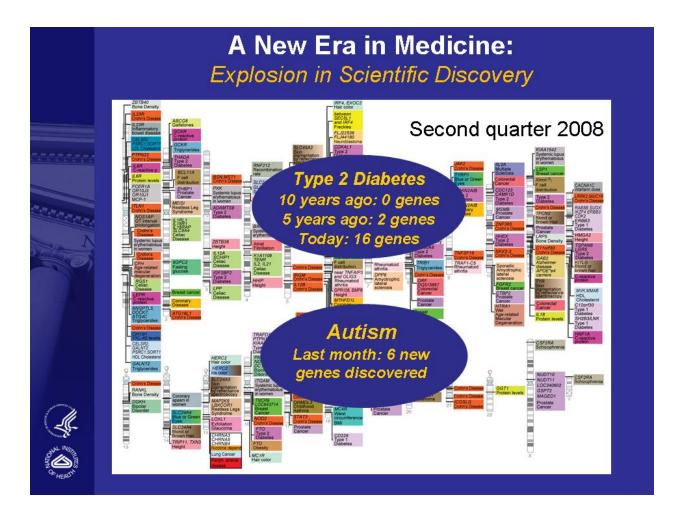


NIH's Public Access Policy

Subcommittee on Courts, the Internet, and Intellectual Property

Elias A. Zerhouni, M.D. Director

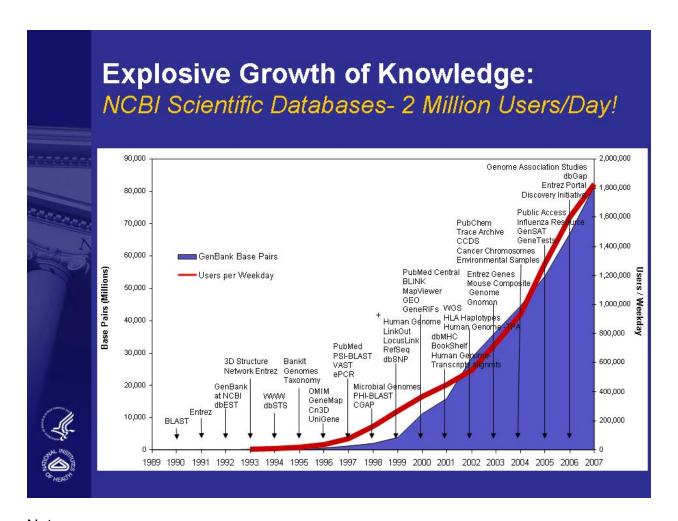
145th Meeting of the National Cancer Advisory Board February 5, 2008; 10:30am-11:30am Building 31, Conference Room 10, 6th Floor C Wing "NIH Director's Report" You will be introduced by Dr. Niederhuber



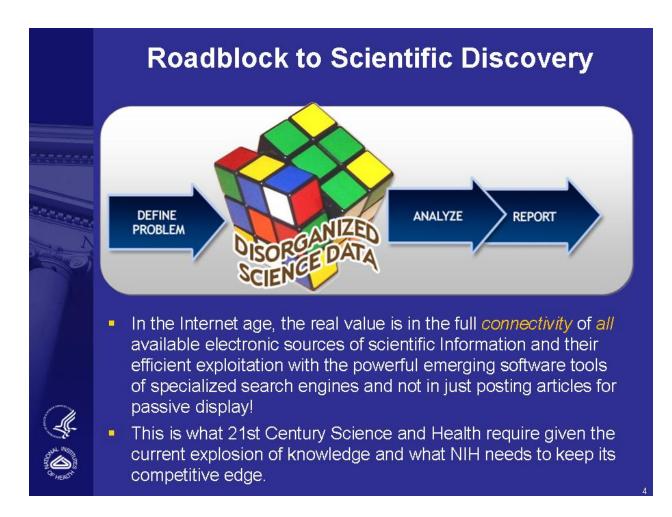
A New Era in Medicine: Explosion in Scientific Discovery

Ten years ago we knew of one gene that was implicated in diabetes. Recent research has resulted in an explosion of knowledge about the complex genetic underpinnings of diabetes. For type 1 diabetes, three genes were known five years ago, ten genes are known today, and discovery of an additional 14 genes is soon to be announced. Similarly, ten years ago, no genes had been found for type 2 diabetes—the most common form of diabetes. Five years ago, two were identified. Today, 16 have been found. These discoveries provide new avenues for exploration as researchers probe the functions of these genes in the hope of establishing targets for novel interventions for the treatment of diabetes.

