

This is an exploration of the efforts to promote open access (OA) to publicly funded scholarly research, specifically those projects supported by the National Institutes of Health (NIH), the largest supporter of medical research in the world. It analyzes the research support for highly cited articles in several science, technology and medical (STM) journals. In addition, the current impact of the NIH's mandatory open, public access policy, which requires freely accessible online publication in the National Library of Medicine's *PubMed Central* within 1 year after initial publication, is reviewed. Finally, this paper discusses the evolution of the NIH policy, opposition to its mandate, and other issues of open access and scholarly publishing.

Many of the basic tenets and values of scholarly publishing, such as editorial independence, objectivity, scientific rigor, and intellectual and academic freedom have been severely tested and sometimes compromised in many of the traditional models of medical scholarly publishing. It's even been concluded by many that pharmaceutical companies view medical journal articles, whose research they fund, as vital marketing tools. In truth, negative clinical trial results are rarely even published (Smith, 2005). While bias is certainly an important issue in medical research, the focus here is on open access issues.

Scholarly Publishing and Open Access (OA)

There are about 50,000 scholarly journals and scientific titles worldwide, half available electronically, with 783 new ones created between 1998 and 2003. Of these, 4,384 are OA journals, with 1681 titles searchable at the article level in the Directory of Open Access Journals (DOAJ), which now features 320,773 full text articles. Medical and public health titles account for 445 of these titles, while 165 are in biology and life sciences. All OA journals listed there are either peer reviewed or have editorial quality control (Welcome to the Directory, 2009).

This growth in OA journals occurs at the same time that TA journals are consolidating in the hands of fewer but larger corporate publishers. These companies are concerned with shareholder value and "knowledge capitalization." Indeed, many libraries are not able to subscribe to all the scholarly titles their users need due to rising journal prices.

Open access was one of the top five science stories of 2003 according to *Nature* and *Science*, both highly rated, traditional Toll Access (TA) journals. This story was highly ranked along with scientific stories about human cloning and genetically modified foods. The big question pondered aloud by these traditional journals was whether all future scientific articles would be available free of charge to readers (Suber, 2003).

Recent open access initiatives in the sciences include OA publishers BioMed Central and the Public Library of Science (PLOS); OA journal, *Open Medicine*; OA archive, High Wire Press, the "world's largest collection of open access, high impact scholarly research online;" and the new OA policy of the National Institutes of Health.

PLOS Biology was one of the first major open access, peer-reviewed scientific journals, begun in 2003. Published by the Public Library of Science, a San Francisco-based group of physicians and scientists dedicated to making medical and other scientific research freely available to the public, its founders included Harold Varmus, 1989 Nobel prize winner and supporter of the NIH open access mandate. Initially, *Nature's* editors considered PLOS as a direct competitor for scholarly biology manuscripts. However, *PLOS*

Biology's mission was to make science research more accessible and to "level the playing field for scientists in smaller or less wealthy institutions." They believed that articles should be judged on their own individual merit and not depend on the image of their host journal. PLoS has begun to develop new impact measures "at the article level that will include citation metrics, usage statistics, blogosphere coverage, social bookmarks, community rating and expert assessment" (About PLoS, 2009).

Conversely, traditional TA publications measure impact factor based on citation frequency and the perceived "prestige" of the journal. In fact, journal prices don't correlate with impact or quality. Carl Bergstrom has shown that journal prices are either unrelated to quality or inversely related to it. He goes on to clarify that there is a startling difference between the prices that university libraries must pay for academic journals owned by commercial publishers and the prices for journals owned by professional societies and university presses" (Expert to Speak, 2009).

The dynamics of scholarly publishing are different than other publishing. Academic authors are not paid by the journal for their work, despite one manuscript representing thousands of dollars of research. Researchers generate and reinforce their credibility and value by being published in a "prestigious" journal. They then can gain tenure, get paid consultancies from pharmaceutical and medical companies, and speaker fees.

Many OA publishers, including PLoS, charge author fees to publish, while others, based on different subsidy models, have no fees. Fee waivers and discounts are also available. The editors' decision to publish a paper in this OA journal is not influenced by an author's ability to pay (Wilinsky, 2005). These author OA fees represent a small percentage of the research costs for a manuscript (Crawford, 2009). The average annual NIH research grant for 2008 was \$403,571 compared to \$378,045 five years earlier, with most projects lasting four years (Research Project Grants, 2009).

