

# Ethical Issues in Medical and Scientific Publishing

Glen P. Campbell, EVP Scientific, Technical Medical Journals, Elsevier



# Agenda



- How big is the problem (challenge)?
- The biomedical journal
- How Elsevier supports editors?
- Case study: what would you have done?

# What we don't know



There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don't know. But there are also unknown unknowns. There are things we don't know we don't know.

Donald Rumsfeld





# The problem is so big that....



**Retraction Watch** launched in August 2010  
(<http://retractionwatch.wordpress.com/>)



Ivan Oransky

Adam Marcus

“Tracking retractions as a window into the  
scientific process”



**‘Leading cancer vaccines researcher retracts paper for figure  
“discrepancies” flagged by watchdog blog’ – today’s headline**

# The problem is so big that....



In 2009, Baystate Medical Center (Tufts University School of Medicine) in Springfield, MA, made public the results of an inquiry into fraudulent research practices by Scott S. Reuben, MD, a Professor of Anesthesiology at the institution. Baystate Medical Center notified affected journals of its conclusion that 19 peer-reviewed articles and 2 abstracts contained fabricated data.

*ANE.0b013e318209736f A & A March 2011 vol. 112 no. 3 512-515*

What about journals that had cited Reuben's research???

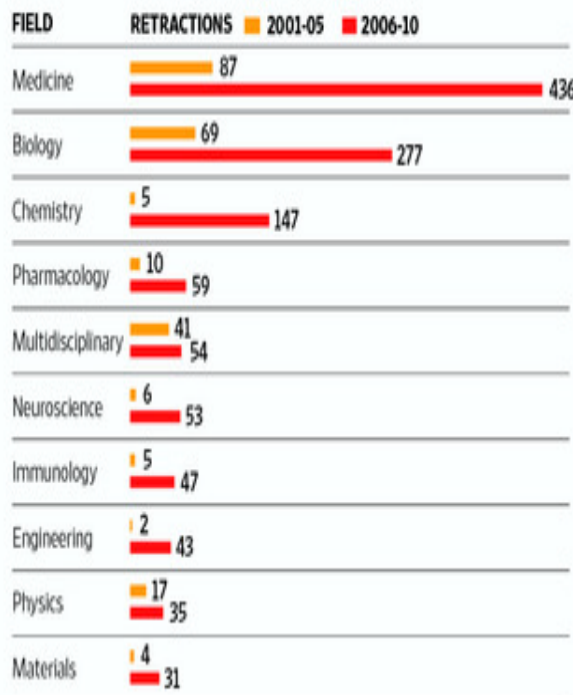
# The problem is so big....



## Spurious Science

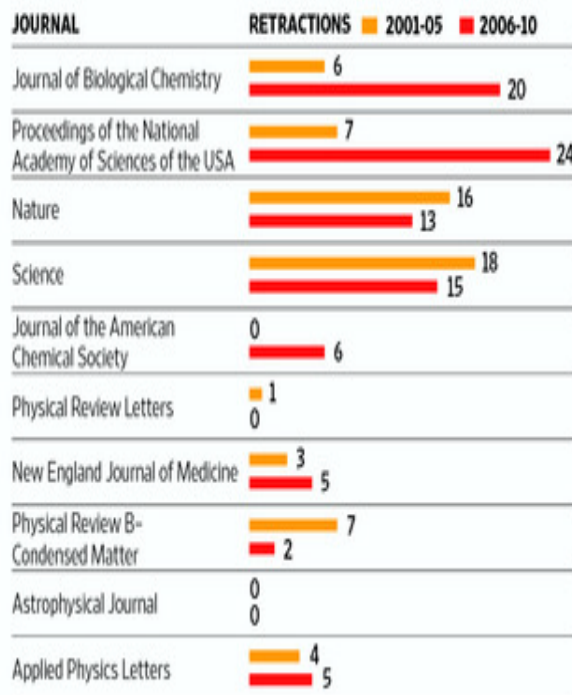
Rising retraction rates suggest that more published findings are unreliable, cannot be replicated or are simply wrong.

