PBMs preferential placements or exclusionary access for its non-blockbuster drugs, thereby excluding rivals. This sort of cross-product bundling scheme can lock out new competitors—even if their products are more affordable or effective. Based on these facts, the Commission's complaint charged that Amgen's acquisition of Horizon would give Amgen the ability and incentive to engage in similar cross-product bundling that would exclude Horizon's rivals and maintain its monopolies, harming patients in the long run.

The order announced today prohibits Amgen from engaging in any cross-product bundling or exclusionary rebating schemes involving Horizon's monopoly drugs. Several features of this conduct suggest that an order alone can effectively halt it. For example, because this deal would not give a firm control over products or services that its rivals use to compete, it does not raise traditional concerns about degrading competitors' access to key inputs or improper information exchange, which can be achieved through subtle and varied means that are difficult to detect. By contrast, Amgen can only engage in exclusionary rebating schemes and cross-product bundling in partnership with PBMs, who would need to agree to accept rebates in exchange for privileging Amgen's drugs or excluding those of its rivals. Given the significant financial sums involved, these agreements would be documented, and the FTC's proposed order will require Amgen to regularly submit all such agreements and other key documents to aid the Commission in identifying even implicit efforts to bundle. Amgen is also required to notify its trading partners about the FTC's order, ensuring that market participants are on alert about the prohibited conduct and are positioned to report any suspected violations.[11]

The proposed order also prohibits Amgen from acquiring any drugs that could compete with Horizon's two monopoly drugs without first seeking the Commission's approval. Because Amgen could try to neutralize Horizon's rivals not just through excluding them but also through acquiring them, this prior approval provision will position the FTC to block acquisitions that would unlawfully maintain Horizon's monopolies.[12]

Critically, the six state attorneys general who joined the FTC's complaint will be able to independently monitor Amgen's compliance with the proposed order. California, Illinois, Minnesota, New York, Washington, and Wisconsin will also have access to Amgen's documents and reports and will serve as another key check on any violations. I am grateful to our state partners for their close collaboration on this enforcement matter, and empowering them to independently monitor compliance with our consent orders—and take corrective action as appropriate—positions our remedies for greater success.

The FTC assesses each merger based on the specific facts at hand, and there is no guarantee that the relief achieved in this matter would adequately resolve concerns about cross-product bundling in any future merger actions. A distinct feature of the conduct at issue here is that it involves bundling across different insurance benefit arrangements, which makes it easier to detect. The conduct also involves orphan drugs for rare diseases, the selection and administration of which involves providers with incentives to resist and report exclusionary behavior. As the Commission evaluates proposals to settle charges in future pharmaceutical mergers, we will continue to learn from past experience and seek to fully protect the public from deals that violate the antitrust laws. The merger guidelines we recently proposed with the U.S. Department of Justice further describe how we will assess transactions to determine if they may lessen competition or tend to create a monopoly.[13]

Tackling unlawful pharmaceutical mergers is just one aspect of the FTC's work addressing high drug prices. The bundling and exclusionary rebating practices at issue in this matter highlight deeper concerns about how pharmaceutical companies and pharmacy benefit managers may work together to deprive Americans of access to affordable drugs. The FTC continues to scrutinize these practices through its inquiry into PBMs.[14] And our teams will continue to challenge unlawful practices that raise drug prices, inhibit access, stifle innovation, or otherwise hurt patients.

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[11] Any suspicions of order violations by Amgen may be submitted to the Bureau of Competition by email at *antitrust@ftc.gov.*

[12] Statement of the Commission on Use of Prior Approval Provisions in Merger Orders, Fed. Trade Comm'n (Oct. 25, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapprovalstatement.pdf.*

[13] U.S. Dep't of Justice and Fed. Trade Comm'n, *Merger Guidelines: Draft for Public Comment Purposes* (July 19, 2023), *https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf;* Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding FTC–DOJ Proposed Merger Guidelines (July 19, 2023), *https://www.ftc.gov/system/files/ftc_gov/pdf/p234000_chair_statement_re_draft_merger_guidelines.pdf.*

[14] Statement of Chair Lina M. Khan Regarding 6(b) Study of Pharmacy Benefit Managers, Commission File No. P221200 (June 8, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/Statement-Khan-6b-Study-Pharmacy-Benefit-Managers.pdf;* Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices (June 8, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–1198]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on July 7, 2023, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who

are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks (OMB Control No. 0920–1198, Exp. 9/30/2023)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting a three-year Paperwork Reduction Act (PRA) clearance for an Extension of the information collection request (ICR) ''Use of the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks'' (OMB Control No. 0920–1198, Exp. Date 09/30/2023).

An estimated one in six Americans per year becomes ill with a foodborne disease. Foodborne outbreaks of cyclosporiasis, caused by the parasite Cyclospora cayetanensis, have been reported in the United States since the mid-1990s and have been linked to various types of fresh produce. During the 15-year period from 2000–2014, 31 U.S. foodborne outbreaks of cyclosporiasis were reported; the total case count was 1,562. It is likely that more cases (and outbreaks) occurred than were reported. In addition, because of insufficient data, many of the reported cases could not be directly linked to an outbreak or to a particular food vehicle. In recent years, from 2018 onward the number of cases reported annually to CDC has increased substantially to over 1,000 cases; notably, in 2018 and again in 2019 over 2,000 cases were reported.

