

# Research Integrity: Why Is This Such a Problem?

Lee M. Ellis, MD, FACS, FASCO  
Departments of Surgical Oncology, and  
Molecular & Cellular Oncology

- UT MD Anderson Cancer Center
- SWOG
- JAMA Oncology (Deputy Editor)

GCC Workshop: May, 2021

# Research Integrity And Its Effects On Drug Development

- Integrity of laboratory research and how this impacts clinical outcomes
  - The issue at hand
    - The spectrum
  - Why does this occur?
  - What can we do to fix this?

*Find the Fraud?*

*Not enough time...too many other things to talk about*

*if* we used an audience response system

# Potential Audience Responses After This Session

At the end of my talk, you will feel:

- A. Entertained
- B. Angry
- C. Discouraged (how can I trust anything I read?)
- D. Reinvigorated (it is OK to publish in something other than *CNS*)
- E. All of the above

# Everything You Need to Know About Research Integrity From One Site

<https://ori.hhs.gov/infographics>

## 5 QUALITIES OF GOOD RESEARCH MENTORS

"A mentor is a person who has achieved career success and counsels and guides another for the purpose of helping him or her achieve life success."

- RESPECTFUL**  
Demonstrates respect for all laboratory members, which reduces fear and unhealthy competitiveness.
- SUPPORTIVE**  
Supports mentees by acknowledging accomplishments and challenging mentees to develop skills that advance their careers.
- AVAILABLE**  
Establishes open and responsive communication with mentees, which promotes research integrity and discourages questionable research practices.
- PREPARED**  
Anticipates the needs of mentees and is prepared to provide assistance and guidance.
- HONEST**  
Sets high standards for honest reporting of data, regardless of whether the data supports the desired outcome.

**Why is mentorship important?**  
Good mentorship improves the quality and integrity of scientific research.

Responsents in over 50% of ORIs findings of research misconduct by postdocs, students, technicians, and research assistants.

ORIPROTECT

## WRITE ETHICALLY

FROM START TO FINISH

**PREPARE**

- USE PRIMARY LITERATURE**: Secondary sources might have misrepresented the work.
- HAVE A THOROUGH UNDERSTANDING OF YOUR SOURCES**: Accurately communicate their ideas and terminology.

**WRITE**

**CITE YOUR SOURCES**

**DO NOT PLAGIARIZE**

- SELECTIVE REPORTING**: Present unbiased information by acknowledging conflicting evidence and alternative interpretations.
- USE YOUR OWN WORDS AND MAINTAIN THE INTENDED MEANING OF THE SOURCE**
- QUOTE VERBATIM TEXT**: Only include those who have made substantial contributions to a project.
- AVOID GHOST AUTHORSHIP**: Give proper authorship or acknowledgment to those who have contributed to a paper.

Learn more about ethical writing: [ori.hhs.gov/ethical\\_writing](http://ori.hhs.gov/ethical_writing)

## EVERYONE PLAYS A ROLE IN RESEARCH INTEGRITY

A "PUBLISH OR PERISH" CASE STUDY

**PERSONAL LEVEL**

**Bob is falsifying data**  
Bob is looking to end his research. He is being a tight budget and has no resources to continue his work. He has the only way to meet his deadline is to falsify data. What else has he done to contribute to his lab's success?

**PERSONAL LEVEL**

**Bob's lab is under pressure to publish**  
Dr. C. Bob's lab, which was the only lab in the department to receive funding, is under pressure to publish. Bob's lab is the only one in the department that has not published a paper. What can he do to meet his deadline?

**PERSONAL LEVEL**

**The university rewards academic publications and grants**  
The university rewards academic publications and grants. Bob's lab is the only one in the department that has not published a paper. What can he do to meet his deadline?

**PERSONAL LEVEL**

**The research community reinforces the pressure to "publish or perish"**  
The research community reinforces the pressure to "publish or perish". Bob's lab is the only one in the department that has not published a paper. What can he do to meet his deadline?

What can you do to promote integrity from your place in this system?

## RESEARCH TRAINEES

WHAT YOU NEED TO KNOW ABOUT RESEARCH MISCONDUCT

**Misconduct Is Not Limited to Published Research**  
Research misconduct affects everyone.

**There is a Professional You Can Contact**  
The Research Integrity Officer (RIO) is responsible for the day-to-day operations of the research integrity office.

**Anyone Can Report Misconduct**  
Anyone can report research misconduct, including students, postdocs, and faculty.

**Institutions Have Policies to Protect All Involved**  
Research institutions have policies in place to protect the interests of all involved in research.

**You Can Report Research Misconduct Anonymously**  
You can report research misconduct anonymously through a secure online reporting system.

**ORIs research misconduct cases:**  
14% were reported by research trainees  
40% were committed by research trainees

Learn more about responsible research at [ori.hhs.gov](http://ori.hhs.gov)

## POSSIBLE RED FLAGS OF RESEARCH MISCONDUCT

**TIME**  
Unusable data are only generated when there is a pressing deadline  
Experiments are completed faster than usual

**RESULTS**  
Data are too good to be true  
Findings can't be replicated by others in the lab

**LACK OF TRANSPARENCY**  
Raw data can't be produced when requested  
Research materials and protocols are kept hidden  
Work is mostly done when no one else is around

If you suspect research misconduct contact your institution's Research Integrity Officer or ORI at [AsAORI@hhs.gov](mailto:AsAORI@hhs.gov)

## YOU SUSPECT RESEARCH MISCONDUCT NOW WHAT?

**IF YOU ARE SUSPICIOUS**

- AVOID CONFRONTATION**: Direct confrontation may lead to retaliation or loss of funding.
- KEEP NOTES**: Document details and save communications related to the suspected misconduct.
- CONSULT YOUR RESEARCH INTEGRITY OFFICER (RIO)**: RIOs can help you better understand the situation.

**IF YOU ARE WORKING WITH A RESEARCHER WHO YOU SUSPECT HAS COMMITTED RESEARCH MISCONDUCT**

- REPORTING MISCONDUCT IS DIFFICULT... BUT IT CAN BE WORTH IT.**
- REPORTING MISCONDUCT HELPS:**
  - Protect the reputation and career of the accused
  - Prevent the repetition of the same behavior
  - Protect the public's health and safety

**WHEN YOU REPORT**

- BE SPECIFIC**: Provide the RIO with specific examples of suspected misconduct.
- BE PREPARED FOR SILENCE**: Institutional policies may limit your access to confidential information.
- BE AVAILABLE**: The RIO may request your help identifying and analyzing evidence.
- BE PATIENT**: Research misconduct proceedings take considerable effort and time.

**MAKE AN INFORMED DECISION**  
If you want to self-report or report misconduct contact ORI at 844-543-5800 or [AsAORI@hhs.gov](mailto:AsAORI@hhs.gov)

## 5 WAYS SUPERVISORS CAN PROMOTE RESEARCH INTEGRITY

**1. BE AVAILABLE & APPROACHABLE**  
Are you a principal investigator, research coordinator, academic advisor, or mentor? Have you set these expectations for a unique position to enforce exceptional research practices among the next generation of researchers?

**2. REVIEW RAW DATA**  
You are responsible for the integrity of your team's data.

**3. COMMUNICATE EXPECTATIONS**  
Prevent misunderstandings by making sure everyone is on the same page.

**4. PROVIDE TRAINING AND GUIDANCE**  
Avoid making assumptions about anyone's skills or knowledge.

**5. RESEARCH INTEGRITY OFFICER**  
Be prepared in case you ever suspect research misconduct.

Find out more: [ori.hhs.gov](http://ori.hhs.gov), [ORIs@hhs.gov](mailto:ORIs@hhs.gov), [www.ori.hhs.gov](https://www.ori.hhs.gov)

## WHAT DRIVES PEOPLE TO COMMIT RESEARCH MISCONDUCT?

These quotes come from people who submitted for research misconduct or advised ORI of research integrity cases.

- POOR SUPERVISION**: "I WAS SCARED TO GO TO MY PI. HE USED TO SCREAM & YELL AT US WHEN THINGS DID NOT WORK AS PLANNED."
- INADEQUATE TRAINING**: "AFTER TWO YEARS OF A POSTDOCTORAL FELLOWSHIP... I STILL DON'T KNOW HOW TO PROPERLY PUBLISH WESTERN BLOT DATA."
- COMPETITIVE PRESSURES**: "I FELT IT WAS NECESSARY TO GET A PAPER IN A HIGH-PROFILE JOURNAL IN ORDER TO GET A FACULTY POSITION."
- PERSONAL CIRCUMSTANCES**: "I HAD BEEN APPLYING FOR A GREEN CARD AND FELT PRESSURED TO MAKE A GOOD PAPER AND GET GOOD PUBLICATIONS."
- INDIVIDUAL PSYCHOLOGY**: "HALF OF ME WANTED TO MAKE [MY PI] PROUD. THE OTHER HALF WAS TERRIFIED OF FAILING... SO I FABRICATED A PIECE OF DATA."

Seek support from a mentor if stressors are impacting your work.

## YOU'VE BEEN ACCUSED OF RESEARCH MISCONDUCT NOW WHAT?

**PROSECUTION AGENCY**  
Division of the Inspector General's authority is limited to the extent possible, in those cases where to be, conducted with a minimum of disruption to the research program.

**PROSECUTION AGENCY**  
The Inspector General's authority is limited to the extent possible, in those cases where to be, conducted with a minimum of disruption to the research program.

**PROSECUTION AGENCY**  
The Inspector General's authority is limited to the extent possible, in those cases where to be, conducted with a minimum of disruption to the research program.

**PROSECUTION AGENCY**  
The Inspector General's authority is limited to the extent possible, in those cases where to be, conducted with a minimum of disruption to the research program.

**PROSECUTION AGENCY**  
The Inspector General's authority is limited to the extent possible, in those cases where to be, conducted with a minimum of disruption to the research program.

## IT'S A SLIPPERY SLOPE TO RESEARCH MISCONDUCT

Small lapses in judgment can lead to a slippery slope ending in research misconduct.

**1. TAKING SHORTCUTS**  
Lack of care in experimentation that might impact reproducibility.

**2. CHEATING**  
Such as padding, which is inflating your resume, can establish improper behavior patterns.

**3. "BEAUTIFICATION" OF IMAGES**  
Retouching or unaltered features, even if unrelated to the result, could be considered significant.

**4. LACK OF APPROPRIATE CONTROLS**  
Failing to perform a control with the experimental sample could affect result interpretation.

**5. COMPOSITE IMAGES**  
Assemblies of images that are not clearly labeled, such as a montage of cell images from the same experiment but not labeled as such.

**6. OUTLIERS**  
Changing outlier data without appropriate pre-approval justification, which alters the overall conclusion of the analysis.

**7. IMAGE MANIPULATION**  
Splicing, cutting, or erasing images without proper documentation, changing, that alters the results or falsely claims to result, which was not labually done.

Questionable or Debatable Research Practices may be considered research misconduct in some cases, but the facts of each case differ and must be individually evaluated.