### Retractions are rising across most fields...



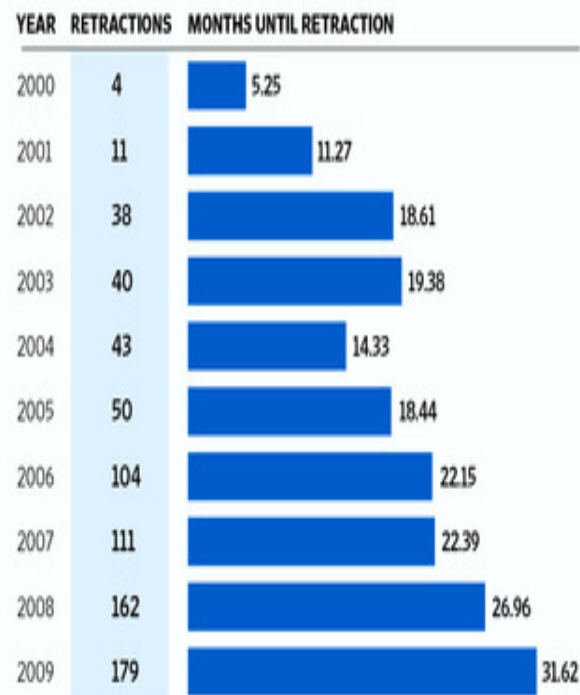
### ...including at some of the most influential journals...

The top science journals ranked by total citations.



### ...while lag time grows between publication and retraction.

Average time, in medicine and biology.\*

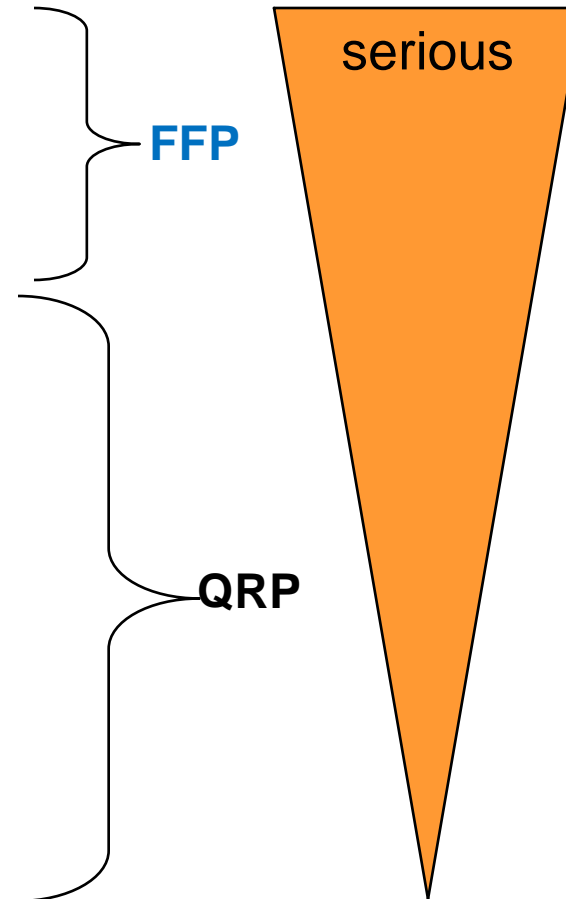


Sources: Thomson Reuters (retractions by field and journal); R. Grant Steen, Journal of Medical Ethics, Dec 2010 (retraction time)

\*Based on an analysis of 742 medicine and biology papers retracted from the PubMed database

# Types of scientific misconduct

- Fabrication of data or cases
- Wilful falsification of data
- Plagiarism
- No ethics approval
- Not admitting missing data
- Ignoring outliers
- No data on side effects
- Gift authorship
- Redundant publication
- Inadequate literature search



*QRP= Questionable Research Practice; FFP = Falsification, Fabrication, Plagiarism*

- Taking credit for others' text and ideas
  - Extent matters
    - Literal copying
    - Substantial copying
    - Paraphrasing (human judgment?)
- Unintentional
  - Self-plagiarism?
- Cultural differences?



# How big is the problem?



- Technology: Easier to 'steal', to catch 'thief', to report
- Motivations: activism, genuine concern, hidden interest
- More cases or just more publicity?
  
- Up to 200,000 of 17 million articles in Medline database may be duplicates, or plagiarized  
Errami & Garner. *Nature* **451**, 397-399 (2008)



# Agenda



- How big is the problem?
- The biomedical journal
- How Elsevier can help
- Case study: what would you have done?

