January 21, 2010

Diane C. DiEuliis, PhD
Assistant Director, Life Sciences
Office of Science and Technology Policy
Attn: Open Government
725 Seventeenth Street, NW
Washington, DC 20502

Dear Diane:

The American Society for Investigative Pathology (ASIP) publishes *The American Journal of Pathology* (AJP) and co-publishes *The Journal of Molecular Diagnostics* (JMD) with the Association for Molecular Pathology (AMP). AJP has been published for over 100 years and was commercially managed until 1992, at which point ASIP assumed the role of self-publisher. JMD was founded in 1998 as a self-published journal, which was a joint venture between ASIP and AMP. We have the experience of successfully managing both journals during revolutionary change, including the commercialization of the internet, web-based journal distribution, online Continuing Medical Education associated with the journals, electronically managed peer review, digital file-based production workflows, programming language changes from SGML and HTML to the NLM-DTD, and user-driven features and functionality only possible through the development of electronic tools and internet accessibility.

As a small biomedical society, ASIP faced significant challenges to continue self-publishing two high-profile pathology journals through this turbulent period. We have 6 staff members working full-time for the journals to manage peer-review and production, and 5 executive staff members contributing a combined total of 2.3 FTEs to manage the day-to-day business and strategic planning for the journals' access and visibility, content and user value, and financial viability. AJP has been the #1 or #2 journal in Pathology (according to ISI rankings) for all of the years ASIP has self-published it. JMD has climbed steadily up the ISI rankings since 2000 and is now #14 in Pathology among 69 journals. We believe our journals are run efficiently and effectively and their institutional pricing is reasonable. In fact, for the past three years, the journal prices have not been raised, in part to rule out price as a factor in analyzing subscription renewals. Yet subscription renewals declined precipitously in recent years; a period of time coincident with the free access embargo policy of AJP being reduced from 12 months to 6 months. As a consequence, ASIP moved its free access embargo on AJP from 6 months to 12 months in 2009 (the embargo for JMD was and remains 12 months), on both the official journal site on HighWire Press and on the PubMed Central archive.

ASIP shares the concerns and recommendations expressed by our peers in their comments submitted to OSTP. Specifically, we approve of the comments provided to you by the Association of American Publishers, the D.C. Principles Coalition for Free Access to Science, the Association of Learned and Scholarly Society Publishers, and the Federation of American Societies for Experimental Biology. We urge OSTP to fully consider the detailed explanations of important factors thoughtfully outlined by AAP, the Coalition, ALPSP and FASEB in response to OSTP's request for comments.

In reading the nine sets of questions asked by OSTP, ASIP leadership observed that every question assumed a bias toward making peer-reviewed full-text articles open sooner and to worldwide audiences, without what we feel is due consideration for whether that meets the objective of 'maximizing the return on Federal investments made in R & D.' ASIP fully supports this objective, but

believes the Federal government is taking a narrow and short-sighted approach to maximizing their return by focusing squarely on free access to peer-reviewed scholarly publications to a degree that publishers of all types have cautioned will upset the business balance of scholarly publishing now and forever.

As stated in the introduction to the RFI, 'the Administration is exploring ways to leverage Federal investments to increase access to information that promises to stimulate scientific and technological innovation and competitiveness.' In the series of questions asked by OSTP, we find no connection that will produce evidence of how worldwide access to full-text articles generated by publishers will help the U.S. achieve greater competitiveness and innovation – the fundamental goal of the Administration. The Federal government would be hard-pressed to show how subscription-based access to peer-reviewed scientific literature has truly restricted innovation or how making articles based on NIH-funded research free worldwide helps the U.S. achieve greater competitiveness and innovation. Currently, 56% of published articles in our journals come from U.S. authors and 70% of our readership is from outside the U.S. This data indicates the U.S. carries a higher relative burden of research funding that benefits the rest of the world. Finally, with generous voluntary changes in access policies by almost every publisher (commercial or society) over the past 10 years, patients and patients' families are getting access to the subscription-based peer-reviewed scientific literature they need. ASIP, along with many publishers, provides special free access of full-text to any patient (or family member) who requires materials for their personal educational use. If OSTP remains concerned about this issue, perhaps patient access exceptions should be dealt with separately, instead of under sweeping regulation with many other consequences.

As this Administration attempts to sincerely address fundamental and pressing concerns, ASIP asks the question we think OSTP needs to answer - what scientific content has the most merit for reaching the goals of innovation and competitiveness and are there technical ways to access that content without upsetting the balance of scholarly publishing? Pathology stands at the crossroads of basic research and clinical translation and we read with great interest a recent article by Daniel Castro of the Information Technology and Innovation Foundation, entitled *The Role of Information Technology in Medical Research* (http://itif.org/files/2009-it-medical-research.pdf). In his article, Mr. Castro defines the key elements of biomedical advances as data sources, such as GenBank and caBIG, and data search tools, such as BLAST and Entrez (at NCBI). Mr. Castro rightly refers to the usefulness of publications as merely derivatives of the data. The author describes in some detail the substantial and growing investment in database and search tool development across NIH institutes. Specifically, he notes that NCBI was established by Congress in 1988 to create a national repository for molecular biology information and supports its mission by *developing the information systems and software applications needed to store and analyze molecular biology and genetic information*. **ASIP believes NCBI's greatest contributions to this Administration's goals of innovation and competitiveness would be made by maintaining their focus and funding on these core activities; not on redundant publication and archiving of full-text articles.**

Among many conclusions, Mr. Castro makes the following (quoted) points:

- The *United Kingdom* is uniquely positioned to benefit from advancements in health informatics research because it is significantly ahead of the *United States* in its transition to electronic health records among primary care providers.
- The United States currently lacks the capacity being developed by the NHS (in the UK) to turn its existing or future electronic health records into a usable database for medical research.

- To address this deficiency, future efforts in the United States to speed adoption of electronic health records systems should include functional requirements to allow the secondary use of medical data for research.
- Continued funding is necessary to develop the technical infrastructure and data standards needed to improve data sharing between existing systems.
- The goal should be to develop a national data-sharing infrastructure to support health informatics research, rather than to create isolated, project-specific research databases.
- Many current or proposed projects focus on adding an additional layer of reporting requirements to health care providers to gain access to important patient data rather than simply making all patient data accessible for research.
- A mechanism is needed to allow relevant medical data to be shared for authorized medical research in a timely and efficient manner.
- Safeguards must be in place to protect patient privacy, but these individual protections must be balanced against the potential benefits from research.
- NIH has acknowledged that state and federal laws, including the HIPAA Privacy Rule, may interfere with data sharing.

These points should shock and stimulate a serious call to action by this Administration to focus its efforts in the right areas and not be distracted by policies that detract resources from these concerns. The issues that need urgent attention are not resolved by expanding policies that fund and enable Federal agencies to duplicate the publication of full-text peer-reviewed scientific literature that is already publicly available, if not free.

Finally, ASIP challenges 'free access' publishers, like the Public Library of Science, to prove the viability of their business models without outside grant sources or substantial membership revenues, which are unattainable for most professional societies. Conversely, ASIP would welcome OSTP's private, comprehensive review of our journal operations to more accurately gauge the effects of the NIH policy on a typical scholarly society. We would also welcome inclusion of our members in high-level discussions of how to transition more medical research into clinical success stories and commensurate innovation and competitiveness.

Sincerely yours,

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and
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