## THE RESEARCH COMMUNITY SAFEGUARDS SCIENTIFIC INTEGRITY

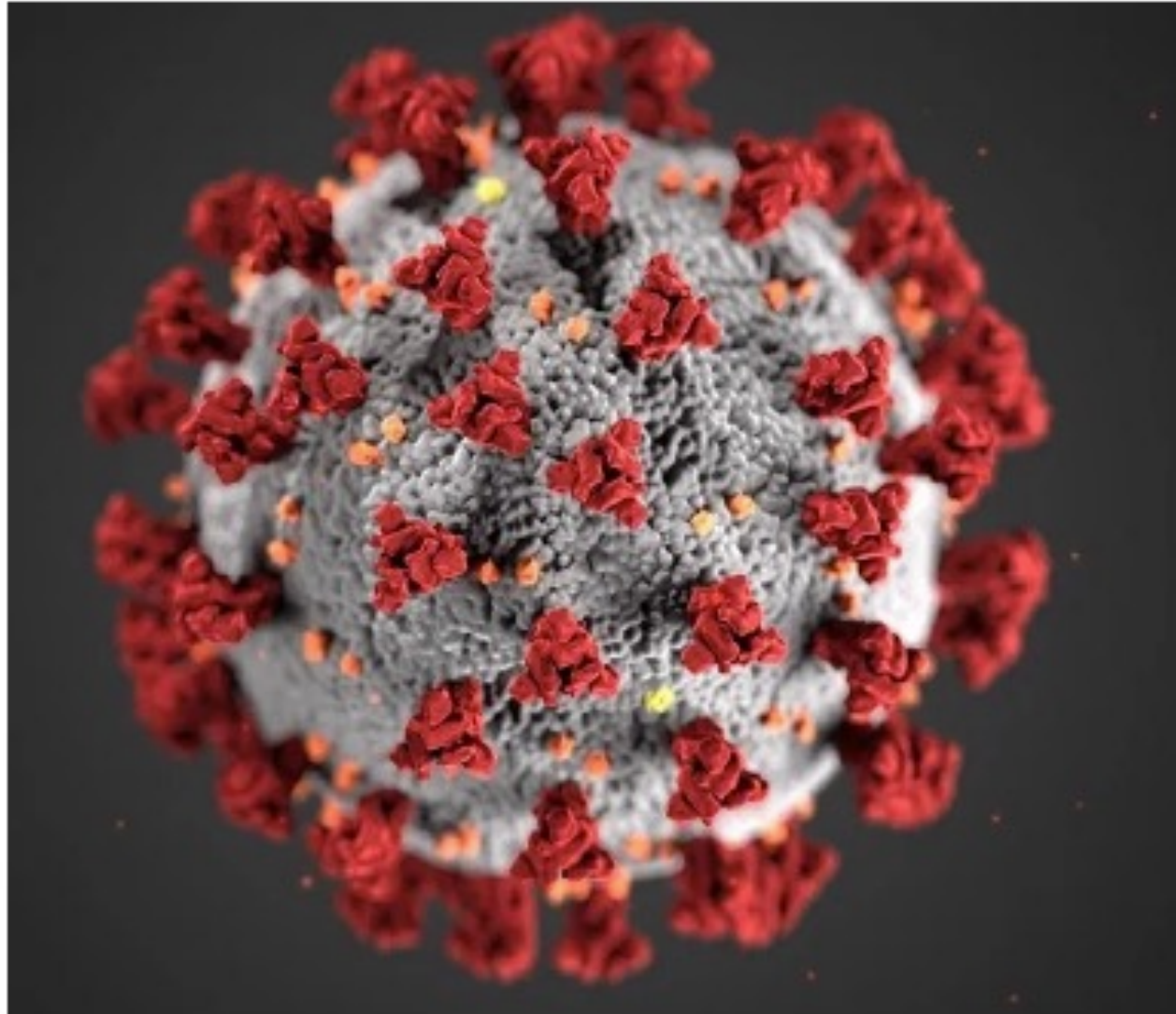
**WHAT'S YOUR ROLE?**

- RESEARCHERS**: Reproduce, report on, and openly debate research results.
- FUNDING AGENCIES**: Ensure funding of quality research through rigorous grant review.
- INSTITUTIONS**: Foster a culture of research integrity through mentoring, education, and policies.
- WHISTLEBLOWERS**: Draw attention to questionable research.
- GOVERNMENT REGULATORY AGENCIES**: Protect humans, animals, and the dollars in research and handle research misconduct allegations.
- JOURNALS & PEER REVIEWERS**: Evaluate submissions to disseminate accurate research.

Learn more about responsible research with our educational materials at [ori.hhs.gov/resources](http://ori.hhs.gov/resources)

# Retraction Watch

**Retracted coronavirus (COVID-19) papers**



# COVID Retractions as of May 23, 2021

**Retracted**

- "SG Technology and Induction of coronavirus in skin cells," published in *Biological Regulators & Homeostatic Agents* on July 16, 2020, withdrawn on July 24, 2020. Our coverage here.
- "A review of convalescent plasma transfusion in COVID-19: Old wine reserved for special occasions," published in *Lung India* on September 16, 2020; retracted December 31, 2020.
- Acute necrotizing myelitis and acute motor axonal neuropathy in a COVID-19 patient," published in *Journal of Neurology* on August 9, 2020; unknown date of retraction.
- "An epidemiological investigation of a new coronavirus pneumonia cluster epidemic spread in public transportation" (also titled "An epidemiological investigation of 2019 novel coronavirus diseases through aerosol-borne transmission by public transport"), published in early March in *Practical Preventive Medicine and Retracted* sometime in mid-April. More context here.
- "Anal swab as the potentially optimal specimen for SARS-CoV-2 detection to evaluate the hospital discharge of COVID-19 patients," published on August 14, 2020 in *Future Microbiology*; retracted on April 13, 2021.
- "Analysis of Ten Microsecond simulation data of SARS-CoV-2 dimeric main protease," preprint posted on *bioRxiv*, April 12, 2020, withdrawn April 16, 2020.
- "Analysis of thin-section CT in patients with coronavirus disease (COVID-19) after hospital discharge," published on May 15, 2020 in *Clinical Imaging*; retraction date/cause is unknown.
- Autopsy and Histologic Findings of Patients with New Coronavirus Pneumonia: The Pathologic Association with Hypoxemia," published on February 13, 2020 in *Medical Science Monitor*; retracted on March 7, 2021.
- "Calcifediol Treatment and COVID-19-Related Outcomes," posted to *Preprints with The Lancet* on January 22 and removed on February 19, 2020. Our coverage here.
- "Can quantitative RT-PCR for SARS-CoV-2 help in better management of patients and control of coronavirus disease 2019 pandemic?" published on November 16, 2020 in *Indian Journal of Medical Microbiology*; unknown date of retraction.
- "Can Traditional Chinese Medicine provide insights into controlling the COVID-19 pandemic: Serpenitization-induced lithospheric long-wavelength magnetic anomalies in Proterozoic bedrocks in a weakened geomagnetic field mediate the aberrant transformation of biogenic molecules in COVID-19 via magnetic catalysis," published in *Science of the Total Environment* on October 8, 2020, "temporary removal" on November 5, 2020, subsequently retracted on an unknown date. Our coverage here.
- "Mechanical ventilation in COVID-19: Is it due to patient or virology factors," published on June 14, 2020 in the *Annals of Medicine and Surgery*; date of retraction is unknown.
- "Mental health burden for the public affected by the COVID-19 outbreak in China: Who will be the high-risk group?," published April 14, 2020 in *Psychology, Health & Medicine* and retracted on October 23, 2020. Our coverage here.
- "Mental health status and coping strategy of medical workers in China during the COVID-19 outbreak," preprint posted on *medRxiv* on February 25, 2020, withdrawn on March 7, 2020.
- "Mortality of a pregnant patient diagnosed with COVID-19: A case report with clinical, radiological, and histopathological findings," published in *Travel Medicine and Infectious Disease* on April 11, 2020, retracted on May 2, 2020. Our coverage here.
- "mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Approach," published December 31, 2020 in *The Journal of Allergy and Clinical Immunology: In Practice*. Temporary Removal published on unknown date.
- "Needed: Less influenza vaccine hesitancy and less presenteeism among health care workers in the COVID-19 era," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "No Deleterious Effect of Lockdown Due to COVID-19 Pandemic on Glycaemic Control, Measured by Glucose Monitoring, in Adults with Type 1 Diabetes," published on May 12, 2020 in *Diabetes Technology & Therapeutics*; retracted July 27, 2020. Our coverage here.
- "Noninvasive versus Invasive ventilation: one modality cannot fit all during COVID-19 outbreak," published on July 8, 2020 in the *Korean Journal of Anesthesiology*; retracted on September 14, 2020. Our coverage here.
- "Noteworthy Neurological Manifestations Associated With COVID-19 Infection," published on July 3, 2020 in *Cureus*; retracted on March 5, 2021.
- "Novel research opportunities: an unfortunate small silver lining to COVID-19," published on October 2, 2020 in *Early Human Development*; retracted on sometime in March, 2021. See our coverage here.
- "Novel research opportunities 2: An unfortunate small silver lining to COVID-19," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Nurses reports of actual work hours and preferred work hours per shift among frontline nurses during coronavirus disease 2019 (COVID-19) epidemic: A cross-sectional survey," published on May 16, 2020 in the *International Journal of Nursing Studies*; date of retraction is unknown.
- "Can You AI Differentiate Cats from Covid-19? Simple Efficient Uncertainty Estimation for Deep Learning Safety" reportedly to be presented at the *ICML 2020 Workshop on Uncertainty and Robustness in Deep Learning* in July 2020, removed sometime before June 17, 2020. *Improbable Research* discusses it here.
- "Cardiovascular Disease, Drug Therapy, and Mortality in Covid-19," published in the *New England Journal of Medicine* on May 1, 2020, subjected to an expression of concern on June 2, 2020 and retracted on June 4.
- "Characteristics and risk factors for COVID-19 diagnosis and adverse outcomes in Mexico: an analysis of 89,756 laboratory-confirmed COVID-19 cases," published in the *European Respiratory Journal* on July 31, 2020, and retracted on March 4, 2021.
- "Chinese medical staff request international medical assistance in fighting against COVID-19," letter in *The Lancet* published February 24, 2020 and retracted February 26, 2020. More context here.
- "Chinese mental health burden during the COVID-19 pandemic," published in *Asian Journal of Psychiatry* on April 14, 2020 and retracted on November 4, 2020. Our coverage here.
- "Clinical and Epidemiological Characteristics of 34 Children With 2019 Novel Coronavirus Infection in Shenzhen," published in *Zhonghua Er Ke Za Zhi* on February 17, 2020, date of retraction unknown.
- "Clinical manifestations and outcome of SARS-CoV-2 infection during pregnancy," published on March 5, 2020 in *Journal of Infectious Diseases*; unknown date of retraction. Hat tip.
- "Chloroquine or hydroxychloroquine for COVID-19: why might they be hazardous?" published in *The Lancet* on May 22, 2020; retracted and replaced July 9, 2020. Our coverage here.
- "Clinical sequelae of the novel coronavirus: does COVID-19 infection predispose patients to cancer?," published in *Future Oncology* in May 2020, retracted for plagiarism in December 2020. Our coverage here.
- "Computational analysis suggests putative intermediate animal hosts of the SARS-CoV-2," preprint posted on *bioRxiv* on April 5, 2020, withdrawn April 20, 2020.
- "Convalescent plasma therapy in COVID 19: Every dark cloud has a silver lining," published on October 16, 2020 in *Journal of Anesthesiology Clinical Pharmacology*; retracted January 18, 2021.
- "Corona Virus Killed by Sound Vibrations Produced by Thali or Ghanti: A Potential Hypothesis," published in March-August 2020 issue of *Journal of Molecular Pharmacology and Therapeutics* and *Journal Affairs*; date of retraction is unknown.
- "Coronavirus disease-2019: A brief compilation of facts," published on May 8, 2020 in the *Journal of Oral and Maxillofacial Pathology*; retracted in the May-August 2020 issue.
- "Countering fake news in the COVID-19 era: The public's opinion on the role of an honest and reliable website," published on November 17, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19: A global and continental overview of the second wave and its (relatively) attenuated case fatality ratio," published on October 3, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19: Combined supply-side and demand-side shocks, so lift restrictions (carefully) lest GDP declines ultimately kill more than COVID-19," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19: Mathematical estimation of delay to deaths in relation to upsurges in positive rates," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19: The possible seasonal shape of things to come," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19, Suicide, and Femicide: rapid research using Google Search," published on January 22, 2021 in *The Journal of General Psychology*; retracted on May 19, 2021. See our coverage here.
- "COVID-19 and potential global mortality - Revisited," published on April 30, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19 Emergency Responders in FDA's Center for Drug Evaluation and Research," published sometime after April 6, 2020 in *Journal of the American Pharmacists Association*, date of retraction unknown.
- "COVID-19 in Africa and collateral effects on health systems and their immunization programs," published on October 9, 2020 in *Vaccine*; retraction date is unknown.
- "COVID-19 is aegist, sexist, ruthless, dispassionate and opportunistic - Protecting our vulnerable," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19: its novel vaccination and fake news - What a brew," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "COVID-19 related acute decline in paediatric admissions in Malta, a population-based study," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Decrease in Hospitalizations for COVID-19 after Mask Mandates in 1083 U.S. Counties," *medRxiv* preprint posted on October 23, 2020 and withdrawn on November 4, 2020.
- "Selenium-associated gene signatures within the SARS-CoV-2-host genomic interaction interface," published on July 15, 2020 in *Free Radical Biology & Medicine*; date of retraction is unknown.
- "Sharp decline in acute and elective hospital attendances and admissions due to COVID-19 in Malta (Q1 2020) - A population-based study," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Smoking Prevalence is Low in Symptomatic Patients Admitted for COVID-19," *medRxiv* preprint posted May 10, 2020 and withdrawn June 13, 2020.
- "Some health effects of global warming," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Sports and sportsmen as role models - or otherwise - in the COVID-19 era," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Subsegmental Thrombus in COVID-19 Pneumonia: Immuno-Thrombosis or Pulmonary Embolism? Data Analysis of Hospitalized Patients with Coronavirus Disease," published on August 24, 2020 in *Heart, Lung and Circulation*; retraction date is unknown.
- "The early cryptic transmission and evolution of SARS-CoV-2 in human hosts," preprint posted on November 17, 2020 in *SSRN: Social Science Resource Network*; withdrawn at an unknown date. Coverage in the media here.
- "The Role of Vitamin D in Suppressing Cytokine Storm in COVID-19 Patients and Associated Mortality," preprint posted on April 10, 2020 in *medRxiv*; withdrawn on April 15, 2020.
- "Theoretical novel COVID-19 vaccination risk of rare and severe adverse events versus COVID-19 mortality," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "The way in which COVID-19 changed behaviour on social media in Malta," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "The Spanish Flu, COVID-19 and Malta's reactions: Contrasts and similarities," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "To wear or not to wear? Adherence to face mask use during the COVID-19 and Spanish influenza pandemics," published on November 12, 2020 in *Early Human Development*; retracted sometime in March, 2021. See our coverage here.
- "Treatment Response to Hydroxychloroquine, Lopinavir/Ritonavir, and Antibiotics for Moderate COVID 19: A First Report on the Pharmacological Outcomes from South Korea," preprint posted May 18, 2020 in *medRxiv*, and with-
- "Hospital factors associated with SARS-CoV-2 infection among healthcare personnel in Greece," published in *The Journal of Hospital Infection* on October 22, 2020, "Temporary Removal" date not provided. Still showing temporary removal as of December 29, 2020.
- "Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis," published in *The Lancet* on May 6, 2020, subjected to an expression of concern on June 2 and retracted on June 4.
- "Hydroxychloroquine plus azithromycin: a potential interest in reducing in-hospital mortality due to COVID-19 pneumonia (HE-ZY-COVID)?" preprint posted on *medRxiv*, May 11, 2020, withdrawn on May 20, 2020. Our coverage here.
- "Incidence and mortality of COVID-19 in Iranian multiple sclerosis patients treated with disease-modifying therapies," published September 15, 2020 in *Revue Neurologique* and retracted on October 8, 2020.
- "Impact of lockdown and health anxiety during COVID 19 pandemic among inpatients of a psychiatric hospital: an observational study," published on November 10, 2020 in the *Asian Journal of Psychiatry*; unknown date of retraction.
- "Intersectionality and Inequalities in Medical Risk for Severe COVID-19 in the Canadian Longitudinal Study on Aging," published September 24, 2020 in *The Gerontologist*; retracted January 22, 2021.
- "Intracranial Hemorrhage in COVID-19 Patients on ECMO: Challenges and Future Directions," published on June 6, 2020 in the *Journal of Cardiothoracic and Vascular Anesthesia*; retraction date is unknown.
- "Ivermectin in COVID-19 Related Critical Illness," preprint posted in April 2020 on *SSRN: Social Science Resource Network*; retracted sometime in May. Reporting from *The Scientist* here.
- "Liver impairment associated with disease progression in Covid-19 patients," published April 15, 2020 in *Liver International* and retracted in August/September 2020.
- "Lung disease severity, Coronary Artery Calcium, Coronary Inflammation and Mortality in Coronavirus Disease 2019," *medRxiv* preprint posted May 6, 2020 and withdrawn June 20, 2020.
- "Lung ultrasound score in establishing the timing of intubation in COVID-19 interstitial pneumonia: A preliminary retrospective observational study," published in *PLOS ONE* on September 3, 2020; Expression of concern published in *PLOS ONE* on November 30, 2020; retracted December 23, 2020. Our coverage here.
- "Malta tourism losses due to second wave of COVID-19," published on October 1, 2020 in *Early Human Development*; retracted sometime in March, 2021.
- "Managing college operations during the coronavirus outbreak," published April 5, 2020 in *Journal of the American Pharmacists Association*, date of retraction un-