Autism is another example of an explosion of knowledge that needs to be exploited. Two years ago, we were able to associate only 3-5% of autism with genetic mutations, within the last 12 months, 15% of autism is understood to be based on genetics – 6 of these genes were announced just last week. These are great leads – but now we need to pursue them aggressively. We also need to improve our tools for detection because we know that the earlier we can detect this devastating disorder, the better the outcome. Our ultimate goal is to develop new and better interventions strategies to be used as early as possible. And while we attacking this set of leads are have not let up in looking for more. We are undertaking a monumental effort to fully sequence at least 50 genes, which we hope will exponentially increase our search for a cure. In cancer, there are a plethora of new leads.

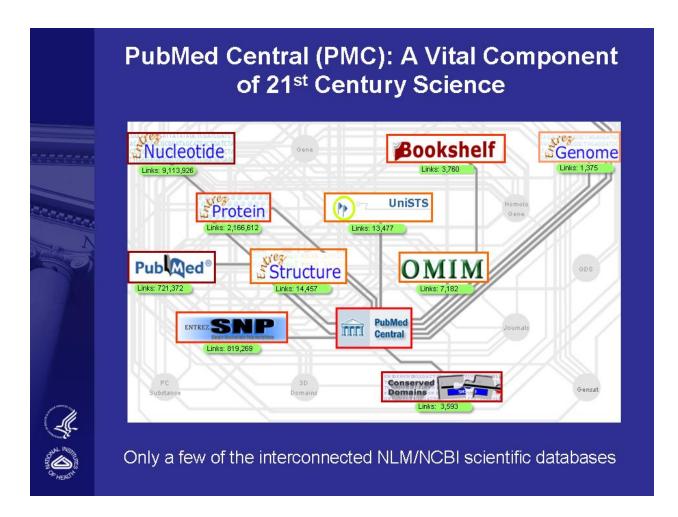


Explosive Growth of Knowledge: NCBI Scientific Databases- 2 Million Users/Day!



Roadblock to Scientific Discovery

- In the Internet age, the real value is in the full *connectivity* of *all* available electronic sources of scientific Information and their efficient exploitation with the powerful emerging software tools of specialized search engines and not in just posting articles for passive display!
- This is what 21st Century Science and Health require given the current explosion of knowledge and what NIH needs to keep its competitive edge.

