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The Impact of Government-Mandated Public Access to Biomedical Research: An Analysis of the New NIH Depository Requirements

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The Impact of Government-Mandated Public Access to Biomedical Research: *An Analysis of the New NIH Depository Requirements*

Kristopher Nelson¹

On December 26, 2007, President Bush signed the Consolidated Appropriations Act of 2008. The bill, which became Public Law 110-161, contained a new requirement that manuscripts developed through funding by the National Institutes of Health (NIH) be made available to the public, free of charge, within one year after publication. This new mandatory requirement struck a compromise position between the existing pay-to-access model of private journal publishers and the potential free-for-all of the public domain. But did it go far enough? Should Congress have adopted a more aggressive policy of opening access to research? Alternatively, did Congress go too far, and as a result have we crippled scientific publishing?

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Introduction

On December 26, 2007, President Bush signed the Consolidated Appropriations Act of 2008. The bill, which became Public Law 110-161, contained a new requirement that manuscripts developed through funding by the National Institutes of Health (NIH) be made available to the public, free of charge, within one year after publication. This new mandatory requirement struck a compromise position between the existing pay-to-access model of private journal publishers and the potential free-for-all of the public domain.² But did it go far enough? Should Congress have adopted a more aggressive policy of opening access to research? Alternatively, did Congress go too far, and as a result have we crippled scientific publishing?

In this article, I will examine four models of access: the more *traditional publishing* model, where access to scientific articles requires payment to a private publisher, and where the publisher typically owns the copyright and exercises close control over use; *public domain* access, where all information is freely accessible, freely reusable, and unprotected by copyright; the *open access* model, where articles are free to access immediately upon publication, and many copyright restrictions are lifted, but some still remain; and the *public access* model adopted by Congress and implemented by the National Institutes of Health, where access is granted free of charge after a year, but many copyright restrictions remain.

² An earlier bill introduced by Representative Martin Sabo (D-Minn) would have mandated that all research “substantially funded by the Federal Government” would immediately enter the public domain. See H.R. 2613, the Public Access to Science Act, available at <http://thomas.loc.gov/cgi-bin/query/z?c108:H.R.2613>:

Throughout my analysis, I will rely on an analytic structure used by others to examine scholarly publishing generally. This structure posits that “[s]cholarly publishing fills at least three purposes within a scholarly community: publicity, access and trustworthiness.”³ Publicity is the process by which a potential audience learns about a work, and includes, for example, advertising and citations by other scholars.⁴ Accessibility refers to the ways in which readers can access the work, and includes issues of subscription fees, long-term storage of manuscripts, and so on.⁵ Trustworthiness is connected to the quality of a work, and has to do with how much faith a reader can place in a work, even before reading the work itself.⁶ Nicholas Bramble writes that “a description of open access as a robust systemic reform to traditional subscription-based publishing (as opposed to an optional add-on feature that sits on top of an existing publishing regime) must account for all three of these functions.”⁷

However, while useful, this structure is grounded firmly in the traditional publishing model. To better understand some of the appeal of other approaches, we need a fourth factor, which I will term “reusability.” Reusability attempts to describe the limits placed on a work’s reuse, such as whether it is acceptable or not to photocopy an article

³ Mary Anne Kennan and Dubravka Cecez-Kecmanovic, *Reassembling scholarly publishing: Institutional repositories, open access, and the process of change*, 18th Australasian Conference on Information Systems, at 2 (2007). See also Nicholas Bramble, *Open Access: Problems of Collective Action and Promises of Civic Engagement*, 6-9 (2008); Michael J. Madison, *The Idea of the Law Review: Scholarship, Prestige, and Open Access*, 10 LEWIS & CLARK L. REV. 901 (2006) (manuscript at 3-4), available at http://works.bepress.com/michael_madison/5; Rob Kling & Geoffrey McKim, *Scholarly Communication and the Continuum of Electronic Publishing*, 50 J. AM. SOC’Y FOR INFO. SCI. 890 (1999).

⁴ Kennan, *supra* note 3, at 2.

⁵ *Id.*

⁶ *Id.*

⁷ Bramble, *supra* note 3, at 7.

and share it with colleagues, or to put an article you have published on your own Web site. Note that it is important to distinguish this element from the use of what is described within the article, which would bring us into the realm of, for example, patent law. Reusability instead refers to the use and reuse of the work itself, not the processes, methods, discoveries, concepts, or equipment described within it.

Building on these five factors (publicity, access, trustworthiness, and reusability), I will apply this structure to the four publishing models I described above: traditional publishing, the public domain, open access, and, finally, the public-access approach adopted by the NIH, which requires the deposit of manuscripts prepared through NIH funding in a centralized, free-of-charge repository. The goal of analyzing and comparing each of these approaches is to better understand the impact of Division G, Title II, Section 218 of Public Law 110-161 on science and scientific publishing.

BACKGROUND

Copyright, like any form of property right, is a *bundle* of rights. That is, individual rights may be split from the whole and be treated as distinct elements for the purposes of selling, buying, or licensing the property. In terms of copyright, these rights generally involve restricting or controlling publication or distribution, performance, and display. In the terms of my analysis, much of the control granted by copyright is thus over the reusability of the work itself, as opposed to what is described therein.⁸

⁸ What is described in a copyrighted work is not typically protected by copyright, although it may have protection through other forms of intellectual property law, such as patents. For more on intellectual property in general, see Robert Merges, et. al., *Intellectual Property in the New Technological Age* (4th ed. 2007).

Historically, it was the printing press that drove the desire for copyright protection in Europe for the first time.⁹ Once printing and reprinting became mechanized, printers began to want protection for their publishing efforts. Centers of printing became the early adopters of copyright protection. Thus, as a leading publishing center in the 16th Century, Venice enacted what might well have been the first copyright statute in 1517, broadened it in 1533, and then moved beyond printers to consider the rights of authors works as well as printers.¹⁰ In England, the source of our common-law legal system, various royal charters, Star Chamber decrees, and “privileges” existed as early as 1586, but statutory copyright as we know it today first emerged with the passage of the Statute of Anne in 1710.¹¹ It granted authors and publishers a limited exclusive right to works they wrote or published.¹²

In the United States, the early framers of our government enshrined the granting of exclusive rights to intellectual property in the Constitution in 1776, giving Congress the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”¹³

Building on this early foundation, we in the United States continue to conceive of copyrights and patents as a *quid pro quo* where exclusive rights for a limited time are granted in return for public benefits. Intellectual property is a “tool that provides neces-

⁹ Craig Dallon, *The Problem with Congress and Copyright Law: Forgetting the Past and Ignoring the Public Interest*, 44 SANTA CLARA L. REV. 367 (2004).

¹⁰ *Id.* at 386-87.

¹¹ *Id.* at 398.

¹² *Id.* at 408-09.