Total of 126!!

**Subject:** [EXT] Re:L M Ellis 'sBook

**Date:** Monday, May 24, 2021 at 11:37:13 PM Central Daylight Time

**From:** Julie Ford

**To:** Ellis, Lee M

**WARNING:** This email originated from outside of MD Anderson. Please validate the sender's email address before clicking on links or attachments as they may not be safe.

Dear Dr.L M Ellis ,

I am Julie Ford, an Editorial assistant from a UK based Publishing Company contacting you with the reference from our editorial department. Basing on your outstanding contribution to the scientific community, we would like to write a book for you.

Researchers like you are adding so much value to the scientific community, yet you are not getting enough exposure. No matter how many papers you publish in famous journals, you will be still unknown to common people. To solve this problem, we came up with this unique solution.

With our book writing service, we will write your research contributions in common man's language. We will also include all your published papers into this book in a way that a common man can understand it. And then, we will publish your book with our publishing group. Before, publication, we will send the draft to you for scientific accuracy, once you approve our draft, we then proceed for publication. You will get all the rights of your book, and all the sales generated from your book will be credited to you.

Your book will then be listed on famous websites like Amazon, eBay, Good Reads, and many other popular book websites. As a result, you will get good credit and people will recognize your hard work and your scientific contributions.

Last but not least, after the publication of your book, it will be published in Google News, Yahoo, and other major news channels. What more can you ask for?

All we need is your book writing contract, and you will get all the rights for your book.

I will be waiting to hear from you.

Best regards.  
Julie Ford.



# PubPeer

## Gamma-tocotrienol promotes TRAIL-induced apoptosis through reactive oxygen species/extracellular signal-regulated kinase/p53-mediated upregulation of death receptors

Molecular Cancer Therapeutics (2010) - 12 Comments

pubmed: 20682650 doi: 10.1158/1535-7163.mct-10-0277 issn: 1538-8514 issn: 1535-7163

Ramaswamy Kannappan, Jayaraj Ravindran, Sahdeo Prasad, Bokyung Sung, Vivek R. Yadav, Simone Reuter, Madan M. Chaturvedi, Bharat B. Aggarwal

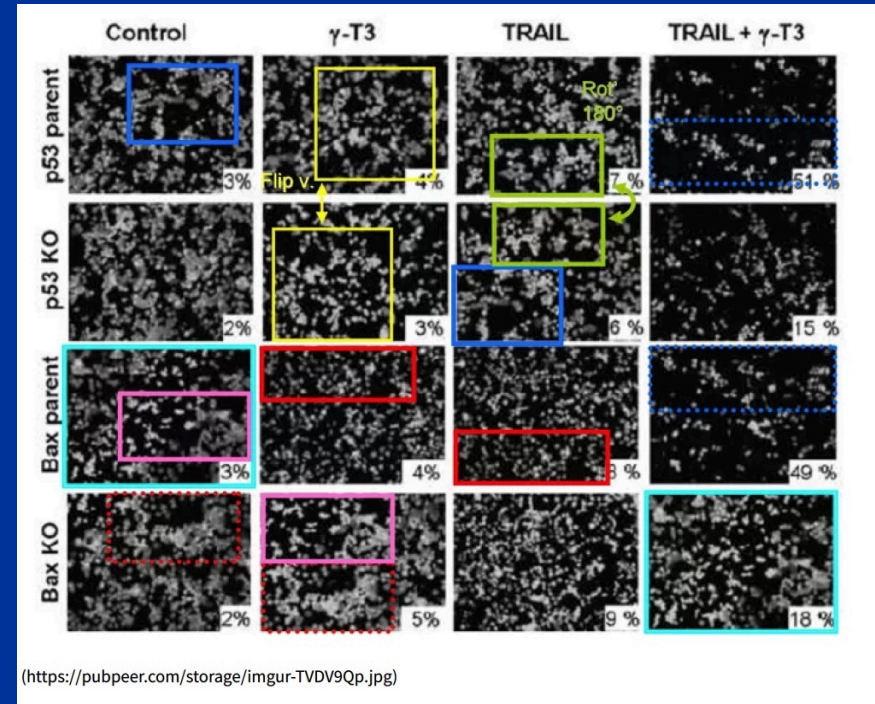
#1 Paul S Brookes commented 6 years ago

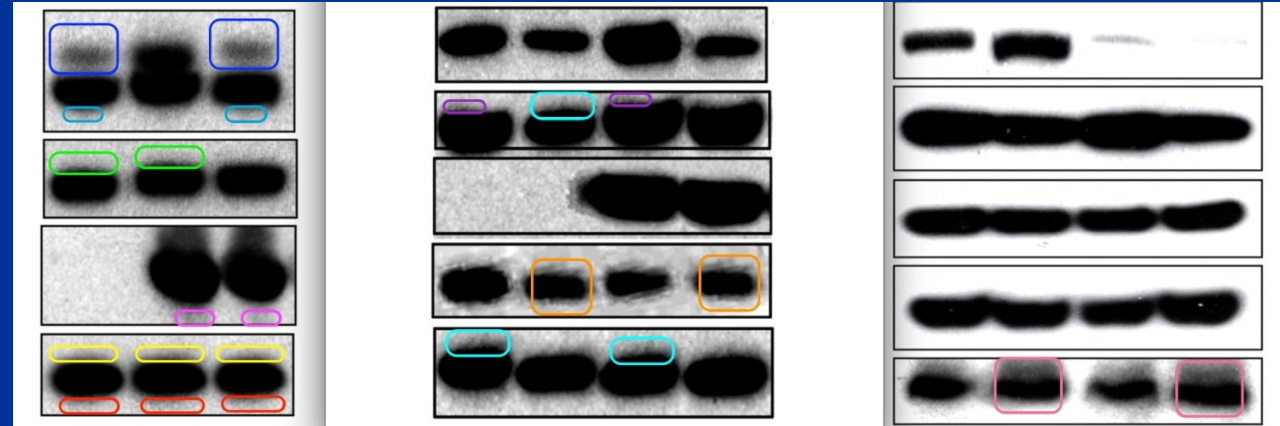
Seeing this beautiful example of "creative image management" highlighted on Twitter (actually had over 100 re-tweets at last count)....

<https://pubpeer.com/publications/B0EE98F42E52EE4F8B130E20059699>

(<https://pubpeer.com/publications/B0EE98F42E52EE4F8B130E20059699>)

... reminded me of this one that's been sitting in the archives for a few years. It's really one of my favorite examples of the art. Should be in all the textbooks.





Elisabeth Bik  
@MicrobiomDigest  
Science consultant, PhD. Microbiome,  
science integrity, image forensics

# Image Manipulation/Duplication

Elisabeth Bik

## Analysis and Correction of Inappropriate Image Duplication: the *Molecular and Cellular Biology* Experience

Elisabeth M. Bik,<sup>a</sup> Ferric C. Fang,<sup>b,f</sup> Amy L. Kullas,<sup>c</sup> Roger J. Davis,<sup>d</sup> Arturo Casadevall<sup>e</sup>

**ABSTRACT** We analyzed 960 papers published in *Molecular and Cellular Biology* (MCB) from 2009 to 2016 and found 59 (6.1%) to contain inappropriately duplicated images. The 59 instances of inappropriate image duplication led to 41 corrections, 5 retractions, and 13 instances in which no action was taken. Our experience suggests that the majority of inappropriate image duplications result from errors during figure preparation that can be remedied by correction. Nevertheless, ~10% of papers with inappropriate image duplications in MCB were retracted (~0.5% of total). If this proportion is representative, then as many as 35,000 papers in the literature are candidates for retraction due to inappropriate image duplication. The resolution of inappropriate image duplication concerns after publication required an average of 6 h of journal staff time per published paper. MCB instituted a pilot program to screen images of accepted papers prior to publication that identified 12 manuscripts (14.5% out of 83) with image concerns in 2 months. The screening and correction of papers before publication required an average of 30 min of staff time per problematic paper. Image screening can identify papers with problematic images prior to publication, reduces postpublication problems, and requires less staff time than the correction of problems after publication.