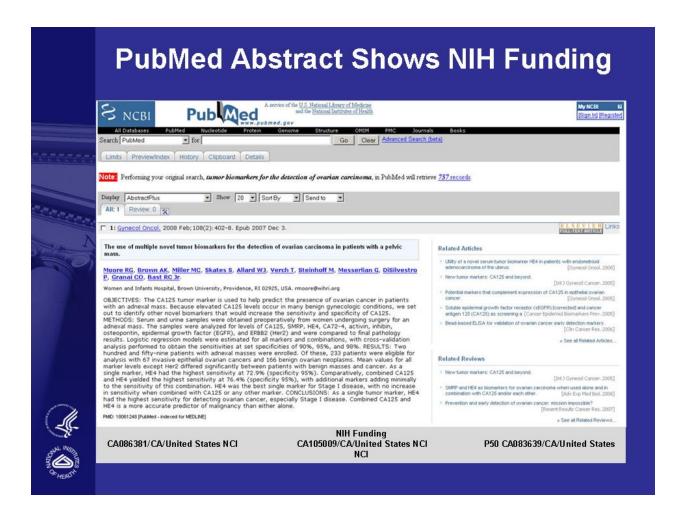


PubMed Central (PMC): A Vital Component of 21st Century Science

Only a few of the interconnected NLM/NCBI scientific databases



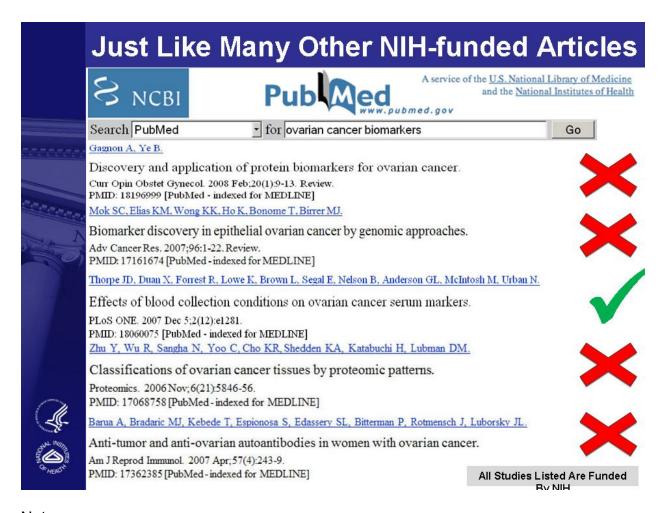
The World Before Public Access



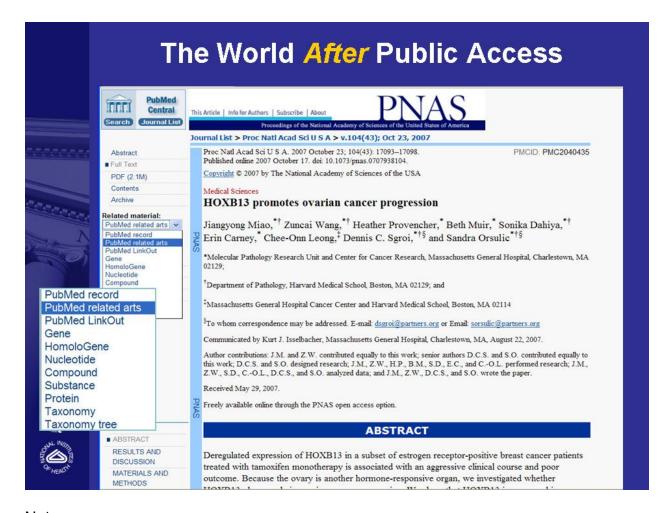
PubMed Abstract Shows NIH Funding



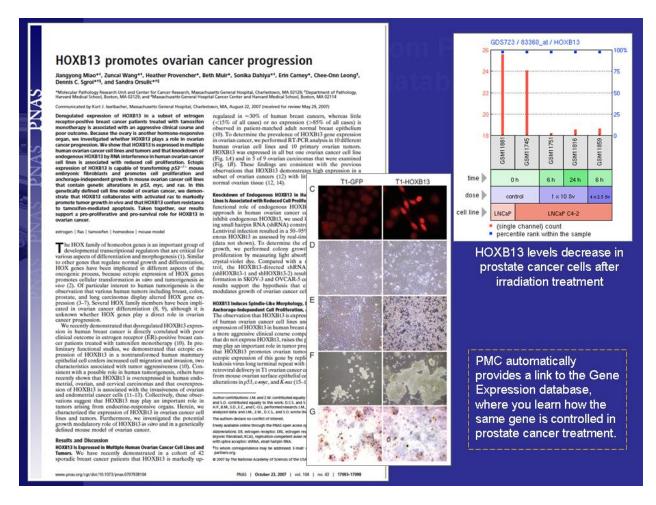
But NIH-funded Article Isn't Available



Just Like Many Other NIH-funded Articles



The World After Public Access



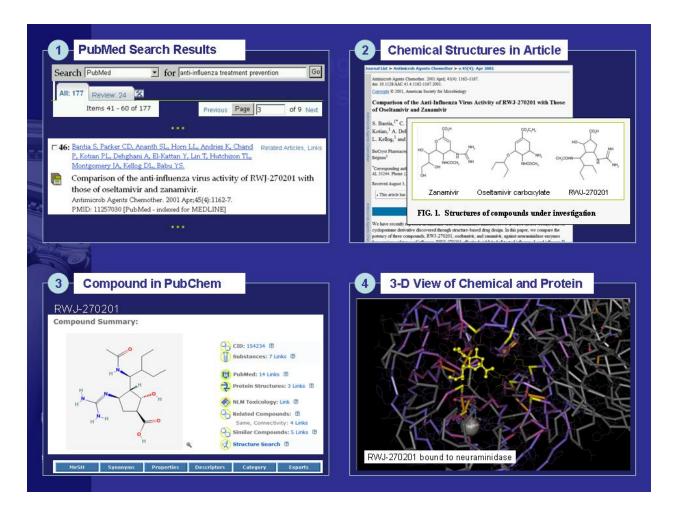
The HOXB13 Gene

HOXB13 is a gene that is important in the development of the embryo.