HighWire Press, an OA archive and division of Stanford University Libraries, is an open archive which "partners with influential scholarly societies, university presses and publishers to create a collection of the finest, fully searchable research and clinical literature online." It works with 71 of the 200 most frequently cited STM journals. High Wire features free full-text access to over 1.9 million articles (About HighWire Press, 2009).

It seems self-evident that there should be free public access to publicly funded research, but, prior to the NIH voluntary, now mandatory policy, this was not a universally accepted practice. The primary argument for supporting open access is that taxpayers should be able to openly access federal agency supported research without paying a second time to a conventional, TA journal. Secondly, the argument is that these federal funds should be spent in the public interest rather than as a source of profit by privately owned publishers. Support for the NIH public policy mandate is quite widespread, with over 30 countries having signed the "Declaration on Access to Research Data from Public Funding" developed by the Economic Co-operation and Development (OECD) (Suber, 2002).

In theory, people could go to their local public library branch to read health-related scholarly articles, but even academic libraries cannot afford to subscribe to all of the top scholarly titles. Even universities, such as San Jose State University (SJSU), can only

afford to subscribe to a select number of titles. There are two ways that an article becomes open access (OA):

1. An article is published in a TA journal, then self-archived in an OA eprint archive (green OA).
2. An article is published in an OA journal that doesn't charge access fees to cover its costs by charging the users access tolls (gold OA). (Goodman and Hamad, 2004).

Fortunately, copyright law allows authors to transfer copyright to a TA publisher while still retaining rights to self-archive in a repository, include excerpts of the work in other future manuscripts, put it on one's web site, or just hand it out in class (Author Rights, 2006).

Surprisingly, a current study recently determined that the cost to publish humanities and social science journals was \$566/page compared to only \$266/page for science, technical and medical (STM) journals. (Waltham, 2008). The average social science article cost \$9,994 in 2007, compared to \$2,670 for an STM article. These humanities-themed articles also tended to be longer (19 pages) compared to STM manuscripts (12 pages) and had lower acceptance rates. The eight humanities and social science journals reviewed accepted 11% of articles submitted, while STM journals accepted 42%.

Interestingly, this study concluded that the current "author pays" OA policy used successfully by scientific journals since 2003 is not a sustainable option for humanities and social science articles, based on recent figures from humanities and social science associations (Howard, 2009).

The National Institutes of Health: Public Access Policy

The National Institutes of Health (NIH), under the Department of Health and Human Services, spends over \$28 billion annually in health-related research, making it the largest supporter of medical research in the world. The majority of these funds (83%) are distributed annually by 50,000 competitive grants to 325,000 researchers in major universities, medical schools, and other research centers, while 10% of its research budget supports NIH researchers in terms of publications, an average of 60,000 NIH-funded studies are published annually. Indeed, research in most fields in the U.S. today is funded by federal agencies (About NIH, 2009).

The National Institutes of Health is very prominent in scientific research funding in the U.S. and the world. The NIH awards research grants annually from 27 specialty centers and offices, including the National Cancer Institute, National Heart, Lung, and Blood Institute, National Institute of Diabetes and Digestive and Kidney Diseases, and the National Institute of General Medical Sciences. (Institutes, Centers, 2009).

The NIH Public Access bill, which was introduced and passed in the House of Representatives in December, 2007 was intended to ensure that the results of these studies would be freely accessible. Open access to the articles, after a twelve month "exclusive" period in which publishers can still profit from providing access to top scientists and researchers, makes sure that those who pay for the research, U.S. taxpayers, can have equal access to that information.

After a public comment period and hearings on the wording of the public access policy, the policy was made permanent when signed into law as the Omnibus Appropriations Act (as P.L. 111-8) in March, 2009, by President Obama. The current administration has several supporters of the OA policy, such as Harold Varmus, former NIH director, and co-founder of PLoS Biology. Varmus currently co-chairs the Council of Advisors on Science and Technology (Baker, 2009).