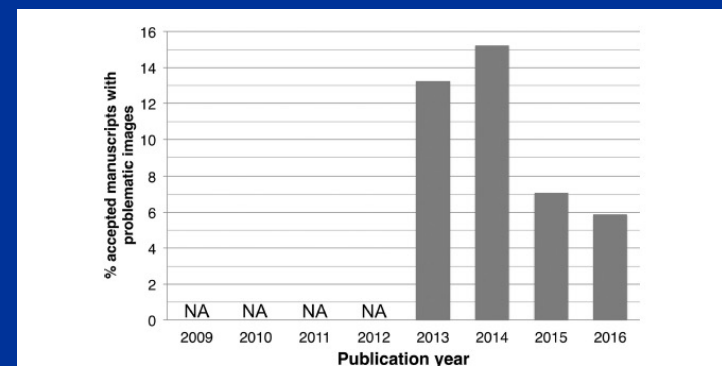
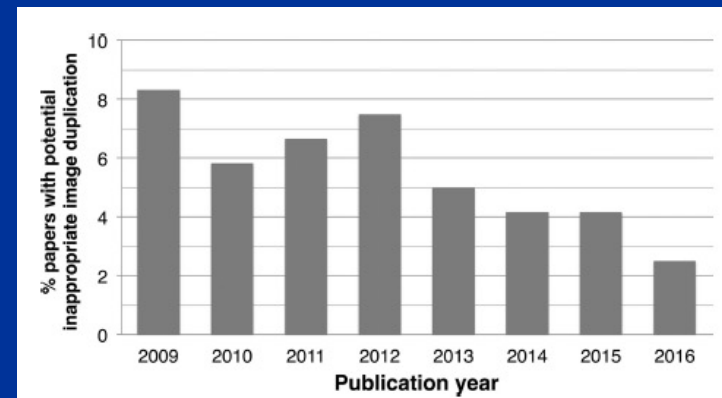


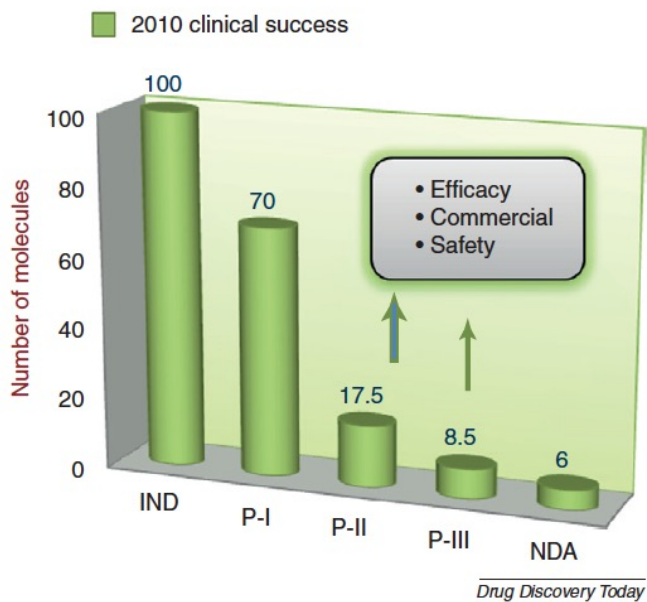
FIG 2 Percentage of accepted MCB manuscripts that were found to have problematic images, 2013 to 2016. No screening for problematic images was done before 2013. NA, not applicable.

# Retraction Watch and PubPeer

- Retraction Watch
  - Editors comment on retracted papers
- PubPeer
  - Peer's comment on papers (sometimes names disclosed, sometime not)
    - Up to you to determine validity of “concerns”
- Microbiome Digest/Elisabeth Bik
- ORI

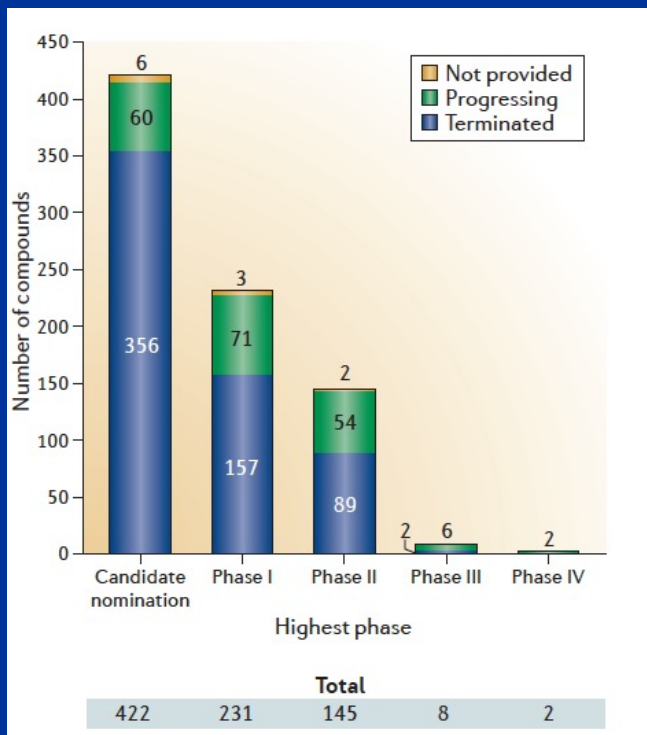
OK, Let's Take a Deeper Dive.....

# Drug Development Failure Rates are Too High! (duh)



**FIGURE 3**  
Productivity trend during 2009 and 2010. The clinical rate of success is depicted as percentage surviving at each clinical phase based on attrition observed during 2009 and 2010.

Khanna, Drug Disc Today, 2012



Waring, Nat Rev Drug Disc, 2015

-On average, it costs over a billion dollars to take a drug through Phase III, and the time to do this is 13-15 yrs.  
 -To improve upon this dismal ~5% success rate, we must *have more confidence in data* from very early in the drug development process\*

\* A more recent publication listed this at ~3.5% for cancer



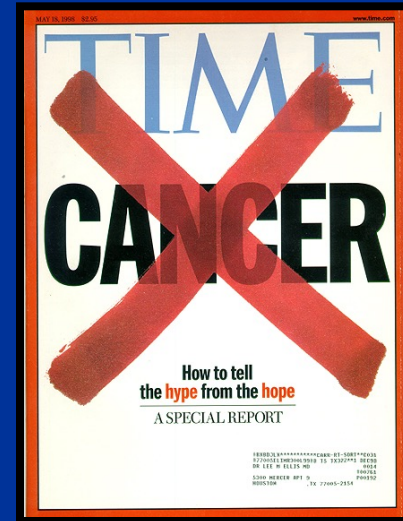
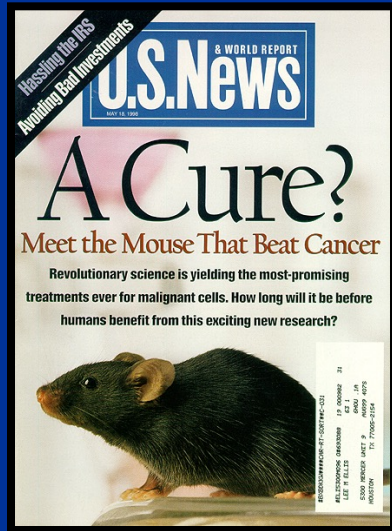
Bob Radinsky, PhD

*MDACC (1989-2000) → Amgen (2000)*

“Lee, do you realize that most of what’s published in academia cannot be reproduced?”

“Glenn Begley has been prospectively collecting this data from studies done at Amgen”

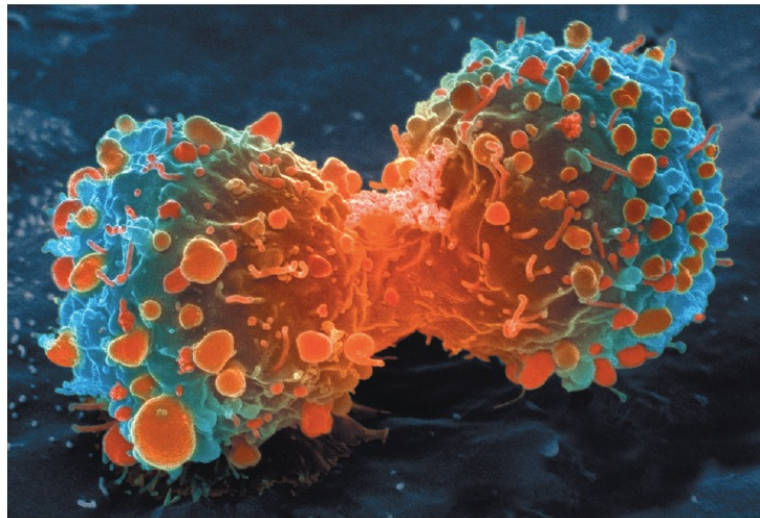
# Why Haven't We Made Greater Strides in Treating Patients With Metastatic Disease?



- Perhaps the data leading to clinical trials are not as sound as they should be
  - What is the cause of this?



# Reports on Issues With Data Reproducibility



Many landmark findings in preclinical oncology research are not reproducible, in part because of inadequate cell lines and animal models.

