HHS Inspector General to Review FDA Accelerated Approval Pathway

The Office of Inspector General (OIG) of the U.S. Health and Human Services announced on August 4 that it would launch a review process of the recent U.S. Food and Drug Administration (FDA) approval of Aduhelm (aducanumab) to treat patients with Alzheimer disease under the accelerated approval pathway. The pathway allows the FDA to approve drugs that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint. According to an OIG press release, this approval "raised concerns due to alleged scientific disputes within the FDA, the advisory committee's vote against approval, allegations of an inappropriately close relationship between the FDA and the industry, and the FDA's use of the accelerated approval pathway." In the review, the OIG will assess how the FDA implements the accelerated approval pathway and manages interactions with outside parties, as well as other aspects of the process, such as deciding how scientific disputes are resolved. FDA's relevant policies and procedures, along with compliance, will be included in the review, based on a sample of drugs approved using the accelerated pathway. The OIG will not assess the scientific appropriateness of the FDA approval of any drugs under review. This work may result in multiple reports, expected to be issued in 2023.

Office of Inspector General
U.S. Health and Human Services

FIND Bills in House and Senate

On July 16, Congresspersons Scott Peters (D-CA), Bobby Rush (D-IL), Neal Dunn (R-FL), and Greg Murphy (R-NC) introduced the Facilitating Innovative Nuclear Diagnostics (FIND) Act of 2021 (HR 4479), intended to significantly expand patient access to advanced nuclear diagnostic imaging technologies. The bill (previously HR 3772) targets creation of a legislative fix to the Center for Medicare and Medicaid Services (CMS) bundling of diagnostic radiopharmaceuticals in the hospital outpatient space after a 3-year pass-through period postapproval by the U.S. Food and Drug Administration.

SNMMI and its coalition partners, the Medical Imaging & Technology Alliance and the Council on Radionuclides and Radiopharmaceuticals, in addition to dozens of patient advocacy organizations, praised the proposed legislation. "Innovative radiopharmaceuticals are revolutionizing the diagnosis and treatment of a wide variety of diseases, but under current CMS payment policies, these remarkable agents often are not available to Medicare beneficiaries, resulting in inequities in health care. The FIND Act addresses this current important problem and will improve access to these life-saving imaging agents," said Richard Wahl, MD, president of SNMMI.

"America leads the world in medical research and innovation—but far too often, patients are unable to access the benefits of innovative medical technologies because of outdated Medicare reimbursement policy," added Representative Dunn at the act's introduction. "The FIND Act is a common-sense, bipartisan proposal to address these current reimbursement problems, giving patients access to the diagnostic tools they need, when they need them. Early detection saves lives and we must do what we can to expand access to these life-saving tools."

On August 4, Senators Marsha Blackburn (R-TN) and Tammy Baldwin (D-WI) introduced a companion bill in the U.S. Senate (S. 2609). "Innovative technology like diagnostic radiopharmaceuticals are important tools in detecting and treating diseases such as cancer and Alzheimer's," said Senator Blackburn. "The FIND Act would increase patient access to more cost-effective treatment options while promoting further research and development opportunities for medical manufacturers."

The FIND Act addresses structural issues in the packaging methodology used in the Medicare outpatient setting by directing the Department of Health and Human Services to pay separately for all diagnostic radiopharmaceuticals with a cost threshold per day of $500. If passed, this bill would give patients greater access to a wide range of diagnostic radiopharmaceuticals that can better detect conditions such as heart disease, Alzheimer and Parkinson disease, breast and prostate cancer, and neuroendocrine tumors. This legislation would also help providers better manage costs while delivering more targeted and cost-efficient care.

For more information on the FIND Act, including avenues for advocacy, please see: https://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=34002&navItemNumber=34003.

SNMMI

New NIA Alzheimer Trial Recruitment Tool

The National Institute on Aging (NIA) announced on July 30 at the annual meeting of the Alzheimer's Association International Conference a new online research tool to help increase participation by traditionally underrepresented populations in clinical trials focusing on Alzheimer disease (AD) and related dementias. Called Outreach Pro, the tool will enable researchers to create and customize participant recruitment communications, such as websites, handouts, videos, and social media posts.

"We are facing a critical and growing need for people living with Alzheimer's and related dementia, as well as those at higher risk, and healthy people, to participate in clinical trials," said NIA Director Richard J. Hodes, MD. "That need is especially acute for frequently underrepresented groups such as Black and Hispanic Americans, which is why Outreach Pro includes an emphasis on helping clinical trial

researchers connect with these and other important communities."

Outreach Pro is one of a suite of NIA efforts to implement the National Strategy for Recruitment and Participation in Alzheimer's and Related Dementias Clinical Research (2018). To use Outreach Pro, researchers and clinicians first select desired templates with 1 of 3 communication goals: (1) to educate about AD, related dementias, and/or brain health; (2) to increase awareness and interest in AD and related dementias clinical trials; or (3) to provide information about a specific AD or related dementia clinical trial currently enrolling participants. Each template can be customized using a central library of messages, headlines, photos, and text that have been tested in individuals representing diverse and underserved populations. The materials will be available initially in English and Spanish, with plans for adding Asian American and Pacific Islander resources and languages later in 2021. Materials for American Indian and Alaska Native communities will be developed and added in 2022. NIA developed Outreach Pro and its content systematically by using literature reviews, environmental scans, listening sessions with stakeholders, focus groups, national surveys, and user testing. NIA plans to add content and scale up the tool's capabilities based on feedback and performance measurement.

In total, NIA is currently supporting 270 AD and related dementia clinical trials. Additional information on Outreach Pro is available at: https://outreachpro.nia.nih.gov/.

