation proved to be catastrophic to human life, despite so many warning signs.

When enforcers conduct wide-ranging, intensive inquiries that do not uncover unlawful conduct, then, of course, they cannot take action. However, when they wear blindfolds or cling to the status quo, they cannot assume that the public is protected.

For these reasons, I respectfully dissent.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2019-0112]

Priority Topics for the Community Preventive Services Task Force (CPSTF); Request for Information

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment to identify topics of public health importance that will form the basis of Community Preventive Services Task Force (CPSTF) evidence-based recommendations. CDC will use this information to support the CPSTF in its selection of priority topics to guide its work over the next five years. This docket will provide the opportunity to expand the current body of knowledge and identify important evidence gaps.

DATES: Written comments must be received on or before January 23, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0112, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Julie Zajac, Centers for Disease Control and Prevention, Office of the Associate Director for Policy and Strategy, Community Guide Office, 1600 Clifton Road NE, Mail Stop V25-5, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Julie Zajac MPH, Community Guide Office, Office of the Associate Director for Policy and Strategy, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mail Stop V25-5, Atlanta, GA 30329. Phone: 404-498-1827; Email: cpstf@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions:

1. What public health topics should be prioritized for CPSTF systematic reviews assessing the effectiveness and economic merits of public health programs, services, and other interventions?

2. What is the rationale for choosing these topics?

3. What are examples of published studies on interventions within these topics?

Possible domains to consider in answering these questions include (but are not limited to):

- Burden of disease and preventability
- Presence of important health disparities
- Alignment with national efforts (e.g., Healthy People 2020 or 2030)
- Ability to provide users with an adequate menu of options for addressing the health topic (i.e., recommendations or findings for multiple interventions within the same topic)
- Balance across public health topics
- Complementary work of other bodies that provide guidance or recommendations on addressing health issues (e.g., U.S. Preventive Services Task Force, Advisory Committee on Immunization Practices). Specific citations or websites that support suggested topics, rationale, or demonstrate available evidence would be helpful. Please feel free to respond to any or all of the questions.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. Note that personal information such as name, contact information, or other information that identifies an individual appearing in the body of submitted comments will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Previous Areas of Focus: The CPSTF conducted the previous prioritization process in 2015 and identified the following list of topics to guide its work:

- Cardiovascular Disease Prevention and Control
- Diabetes Prevention and Control
- Environmental Health
- Injury Prevention
- Mental Health
- Obesity Prevention and Control (includes Nutrition)
- Older Adult Health
- Physical Activity
- Sleep Health
- Social Determinants of Health
- Substance Abuse (e.g., Prescription Drug Overdose)
- Violence Prevention

Background

When communities need to know how to protect and improve their population's health, they turn to The Community Guide, a collection of evidence-based recommendations and findings from the CPSTF. The CPSTF makes evidence-based recommendations about the effectiveness and economic merits of public health programs, services, and other interventions used in real-world settings—such as communities, worksites, schools, faith-based organizations, military bases, public health clinics and departments, and integrated healthcare systems. Systematic reviews are conducted in accordance with the highest international standards, using a transparent and replicable methodology that accounts for the complexities of real-world public health interventions. CPSTF recommendations are based on systematic reviews, which help make sense of large bodies of scientific literature by applying the scientific process to summarize evidence about the effectiveness of particular approaches for addressing a public health problem. CDC provides administrative, scientific, and technical support for the CPSTF.

The CPSTF periodically updates its priority topics so that its recommendations are responsive to changes in evidence, burden of disease, changing epidemiology, and changes in how interventions are delivered (e.g., use of technology). The CPSTF uses a multi-stage process to identify and prioritize topics. A prioritization committee seeks input from its members and liaison organizations, subject matter experts, public health authorities, the public, and other stakeholders. The topic areas identified are then ranked and prioritized by the full CPSTF using established criteria.

The criteria established by the CPSTF (such as the domains listed above) are then applied to each of the identified topics and presented to the full CPSTF for its discussion, expert assessment, and arrival at a final set of priorities.

CDC welcomes input to this docket from a diverse range of perspectives. The input will inform CDC's support to the CPSTF in its work to select priority topics and will improve the credibility and transparency of the process.

Dated: November 27, 2019.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5120]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on December 18, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-5120. The docket will close on December 17, 2019. Submit either electronic or written comments on this public meeting by December 17, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 17, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before December 10, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will