## Raise standards for preclinical cancer research

C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

Attempted to reproduce 53 "landmark" oncology publications

→ 6/53 reproduced<sup>5</sup>

ident studies<sup>1</sup>

arate ALS mouse  
cal trial of more

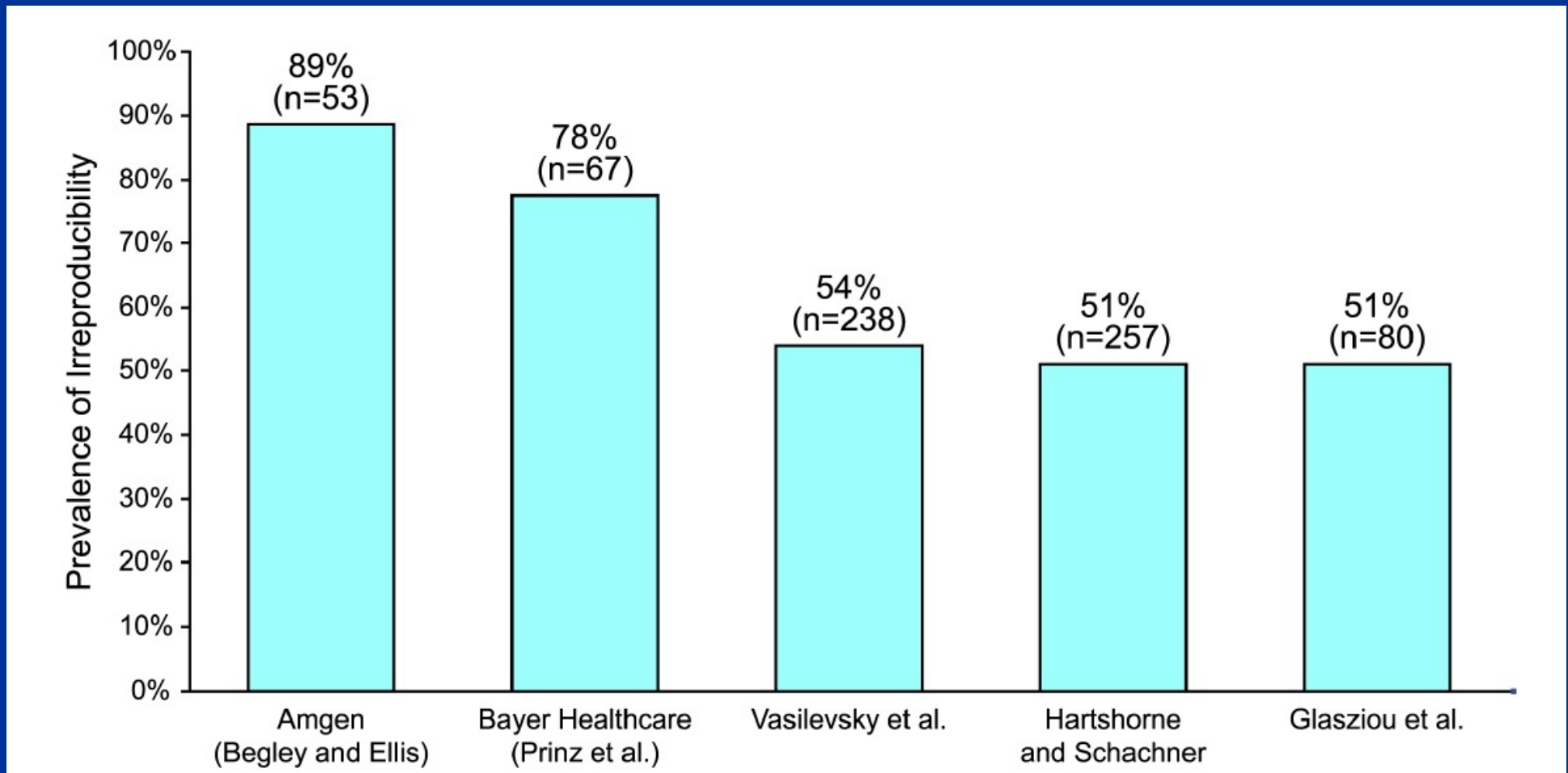
rd injury studies

studies

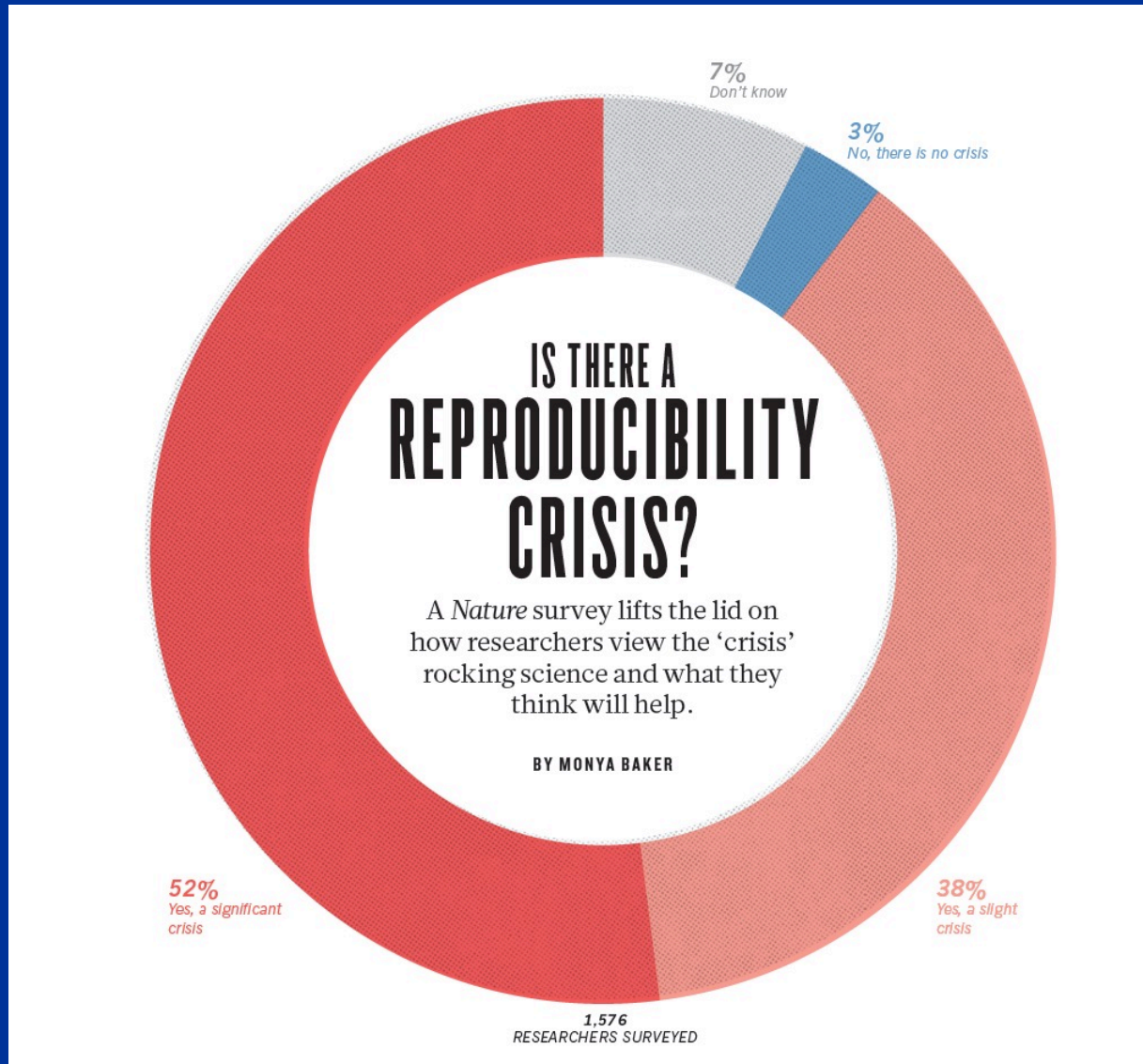
1. Scott et al. Amyotroph Lateral Scler. 9, 4-15 (2008).  
2. Gordon et al. Lancet Neurol. 6, 1045-1053 (2007).  
3. Stuart et al. Experimental Neurology 233, 597-605 (2012).

4. Prinz et al. Nat Rev Drug Discov. 10, 712 (2011).  
5. Begley and Ellis. Nature. 483, 531-3 (2012).

# The Prevalence of the Lack of Reproducibility in *Recently* Published Studies



# Nature Survey, May 2016



# The Spectrum of Reporting Preclinical and Clinical Data

*Not all non-reproducible events are due to evil people*

Honest      Sloppy      Selective Reporting      Falsification      Fabrication



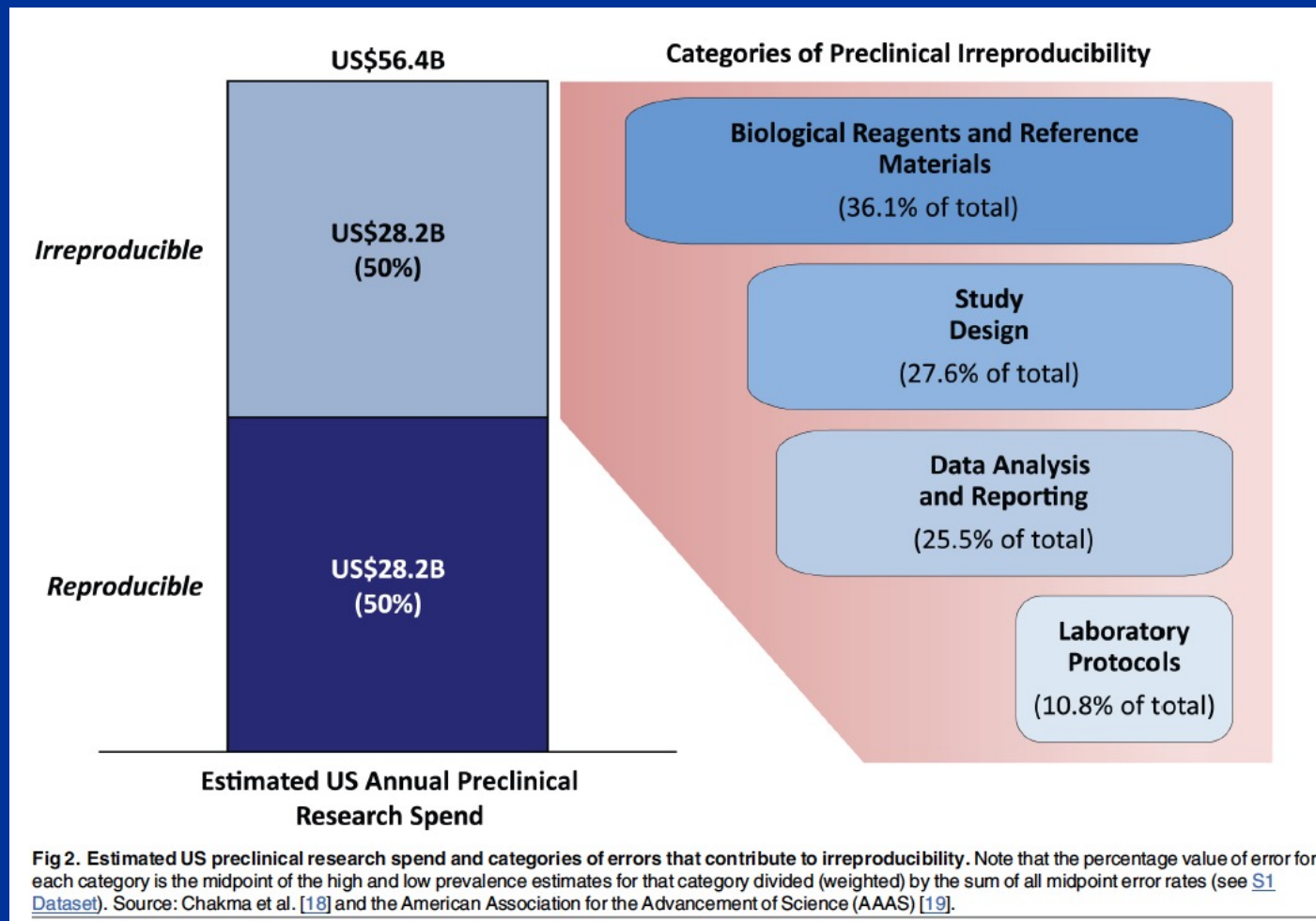
What are the consequences?

- Clinical trials that are bound to fail
- Wasted time and effort of investigators and trainees
- A waste of money to try build on studies that are not sound
- Loss of confidence from our community

# The Economics of Reproducibility in Preclinical Research

Leonard P. Freedman<sup>1\*</sup>, Iain M. Cockburn<sup>2</sup>, Timothy S. Simcoe<sup>2,3</sup>

1 Global Biological Standards Institute, Washington, D.C., United States of America, 2 Boston University School of Management, Boston, Massachusetts, United States of America, 3 Council of Economic Advisers, Washington, D.C., United States of America



# The Spectrum of Reporting Preclinical and Clinical Data

Honest Sloppy Selective Reporting Falsification Fabrication



- Inappropriate Stats
- Cell line contamination/drift
- Journals don't like negative data
  - Therefore, PIs don't like negative data

# Selective Reporting of Laboratory Studies

- Journals prioritize “positive” results
  - If a drug works in 2 cell lines, and does not in 8, we only see the results on the 2 cell lines
- Students, post-docs, and faculty need publications for advancement
  - “*Publish or perish*”
  - In many labs, 2 trainees work on the same project competing with each other...*guess who wins?*
- Therefore, we tend to report only the “positive” data and ignore the negative data

## Highlight negative results to improve science

*Publishers, reviewers and other members of the scientific community must fight science's preference for positive results – for the benefit of all, says Devang Mehta.*

The pressure to publish a positive story can also lead scientists to spin their results in a better light, and, in extreme instances, to commit fraud and manipulate data. In fields such as biotechnology and genomics, social scientists have already pointed out that hyping up the science could foster unrealistic expectations in an already sceptical public, counter-intuitively leading to greater distrust when real-world advances come at a slower pace.

**We need reviewers and publishers to commit to publishing negative results in their journals. We need academic conferences to embrace honest discussions of failed experiments. We need funding agencies to support scientists who produce sound negative results. And, as scientists, we must acknowledge that all important work should be recognized, irrespective of its outcome.**



# The Spectrum of Reporting Preclinical and Clinical Data

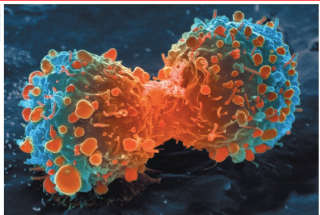
*The more difficult issue to address*

Honest Sloppy Selective Reporting Falsification Fabrication



Let's Talk About  
"Misconduct"

*Do Investigators Intentionally Falsify  
or Fabricate Data?*



Many landmark findings in preclinical oncology research are not reproducible, in part because of inadequate cell lines and animal models.  
Raise standards for preclinical cancer research  
C. Glenn Begley and Lee M. Ellis propose how methods, publications and incentives must change if patients are to benefit.

To: Ellis, Lee M

Dear Sir,

I read your article titled “Raise standards for preclinical cancer research” published in Nature. I felt so happy to learn that the scientific community has been realizing a fact that people in cancer research field have been publishing fraud/non-reproducible data.

I lost my father, 2 of my uncles, aunt and two sister-in-laws because of cancer. Above bitter experiences made me to dedicate my life in finding solution to cancer. With a well-defined career goal of finding treatment to cancer, I entered into cancer research. After completion of Ph.D. from a Nobel Laureate group in Germany, I went to US to work on cancer. As a postdoc in the US, I had to change 7 research labs in 7 years due to the following reason:

PI's wanted me to produce falsified data and I refused to do so. Many PIs fired me as soon as they realized that I don't do wrong things. To cover them up, they sabotaged my professional life as well personal character.