# Ethical “Hot” Issues – Biomedical Journals



- Authorship Decisions
- Conflicts of Interest
- Role of Funders
- Patient Safety and Privacy

- Public achievement of the accomplished work
  - Data responsibility
  - Intellectual input
    - Development of concept
    - Interpretation of data
- Most sensitive part of data reporting
  - Ideally made before study starts
- Issues:
  - Who qualifies?
  - Is order important?
  - How to solve unusual circumstances?
  - How to avoid authorship misuse?



Vancouver guideline states that an author must:

- Substantially contribute to study conception and design, data acquisition, analysis and interpretation
- Draft or revise the article for intellectual content
- Approve the final version

An author must participate in **all three steps**

- Authors are ranked in order of magnitudes of their input into the research:
  - First Author conducts and/or supervises the data analysis and the proper presentation and interpretation of the results
  - Puts paper together and submits the paper to journal
- Co-Author(s)
  - Makes intellectual contributions to the data analysis and contributes to data interpretation
  - Reviews each paper draft
  - Must be able to present the results, defend the implications and discuss study limitations

# Authorship unusual circumstances & authorship contributors



- What about people who contribute significantly but do not meet all three criteria and what about large multi-center studies?

Two new categories:

Contributors & Acknowledged Individuals

- When author number exceeds a specified threshold:
  - Contribution instead of authorship
- Multicenter trials
  - List of clinicians and study-organizations
  - A statement of the contribution of each individual

# Authorship

## Acknowledged individuals



- Staff who made a direct contribution to a study but did not fulfill the criteria for authorship:
  - General support
  - Technical help
  - Statistical, graphics
  - Library support
  - Critical review of the paper drafts



- Gift (guest) authors
  - Confer a stamp of authority
  - No intellectual contribution
- Ghost (omitted) authors
  - Neglected authors who made major contributions
  - Professional (paid) writers

Both to be avoided at all costs

# Conflicts of Interest - definition



“ Exist when an author (or author’s institution), reviewer, or editor has a relationship that inappropriately influence (biases) his or her actions (relationships that are also known as dual commitments, competing interests, or competing loyalties). ”

# Conflicts of Interest - issues



- May affect perception
  - Perceived Col
- May bias results as well as affect perception
  - Real Col

**" ...It is a condition and not a behavior" ...**

# Conflicts of Interest Causes

# Conflicts of Interest Solutions



- Direct financial conflict:
    - Employment
    - Stock ownership
    - Grants
    - Patents
  - Indirect financial conflict:
    - Honoraria
    - Mutual fund ownership
    - Consultancies to investment industry
    - Expert testimony
  - Intellectual & Career conflict:
    - Competition
    - Promotion
  - Institutional conflict
  - Personal beliefs
- Transparency and disclosure
  - Admitting mistakes
  - Firm guidelines
  - Individual journal commitment



- Who is the funder?
- Who controls data collection, analysis and interpretation?
- Who controls the writing and publication decision?

## Funding Source Issues

- Conflicts of Interest
  - Financial incentives
- Publication Biases
  - Greater likelihood that positive result studies will be:
    - Submitted for publication
    - Published
    - Published quickly

- Control of Data:
  - Investigators must not sign contracts with restrictions
  - Sponsors must not be able to veto publication
  - Disclosure of sponsors' role critical in:
    - Study design
    - Data interpretation
    - Manuscript's preparation, review and approval
- Prevention of Publication Bias:
  - Disclosure of design of all clinical trials is urged
  - Clinical trial registration is currently required by many, but not all journals
  - Disclosure of results of all clinical trials is recommended

- Ethics Committee Approval
  - Where does clinical practice end and research begin?
  - Are standards the same for public institutions vs. private practices?
- Patient informed consent
  - “Nothing about me without me”
    - Do patients understand whether or not they will be identified?
    - Do patients understand how their data will be used in research?
    - Do patients understand the associated benefits and risks?
    - What about research in children, mentally disabled, or in different cultural settings?

# Agenda



- How big is the problem?
- The biomedical journal
- Elsevier's role
- Case study: what would you do?