¹³ U.S. CONST. art. I, § 8, cl. 8.

sary incentives to creators and innovators” in order to “encourage the production of new scholarship and inventions,” a view reflected in numerous judicial opinions.¹⁴ Despite some resistance from our trading and treaty partners,¹⁵ the current conception in the U.S. is one of property rights and monetary incentives for copyright and patent holders: the typical belief expressed in our negotiations is that “broader, longer and stronger protection of intellectual property rights provides the right incentives for continuous innovation.”¹⁶

This *quid-pro-quo* balance between the public, who funds research through taxes, and publishers, who benefit by selling access to the fruits of the public’s investment, is one that Congress decided needed adjusting.¹⁷ A growing bipartisan belief in and out of Congress was that the original funders of research—the public—ought be entitled more directly to the results of that research.¹⁸ In essence, the thought went, if the public funded it, the public ought to have access to it.

¹⁴ David Opderbeck, *A Virtue-Centered Approach to the Biotechnology Commons (Or, the Virtuous Penguin)*, 59 Me. L. Rev. 317-20 (2007).

¹⁵ Examine, for example, the “moral rights” requirements of integrity and attribution of the Bern Convention. World Intellectual Property Organization, Summary of the Berne Convention for the Protection of Literary and Artistic Works (1886), http://www.wipo.int/treaties/en/ip/berne/summary_berne.html (last visited June 4, 2008) (“The Convention also provides for ‘moral rights,’ that is, the right to claim authorship of the work and the right to object to any mutilation or deformation or other modification of, or other derogatory action in relation to, the work which would be prejudicial to the author’s honor or reputation.”).

¹⁶ Armbruster, *supra* note 22, at 6.

¹⁷ For additional information on the legislative history of Public Law 110-161, see Bramble, *supra* note 3, at 30-33.

¹⁸ See Bramble, *supra* note 3, at 31-32. See also The Alliance for Taxpayer Access, An Open Letter to the U.S. Congress Signed by 26 Nobel Prize Winners, <http://www.taxpayeraccess.org/bof.html> (last visited June 4, 2008).

In an attempt to achieve this, Public Law 101-161 requires that all investigators funded by the National Institutes of Health must submit an electronic version of their final peer-reviewed manuscript to PubMed Central (PMC).¹⁹ PubMed Central will then make the work “publicly available no later than 12 months after the official date of publication.”²⁰ Previous policies provided for a voluntary depository mechanism, but were largely ineffective.²¹ Other funding organizations, such as the Howard Hughes Medical Institute and the Wellcome Trust, have also recently moved to require scientists to deposit electronic copies of manuscripts in publicly-accessible repositories.²²

These approaches to adjusting the balance have built on the prior work of the scientific open-access movement, which began to gain momentum in 1998 through the efforts of the Scholarly Publishing and Academic Resources Coalition (SPARC).²³ This led to the founding of the Public Library of Science (PLoS), and the eventual launch in 2003 of a group of open-access journals, primarily focused on medicine and biology.²⁴ Other

¹⁹ See PMC Overview, <http://www.pubmedcentral.nih.gov/about/intro.html> (last visited June 4, 2008) (“PubMed Central is a free digital archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health”).

²⁰ See Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research (NOT-OD-08-033) (2008), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html> (last visited June 4, 2008). See also Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008).

²¹ See Rick Weiss, Government Health Researchers Pressed to Share Data at No Charge, WASH. POST, Mar. 10, 2006, at A17, available at <http://www.washingtonpost.com/wp-dyn/content/article/2006/03/09/AR2006030901960.html> (“Less than 4 percent filled out the online form to make their results available for public viewing”).

²² Ted Agres, “Open access” opening wider, THE SCIENTIST, <http://www.the-scientist.com/news/display/53366/> (2007).

²³ David W. Opderbeck, *The Penguin’s Paradox: The Political Economy of International Intellectual Property and the Paradox of Open Intellectual Property Models*, 18 STAN. L. & POL’Y REV. 107-08 (2007)

²⁴ *Id.* at 108-09.

notable open-access efforts include ArXiv, the Social Science Research Network (SSRN), BioMed Central, and Berkeley Electronic Press.²⁵

Open-access approaches are informed by a broader international movement towards open-access scholarship generally, including the Budapest Open Access Initiative,²⁶ the Bethesda Statement on Open Access Publishing,²⁷ and the Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities.²⁸

THE TRADITIONAL PAY-FOR-ACCESS PUBLISHING MODEL

Before we go further into alternative approaches, we must first look at the traditional scientific publishing model. As I noted at the beginning, traditional scientific scholarly publishing serves at least three critical purposes within the scientific community: publicizing or marketing ideas, knowledge, research, and advances; providing access to those same ideas and research; and ensuring the quality and trustworthiness of ideas, knowledge and research.²⁹

The publishing process typically begins with a scientist submitting his or her manuscript to a publisher. The manuscript then undergoes peer review (that is, evaluation by other scientists), which is managed by the publisher using unpaid reviewers who

²⁵ Chris Armbruster, *Open Access in Social and Cultural Science: Innovative Moves to Enhance Access, Inclusion and Impact in Scholarly Communication*, 6 POLICY FUTURES IN EDUCATION 4 (2008) (forthcoming). Available at <http://ssrn.com/abstract=849305>.

²⁶ Budapest Open Access Initiative (Feb. 14, 2002), available at <http://www.soros.org/openaccess/read.shtml>.

²⁷ Bethesda Statement on Open Access Publishing (June 20, 2003), available at <http://www.earlham.edu/~peters/fos/bethesda.htm>.

²⁸ Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities (Oct. 22, 2003), available at <http://www.zim.mpg.de/openaccess-berlin/berlindeclaration.html>.

²⁹ Kennan, *supra* note 3, at 2.

are typically experts in the material. This process may generate new edits which are then incorporated back into the original manuscript. The end result of this is a final, peer-reviewed manuscript, which is then copyedited by the author and the publisher's editors.

Once approved and copyedited, articles are then published, today usually in both print and electronic form. They are then indexed and stored in various databases or repositories, either maintained by the publisher or by third-party services such as the Science Citation Index by Thomson. Readers, or the institutions they belong to (libraries, corporations, universities, and so on), then pay for access to the full text of the published work.

In the traditional model, publicity typically comes through subscription mailings, abstracting, advertising, indexing and citation.³⁰ Abstracting and indexing are key tools, as publisher's typically provide free abstracts and citation information as a means of increasing demand for the full-text article itself.³¹ It is in the best interest of journal publishers to publicize manuscripts in any way possible (short of providing the full text for free), since a greater desire for access means more customers and thus greater profit.

Traditional publishing earns mixed marks in the category of accessibility. In terms of stability of access over time, traditional journal publishers earn relatively high marks by allowing for consistent, long-term access to works. They accomplish this through archiving printed materials (which can also be archived by libraries) and maintaining their own databases and repositories. On the other hand, modern publishers often tend to hinder long-term electronic storage and access in that they typically refuse to

³⁰ *Id.*

³¹ *Id.*

allow anyone else to archive the electronic works they publish. This has the potential to create a situation where the entire record of a journal vanishes with a natural disaster or even the bankruptcy of a publisher. This is one of the concerns addressed by both open and public access.