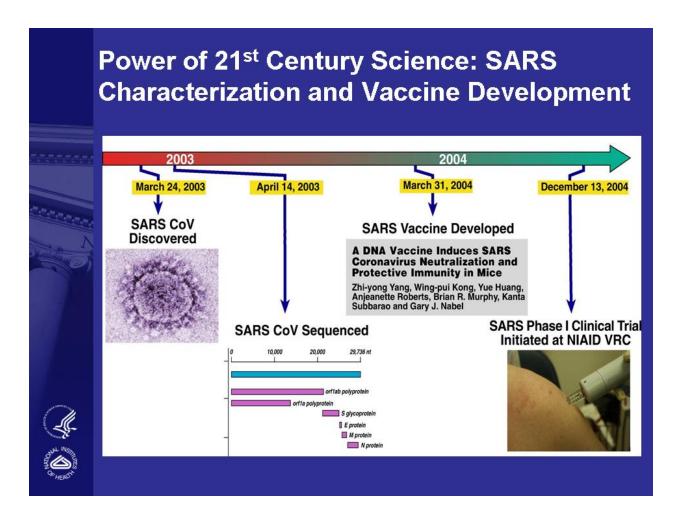
The PNAS Paper shows that the HOXB13 gene makes ovarian cancers grow faster.

In another NCBI database of gene expression experiments, there is a record that shows that the HOXB13 gene is also present in prostate cancer, and the levels can be reduced by radiation treatment.

Even though there is no direct link or citation to this experiment in the research article, we know they are related because our linking system knows that both the experiment and the article are referring to the same gene. So the power of this approach is that a person looking at the ovarian cancer article discovers that HOXB13 is also important in prostate cancer without having to know about or search another database.



No Notes



Power of 21st Century Science: SARS Characterization and Vaccine Development



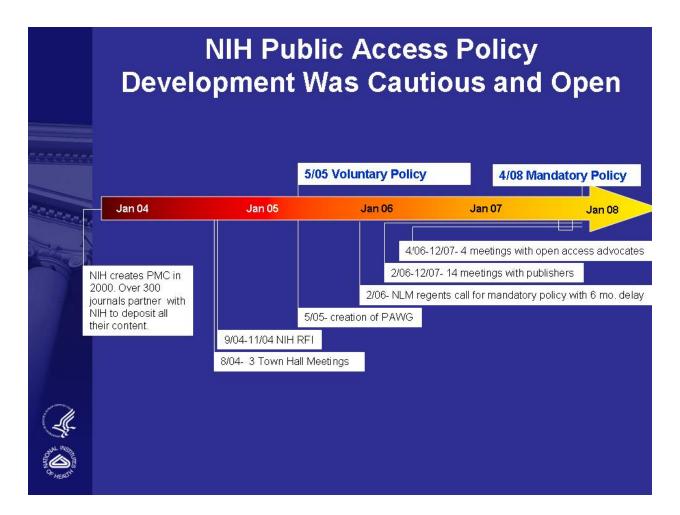
Is There Evidence of a Deleterious Impact of Public Access?

- Since 2000, almost 500 journals have elected to fully participate in PubMed Central and provide all their content with embargo period up to 12 months – many reduced their embargo period to less than 12 months
- Through websites such as HighWire press, many publishers make their full content electronically available for free after 12 months
- No negative economic or peer review impact has been demonstrated for these publishers

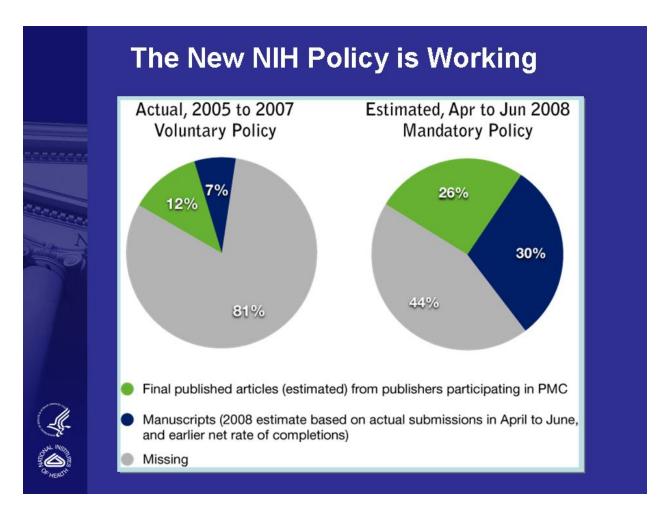
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NIH Public Access Policy Development Was Cautious and Open



The New NIH Policy is Working

The CACR for year-end 2007 reported a total of 14,937 papers (13,519 from NIHMS and 1418 from NIH Portfolio) collected under the Policy from May 2005 through Dec. 2007. In the six or so months since then, authors have approved roughly 1,500 more papers that were deposited in the NIHMS prior to 2008, but did not yet have the necessary author approvals when the CACR numbers were developed.