Situation in cancer research field is so bad that nearly 90% of scientists in cancer research field, especially in the US, have been publishing fraud data. [REDACTED]

- 1) Publish fraud data
- 2) Meet all legal requirements to get grants from funding agencies
- 3) Lobby with the members of funding agency study sections by offering donations, effortless favor and get grants
- 4) Bargain high salaries with institutions where they are working using funding as bait

# Stimulus-triggered fate conversion of somatic cells into pluripotency

Haruko Obokata<sup>1,2,3</sup>, Teruhiko Wakayama<sup>3†</sup>, Yoshiki Sasai<sup>4</sup>, Koji Kojima<sup>1</sup>, Martin P. Vacanti<sup>1,5</sup>, Hitoshi Niwa<sup>6</sup>, Masavuki Yamato<sup>7</sup> & Charles A. Vacanti<sup>1</sup>

30 JANUARY 2014 | VOL 505 | NATURE

# Does Misconduct Occur in the Clinic?

*Dr. Baggerly will “wow” you with his talk on this!!*

## The Anil Potti retraction record so far

Tracking retractions as

with 16 comments

A [60 Minutes segment Sunday on Anil Potti](#) has drawn national attention to the case, so we thought this would be a good time to compile all of the retractions and corrections in one place.

Duke has [said](#) that about a third of Potti's 40-some-odd papers would be retracted, and another third would have “a portion retracted with other components remaining intact,” so this list will continue to grow. We'll update it as we hear about new changes.

Retractions:

1. [“Gene-expression patterns predict phenotypes of immune-mediated thrombosis,”](#) in *Blood*
2. [“Upregulated Oncogenic Pathways in Patients Exposed to Tobacco Smoke May Provide a Novel Approach to Lung Cancer Chemoprevention,”](#) in *CHEST*
3. [“Characterizing the Clinical Relevance of an Embryonic Stem Cell Phenotype in Lung Adenocarcinoma,”](#) in *Clinical Cancer Research*
4. [“An Integrated Genomic-Based Approach to Individualized Treatment of Patients With Advanced-Stage Ovarian Cancer”](#) in the *Journal of Clinical Oncology (JCO)*
5. [“Pharmacogenomic Strategies Provide a Rational Approach to the Treatment of Cisplatin-Resistant Patients With Advanced Cancer”](#) also in the JCO
6. [“Gene Expression Signatures, Clinicopathological Features, and Individualized Therapy in Breast Cancer”](#) in the *Journal of the American Medical Association (JAMA)*
7. [“Validation of gene signatures that predict the response of breast cancer to neoadjuvant chemotherapy: a substudy of the EORTC 10994/BIG 00-01 clinical trial,”](#) in *The Lancet Oncology*
8. [“Genomic signatures to guide the use of chemotherapeutics,”](#) in *Nature Medicine*
9. [“A Genomic Strategy to Refine Prognosis in Early-Stage Non-Small-Cell Lung Cancer,”](#) in the *New England Journal of Medicine (NEJM)*
10. [“An Integrated Approach to the Prediction of Chemotherapeutic Response in Patients with Breast Cancer”](#) in *PLoS ONE*
11. [“A genomic approach to colon cancer risk stratification yields biologic insights into therapeutic opportunities”](#) in the *Proceedings of the National Academy of Sciences (PNAS)*



Ivan Oransky  
RetractionWatch.com

# China's drug industry clinical trial data falsified

■ Companies were thought to be cutting corners because of the lack of profitability in China's pharmaceutical market.

*By Jen Offord*

*October 2, 2016 17:46 BST*

A government investigation in China has found that the result of 80% of the country's clinical trials are fabricated, according to a report.

The investigation, which took place over a year, examined data from 1,622 clinical trials of pharmaceutical drugs which were awaiting approval by the country's regulator for mass production, and found that there was no basis for the results recorded.

# What is the Impact of Retracted Clinical Papers on Patients?

Retractions in the medical literature: how many patients are put at risk by flawed research?

R Grant Steen

*J Med Ethics* (2011)

**Table 1** Summary of the impact of 180 retracted clinical papers

	Number	Average per retracted paper
Citations of retracted papers		
Total citations	5503	30.6
Research-related citations	5143	28.6
Post-retraction citations	1973	11.0
Retraction-related citations	360	2.0
Review papers	1372	7.6
Patient studies	851	4.7
Subjects enrolled in retracted papers		
Total subjects	28 783	160.8
Patients at risk	17 783	99.3
Patients treated	9189	51.3
Subjects enrolled in secondary papers		
Total subjects	445 064	2472.6
Patients at risk	165 588	919.9
Patients treated	70 501	391.7

**Table 4** Comparison of studies retracted for fraud and for error

	Fraud (n=70) average	SD	Error (n=110) average	SD
Citations per retracted paper				
Total citations	34.8	77.8	29.0	83.5
Research-related citations	31.4	75.4	27.8	82.9
Post-retraction citations	8.6	12.6	12.8	29.7
Retraction-related citations	3.4	10.8	1.2	1.4
Review papers	8.9	22.9	7.1	21.5
Patient studies	5.9	9.7	4.2	8.0
Subjects enrolled in retracted papers				
Total subjects	147.0	291.5	163.2	411.8
Patients at risk	125.9	281.7	84.4	143.7
Treated patients	96.2	277.1	24.2	72.6
Subjects enrolled in secondary papers				
Total subjects	1,318.1	4648.7	3,272.4	25678.1
Patients at risk	1,075.2	4496.5	857.7	3883.5
Treated patients	882.4	4504.1	103.9	438.4

- Retracted papers impacted an average of 2,600 patients/paper
  - When papers were retracted for fraud, ~1,500 patients were impacted
- \*\*\*This does not take into account patients impacted by fraudulent or faulty preclinical studies!!

# Famous Fraudulent Papers The Impacted Patient's Lives!

- Breast cancer and bone marrow transplants
  - Bezwoda et al. 1999 ASCO Annual Meeting
- Autism and vaccines
  - Wakefield et al. 1998 The Lancet
- Stem cells and tracheal transplants
  - Macchiarini et al. Karolinska, The Lancet

Wikipedia provides great summaries



# Vaccines and Autism

## Wakefield, et al. Lancet 1998

- Wakefield did not conduct the study according to ethical standards for research.
- Wakefield lied in the *Lancet* paper when he wrote that the participating children were referred independently after being diagnosed with IBD or other major GI issues. In fact, many of the children were chosen specifically by Wakefield, and others were recruited with the help of the same lawyer who was paying him to conduct the study.
- Wakefield subjected vulnerable autistic and other developmentally challenged children to a variety of difficult GI tests, including colonoscopy and lumbar puncture (i.e., spinal tap), without any medical indication to benefit the children.
- Even before publication of the study, Wakefield was working on patenting his own version of a measles vaccine, which he would sell at a great profit as a supposedly “safe” alternative to the MMR vaccine. The father of one of the children in Wakefield’s study was a cofounder of the planned business that would market this product.
- Unrelated to the particular paper in question, the GMC panel also found that Wakefield had paid children at his own son’s birthday party £5 each so he could draw their blood for use in his research. He later joked about this during a lecture.
- And more including financial conflict of interest

# No Institute Is Immune!

## Journal retracts 7 papers by MD Anderson cancer researcher long under investigation

An MD Anderson Cancer Center researcher who has been under investigation by the institution for at least several years has had seven papers retracted from a single journal. Bharat Aggarwal told us in 2012 that MD Anderson was investigating his work, but in 2013 threatened to sue us for reporting on the case. Aggarwal is ... [Continue reading](#) →

## Data fabrication by ex-Harvard researcher takes down paper on Huntington's disease

### Harvard teaching hospital to pay \$10 million to settle research misconduct allegations

Brigham and Women's Hospital and its parent healthcare network have agreed to pay \$10 million to settle research misconduct allegations. The settlement was announced on Monday. The allegations stem from a paper published in *Cell* in 2013. ... [Continue reading](#) →

## MD Anderson Novartis

A former postdoctoral fellow at MD Anderson was investigated for falsifying data in a study of a Novartis drug. The U.S. Office of Research Integrity (ORI) announced that the researcher had falsified data by falsifying Figure 8a in "Novel HSP90 Inhibitor NVP-HSP990 Targets Cell-Cycle Regulators to Ablate Olig2-Positive Glioma Tumor-Initiating ... [Continue reading](#) →

As PIs, we have to keep track of data in real time, not just when ready for submission to *CNS*.

## A cancer researcher said she collected blood from 98 people. It was all her own.

A researcher collected her own blood and forged the labels so it would appear to be samples from nearly 100 people, according to a new finding of research misconduct released today by the U.S. Office of Research Integrity (ORI). The former researcher at the University of Texas MD Anderson Cancer Center swapped her own blood ... [Continue reading](#) →



Two identical retraction notices have popped up for MIT professor [Robert Weinberg](#), a highly-cited cancer researcher who had [a retraction](#) and a [correction](#) in 2013, both in *Cancer Cell*.

These two new retractions, in *Genes and Development*, stem directly from [another paper by Weinberg and colleagues in Cell](#) that will apparently be retracted, as the "same analytical methodology was used," according to the notices [see bottom of the post for an update].

# An IRB Approved Survey Conducted at The MD Anderson Cancer Center

OPEN ACCESS Freely available online



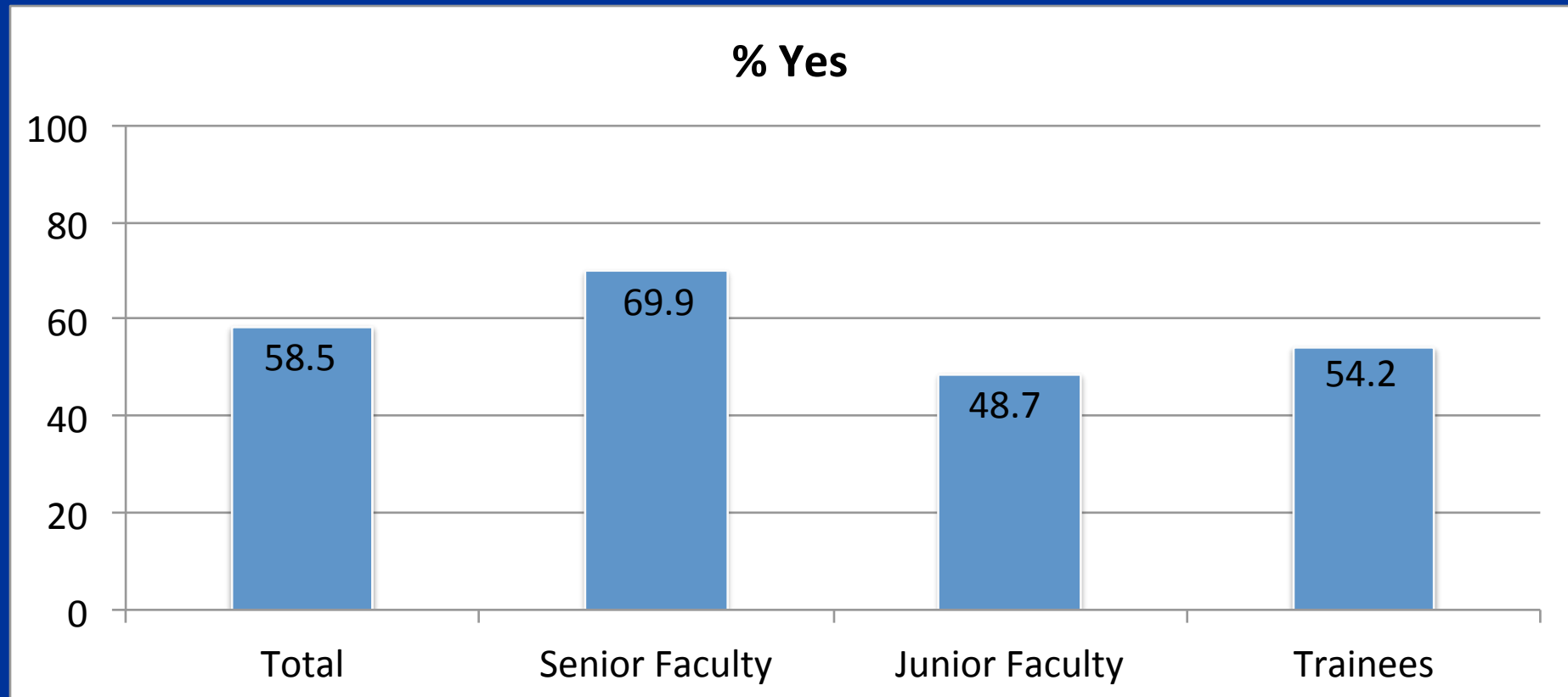
## A Survey on Data Reproducibility in Cancer Research Provides Insights into Our Limited Ability to Translate Findings from the Laboratory to the Clinic

Aaron Mobley<sup>1</sup>, Suzanne K. Linder<sup>2</sup>, Russell Braeuer<sup>1</sup>, Lee M. Ellis<sup>1,3\*</sup>, Leonard Zwelling<sup>4\*</sup>

240 responses in 6 hrs  
311 responses after 3 days

IRB Approved Protocol  
PI: Len Zwelling, MD  
Co-PI: Lee Ellis

# Have You Ever Tried To Reproduce A Finding From A Published Paper And Not Been Able To Do So?



# Driving Forces for Irreproducible Data

(>90 respondents-Trainees Only)

- Were you ever **pressured to publish findings** of which you had doubt?
  - 22%
- Have you noted **pressure from a mentor** to prove that his/her hypothesis was correct, even though the data you generated may not support the hypothesis?
  - 31%
- Are you aware of mentors who require a **high impact publication** before a trainee can leave the lab?
  - 49%

# Selected Comments From the Survey

- crumbling of integrity and value - bean counters judging science by journal names - institutional failure on dealing with alleged fraud.
- Everything here in US is screwed up. There is nothing to do other than move out. .... Who publishes more deserve respect, while others who are honest and cast doubt about their own results (or third party results) as condemned. There is no way out. It is either join the "bright team" or be labeled as incompetent.
- ... my previous mentor and also our current neighbor lab PI push too much to produce best data all the time. .. sometimes it make trainee consider manipulates data only to escape from stress. Especially, many international trainees (postdoc) also have VISA issue. Thus, PI starts push them with visa issue trainees feel a lot of stress and eventually it make them can do whatever PI WANT.
- From my experience, no one will help you if you stand up for what is right. ....The system is unfortunately broken ....
- Pressure is ....from the job market and funding dynamics. The impact factor insanity is destroying science. A small group of powerful editors and friends control everything.