The greatest limitation on accessibility created by traditional publishers, however, is that of price, and especially fast-rising costs that make it hard for subscribers to afford access to as many titles as they may wish. According to the American Library Association,

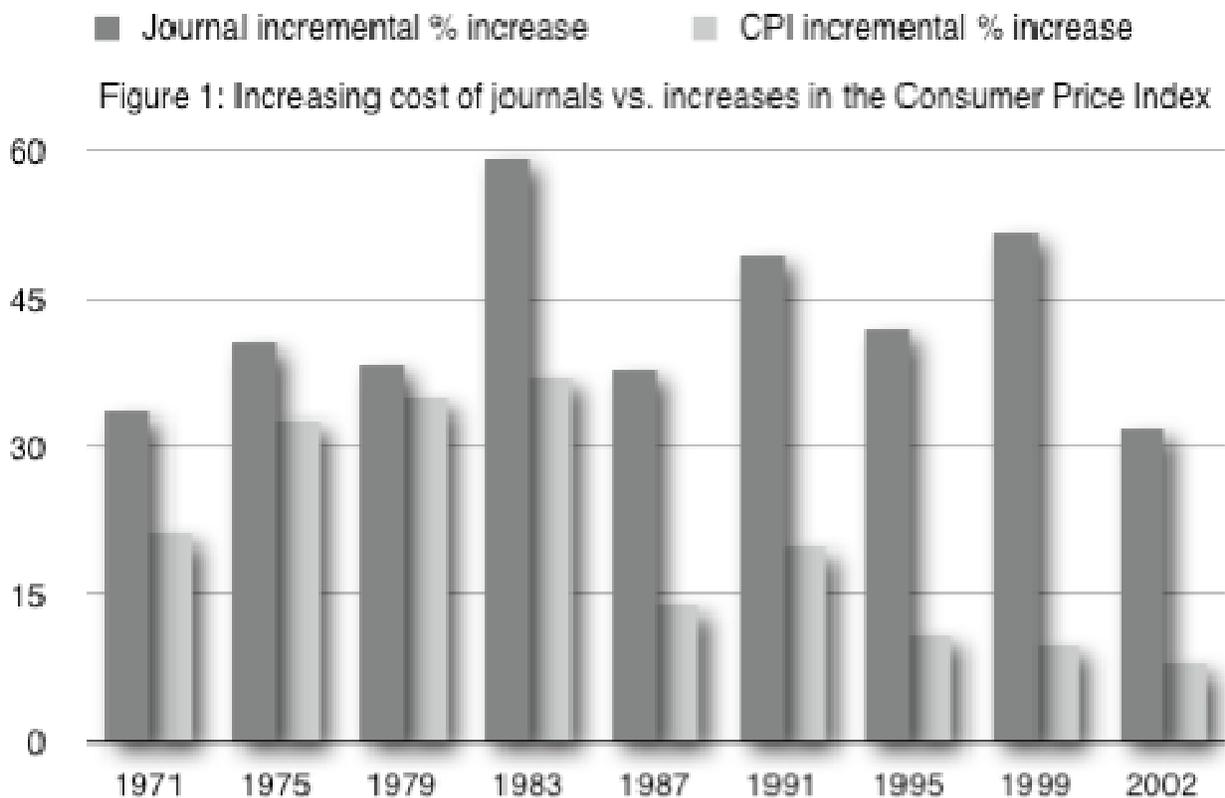
Worldwide journal prices continue to rise significantly faster than inflation and library budgets. In North America, for example, research libraries spent 227% more on journals in 2002 than in 1986. The Consumer Price Index rose 57% during this same period. In the United Kingdom, journal prices rose 158% between 1991 and 2001 compared to a 28% increase in inflation. The trends are very similar across higher education institution types. Journal inflation continues to increase at a rate of 6-12% annually. Purchasing a journal subscription can be described as a mortgage on a library's budget.³²

Figure 1 shows the widening disparity between increases in the general Consumer Price Index (CPI) and that of medical journal prices.³³

³² Economics of Scholarly Publishing, American Library Association, <http://www.ala.org/ala/acrl/acrlissues/scholarlycomm/scholarlycommunicationtoolkit/librarians/librarianeconomics.cfm> (last visited June 8, 2008).

³³ Joan Schlimgen & Michael Kronenfeld, *Update on inflation of journal prices: Brandon/Hill list journals and the scientific, technical, and medical publishing market*, 92 J MED LIBR ASSOC 307, 308-09 (2004). Available at <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=442172&blobtype=pdf>.

The reasons for rising prices are not straightforward, and include commercial publishers’ “relentless drive towards profits”; mergers of major publishers, resulting in



reduced market competition; and “bundling” of strong and weak titles into a single purchasing agreement.³⁴ The resulting high prices “create barriers to the wide distribution of scientific discovery, and those barriers in turn have serious consequences for the public interest.”³⁵ This is true both within the United States and, perhaps especially, in developing countries where scientists and doctors cannot afford access. The consequences in some cases of not “translating research from the laboratory into life-saving drugs, treatments, and diagnostic tests . . . may ultimately cost lives.”³⁶

³⁴ *Id.* at 310.

³⁵ *Id.* at 311.

³⁶ *Id.*

Trustworthiness and quality are traditionally achieved through editorial standards, a journal's reputation over time, and peer review by other, well-regarded and knowledgeable scientists and scholars who have carefully read and judged published manuscripts.³⁷ In the traditional model, scholars submit their articles to journals, where a professional editorial staff processes them and sends them out to other scientists for peer review. Unlike professional editorial staff, reviewers are experts in same field as the author of the article, but are unpaid for their reviewing duties. Typically peer reviewers provide comments, suggestions, and criticisms which are usually returned to the author of the article, who revises and resubmits the manuscript. Alternatively, editors may simply reject an author's submission based on the feedback of reviewers.

The result of this has been a market that favors publishers over both authors and readers. Scientists must author works both to advance their careers and to share their knowledge. On the flip side, they must read published journals in order to understand and benefit from their peers. The "publishers are in the enviable position of selling research which they neither produced nor paid for to a high-demand market."³⁸ The resulting "low elasticity of customer demand in this market enables them to function as monopolists in many fields."³⁹ This causes one key problem with traditional scientific publishing: limited accessibility due to cost.

One reason for this is that the original authors lack significant rights to their manuscripts once turned over to a publishing company, as most journals require au-

³⁷ Kennan, *supra* note 3, at 2. See also MC Drott, *Open Access*, 40 ANNUAL REVIEW OF INFORMATION SCIENCE AND TECHNOLOGY 79 (2006).