National Institute on Aging

NIH Expands Biomedical Research in the Cloud

The National Institutes of Health (NIH) announced on July 10 that Microsoft Azure had joined the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative as the newest cloud service provider to support biomedical research. Google Cloud and Amazon Web Services joined the initiative in 2018. The STRIDES Initiative aims to accelerate biomedical research in the cloud by reducing economic and process barriers as well as providing cost-effective access to cloud platforms, training, cloud experts, and best practices for optimizing research.

The initiative has already expanded access to critical infrastructure and cutting-edge cloud resources for NIH researchers, as well as NIH-funded investigators at more than 2,500 academic institutions across the United States. To date, NIH has helped more than 425 research programs and projects leverage cloud resources through the STRIDES initiative. Researchers have collectively used more than 83 million h of computational resources to access and analyze more than 115 petabytes of high-value biomedical data in the cloud. By leveraging the initiative, the National Library of Medicine's Sequence Read Archive (among the world's largest publicly available genome sequence repositories) migrated more than 43 petabytes of next-generation sequencing data to the cloud, easing access for millions of researchers. Researchers can now search the entire catalog of genomic data and take advantage of the computational tools for analysis.

A central tenet of the STRIDES Initiative is that data made available through these partnerships will incorporate standards endorsed by the biomedical research community to make data findable, accessible, interoperable, and reusable (FAIR). "NIH has an ambitious vision of a modernized, FAIR biomedical data landscape," said Susan K. Gregurick, PhD, associate director for Data Science and director of the Office of Data Science Strategy at NIH. "By partnering with Microsoft Azure, which has over 3 decades of experience in the cloud space, we can strengthen NIH's data ecosystem and accelerate data-driven research and discovery." Additional information is available at: https://datascience.nih.gov/strides/.

National Institutes of Health

Medical Imaging Radiation Limits

On August 11 the American Association of Physicists in Medicine (AAPM), the American College of Radiology, and the Health Physics Society issued a joint statement in opposition to cumulative radiation dose limits for patient imaging, citing potential adverse effects on patient care. The statement comes in response to an opposing position by several organizations and recently published papers on the high-profile topic. According to the statement "the decision to perform a medical imaging exam should be based on clinical grounds, including the information available from prior imaging results, and not on the dose from prior imaging-related radiation exposures." In a related press release, AAPM stated its recommendation "against using dose values, including effective dose, from a patient's prior imaging exams for the purposes of medical decision-making. Using quantities such as cumulative effective dose may, unintentionally or by institutional or regulatory policy, negatively impact medical decisions and patient care." In addition, the position statement applied to "the use of metrics to longitudinally track a patient's dose from medical radiation exposures and infer potential stochastic risk from them." It does not apply to the use of organ-specific doses for purposes of evaluating the onset of deterministic effects (e.g., absorbed dose to the eye lens or skin) or performing epidemiologic research. The joint statement, a list of answers to frequently asked questions on the topic of medical radiation safety, and a list of references to research papers supporting the signatories' position is available at: https://www.aapm.org/org/policies/details.asp?id=1533.

American Association of Physicists in Medicine

FDA and Collaborative Communities

The U.S. Food and Drug Administration (FDA) announced on August 4 participation in several new "collaborative communities" designed to address challenges in patient health care. Collaborative communities are continuing forums in which private and public sector representatives work together on medical device challenges to achieve common objectives and outcomes. "We're pleased to announce the progress we've made with participation in collaborative communities. These collaborations with diverse stakeholders are not only a strategic priority for the FDA's Center for Devices and Radiological Health, they also provide much needed forums for deep discussion and solution-driven initiatives to tackle important issues within the medical device ecosystem," said Jeff Shuren, MD, JD, director of the Center for Devices and Radiological Health. "The insights and outcomes developed by these groups will have long-standing impacts on public health."

The FDA currently participates in 12 collaborative communities, which are established, managed, and controlled by external stakeholders. These communities are collectively charting paths to accelerate and address regulatory science and other knowledge gaps to aid in medical device review and oversight. They may also impact the delivery of health care and change clinical care paradigms. The most recent collaborations focus on topics such as: medical device development and product quality; understanding of valvular heart disease; innovations in digital pathology; reducing rates of intended self-injury and suicidal acts by individuals with diabetes; and strategies to increase the awareness, understanding, and participation of racial and ethnic minorities in the medical technology industry.

Collaborative communities are convened by interested stakeholders and may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. The FDA does not establish, lead, or operate the communities, nor are they intended to advise the FDA. Instead, the FDA may participate in the community to contribute its knowledge and perspective to discussions of public health challenges and solutions. For more about the FDA and collaborative communities, see: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together.

U.S. Food and Drug Administration

Breast Cancer Risk in Health Professionals

In a study published on August 9 ahead of print in the *American Journal of Preventive Medicine*, Shen et al. from the Kaohsiung Municipal Ta-Tung Hospital, Kaohsiung Medical University Chung-Ho Memorial Hospital, and Kaohsiung Medical University (Kaohsiung City, Taiwan) and the Ministry of Labor (Taipei, Taiwan) reported on a 35-year longitudinal study of breast cancer risk among health professionals. The study included data from 4 country-wide population-based databases in Taiwan, including matched cohorts of 277,543 health professionals and 555,086 non–health professionals. The researchers found that health professionals had a significantly higher risk of breast cancer and that this elevated risk was associated with birth age, job tenure, rotating day/night work, and several specific health professional license types, including physician, pharmacist, registered nurse, midwife, medical technologist, and psychologist. The authors suggested that regular ultrasound for younger women health care professionals and mammography for those older than 45 y should be considered.

American Journal of Preventive Medicine