# **A Survey on Data Reproducibility and the Effect of Publication Process on the Ethical Reporting of Laboratory Research**

Delphine R. Boulbes<sup>1</sup>, Tracy Costello<sup>2</sup>, Keith Baggerly<sup>3</sup>, Fan Fan<sup>1</sup>, Rui Wang<sup>1</sup>,  
Rajat Bhattacharya<sup>1</sup>, Xiangcang Ye<sup>1</sup>, and Lee M. Ellis<sup>1,4</sup> Clin Cancer Res; 2018

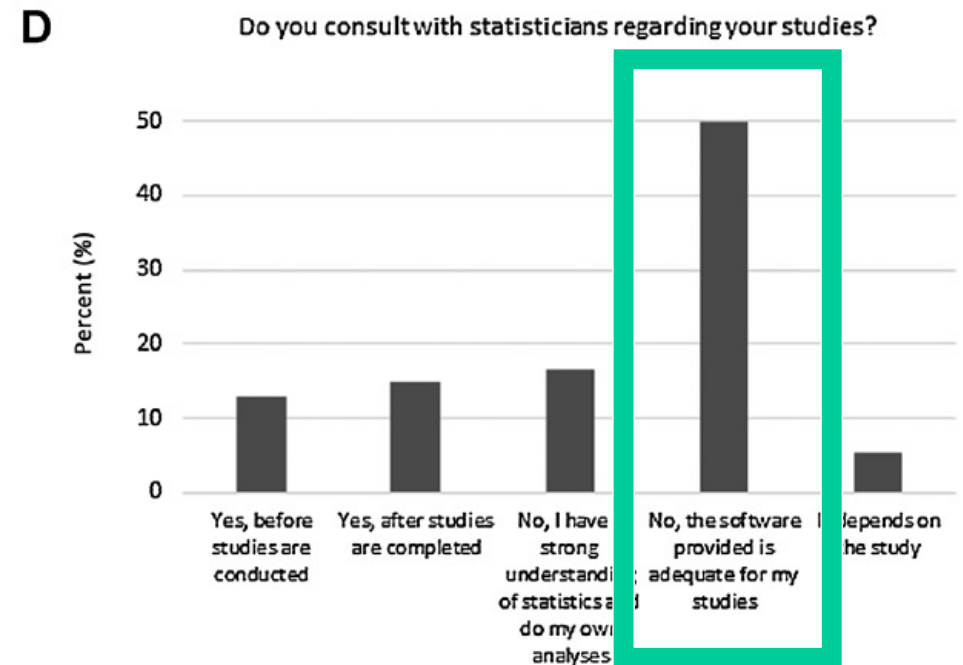
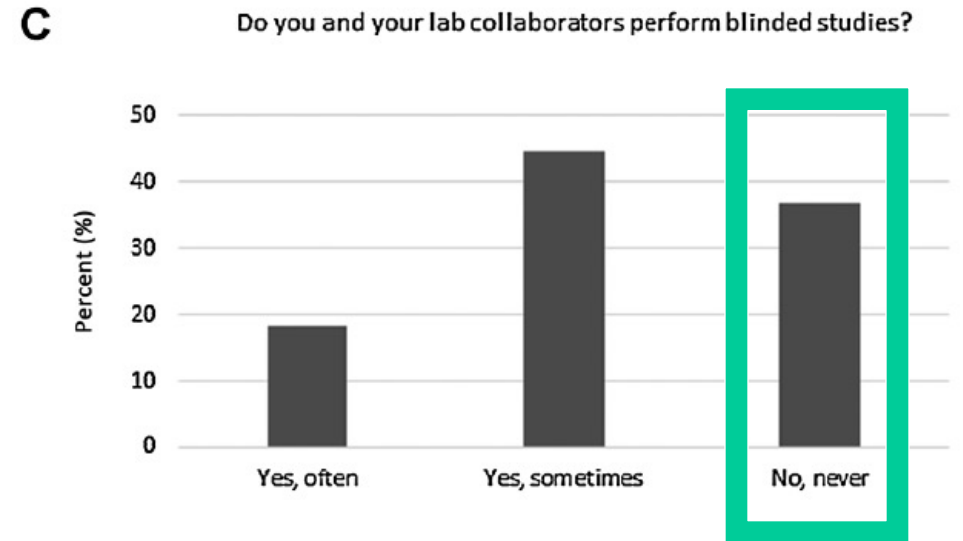
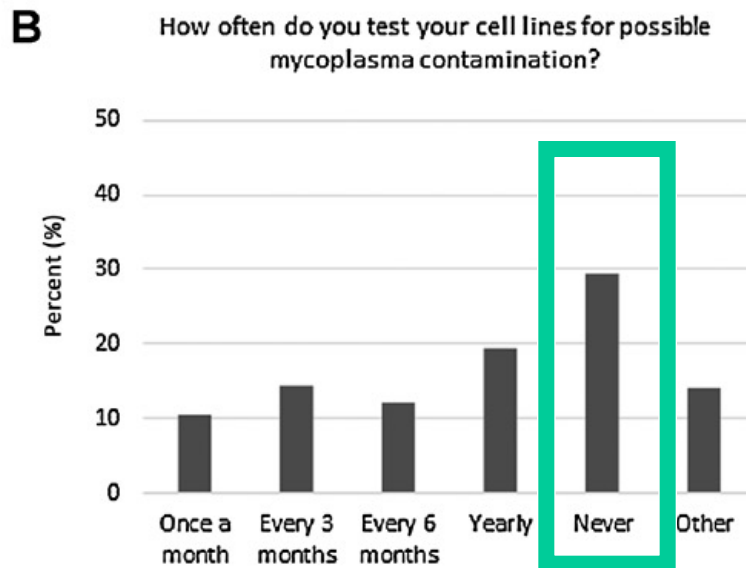
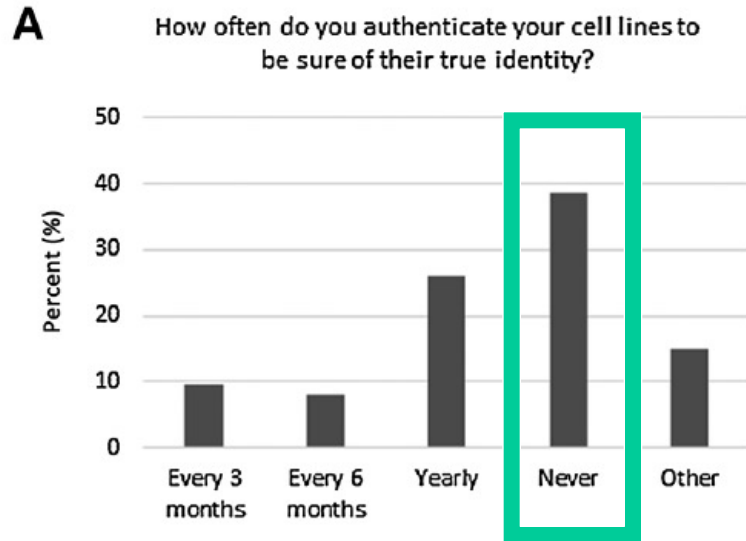
## Population Characteristics (n=467)

Characteristics	N (%)
Population	Students 10.7% Postdocs 89.3%
Field of expertise	Cancer Biology 60.6% Biology (Other) 10.5% Neuroscience 6.9% Microbiology/Virology 6.2% Biotechnology 4.5% Immunology 2.6% Chemistry 2.5% Physics 2.6% Molecular Biology/Biochemistry 1.9% Plant Biology 1.7%
Career goals	PI in Academia 39.4% Undecided 40.9% Industry/Private sector 11.8% Academia/Government (Other) 2.6% Writing/Editing/Publishing 1.4% Science Policy/Regulatory Affairs 1.3% Other 2.6%

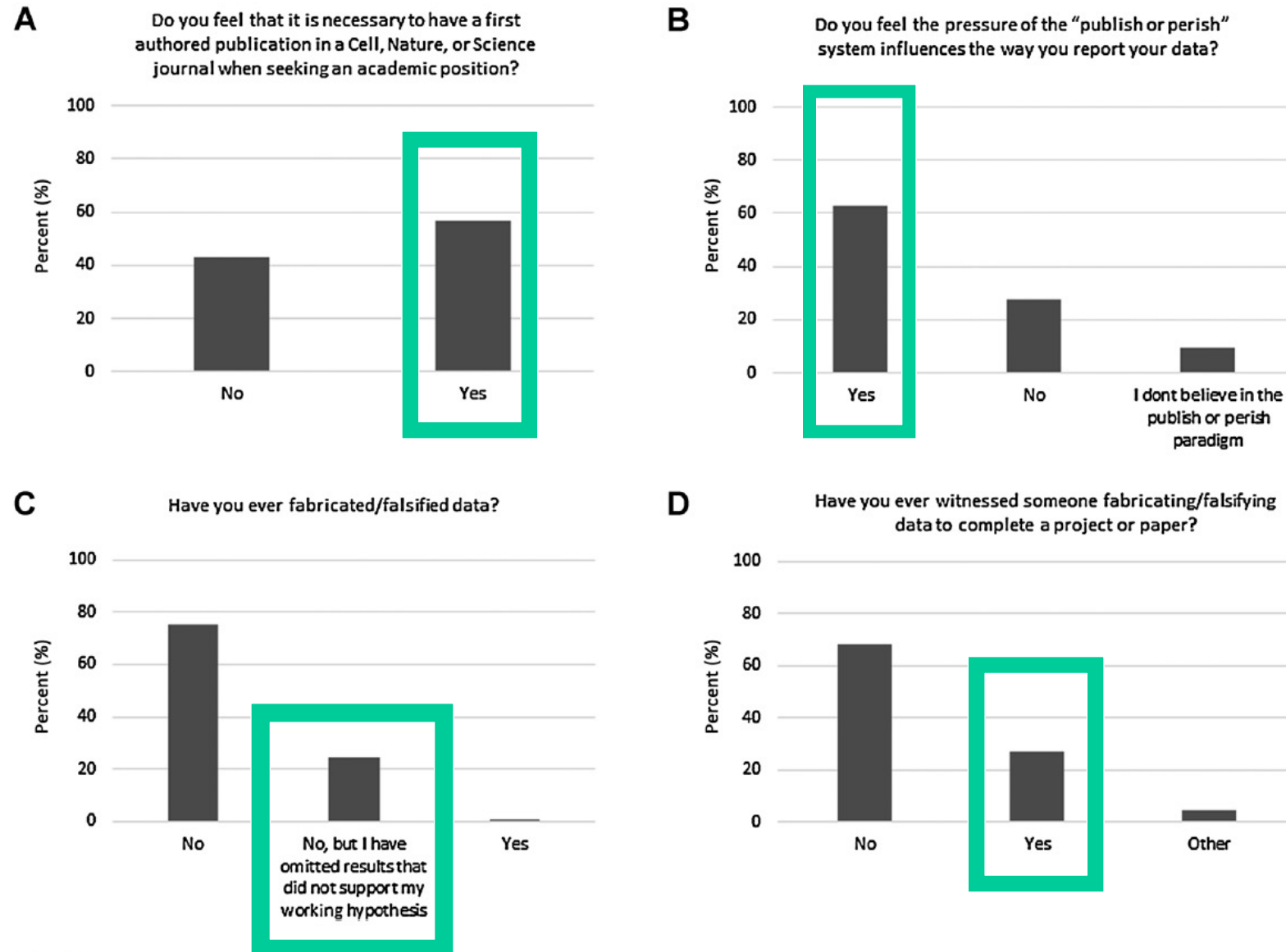
eligibility criteria of 1) being a graduate student or postdoctoral fellow and 2) performing bench science, 467 of our total 576 respondents were deemed eligible.