³⁸ Judith M. Panitch and Sarah Michalak, *The Serials Crisis (2005)*, available at <http://www.unc.edu/scholcomdig/whitepapers/panitch-michalak.html>

³⁹ Bramble, *supra* note 3, at 3.

thors to sign over ownership rights in order to be published. These exclusive rights enjoyed by publishers have allowed the new copyright owners to “rapidly and steeply raise subscription, license and pay-per-view prices.”⁴⁰ This makes good economic sense if you are a publisher. From the perspective of universities and other institutions, on the other hand, the traditional model does not make economic sense, as it requires them to pay out at many points in the process: “they pay the salaries and research costs of faculty members and associates, they pay the submissions fees and page charges levied by most subscription journals, and they pay increasingly high subscription fees to read what their own and other authors actually publish in these journals.”⁴¹

The traditional model of scientific publishing creates a significant tension between the goals of the publisher and the goals of researchers. Publishers “seek the greatest possible return on their investment” while scientists are much more concerned with achieving “the widest possible distribution and impact.”⁴² Submission contracts requiring scientists to sign over ownership rights to their articles put the power of determining accessibility in the hands of the publishers, and may frustrate scientists’ attempts to disseminate their own research.⁴³ Publishers seek to restrict dissemination and access in

⁴⁰ Samuel Trosow, *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?* (2003). Available at http://publish.uwo.ca/~strosow/Sabo_Bill_Paper.pdf.

⁴¹ Bramble, *supra* note 3, at 5.

⁴² Dan Hunter, *Walled Gardens*, 62 WASH. & LEE L. REV. 607, 614 (2005). *See also* Bramble, *supra*, at 5.

⁴³ I experienced this conflict first hand while working as an information technology staff member at a cancer research center. Our scientists would, at times, post copies of their own published articles on their own Web sites to facilitate access by other scientist and students. We often had to require them to remove *their own articles* because neither we nor they had permission from the copyright owner to publish them in this manner. This often baffled scientists, who, despite having signed the contracts relinquishing their ownership, still believed, in a common-sense way, that they still *owned* what they had invested so much time and energy in, and for which they had received no monetary compensation from the new owner.

order to maximize profits, while scientists wish to share their own research as widely as possible, and in return want broad and easy access to the research of others.

THE PUBLIC DOMAIN

Public domain dissemination stands in stark contrast to traditional publishing models.⁴⁴ Putting something in the public domain means relinquishing all rights to it, and allowing anyone to reuse, change, modify, republish, or even to sell it. In essence, the article now belongs to the public as a whole, not to any one individual. Putting something into the public domain may be voluntary or not, as the public domain is where works whose copyrights have expired live.⁴⁵

Because the work belongs to the public once it is in the public domain, it cannot be re-copyrighted again. This is one of the few restrictions on use. But derivative works based upon the original work can be copyrighted with no legal requirements of attribution, licensing, or remuneration, provided sufficiently new material is present.⁴⁶ Thus, in some sense, at least, works in the public domain have the potential to provide the greatest benefit to the public because they allow the public to make the greatest use of them.

In our analytic terms the reusability of public-domain works is at the extreme end of the scale, since the only restriction on reuse is that such materials cannot be re-copyrighted. In one sense, their accessibility could also be considered the maximum

⁴⁴ In many respects, of course, traditional publishing developed in reaction to what we now term the “public domain,” which was essentially the default status of any written work previously.

⁴⁵ For works published today, copyright is generally 70 year’s after the author’s death, or, for some works, 95 years from publication or 120 years from creation. Older works enjoyed shorter-term protection. *Copyright Office Basics*, Circular 1, United States Copyright Office, available at <http://www.copyright.gov/circs/circ1.html> (last visited June 9, 2008).

⁴⁶ See, e.g., *Copyright Registration for Derivative Works*, Circular 14, United States Copyright Office, available at <http://www.copyright.gov/circs/circ14.html> (last visited June 9, 2008).

possible on the accessibility scale. After all, works in the public domain are essentially free. However, partly because no one owns these works, anyone in the business of facilitating access is free to charge for the privilege of access. In other words, to borrow a colorful analogy from the open-source software movement, public domain works are “‘free’ as in ‘free speech,’ not as in ‘free beer.’”⁴⁷ Without an intermediary, works in the public domain may well simply fall from view entirely, and accessibility is thus tied to the intermediary facilitator and not to the work’s public domain status itself.⁴⁸

This is the downside to the freedoms of the public domain: without intervention, there is no compendium of works in the public domain and no consistent system for allowing access. Without an intermediary, there is also no publicity for such works, and no mechanism for quickly determining the trustworthiness of a work. Each individual work must be evaluated on its own merits, and must be sought out by the potential reader.

On the other hand, since items in the public domain belong to everyone, anyone can choose to build mechanisms for facilitating access to public-domain materials, and can even charge for that access. They can publicize this service, of course, and they can evaluate the works in various ways to increase a reader’s trust in them. Thus, although the public domain can be seen as the polar opposite of the traditional scientific publishing model, it is in many ways quite amenable to capitalist reuse by for-profit businesses (or to public-spirited reuse by non-profits). But since anyone can take the work and do

⁴⁷ GNU Project, The Free Software Definition, <http://www.gnu.org/philosophy/free-sw.html> (last visited March 31, 2008). See also Robin Feldman and Kristopher Nelson, *Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks*, NORTHWESTERN JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY 14 (2008) (forthcoming).

⁴⁸ In the legal context, compare, for example, access to statutes through Westlaw and LexisNexis (expensive, but effective at facilitating access to even obscure statutory information) with that provided by a general-purpose service like Google Search (free, but it may or may not provide access to exactly what you need in the way that you need it).

the same thing again, the incentive for business to increase accessibility, publicity, and trustworthiness for public domain materials is often lacking, making this approach a difficult sell as a broadly applicable solution to the current problems of scientific publishing.⁴⁹

THE NEW OPEN ACCESS MODEL

In the traditional model described above, scientists typically sign away most of the sticks in their bundle of rights in order to be published. “Open Access,” writes Chris Armbruster, “runs against a publishing model that turns the article into a commodity as scientists and scholars sign away the copyright. Publishers that become the ‘content owner’ may use exclusive copyright to levy subscription fees, site licenses and pay-per-view charges.”⁵⁰ “Moreover,” he continues, “the new content owner sells back their work to university libraries, colleagues and students at monopoly prices.”⁵¹

According to Peter Suber, a policy strategist for open access to scientific and scholarly research literature, true “open access” removes both “*price barriers* (subscriptions, licensing fees, pay-per-view fees) and *permission barriers* (most copyright and licensing restrictions).”⁵² It “means immediate, permanent, free online access to the full text of all refereed research journal articles (2.5 million articles a year, published in

⁴⁹ At least one scholar has argued that works generated from federally subsidized research should immediately enter the public domain. See Samuel Trosow, *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?* (2003). Available at http://publish.uwo.ca/~strosow/Sabo_Bill_Paper.pdf. See also Sabo Bill, *supra* note 2.