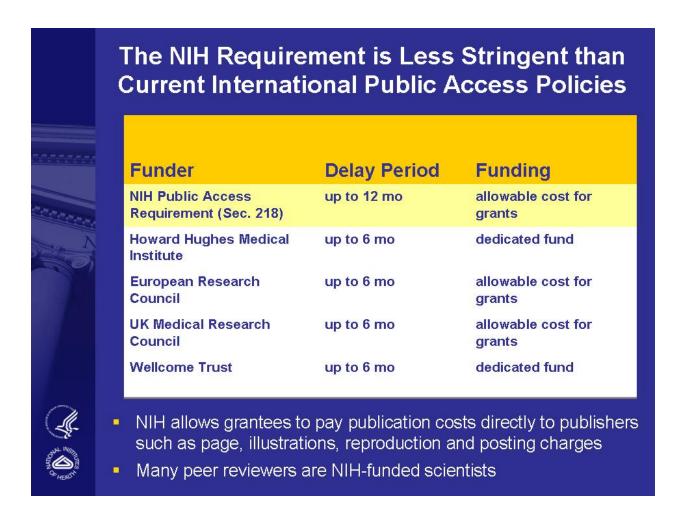
The new total number of manuscripts deposited via the NIHMS between May 2005 and Dec. 2007 that now are ready for, or loaded into, PMC is 15,011. Based on a policy target of 80,000 NIH-funded articles per year, that represents a 7% rate for manuscripts deposited via the NIHMS.



Many Publishers Now Deposit Manuscripts on NIH-funded Author's Behalf

Some Allow Embargoes of Less Than 12 months

As of September 2008



The NIH Requirement is Less Stringent than Current International Public Access Policies

Funder	Delay Period	Funding
NIH Public Access Requirement (Sec. 218)	up to 12 mo	allowable cost for grants
Howard Hughes Medical Institute	up to 6 mo	dedicated fund
European Research Council	up to 6 mo	allowable cost for grants
UK Medical Research Council	up to 6 mo	allowable cost for grants
Wellcome Trust	up to 6 mo	dedicated fund

- NIH allows grantees to pay publication costs directly to publishers such as page, illustrations, reproduction and posting charges
- Many peer reviewers are NIH-funded scientists

NIH Public Access Policy Only Requires Limited, Nonexclusive Right to Post Electronically After 12 Months: Transfer of All Other Copyrights to the Publishers is Preserved Before Public **Under Public** Copyrights Access Access Reproducing Articles Author→Publisher Author→Publisher Preparing Derivative Works Author→Publisher Author→Publisher Posting NIH-funded Author's Manuscripts to PMC after 12 months **Author Retains Right** Author→Publisher Posting Publisher's Published Articles Author→Publisher Author→Publisher Arising from NIH funds to PMC Posting Published Articles Not Arising from NIH Funds to PMC Author→Publisher Author→Publisher Posting Articles or Manuscripts to Other Archives Author→Publisher Author→Publisher Distributing Copies for Transfer Author→Publisher Author→Publisher Distributing Copies for Sale Author→Publisher Author→Publisher

Notes:

NIH Public Access Policy Only Requires Limited, Nonexclusive Right to Post Electronically After 12 Months:

Transfer of All Other Copyrights to the Publishers is Preserved

Copyrights	Before Public Access	Under Public Access
Reproducing Articles	Author→Publisher	Author→Publisher
Preparing Derivative Works	Author→Publisher	Author→Publisher
Posting NIH-funded Author's Manuscripts to PMC after 12 months	Author→Publisher	Author Retains Right
Posting Publisher's Published Articles Arising from NIH funds to PMC	Author→Publisher	Author→Publisher
Posting Published Articles Not Arising from NIH Funds to PMC	Author→Publisher	Author→Publisher
Posting Articles or Manuscripts to Other Archives	Author→Publisher	Author→Publisher
Distributing Copies for Transfer	Author→Publisher	Author→Publisher
Distributing Copies for Sale	Author→Publisher	Author→Publisher





- Applying 21st information technology to the NIH investment to promote science and health in the context of a globally wired and networked world of scientific information
- Making NIH more transparent and accountable and better able to make strategic decisions about its portfolio
- Ensuring more rapid scientific progress and the discovery of new treatments



What is at Stake

- About 80,000 journal articles that arise from NIH funds each year, and represent roughly \$23 billion of taxpayer investment
- Applying 21st information technology to the NIH investment to promote science and health in the context of a globally wired and networked world of scientific information
- Making NIH more transparent and accountable and better able to make strategic decisions about its portfolio
- Ensuring more rapid scientific progress and the discovery of new treatments



It is my opinion that Public Access to an interconnected world of scientific information databases provides one of our most powerful new tools to accelerate discovery and combat disease. To take this access away now would be a historic mistake.