Collecting the requisite data for the initial hypothesis-generating phase of investigations of multistate foodborne disease outbreaks is associated with multiple challenges, including the need to have high-quality hypothesis-generating questionnaire(s) that can be used effectively in multijurisdictional investigations. Such a questionnaire was developed in the past for use in the context of foodborne outbreaks caused by bacterial pathogens; that questionnaire is referred to as the Standardized National Hypothesis Generating Questionnaire (SNHGQ). However, not all of the data elements in the SNHGQ are relevant to the parasite Cyclospora (*e.g.,* questions about consumption of meat and dairy products); on the other hand, additional data elements (besides those in the SNHGQ) are needed to capture information pertinent to Cyclospora and to fresh produce vehicles of infection. Therefore, the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) has been developed, by using core data elements from the SNHGQ and incorporating modifications pertinent to Cyclospora.

The core data elements from the SNHGQ were developed by a series of working groups comprised of local, State, and Federal public health partners. Subject matter experts at CDC developed the CNHGQ by modifying the SNHGQ to include and focus on data elements pertinent to Cyclospora/cyclosporiasis. Input also was solicited from State public health partners. Because relatively few data elements in the SNHGQ needed to be modified, a full vetting process was determined not to be necessary. The CNHGQ has been designed for administration over the telephone by public health officials, to collect data elements from case-patients or their proxies. The data that are collected will be pooled and analyzed at CDC, to generate hypotheses about potential vehicles/sources of infection.

CDC requests OMB approval to collect information via the CNHGQ from persons who have developed symptomatic cases of Cyclospora infection during periods in which increased numbers of such cases are reported (typically, during spring and summer months). In part because molecular typing methods are not yet available for C. cayetanensis, it is important to interview all case-patients identified during periods of increased reporting, to help determine if their cases could be part of an outbreak(s). The CNHGQ is not expected to entail substantial burden for respondents. The estimated total annualized burden associated with administering the CNHGQ is 1875 hours (approximately 2,500 individuals interviewed × 45 minutes/response). There will be no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Ill individuals identified with cyclosporiasis	Cyclosporiasis National Hypothesis Generating Questionnaire.	2,500	1	45/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–23–22GA]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Expanding PrEP in Communities of Color (EPICC)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on June 13, 2022, to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Expanding PrEP in Communities of Color (EPICC)—New—National Center for HIV, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC is requesting approval for 36 months for a data collection titled, Expanding PrEP in Communities of Color (EPICC). The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to: (1) increase provider knowledge of and comfort with preexposure prophylaxis (PrEP) modalities in clinical practice; and (2) improve PrEP adherence among young men who have sex with men (YMSM). The information collected in this study will be used to: (1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; (2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; (3) evaluate the feasibility and acceptability of the EPICC+ mobile app among YMSM on PrEP; and (4) evaluate the feasibility and acceptability of implementing a provider training.

This study has two aims: In Aim 1, the study team will deliver training to health providers that will focus on implementation of evidence-based tools to enhance the providers' ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence. The study will utilize web-based computer-assisted surveys to measure healthcare provider knowledge both pre- and post-training. Post-training and at three months, providers will complete a patient interaction assessment via teleconference and receive personalized feedback to assess and enhance their tailored motivational interviewing skills.

For Aim 2a, the study will initiate an effectiveness-implementation trial with 400 YMSM to test the effectiveness of the EPICC+ intervention package in increasing PrEP adherence and persistence among YMSM. The intervention will utilize a mobile app-based platform, EPICC+, to support ongoing participant engagement and monitoring, as well as to provide additional adherence support. YMSM participants will complete quarterly web-based computerized assessments during the 18-month follow up period. The assessments will measure PrEP knowledge, usage, and choice, and gather information about sexual behaviors, HIV status of partners, and substance use. YMSM participants will be mailed four dried blood spot collection kits to measure PrEP metabolites (baseline, six, 12, and 18 months). To further examine the participant experience and intervention satisfaction, a subset of YMSM participants (45) will be invited to participate in a web-based exit interview at the close of the follow up period (18 months). Additionally, study staff will collect data to measure mobile app use and conduct medical record abstractions three times during the follow up period (six, 12, and 18 months).

In Aim 2b, the study team will conduct focus groups with health providers from the participating clinics to gather feedback on overall perceptions about the effectiveness of the intervention and the barriers and facilitators to implementation of the evidence-based tools (EBT) within their clinical site. Providers will complete a short web-based computer-assisted pre-focus group survey prior to the virtual two-hour focus group. To describe PrEP services implementation at the facility level, each participating clinic will complete a web-based computer-assisted clinic assessment at six-month intervals during the three-year data collection period (baseline, six, 12, 18, 24, 30, and 36 months).

This study will be carried out in nine clinics located in Chicago, IL; Bronx, New York City, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Tampa, FL; Orlando, FL; and Houston, TX. Aim 1 will include healthcare providers from the nine clinic sites, all involved in the direct delivery of PrEP services. Providers may include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. Health providers will be recruited via staff