⁵⁰ Armbruster, *supra* note 25, at 4.

⁵¹ *Id.* at 6.

⁵² Peter Suber, Open Access Overview, <http://www.earlham.edu/~peters/fos/overview.htm> (Last visited June 19, 2007).

24,000 refereed journals, across all disciplines, languages and nations).⁵³ Importantly, “open access” is *not* the same as “public domain.” Instead, copyright owners give away some sticks in their bundle of property rights, while retaining overall ownership and control, in the hopes of a greater return on their investment than they would get by holding on to those rights or by selling them to a publisher. Open access as described above by Peter Suber is one of many possible compromise positions on the continuum between traditional scientific publishing and the public domain.

The vision of open access is often an idealistic one: “As Open Access becomes the standard academic publishing model a level and competitive field of innovation emerges for all kinds of new tools that will aid scholars in retrieving, evaluating and utilising publications and data.”⁵⁴ But despite this idealism, open access is intended to achieve realistic goals from the perspective of the scientist: increased dissemination of research, increased collaboration, and increased status for the author.⁵⁵

But how well does the open-access model fit what we posited as the four critical elements of scientific publishing (publicity, accessibility, trustworthiness, and reusability)? The short answer is that open access helps most with the second requirement (accessibility).⁵⁶ In addition, open access, in the form articulated by Peter Suber and im-

⁵³ Stevan Harnad, *The Implementation of the Berlin Declaration on Open Access, Report on the Berlin 3 Meeting Held 28 February - 1 March 2005, Southampton, UK*, 11 D-Lib Magazine 3 (2005). Available at <http://www.dlib.org/dlib/march05/harnad/03harnad.html>.

⁵⁴ Armbruster, *supra* note 25, at 19.

⁵⁵ Status in the scholarly world is not just about respect from one’s colleagues. It is absolutely essential to effectively securing funding for future research. In fact, it is critical for even securing a job at all.

⁵⁶ For another application of these three analytical factors to open access, see Bramble, *supra* note 3, at 6-10.

plemented by the Public Library of Science and BioMed Central, makes major changes in the area of reusability as well.

Instead of charging for access to published articles by readers, open-access journals typically require authors to pay an “article-processing charge” (expecting most scientists to pass those costs back on to their funding agency or institution).⁵⁷ In order to make this economically feasible, open-access journals publish exclusively online. This is the model followed by BioMed Central and the Public Library of Science.⁵⁸ Many provide discounted rates for certain classes of author, such as those from developing countries. This “author-pays” model is unheard of in traditional journal publishing, as many journals require that authors pay certain costs related to publishing their manuscript, such as costs for printing color images, and for “reprints” (copies of their own published article for their use).⁵⁹ In this manner, open-access tackles one of the key problems with traditional publishing: lack of access due to cost. In order to deal with the problem of long-term archiving of manuscripts, open-access journals maintain their own electronic archives, support and allow archiving by other repositories, and, finally, encourage self-archiving by authors.⁶⁰

Like traditional publishers, open-access journal publishers try to publicize manuscripts submitted to them. As they typically cannot afford to pay for advertising, and because they do not have subscribers in the same sense as traditional journals, open-

⁵⁷ Schlimgen, *supra* note 33, at 312.

⁵⁸ *Id.*

⁵⁹ *Id.* See also NIH, Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research (NOT-OD-05-022) (2005), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html> (last visited June 5, 2008). See also Bramble, *supra* note 3, at 3.

⁶⁰ Schlimgen, *supra* note 33, at 312.

access journals have had to find different means to publicize themselves and the manuscripts they publish. Like traditional publishers, open-access journals rely on citations by scientists, along with indexing and impact tracking by services such as Thomson's ISI Web of Knowledge (which includes the Science Citation Index, Journal Citation Reports, Biological Abstracts, and more).⁶¹ In addition, they have looked to newer methods to compute and share usage and citation statistics based on their own data in order to publicize manuscripts.⁶²

Once criticism of open access is that readers will have less trust in the articles because there will not be professional editors managing the peer review process, or, alternatively, that there will not be a peer review process at all.⁶³ But the Public Library of Science, for example, still conducts a robust review process, even though it is an open-access journal.⁶⁴ And as we will see later, the public-access policy adopted by the NIH simply "piggy backs" on the existing journal peer-review and publishing system.

⁶¹ *Id.*

⁶² *Id.*

⁶³ See, e.g., PRISM (Partnership for Research Integrity in Science and Medicine), Problems with Government Intervention: Threats to Peer Review, http://www.prismcoalition.org/problems_threats.htm (last visited June 4, 2008) ("Peer review involves the combined efforts of authors, editors, reviewers and publishers, and is financed entirely by publishers, who invest hundreds of millions of dollars in the process. Journals finance the peer review process through journal revenues. It is this business model that has been responsible for the development of the system of global scientific communication over hundreds of years, and it is this model that ensures its sustainability, integrity and independence.")

⁶⁴ See Public Library of Science, Frequently Asked Questions, <http://www.plos.org/about/faq.html> (last visited June 4, 2008). See also Bramble, *supra* note 3, at 18.

Peer review is generally considered essential in the field of medical publishing, whether the work is published through a traditional or an open-access journal.⁶⁵ Traditional publishers argue that they play a critical role in managing peer review process.⁶⁶ Even though they typically do not pay for peer review itself, publishers argue that managing the back-and-forth of peer review is a costly and time consuming, yet critically important, part of modern science. However, peer review is not limited to traditional publishing: the largest open-access publisher in the biomedical field, BioMed Central, maintains a high level of commitment to peer review.⁶⁷ Finally, it is important to remember that traditional peer review is not perfect, as even the most prestigious of the traditionally-managed journals have published results that later turned out to be fraudulent (*Nature*, the cloning fraud) and to have sparked a public health crisis (*The Lancet*, the MMR vaccine).⁶⁸

Open-access journals have a completely different relationship with article reuse than traditional publishers do. For example, the open-access charter of the Public Library of Science (PLOS) allows “all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work” and requires a “complete version of the work and all supplemental materials . . . [to be] de-

⁶⁵ But note that there are other methods for ensuring quality and trust that are different than, or supplemental to, traditional peer review. See, e.g., Bramble, *supra* note 3, at 18-19.

⁶⁶ See, e.g., Weiss, *supra* note 18. See also Bramble, *supra* note 3, at 18.

⁶⁷ See What is BioMed Central?, <http://www.biomedcentral.com/info/> (last visited June 4, 2008) (“BioMed Central is committed to maintaining high standards through full and stringent peer review”).