Prevalence of NIH Funding

A review was conducted of frequently cited articles in three major medical and life science journals to determine the percentage subject to the new NIH mandate. This analysis determined that on average, a high share of the articles received NIH funding, ranging from a low of 44% to a high of 70%, for data available through October 1, 2009. The journals evaluated were the 100 Most-Frequently Cited Articles of the *Journal of the Federation of the American Societies for Experimental Biology (FASEB)*; the *Proceedings of the National Academy of Sciences’ (PNAS)* 50 most-cited articles, and the *New England Journal of Medicine’s (NEJM)* most cited and most blogged articles in the last three months, July – September, 2009.

For the first journal, *FASEB*, 44% (44/100) of the articles received at least one grant from the National Institutes of Health and 10% from pharmaceutical companies. For the second journal, *PNAS*, well over two-thirds (68%) of the articles were NIH-funded, with 14% funded by pharmaceutical companies. For the third journal, (*NEJM*), 70% (7/10) of the most cited articles received funding from NIH, 50% (5/10) from pharmaceutical companies. (Most Cited, 2009). The most blogged articles from the same time period yielded 50% NIH-funded (4/8) articles, with 50% funded by pharmaceutical companies. (Most Blogged Articles, 2009).

	NIH Funding	Pharmaceutical Co.	Article Publication Date
FASEB	44/100(44%)	10/100 (10%)	1991 - 2009
PNAS	34/50 (68%)	7/50 (14%)	1977 - 2009
NEJM (most cited)	7/10 (70%)	5/10 (50%)	1993 - 2009
NEJM (most blogged)	4/8 (50%)	4/8 (50%)	1993 – 2009

Table 1. Funding Sources of Most Cited Articles (through October 1, 2009)

To put these findings further into perspective, figures for the year ending 2008 were studied. *FASEB* has an impact factor of 7.049, ranked #2 of Biology titles (out of 72 titles) per *Journal Citation Reports*. Impact factor is determined by dividing the total number of citations by the number of total articles. For *FASEB*, the number of citations for 2008 was 34,300, divided by the number of items published, which was 412 total articles (Journal Summary List. *FASEB*, 2009).

The comparable impact factor for PNAS is 9.380, ranked #2 of Multidisciplinary Sciences journals (out of 42). It had 416,018 citations and 3508 articles (Journal Summary List. PNAS, 2009). For the *New England Journal of Medicine*, the impact factor is 50.017, ranked #1 of Medicine, General & Internal journals (out of 107); in total, It had 205,750 citations and 356 articles (Journal Summary List *NEJM*, 2009).

An alternative, possibly more useful measure, the Eigenfactor, developed by Carl Bergstrom of the University of Washington, determines an article's worth based on who is citing it. Algorithms are used to evaluate the importance of each journal and its value per dollar. It's significant that all three journals reviewed rank either #1 or 2 in Eigenfactor Score. The table below compares both sets of metrics, including those for two other top rated journals in their category, *PLoS Biology* (OA) (in Biology) and *Nature* (TA) (multidisciplinary sciences. This OA journal is a strong performer, surpassing many subscription journals in impact.

Journal	Total Cites	Total Articles	Impact Factor	Rank	Eigenfactor Score	Rank
<i>FASEB</i>	34300	412	7.049	2*	0.12998	2
<i>PNAS</i>	416018	3508	9.380	2**	1.69817	2
<i>NEJM</i>	205750	356	50.017	1***	0.68029	1
<i>PLoS Biology*</i>	12186	212	12.683	1*	0.15465	1
<i>Nature**</i>	443967	899	31.434	1**	1.76345	1

Table 2. Impact Metrics of Selected Scholarly Journals (Source: Journal Citation Reports. (2008). *Biology **Multidisciplinary Sciences *Medical**

The most frequently cited medical research articles still are authored primarily by researchers with academic affiliations, despite a perceived crisis in academic medicine. The citations thus reinforce the high image of the journal, which can then “attract” more articles. Publishers tend to publish papers because they are cited often, thus creating a self-fulfilling “prestige” cycle. (Patsopoulos, 2006).

It's really not doctors or patients who benefit from this research. One can argue that Toll Access (TA) journal publishers, responsible for initiating peer reviews, printing, and selling the results via subscriptions, are the first in line to benefit (Accessing NIH Research, 2007).

Compliance with the NIH Mandate

The NIH requested voluntary compliance with its open access policy for two years prior to December, 2007. However, without a specific requirement, the actual rate of journals

submitted to PubMed Central only reached 5% in 2006. Just before the policy became mandatory, the rate was hovering around 4%.

