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On behalf of the American Medical Student Association (AMSA), we are pleased to offer the following comments. AMSA is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training. AMSA members rely on publicly funded research during their training as students and later as practicing physicians. Ensuring medical educators and trainees have unfettered access to the most cutting edge research will produce a health professions workforce better prepared to serve our nation's health care needs and compete in the global economy. On behalf of more than 32, 000 members across the country, AMSA supports open access to publicly funded research.

[Question 1]

Are there steps that agencies could take to grow existing and new markets related to the access and analysis of peer-reviewed publications that result from federally funded scientific research? How can policies for archiving publications and making them publically accessible be used to grow the economy and improve the productivity of the scientific enterprise? What are the relative costs and benefits of such policies? What type of access to these publications is required to maximize U.S. economic growth and improve the productivity of the American scientific enterprise?

[Comment 1]

All publicly funded research should be made unconditionally and immediately available for public use and reuse. In contrast to current policy, "open access" refers to the free, immediate, unrestricted availability of high-quality, peer-reviewed scholarship over the internet, combined with the rights to use this information to its fullest possible extent as long as proper attribution to the original article is maintained. Such open access is critical to ensuring the quality of health professional education. Open access allows the most cutting edge research findings to be integrated into medical education to ultimately better prepare future physicians for evidence-based practice, extend standards of care across the board to all medical centers and have baseline therapies to improve upon.

Open access also has economic benefits. Empowering American health professions students with access to the latest research will improve students' ability to compete in the global marketplace and boost US biotechnology competitiveness. Investing in the knowledge and education of today's students will ensure that resources are truly invested in advancements and improvements

on known phenomena and efficient discussions of this knowledge to be exchanged across multidisciplinary groups.

Strong public access policies help level the playing field for students. Open access means American students across institutions will be better prepared to contribute when it's time to put their education to use in the private or public sector. For medical students, this entails providing patient care as a resident and, eventually, attending physician. Having unrestricted access to the most up-to-date clinical trials and evidence-based practices is essential to providing high quality care. For physicians and trainees practicing in rural and underserved communities in the United States and abroad, such access is not readily available as clinics and hospitals are not able to afford expensive journal subscriptions.

[Question 2]

What specific steps can be taken to protect the intellectual property interests of publishers, scientists, Federal agencies, and other stakeholders involved with the publication and dissemination of peer-reviewed scholarly publications resulting from federally funded scientific research? Conversely, are there policies that should not be adopted with respect to public access to peer-reviewed scholarly publications so as not to undermine any intellectual property rights of publishers, scientists, Federal agencies, and other stakeholders?

[Comment 2]

Open access policies are compatible with the existing intellectual property legal framework to protect interests of publishers, scientists, federal agencies and other stakeholders. While NIH policy currently provides for "fair use," broader access to this information is necessary to realize scientific and commercial benefits. Appropriate licenses - such as Creative Commons CC-BY licenses - would support access sooner than current term of copyright permits.

[Question 3]

What are the pros and cons of centralized and decentralized approaches to managing public access to peer-reviewed scholarly publications that result from federally funded research in terms of interoperability, search, development of analytic tools, and other scientific and commercial opportunities? Are there reasons why a Federal agency (or agencies) should maintain custody of all published content, and are there ways that the government can ensure long-term stewardship if content is distributed across multiple private sources?

[Comment 3]

A majority of practicing clinicians and medical students utilize peer-reviewed evidence to guide clinical decision-making on a daily basis. Federal agencies are the most appropriate stewards of centralized repositories for the publicly funded scholarly literature that informs clinical practice. For example, Pubmed Central (PMC), among the most widely used online tools, is the free digital archive of biomedical sciences journal literature at the NIH National Library of Medicine and the designated repository for papers submitted in accordance with the NIH Public Access Policy. While critical to the ability of physicians and students to locate vetted evidence for patient care, this policy still delays access to research by a year and does not include other federal funding agencies such as the Centers for Disease Control or the non-medical research arms of the federal government.

Nonetheless, PMC sees roughly 500,000 unique users each day and is an invaluable resource for medical students, physicians and researchers. PMC is designed to store and cross-reference diverse data sources using a common format enabling efficient searches for full-text articles throughout the entire database to quickly locate pertinent information. PMC also allows integration of its database with other information resources and collaboration with international agencies that share similar goals—namely, free and immediate online access to digital biomedical literature to expand knowledge, innovation and evidence-based clinical care among practitioners and researchers. Having access to a non-biased, non-commercial repository of up-to-date scientific information enables medical students, physicians and researchers to be sure that they are practicing and innovating at the forefront of our collective knowledge.

[Question 8]

What is the appropriate embargo period after publication before the public is granted free access to the full content of peer-reviewed scholarly publications resulting from federally funded research? Please describe the empirical basis for the recommended embargo period. Analyses that weigh public and private benefits and account for external market factors, such as competition, price changes, library budgets, and other factors, will be particularly useful. Are there evidence-based arguments that can be made that the delay period should be different for specific disciplines or types of publications?

[Comment 8]

Due to the rapid pace of medical discovery and therapeutic and technological advancements, it is critical that educational materials reflect the most up-to-date information possible. Physicians-in-training, like other professional students, should have immediate and unfettered access to peer-reviewed literature that results from taxpayer-funded research particularly in light of its implications for patient care and establishment of training and practice norms.

Coursework within problem-based learning and organ systems curricula typical of US medical training institutions is generally completed during one- to three-month-long sequences. An embargo period, therefore, necessarily excludes the latest information that could otherwise be available to students. In the context of hands-on training in teaching clinics and hospitals, the stakes are notably higher. From stroke treatment and care to the management of sepsis, acute coronary syndrome or other health emergencies, many common diseases and conditions are under active research. Appropriate management requires immediate access to the most cutting edge research findings.

The National Institutes of Health as well as other funding agencies worldwide currently use an embargo period from 0-12 months. To date no publisher has provided evidence of financial loss as a result of this policy. An embargo in which a stop-date between 0-12 months is determined by the author has been shown effective across multiple disciplines and hundreds of journals. When considering an embargo period, it is important to weigh the real costs associated with a delay in access. An embargo forces students and clinicians to rely on outdated information, impedes exchange of best practices and follow-on research, diminishes the ability of students to self-educate, and threatens patients' right to receive proper clinical care and recommendations based on latest medical evidence.