⁶⁸ See Chris Armbruster, *Cyberscience and the Knowledge-Based Economy. Open access and Trade Publishing: From Contradiction to Compatibility with Nonexclusive Copyright Licensing*, 12 INTERNATIONAL JOURNAL OF COMMUNICATIONS LAW AND POLICY 12 (2008).

posited immediately in a suitable standard electronic format.”⁶⁹ Under this approach, “authors retain ownership of the copyright for their article, but authors allow anyone to download, reuse, reprint, modify, distribute, and/or copy articles in PLoS journals, so long as the original authors and source are cited. No permission is required from the authors or the publishers.”⁷⁰ BioMed Central has a similar approach to article reuse.⁷¹

THE COMPROMISE OF PUBLIC ACCESS

Looking for a compromise position that would increase the accessibility of publicly-funded research while still protecting the traditional scientific publishing industry, the National Institutes of Health, as directed by Congress, has adopted a less-stringent “public access” standard that primarily addresses only price barriers (subscription fees, for example), not permission barriers (licensing restrictions and other aspects of copyright). From our analytical perspective, that means greater accessibility than traditional publishing, but no real change in terms of publicity, trustworthiness, or reusability. The law now reads:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version

⁶⁹ Public Library of Science, Definition of Open Access, <http://www.plos.org/oa/definition.html> (last visited June 4, 2008).

⁷⁰ Public Library of Science Medicine, Open-Access License, <http://journals.plos.org/plosmedicine/license.php> (last visited June 4, 2008).

⁷¹ See BioMed Central Copyright and License Agreement, <http://www.biomedcentral.com/info/about/license> (last visited June 8, 2008) (Anyone is free to copy, distribute, and display the work; to make derivative works; to make commercial use of the work. Attribution is a required condition: the original author must be given credit for any reuse or distribution, and it must be made clear to others what the license terms of this work are. Any of these conditions can be waived if the author gives permission.)

of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.⁷²

Unlike the open-access licensing used by the Public Library of Science, the NIH imposes no requirement that the author or copyright owner give up more of parts of their bundle of rights they enjoy in the copyright of the work deposited with PubMed Central, except that an NIH-funded author must reserve the right to deposit the article for viewing by the public in the NIH's centralized repository. With this limited reserved access, the public can read the full-text article, cite to it, and exercise general "fair use" exceptions to copyright,⁷³ but cannot, for example, print the article out and make photocopies of it for an entire class, as would be permissible under most open-access approaches. In other words, accessibility is improved as compared to traditional publishing, but reusability is unchanged.

To accomplish this "in a manner consistent with copyright law,"⁷⁴ the NIH asks authors to insert language such as the following into the contractual copyright agreements they sign with publishers: "Journal acknowledges that Author retains the right to provide a copy of the final manuscript to NIH upon acceptance for Journal publication

⁷² Public Law 110-161, <http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.2764.enr>: (last visited June 4, 2008). See also NIH Public Policy Details, <http://publicaccess.nih.gov/> (last visited June 4, 2008).

⁷³ For more on "fair use" and copyright, see, e.g., Lee Wilson, *Fair Use, Free Use, and Use by Permission: How to Handle Copyrights in All Media*, Allworth Press (2005).

⁷⁴ Public Law 110-161, <http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.2764.enr>: (last visited June 4, 2008).

or thereafter, for public archiving in PubMed Central as soon as possible after publication by Journal.”⁷⁵

The goal is to provide the public the ability to access federally-funded research after a reasonable period without expensive subscription fees and without fundamentally altering the economics of the publishing industry. Similar to the balancing of intellectual property rights in the Constitution itself, Congress is seeking: (1) to allow publishers to financially benefit from public investment, while encouraging them to keep investing in improved publishing methods; and (2) to lower the costs and barriers to access and, proponents argue, quicken the pace at which the public is allowed to directly benefit from federal research spending. So how well does the NIH’s public-access approach meet this goal in terms of our four analytical factors of scientific publishing (accessibility, publicity, trustworthiness, and reusability)?

The policy does achieve an increase in the accessibility of federally-funded scientific research, although only after significant time has passed. This compromise, intended to substantially protect the markets of traditional publishers, does exactly that. The largest, most important customers of scientific journals are the same people who author the manuscripts, and scientists need immediate access to the latest scientific advancements. Free access that comes many months later may prove useful in certain situations, but this does not provide a significant enough amount of access such that institutions that house researchers will be able to reduce their journal subscriptions. Nonetheless, this access will provide the general public, scientists researching across disciplines, and scientists and doctors in developing nations, useful access to resources

⁷⁵ NIH Public Policy Details, <http://publicaccess.nih.gov/> (last visited June 4, 2008).

they would otherwise in many cases be unable to read otherwise. So, while it is a compromise that fails to address the budget needs of medical libraries, for example, it will increase access by overall. In addition, by archiving works in a centralized repository it will reduce the likelihood of future loss of access to major portions of a journal's archives.

Since nothing else changes about the journal publishing business in the public-access model as implemented by the NIH, traditional journals will still perform their usual quality-control in terms of peer review and trustworthiness, and they will still use their traditional publicity-generating methods. Finally, other than carving out a narrow, contractual exception to permit placing manuscripts in the NIH's public-access archive, nothing is changed in terms of reusability versus traditional publishing.

Criticism of the Public Access Law

Perhaps in some ways conflating concerns about *public* access with concerns about the broader impact of *open* access, the Bush Administration identified three areas of concern with Public Law 110-161 when it was still pending legislation: (1) the impact on scientific research publishing, (2) the impact on scientific peer review, and (3) “the United States’ longstanding leadership in upholding strong standards of protection for intellectual property.”⁷⁶ The Administration indicates that these concerns should be balanced against “the benefit of public access to taxpayer supported research.”⁷⁷

⁷⁶ Executive Office of the President, Office of Management and Budget, Statement of Administration Policy, October 17, 2007, <http://www.whitehouse.gov/omb/legislative/sap/110-1/s1710sap-s.pdf> (last visited June 8, 2008.)

⁷⁷ *Id.*

Agreeing with the Bush Administration, the traditional publishing industry argued that public access would increase their costs and make them less profitable. David Opderbeck writes that “publishers argued that the public database would erode their subscription base and drive smaller publishers out of business.”⁷⁸ This is one key reason why the requirement allows for 12 months of exclusivity by the publisher before necessitating deposit with the NIH.⁷⁹ Publishers argued that the law would increase the costs of access to their journals, reduce innovation in the publishing realm, and hamper the business of scientific publishing, the free market, and the progress of science. While conceivable, it is unlikely that scientists, who require immediate access to up-to-date research information, would choose not to subscribe to journals simply because they can access the same information a year later. Instead, it is likely that mostly archivists, historians, and the public who will make use of this older information and their newfound freedom of access. Open-access publishing, since it pushes for immediate publication and free access to up-to-date research, would put far more pressure on traditional publishers than the new public-access scheme does.

Since the new law builds on the existing publishing process, including peer review, concerns by publishers and the Bush Administrations about the impact on peer review are mostly subsumed by a discussion of costs and profits. If the new policy drives some publishers out of business and costs others significant amounts of money, publishers could conceivably cut back on their management of the peer review process. Doing this, however, would likely hurt the profits of publishers even more, since it would impact the trustworthiness of their publication, a factor that is absolutely key to their

⁷⁸ Penguin’s Paradox, page 118.