# What are the rules?



- No single universal international set of rules
  - Universities have rules re plagiarism
  - Funding agencies have rules for conflicts of interest
  - COPE and ICJME
  - Elsevier has overall policies & some journals/ societies have their own rules
- How do authors learn the rules?
  - Ethics in publishing not generally core curricula at university

# What rules are clearer than others?



- The clear rules, widely accepted
  - Don't copy
  - Don't pass off the work of others as your own
  - Do genuine research! (not fraud)
- The grayer areas of rules:
  - The various degrees of authorship
  - What level of interests must be disclosed with respect to conflicts, and how are they disclosed?
  - Self-plagiarism



# Elsevier's & Editors' roles



## Elsevier's role

*Guide:* Help Editor decide how to evaluate and investigate;  
provide best available tools

*Support:* Assist Editor in implementation

*Defend:* Stand behind Editor's decision

## Editors' role

*"Editors are often the first recipients of suspicions about studies that may involve misconduct. If editors suspect misconduct by authors, reviewers, editorial staff, or other editors then they have a duty to take action. This duty extends to both published and unpublished papers".*

Source: Committee on Publication Ethics (COPE)

# Common dilemmas



- Time consuming!
- No reply from authors
- No reply from head of institutions
- Inadequate investigation by institution
- No institution
- Managing/analysing raw data
- What to do, if alleged misconduct is unproven
- What to do with authors in future?

# How we help



- Provide clear policies
- Support investigations
- Support from Elsevier's Legal department
- Elsevier's Publishing Ethics Resource Kit (PERK)
- Committee on Publication Ethics (COPE)
- CrossCheck



**Karen Hunter,**  
SVP  
Global & Academic  
Customer Relations



**Mark Seeley**  
SVP  
General Counsel



**Catriona Fennell**  
Director  
Journal Services



**Sabine Kleinert,**  
Senior Executive Editor  
*Vice-Chair*  
*Committee on Publication Ethics*

# Elsevier policies for authors



- Prominent in 'Guide for Authors'
- 'Conflict of Interest' policy
- Mandatory ethics statement in EES



## Ethics in Publishing: Instructions to Authors

For Elsevier Editorial System

This general statement will be supplemented by instructions to authors (as well as in communications to editors and peer reviewers) relevant for each journal. In case the journal is affiliated to or owned by a Society: In the event of any conflict between this statement and Society guidelines, policies or procedures, Society preference prevails.

### Ethics and Procedures

#### *General*

The editor(s) and publisher of this Journal believe that there are fundamental principles underlying scholarly or professional publishing. While this may not amount to a formal "code of conduct", these fundamental principles with respect to the authors' paper are that the paper should:

- be the authors' own original work, which has not been previously published elsewhere
- reflect the authors' own research and analysis and do so in a truthful and complete manner,
- properly credit the meaningful contributions of co-authors and co-researchers,
- not be submitted to more than one journal for consideration (ensuring it is not under redundant simultaneous peer review), and
- be appropriately placed in the context of prior and existing research.

For a full description of the standards of expected ethical behaviour by all parties involved in the publishing process (the author, the journal editor, the peer reviewer, the publisher and the society for society-owned or sponsored journals) please see: [http://www.elsevier.com/wps/find/intro.cws\\_home/publishing](http://www.elsevier.com/wps/find/intro.cws_home/publishing).

Of equal importance are ethical guidelines dealing with research methods and research funding, including issues dealing with informed consent, research subject privacy rights, conflicts of interest, and sources of funding.

While it may not be possible to draft a "code" that applies adequately to all instances and circumstances, we believe it useful to outline our expectations of authors and procedures that the Journal will employ in the event of questions concerning author conduct. Relevant conflicts of interest should be disclosed (see <http://www.elsevier.com/wps/find/authorshome.authors/conflictsofinterest>).