According to NIH statistics, submissions to PubMed Central since the requirement was announced in December, 2007, have risen steadily, from 1255 in January, 2008 to 2765 in April, 2008, the official first month the policy was in effect, which was triple the number of manuscripts submitted the prior year. The highest month to date was recorded in April, 2009, with 7293 total manuscripts, over 250% increase again over 2008. The average submissions per month for 2009, through August, are 5587/month (Monthly Aggregate Submission, 2009). These are significant increases in the numbers of research articles being made available to the taxpayers who fund the research. Indeed, if these submission trends continue, the NIH will achieve or surpass its stated estimate of a 55-60% compliance rate.

Thus, the rate of compliance is largely dependent on the specific wording of the open access policy. This explains the jump in rate from 4% to 60% for the NIH, from voluntary to mandatory language. The dynamics are clear behind this change. The researchers who receive grant funding are generally very careful when it comes to fulfilling grant requirements, since they are usually interested in maintaining good relations with the funder for future support.

Two Sides to NIH Mandate

The NIH mandate, was supported enthusiastically by open source advocates such as the Scholarly Publishing and Academic Resources Coalition (SPARC), library supporters, many in the scientific community, funders, and some scholarly publishers. However, some large science publishers, such as Elsevier, publisher of 1800 journals, have opposed the open access (OA) stipulation even since 2005 when it was still voluntary. Their arguments range from a contention that smaller, specialty publishers will go out of business to a concern that the ability to sell subscriptions to their closed access journals will be hampered. The American Association of Publishers (AAP) complained that the policy was passed without any hearings or studies, despite the fact that the NIH published the proposed policy in the Federal Register in 2004, conducted public meetings with the publishing community and other stakeholders, and received 6000 public comments, which were made public on the NIH website. According to Scholarly Publishing and Academic Resources Coalition's (SPARC) Executive Director, Heath Joseph, the "formulation of this policy has been transparent, straightforward, and has provided plenty of opportunities for all stakeholders to express their concerns..." (Publishers Attack NIH, 2008).

Some publishers also claim that OA would destroy the concept of peer review, by which academic scholars review each others' work to determine worthiness of being published. However, this process is subsidized by a faculty or staff member's university, not by the publisher. For TA or pay-for-access journals, these funders who pay indirectly for peer review pay again via subscription to get access to the published manuscript. Therefore, authors of scholarly works are challenging the publishing status quo for the ownership and control of this intellectual property. Pro-author advocates such as Nick Monfort encourage researchers and authors to refuse to review for non OA journals. Clearly, authors can choose journals that have more lenient copyright policies allowing for OA and other rights retention (Monfort, 2008).

Despite these concerns, Elsevier reported an 11% profit increase with \$814 million USD for 2008. The two divisions of Elsevier and LexisNexis in combination accounted for 79% of parent company, Reed Elsevier's, operating profit (Elsevier – 39%; LexisNexis, 40%). In addition, the company's preliminary financial results claimed a 98% subscription renewal rate, with an increase of 20% in article downloads (Davis & Armour, 2009).

Many large publishers have strategies to retain and improve profits, one of which is bundling in which less popular journal titles are packaged with the most popular ones. For example, 50% of the University of California Libraries' 2002 serials budget went toward Elsevier titles, even though these journals only accounted for 25% of journal use. In fact, publishers make a higher profit on these lower tier (less frequently cited) titles (Suber, 2004).

Ironically, Reed Elsevier in 2004 changed its author policy and began allowing authors to post a free “open access,” eprint archive copy of their manuscript to their own institution's repository. However, not many authors have actually followed up and deposited their works, except for a few in high-energy physics. In addition, in the same year, Springer Verlag, publisher of 1000 journal titles, initiated its Springer Open Choice, which allowed authors for a fee of \$3000 to offer their works in open access (Wilinsky, 2005).

Another effort opposing the NIH open access (OA) mandate, called the Fair Copyright in Research Works Act, a bill (H.R. 6845) was authored and introduced by Rep. John Conyers (D-MI) in September, 2008. This bill sought to overturn the NIH OA requirement and to change copyright law so that other federal agencies would not adopt similar policies. The bill was re-introduced to the 111th Congress. On March 16, 2009, it was referred to the House subcommittee on Courts and Competition Policy. This bill raised the stakes and visibility of the NIH issue, prompting the Association of American Universities (AAU), which represents major universities in the U.S. and Canada, to come out in favor of the NIH OA mandate (Baker, 2008).