⁷⁹ *Id.*

selling to scientific subscribers. In addition, publishers already do not pay peer reviewers. Their costs consist mostly in managing the process. Thus, it is much more likely that other cost-cutting measures would be introduced long before cuts were made that would undermine peer review.

INTELLECTUAL PROPERTY ISSUES

Critics of public access have argued that the approach threatens the existing intellectual property protection schemes used in this country, and also undermines our role in relation to the rest of the world. Arguments have ranged from suggestions that our treaty obligations would be violated, that the law would constitute a compulsory license, that it would be a “taking,” and that it might damage future patent applications. Such concerns need addressing in order to understand the impact of the law. They are also key to understanding limitations of the NIH’s public-access approach, especially in comparison to open access, since many of these limitations come as a reaction to these concerns.

In letters to Congress arguing against requiring public access to federally-funded research, some publishers argued that the law violated U.S. treaty obligations “under Article 13 of TRIPS and Article 9 of the Bern Convention,” and that it would potentially be a “compulsory license.”⁸⁰ Although the mandatory depository requirements could have been implemented in a potentially problematic fashion, the statutory language of the law itself directs the NIH to implement the policy “in a manner consistent with

⁸⁰ Mandatory Public Access to Federally Funded Research Does Not Violate Copyright Obligations, Association of Research Libraries (2007), *available at* http://www.arl.org/sparc/bm~doc/nih_copyright.pdf (last visited June 8, 2008).

copyright law.”⁸¹ To accomplish this, the NIH asks authors, when they sign agreements to publish their articles, to include a clause stating that the author “retains the right to provide a copy of the final manuscript to NIH.”⁸² Such an addition is expressly *contractual*, and thus does not alter copyright as a whole. Authors are free to propose (and journals to accept or not) limited or constrained transfers or licensing of copyrighted works. From the author’s perspective as well, the legislation in no way alters their copyright: instead it creates a contractual obligation based on their receipt of NIH funding. In short, no fundamental alteration of intellectual property law is required to implement the new mandate.⁸³

Public Access Requirements as a “Taking”

Some have also suggested that the provision constitutes a “compulsory license” or, in Constitutional property terms, a “taking.”⁸⁴ However, as noted above, the implementation of the statute involves a contractual arrangement between the NIH and the scientist, and then between the scientist and the publisher. The legislation does not take away something the author already has, but only conditions receipt of federal dollars on specific future actions. This is little different than the government purchasing anything

⁸¹ Public Law 110-161, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h3043eh.txt.pdf

⁸² NIH Public Policy Details, <http://publicaccess.nih.gov/> (last visited June 4, 2008).

⁸³ See also Mandatory, *supra* note 80 (“The proposed legislation concerns contract terms, not copyright exceptions. As such, the proposed legislation in no way implicates Article 13 of TRIPS or Article 9 of the Bern Convention, which address permissible copyright exceptions. These treaty provisions are completely silent on the issue of the terms a funder or other licensee can require of a copyright owner in exchange for valuable consideration.”)

⁸⁴ *Id.*

else: in return for payment (NIH funding) the scientist provides a copy of his or her published work for publication in a publicly-accessible forum.⁸⁵

Patents and “Printed Publications”

Concerns regarding patent issues focused on on the “statutory bars” under United States patent law especially, but also under non-U.S. law.⁸⁶ Specifically:

Since any printed publication that precedes the filing date of an application can be used as prior art when determining novelty of an invention, published NIH documents could jeopardize U.S. patent rights if patent applications are not timely filed and could entirely destroy patent rights in many foreign countries.⁸⁷

The NIH has responded by saying they do not believe courts will consider deposit of a manuscript with the NIH to constitute a “printed publication,” and that they expect courts to continue to use the date of publication in the journal itself instead.⁸⁸ In addition, manuscripts may be embargoed for publication in the NIH public-access database for up to 12 months after publication in the journal itself.⁸⁹ As such, the public-access law is unlikely to materially impact patent protections.

⁸⁵ *Id.*

⁸⁶ See Penguin’s Paradox, p. 118 (explaining that, among other things, there is a statutory bar against granting a patent when the invention has already been disclosed in a printed publication anywhere in the world more than one year previous to the U.S. application for a patent). See also 35 U.S.C. § 102 (2008).

⁸⁷ Examining NIH Policy to Enhance Public Access: Importance of Sharing Results of Government-funded Research, Jun 1 2005 (Vol. 25, No. 11), Genetic Engineering & Biotechnology News. Available at <http://www.genengnews.com/articles/chitem.aspx?aid=443&chid=0> (last visited June 8, 2008).

⁸⁸ Penguin’s Paradox, 119.

⁸⁹ Penguin’s Paradox, 119.

THE IDEAL OF FREE ACCESS BY THE PUBLIC

One of the underlying ideals behind the push for public access has been the idea that, if taxpayers fund research, then those same taxpayers ought to be able to access that research. This idea goes back to the original conception of intellectual property as a *quid pro quo*. But while appealing from a rhetorical standpoint, the idea of allowing the public free access to published journal articles whose development was funded with public monies does have critics:

First, who is and isn't a tax-paying member of the public? And secondly, how does one address this issue on an international scale, i.e. with an international public? In other words, will the taxes paid in one country entitle one to view the content of a journal which is based in another country? . . . [T]his tax-based approach to publishing is far too problematic and contains elements of demagoguery. It is simply not workable. It is important to note that paying taxes does not necessarily grant anyone the right to free access to any goods or services that receive public money in any form.⁹⁰

Another related argument involves the lack of benefit to the public that can be achieved by allowing general access to scientific research and publications:

[S]uch reports use professional, often highly specialized terminology, so it is really questionable whether those who are not part of the scientific community . . . will benefit from the provided information. Secondly, the average taxpayer is probably most interested in clear and sim-

⁹⁰ Mark Graczynski & Lynn Moses, *Open access publishing: Panacea or Trojan Horse?*, 10 MED SCI MONIT ED2, available at <http://journals.indexcopernicus.com/fulltxt.php?ICID=11571> (last visited June 8, 2008).

ple information relevant to their own daily lives, such as “is there a cure for my disease?”⁹¹

A *New York Times* editorial rebuts this position:

Most of us, admittedly, will not have much use for free access to new discoveries in, say, particle physics. But it is a different matter when it comes to medical research. Popular nostrums abound on the Web, but it can be very hard, if not impossible, to find the results of properly vetted, taxpayer-financed science and in some cases it can be hard for your doctor to find them, too. The Public Library of Science could help change all that, creating open access to research. The publishers of scientific journals are naturally skeptical, but the real test will come in the marketplace of ideas.⁹²

The lack of public benefit argument neglects several beneficial aspects of public access. First, the scientific community is part of the public. Publicly-accessible research will directly benefit this population. Second, and relatedly, although the “average taxpayer” may not immediately and directly benefit, there is a (to borrow from economics) a “trickle down” effect of providing access to scientific literature: if it is easier and cheaper for scientists and medical professionals to access information, the “average taxpayer” will indirectly benefit by more informed care providers and by better-informed articles in publications aimed at the lay public. Third, and finally, if taxpayer-funded researchers have cheaper access to scientific information, that drives down the cost of

⁹¹ *Id.*

⁹² New York Times, Op-Ed “Open Access to Scientific Research” (August 7, 2003). <http://www.nytimes.com/2003/08/07/opinion/07THU3.html> (last visited June 8, 2008).

their research, consequently benefitting the “average taxpayer” through reduced costs and faster scientific advancement. However, since the new public-access law only requires free access to manuscripts months after they’re first published, the opportunity for the law to radically change the marketplace in this way is limited.