Last revised: 9 January 2007

# Our guidelines for handling ethics cases



- Gather all relevant information
- Editor is the ultimate decision-maker
- Due process for our authors
- Involve other bodies or agents, if necessary
- Involve Elsevier legal for review/support
- Remedies & sanctions
- Caution regarding defamation claims
- Record and document all claims



# Publishing Ethics Resource Kit (PERK)

- First stop for advice on how to handle ethics cases
- Policies, “case studies”, flow-charts & decision-trees
- Form letters, approved by Legal

## Publishing Ethics Resource Kit (PERK)

### Introduction

The Publishing Ethics Resource Kit (PERK) is an online resource to support journal editors in handling publishing ethics issues. It is a single point of access for information and guidelines on publishing ethics. PERK provides flowcharts to guide editors through processes required to deal with different forms of publishing ethics abuse. Furthermore, it includes form letters to adapt and use for various situations, Q & A information and much more. For more information on this resource kit and how it works, please see [Why PERK?](#) and [How PERK works.](#)

### Decision trees

#### General guidelines (all decision trees)

1. [Authorship complaints](#)
2. [Plagiarism complaints](#)
3. [Multiple, duplicate, concurrent publication/Simultaneous submission](#)
4. [Research results misappropriation](#)
5. [Allegations of research errors and fraud](#)
6. [Research standards violations](#)
7. [Undisclosed conflicts of interest](#)
8. [Reviewer bias or competitive harmful acts by reviewers](#)

### Form letters

- A. [To author](#)
- B. [To complainant re: Author](#)
- C. [To institution](#)
- D. [To other journal \(double publication\)](#)
- E. [To funding agency](#)
- F. [To reviewer](#)
- G. [To complainant re: Reviewer](#)
- H. [To reviewer's institution](#)



*“What's Elsevier's position on publishing ethics?”*

### Menu

- [PERK introduction](#)
- [Why PERK?](#)
- [How PERK works](#)
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- [Decision trees](#)
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- [CrossCheck](#)
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- [About COPE](#)
- [Industry organisations](#)



# Committee on Publication Ethics (COPE)



- Independent body
- Started in 1997 as “self-help” group of editors (e.g. Richard Horton, *Lancet*), now over 5000 members
- As of 2008, all Elsevier journals part of COPE: first major publisher to do so

# What COPE offers



- Website with searchable database of sample cases back to 1997
- Advice on tricky cases. Quarterly teleconferences where you can seek a consultation
- Quarterly newsletter for members only
- Voluntary journal self-audit, using COPE tools & guidelines
- Grants for research on publication ethics
- Online distance-learning modules for Editors

- Huge database: 31+ million articles from 49,000 journals & books donated by 150+ publishers
- Ithenticate software shows any similarities between the article and previously published articles
- 400 Editors piloted in 2009, now widely available

## What Editors are telling us...

- “Handle with care: risk of false positives & false negatives”
- “This is great, now please integrate into EES!”
- “Why can’t I just compare two documents?”
- “Not all sections are equally important: weighting needed”

# Example: CrossCheck user account



Trash

Resubmit



My Documents

Documents

Sharing

Settings

Resubmit

page 1 of 1

<input type="checkbox"/>	Title	Report	Author	Processed ↓	Actions
<input type="checkbox"/>	paperoill.pdf 1 part - 2,171 words	6%		02/24/10	
<input type="checkbox"/>	370_new file 1 part - 2,171 words	6%		02/16/10	
<input type="checkbox"/>	320_exclude small similarities 1 part - 12,035 words	42%		02/16/10	

page 1 of 1



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View: [Recent Uploads](#)



New folder

[New Folder](#)

[New Folder Group](#)

# Example: Crosscheck detailed report



Folder: My Documents Jump to: 320\_exclude small similarities - 32%

## iThenticate® 320\_exclude small similarities

As of: Feb 16, 2010 1:28:39 PM GMT  
12,035 words - 180 matches - 59 sources

**Similarity Index**  
**32%**

Mode: Similarity Report Exclude Quotes Include Bibliography Excluding matches < 40 words

**Arabia, Tunisia, and Turkey.**

It has been found that the reactions of

**monetary policies to stock market price movements are far from homogenous across countries.** 7

The

**paper attempts to put forward some explanations.** Key Words: **Monetary policy, Stock markets, MENA countries, SVAR methodology.** 7

J.E.L. Classifications: E44, E52, E58, G1. 1. Introduction Economists and financiers have recently given evidence of renewed