The 2009 version of Conyers' bill, identical in wording to H.R. 6845, now known as H.R. 801, contains no new language. It prohibits the deposit of these articles into PubMed Central, significantly restricting the accessibility of this publicly-funded research to doctors, researchers, health care professionals, patients, and their families. Such a change would have prevented availability to critical information about healthcare to millions of people. In addition, this broadly worded bill would prohibit open access availability for research funded by all federal agencies. The bill goes on to repeal the “federal purpose” doctrine, in which all federal agencies that fund a copyrighted work reserve the “royalty-free, nonexclusive right to reproduce, publish, or otherwise use the work” for any federal purpose. This would severely restrict usage by the very agencies who fund the research (Terry, 2009). It is still under deliberation in subcommittee.

Another argument that publishers have presented in their support of the Conyers bill is that the NIH mandate prevents full exercise of their copyright agreements. In fact, even though authors transfer most of their rights to the publishers, the authors are still the copyright holders, not the publishers. It's important to know that the NIH requires its grant recipients to retain the key right of being able to retain permission for open access. Therefore, these authors are not transferring all their rights to the publishers. Indeed, copyright law does not require that authors transfer all of their rights to publishers (Suber, 2008, quoted in Rinn Law Library Blog).

Looking Ahead: Other OA Mandates

While the NIH's new policy to require mandatory open source availability of its funded authors is the most visible, well-known recent requirement for such universal access, it is not the first. In fact, the Wellcome Trust, the largest non-governmental biomedical research funder in the United Kingdom, has required its grant recipients since 2005 to provide free access to their papers in the UK Pubmed Central, that country's life sciences repository. In addition, Wellcome recently announced a new \$3.3 million fund to pay author OA publication fees.

Some publishers have been criticized by the research community for benefiting from this open access revenue as a new revenue stream, both making profits from traditional subscription fees and OA publication fees. A more equitable approach has been taken by Oxford University Press, which has lowered its subscription fees by the amount of its OA fees so that they are no longer paid twice for an article. Wellcome Trust, an OA advocate, encourages other publishers to follow suit (Brierly, 2009).

Open Access advocates are now lobbying for enhanced openness, which would take the NIH policy beyond mere compliance to a more comprehensive public access and institutional access policy, modeled after the Harvard open access policy (Thancy, 2009). In February, 2008, the Faculty voted to create a similar policy to spread the "fruits of its research and scholarship as widely as possible" and to grant "permission to make available his or her scholarly articles and to exercise the copyright in those articles. In legal terms, the permission granted by each faculty member is a nonexclusive, irrevocable, paid-up, worldwide license to exercise any and all rights under copyright relating to each of his or her scholarly articles, in any media and authorize others to do the same, provided that the articles are not sold for a profit" (Faculty of Arts, 2008).

Harvard faculty authors will thus retain the right to self archive their peer-reviewed articles and can still pass on all other rights to their publishers. The Harvard librarians will be involved with the creation of a new Office for Scholarly Communication. The new mandate will increase deposit rates, which are low at many academic repositories. At the University of California (UC), the rate is still only 14%. UC is also considering the adoption of a similar permission mandate (Darnton, 2008).

The new policy, the first of its kind by a major university, is a "permission mandate" rather than a depository requirement, for it gives the University non-exclusive rights to put faculty-authored manuscripts into Harvard's own repository. This should ensure that the OA deposit rate would be close to 100% since the responsibility to do it is shifted to librarians (Suber, 2008). This is significant since one-third of TA journals still do not allow any post-publication self-archiving.

Some OA advocates are pushing for the Harvard mandate to become even more definitive, changing to an "immediate deposit mandate" which would allow an author to waive adopting author's addendum (for copyright retention and re-use rights). They would also not allow professor to waive depositing the manuscript while still honoring a publisher's wishes for an embargo period (usually 12 months).

In summary, the open access (OA) movement, while still in its nascent stages, is making progress with the mandatory requirement of NIH-funded articles to be deposited into the

free digital archive of the National Institutes of Health (NIH). OA submissions to PubMed Central are on the increase since the policy's approval in 2007, now representing about 50% of funded projects. Other new OA policies such as the recent Harvard OA policy and the pending University of California proposal bode well for open access advocates.

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