benefit-risk assessments and used case examples, explored PPI methods, and future research topics to improve the use of PPI in regulatory decisions.

Based on feedback attained during the workshop, FDA identified the following parameters to assist in the identification of the priority list of patient preference-sensitive areas for medical device review, where:

- FDA staff are looking to better understand the full impact of the disease or condition and treatment options on patients and/or caregivers;
- Patients may value the benefits and risks of a technology or treatment differently from healthcare professionals and/or caregivers;
- Population-level differences in patient perspectives are not well understood, due to differences in:
  - Demographic characteristics;
  - Stages of disease; or
  - Disease phenotype; and
- There is significant public health impact (such as high mortality or morbidity rates and high prevalence rates of the disease, or few treatment options available such as in rare diseases).

II. Patient Preference-Sensitive Priority Areas

Based on the above parameters, FDA generated a list of priority preference-sensitive areas, and organized the areas into the following categories:

- Patient values in diagnosis and treatment;
- Relevant clinical endpoints for specific patient populations;
- Patient benefit-risk trade-offs for treatment options or diagnostic approaches; and
- Impact of uncertainty in the benefit-risk tradeoffs.

The current collated list of identified patient preference-sensitive areas can be found on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas*. The priorities listed on the web page may be broadly applicable to many diagnostic/therapeutic areas, while others are specific to a disease/condition or technology. This is not an exhaustive list of all patient preference-sensitive areas, and the prioritization of these areas may shift over time as health technologies and patient preference methodologies advance.

III. Other Issues for Consideration

FDA is soliciting public input from interested persons on the identified priority list of patient preference-sensitive topics captured on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas*. In addition, FDA is interested in responses to the following questions:

1. Do any existing topics on the Priority List of Patient Preference-Sensitive Areas need to be refined to better represent patient preference-sensitive areas important to regulatory efforts? And, if so, how? Please provide an explanation to support any recommended refinements.

2. Are there other areas not listed on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas* that FDA should consider as priority patient preference-sensitive areas? If there are additional areas for consideration, please identify and provide an explanation for each additional area using the parameters outlined in Section I: Background.

3. Are there ongoing studies or published studies that adequately address any of these patient preference-sensitive areas in a regulatory context? If so, please provide information or references regarding the studies.

IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling—Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications*.
2. MDUFA Performance Goals and Procedures, Fiscal Years 2019 through 2022, available at *https://www.fda.gov/media/102699/download*.

Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation Workshop at *https://www.fda.gov/science-research/advancing-regulatory-science/advancing-use-patient-preference-information-scientific-evidence-medical-product-evaluation*.

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09051 Filed 5–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9858, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm*. For further information about ULTOMIRIS (ravulizumab-cwvz) go to the ''Drugs@FDA'' website at *https://*

www.accessdata.fda.gov/scripts/cder/daf/.

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09005 Filed 5–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Developing an STD Federal Action Plan

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: To help inform the development of the Sexually Transmitted Diseases (STD) Federal Action Plan, HHS seeks input from stakeholders on what strategies can be implemented by federal agencies to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STDs.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 5:00 p.m. ET on June 3, 2019.

ADDRESSES: Electronic responses are strongly preferred and may be addressed to *STDPlan@hhs.gov.* Written responses should be addressed to: U.S. Department of Health and Human Services, 330 C Street SW, Room L001, Washington, DC 20024; Attention STD RFI.

FOR FURTHER INFORMATION CONTACT: Melissa Habel, MPH in the HHS Office of HIV/AIDS and Infectious Disease Policy, (202) 795–7697.

SUPPLEMENTARY INFORMATION: Rates of sexually transmitted diseases (STDs) in 2017 reached an all-time high among males and females and all racial and ethnic groups. Since 2013, reported chlamydia rates have increased 22%, gonorrhea rates 67%, syphilis rates 76%, and congenital syphilis rates 154%; the combined number of cases was 2.3 million up from 1.8 million in 2013.[1] These infections can lead to long-term health consequences such as infertility and can facilitate HIV transmission. While gonorrhea, chlamydia and syphilis infections have grown considerably over the past four years, human papillomavirus (HPV) remains the most commonly sexually transmitted infection in the U.S., affecting close to half of adults of reproductive age. HPV infections result in approximately 33,700 cases of certain types of cancer each year in the U.S.[2] Most of these cancers are preventable through the use of the HPV vaccination series. These numbers represent real people and expose hidden fragile populations who are not getting the preventive services and health care they need. While STDs affect all groups of the U.S. population, they disproportionately affect certain vulnerable groups such as pregnant women, youth ages 15–24 years, men who have sex with men, and racial and ethnic minorities. Beyond the impact on an individual's health, in 2013 it was estimated that STDs cost the U.S. health care system more than $16 billion annually, and STDs have increased dramatically since then.[3]

To respond and address the STD public health epidemic, OHAIDP in collaboration with other federal partners is leading and coordinating development of a STD Federal Action Plan. The development process for the action plan will seek input from subject matter experts, nonfederal partners and stakeholders including health care providers and systems, state, tribal, and local health departments, community-based and faith-based organizations, national professional organizations, researchers, advocates, and persons whose lives have been affected by these infections. The action plan is expected to address prevention, diagnosis, care and treatment, as well as coordination of efforts, policies, and programs throughout the federal government. It will also address stigma, discrimination, co-infections (*e.g.,* HIV and viral hepatitis), and social determinants of health.

This request for information seeks public input on how the federal government should address the rising rates of STDs and what strategies can be implemented to improve the efficiency, effectiveness, coordination, accountability, and impact of the federal response to STD prevention, care and treatment policies, services and programs. The information received will inform the STD Federal Action Plan.

Topics of interest include but are not limited to the following:

1. How should the federal government address the rising rates of STDs?

2. What strategies can be implemented by federal agencies to improve the efficiency, effectiveness, coordination, accountability, and impact of our national response to increasing rates of STDs for all priority populations?

3. What are the barriers to people getting the quality STD health services they deserve? What strategies can be implemented by federal agencies to overcome these barriers?

4. How can federal agencies influence, design and implement STD-related policies, services and programs in innovative and culturally-responsive ways for priority populations?

5. How can the federal government help to reduce STD-associated stigma and discrimination?

Dated: April 11, 2019.

Tammy R. Beckham,

Director, Office of HIV/AIDS and Infectious Disease Policy.

Footnotes

1. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2017. Atlanta: U.S: Department of Health and Human Services, 2018: Available at *https://www.cdc.gov/std/stats.*
2. Eng TR, Butler WT, editors; Institute of Medicine (US). Summary: The hidden epidemic: Confronting sexually transmitted diseases. Washington (DC): National Academy Press; 1997. p. 43.
3. Owusu-Edusei K Jr, Chesson HW, Gift TL, et al. The estimated direct medical cost of selected sexually transmitted infections in the United States, 2008. Sex Transm Dis 2013; 40(3):197–201. DOI:10.1097/OLQ.0b013e318285c6d2.

[FR Doc. 2019–09113 Filed 5–2–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1901–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—January Through March 2019

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from January through March 2019. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jason Green, by telephone at (571) 777–2723, or by email at *jason.green@hhs.gov.*