**interest in understanding the interaction between asset markets and monetary policy.** 5

- 1 1,099 words / 9% - Internet from Apr 19, 2009 [meeaweb.org](http://meeaweb.org)
- 2 594 words / 5% - CrossCheck
- 3 183 words / 2% - CrossCheck
- 4 138 words / 1% - Internet from Aug 15, 2009 [www.erf.org.eg](http://www.erf.org.eg)
- 5 130 words / 1% - Internet from Feb 4, 2010 [www.cbe.anu.edu.au](http://www.cbe.anu.edu.au)
- 6 122 words / 1% - Internet [www.amf.org.ae](http://www.amf.org.ae)



## Publishing Ethics" Statement

[http://www.elsevier.com/wps/find/intro.cws\\_home/publishing](http://www.elsevier.com/wps/find/intro.cws_home/publishing)

## "Standard Operating Procedures" Editorial Manual

<http://www.elsevier.com/wps/find/editorsinfo.editors/sopethics>

## Conflict of Interest Policy

<http://www.elsevier.com/wps/find/authorshome.authors/conflictsofinterest>

## Legal guide to plagiarism

<http://www.elsevier.com/wps/find/editorsinfo.editors/ethicshelpdesk>

## EES

"Headline" statement on ethics

Internal "duplicate text" checking



## Council of Science Editors

[http://www.councilscience.org/editorial\\_policies/white\\_paper.cfm](http://www.councilscience.org/editorial_policies/white_paper.cfm)

## World Association of Medical Editors

<http://www.wame.org/ethicsrsource.htm>

## Committee on Publication Ethics

<http://www.publicationethics.org.uk>

# Agenda



- How big is the problem?
- The biomedical journal
- Elsevier's role
- Case study: what would you do?

# Case study: what would you do?



*Dr Smith complains that your journal has published an article that plagiarises his work & demands that you retract the article.*

*You refer to the article and find:*



## *5.3. Experiment 3: Smith\_Data set*

The Smith\_Data is a simulation data set which used to test three anomaly detection algorithms by Smith et al. in the literature [10].

## **Acknowledgments**

We would like to thank Doctor X for his help in providing the experimental data sets.

## **References**

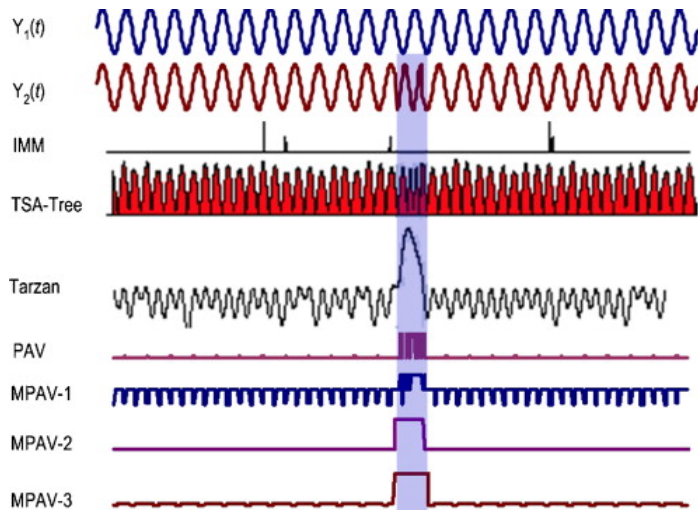
10. Smith, J. *Information Systems* **13** (2001), pp. 63–86.

# Case study: what would you do?



“The Editorial board did...nothing. The Editorial board is either incompetent or lazy or both”

[smith.blogspot.com](http://smith.blogspot.com)



## ERRATUM

*“We deeply regret this error and we offer our sincere and unreserved apologies to readers of the journal for this, and especially to the authors of the above-mentioned papers.”*

# Another quote



“To love what you do and feel that it matters...how could anything be more fun?”

Katherine Graham, American Publisher

# Another more quote



- Publishing is central to making scientific progress:
  - Building on individual work and that of others
  - Formulating new questions

“Publication is not the end, but the beginning...”



# The last quote...



The library connects us with the insight and knowledge, painfully extracted from Nature, of the greatest minds that ever were, with the best teachers, drawn from the entire planet and from all our history, to instruct us without tiring, and to inspire us to make our own contribution to the collective knowledge of the human species. I think the health of our civilization, the depth of our awareness about the underpinnings of our culture and our concern for the future can all be tested by how well we support our libraries.

— *Cosmos*

Carl SAGAN

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