Conclusion

Public Law 110-161 contained a potentially radical new requirement: “As of April 7, 2008, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication.”⁹³ The goal of this new mandate was a compromise position that attempted to improve access to government-funded medical research without overly damaging the business model of traditional scientific publishers.

Certainly the new law opens up access to medical research in a way never before required by law. However, this greater openness is tempered by some key limitations, above all the length of time journals are permitted exclusive rights to control access: 12 months. A year is simply too long a time period for the law to have a significant impact on how scientists learn from other scientists. Nonetheless, this time frame is good enough in many cases for the general public, for students, and for researchers working outside their primary discipline. It also provides useful access for scientists and doctors in developing countries. For these groups, free access may well open up opportunities for research that they would otherwise never have had. A move from no access to some access is significant. In addition, by retaining works outside the bounds of the business

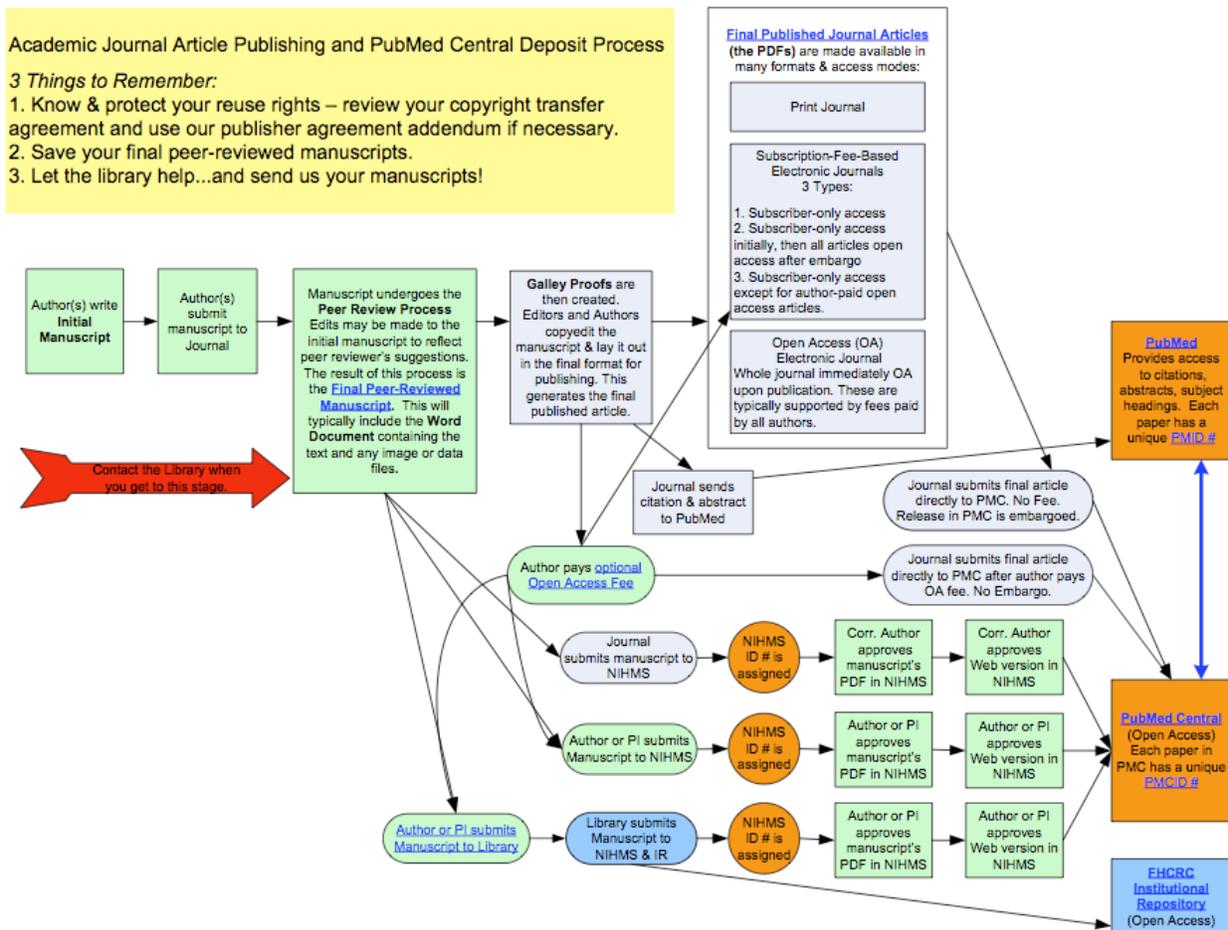
⁹³ NIH Public Policy Details, <http://publicaccess.nih.gov/> (last visited June 8, 2008).

operations of journal publishers, there is a much-reduced possibility that large swaths of manuscripts will be lost over time. PubMed Central will likely prove a gold mine of useful research for historians of medical science in the future.

One unanticipated negative impact has been on the scientific support staff at institutions and universities. Previously, authors typically managed their own journal publishing process. With the seemingly simple new requirement of depositing manuscripts with the NIH post-publication, along with the increase in non-traditional journals, support staff have stepped in to better manage the increasingly complex process.

The result has been a shift to a more complex process of manuscript submission. The following diagram, prepared by Ann Marie Clark, director of the Arnold Library, illustrates the new process at Fred Hutchinson Cancer Research Center, a Seattle-based, heavily NIH-funded non-profit institu-

tion:



Major proponents of open and public access—librarians and other scientific support staff—have been surprised by the complexity and additional processing required to comply with the new public-access mandate, especially when the additional complexity of managing multiple types of publisher (traditional and several varieties of open access, and everything in between) is factored in as well.

But overall, the move towards greater public access to research is a move in the right direction. The benefits of long-term archiving and free access by those who might not otherwise be able to afford it outweigh the negatives of increased support-staff workload and potentially reduced markets for traditional publishers. Certainly the law

could have done more, but in many ways it is up to scientists and researchers themselves to push for greater moves in the direction of open access, if that is what will benefit science and discovery in the long term. Government can only mandate so much; beyond that, it is up to us to go the rest of the way.