# Best Research Practices



# Research Integrity and Reporting Transparency



**Figure 3.**

Responses to questions about research integrity and transparency. Responses were provided by all 467 respondents to questions 5 (A), 27 (B), 10 (C), and 11 (D).

# The Erosion of Research Integrity: *The Need For a Culture Change*

- Integrity of laboratory research and how this impacts clinical outcomes
  - The issue at hand
    - The spectrum
  - Why does this occur?
  - What can we do to fix this?

# Causes of “Massaging” of Data

## Trainees

Occurs when trainees have a strong mentor  
- trainees do not want to challenge the hypothesis of the mentor - sometimes this is cultural

- it is hard to challenge a mentor in the US when English is a 2nd language

Need high impact publications to obtain a job (or many pubs)

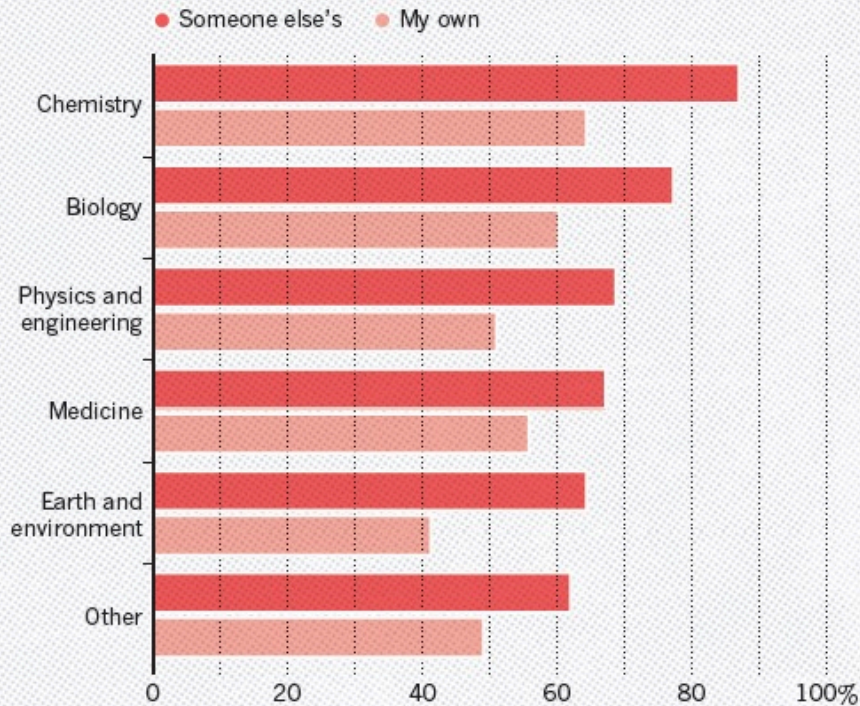
Cannot leave that lab as a post-doc, or cannot complete thesis as a student, unless you have a high impact publication

## Faculty

# Nature Survey, May 2016

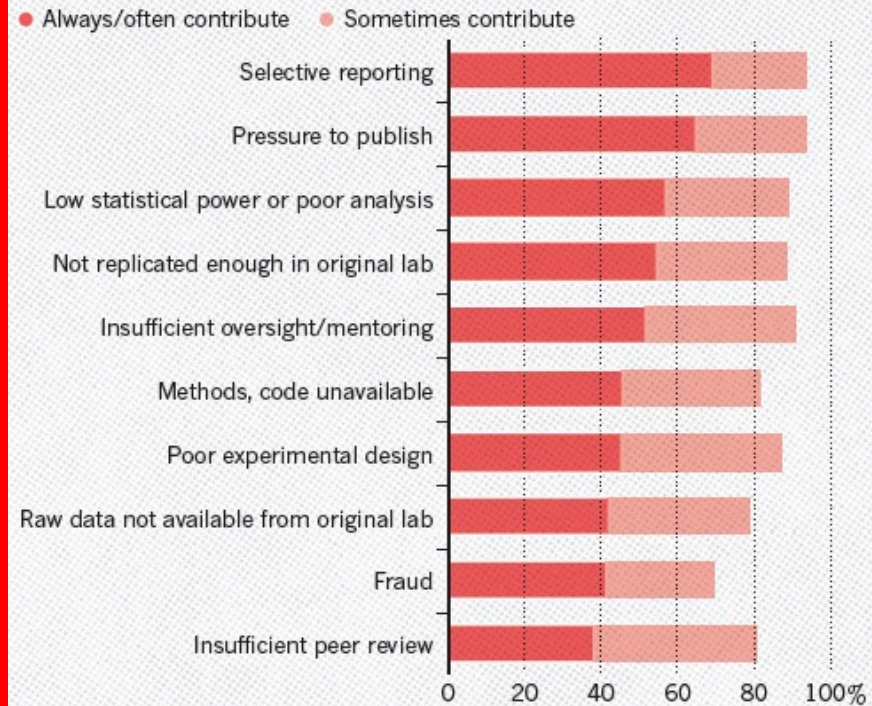
## HAVE YOU FAILED TO REPRODUCE AN EXPERIMENT?

Most scientists have experienced failure to reproduce results.



## WHAT FACTORS CONTRIBUTE TO IRREPRODUCIBLE RESEARCH?

Many top-rated factors relate to intense competition and time pressure.



Let's Talk About  
High Impact Publications  
and *“Impact Factor Mania”*

And what this does to our culture!

# Quote to a Post-Doc From a Successful Physician Scientist

*“You are nothing unless you  
publish in CNS!”*

# Causes for the Persistence of Impact Factor Mania

mBio 2014

Arturo Casadevall,<sup>a</sup> Ferric C. Fang<sup>b</sup>

Departments of Microbiology & Immunology and Medicine, Albert Einstein College of Medicine, Bronx, New York, USA<sup>a</sup>; Departments of Laboratory Medicine and Microbiology, University of Washington School of Medicine, Seattle, Washington, USA<sup>b</sup>

*“...associating the value of research with the journal where the work was published rather than the content of the work itself. The mania is causing profound distortions in the way science is done that are deleterious to the overall scientific enterprise.”*

**distortions in the way science is done that are deleterious to the overall scientific enterprise.** In this essay, we consider the forces responsible for the persistence of the mania and conclude that it is maintained because it disproportionately benefits elements of the scientific enterprise, including certain well-established scientists, journals, and administrative interests. Our essay suggests steps that can be taken to deal with this debilitating and destructive epidemic.

---

Should we eliminate the Impact Factor?

Nathan S. Blow, Ph.D., Editor-in-Chief, *BioTechniques*

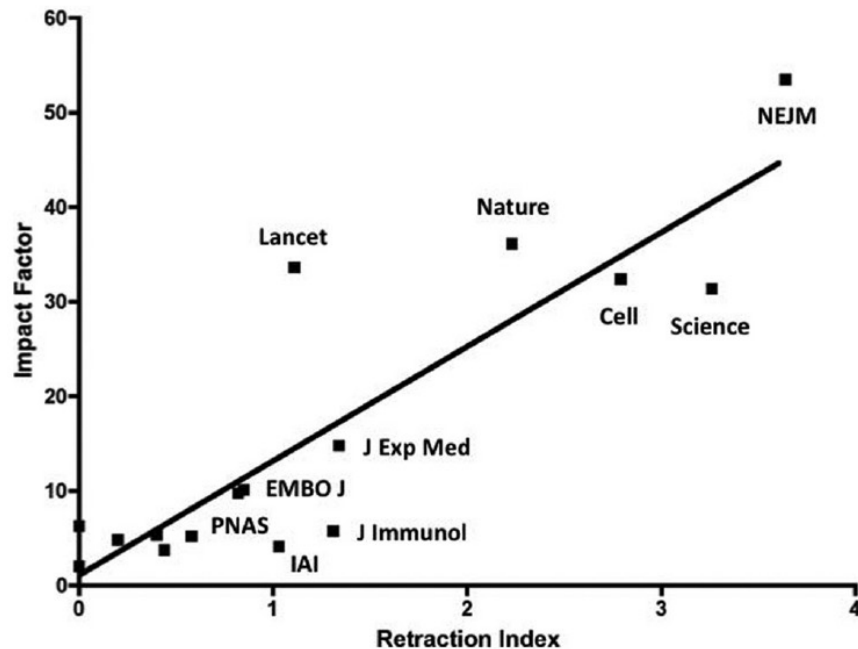


## EDITORIAL

Fang and Casadevall  
Infection and Immunity, 2011

### Retracted Science and the Retraction Index<sup>▽</sup>

Articles may be retracted when their findings are no longer considered trustworthy due to scientific misconduct or error, they plagiarize previously published work, or they are found to violate ethical guidelines. Using a novel measure that we call the “retraction index,” we found that the frequency of retraction varies among journals and shows a strong correlation with the journal impact factor. Although retractions are relatively rare, the retraction process is essential for correcting the literature and maintaining trust in the scientific process.



The higher the impact factor, the higher the retraction index (also in the New York Times)

“A man who has committed a mistake, and doesn’t correct it, is committing another mistake.”  
—attributed to Confucius

### Misconduct accounts for the majority of retracted scientific publications

PNAS, 2012

Ferric C. Fang<sup>a,b,1</sup>, R. Grant Steen<sup>c,1</sup>, and Arturo Casadevall<sup>d,1,2</sup>

Departments of <sup>a</sup>Laboratory Medicine and <sup>b</sup>Microbiology, University of Washington School of Medicine, Seattle, WA 98195; <sup>c</sup>MediCC! Medical Communications Consultants, Chapel Hill, NC 27517; and <sup>d</sup>Department of Microbiology and Immunology, Albert Einstein College of Medicine, Bronx, NY 10461

Edited by Thomas Shenk, Princeton University, Princeton, NJ, and approved September 6, 2012 (received for review July 18, 2012)

# Nobel winner declares boycott of top science journals

Randy Schekman says his lab will no longer send papers to Nature, Cell and Science as they distort scientific process

How journals like Nature, Cell and Science are damaging science

Monday 9 December 2013 14.42 EST

Leading academic journals are distorting the scientific process and represent a "tyranny" that must be broken, according to a Nobel prize winner who has declared a boycott on the publications.

Schekman criticises Nature, Cell and Science for artificially restricting the number of papers they accept, a policy he says stokes demand "like fashion designers who create limited-edition handbags." He also attacks a widespread metric called an "impact factor", used by many top-tier journals in their marketing.

*Final, Final* Comment on Impact  
Factor Mania

*Strive for Nature*

*But Don't Lie or Die for Nature*

*(or compromise your ethics)*

# The Erosion of Research Integrity: *The Need For a Culture Change*

- Integrity of laboratory research and how this impacts clinical outcomes
  - The issue at hand
    - The spectrum
  - Why does this occur?
  - What can we do to fix this?

# The erosion of research integrity: the need for culture change

## Panel: Suggested approaches to improve data reproducibility in preclinical studies\*

### Publication requirements:

- Appropriate statistical analysis determined a priori
- Use of REMARK biomarker criteria
- Expanded methods sections
- Expedited data deposition to public databases
- Cell line identification confirmation
- Validation of reagents including antibody specificity
- Blinded assessments by at least two independent observers
- Pre-established inclusion and exclusion criteria
- Sign off by all coauthors that all relevant data, both positive and negative, have been submitted either in the manuscript or online
- Expanded materials and methods sections online
- Change the emphasis of the NIH biosketch (abbreviated CV) to highlight actual contributions to science and medicine
- Assessment of faculty candidates should include more than the number of publications in high-impact journals
- Sharing of unique resources (eg, cell lines and mouse models) with a standard single page material transfer agreement
- Journals should allow and encourage publication of negative results
- Journals should allow so-called imperfect data—biology is not all or none
- Mechanisms for online feedback on studies (eg, PubPeer, PubMed Commons) and allow commentary without the need for a subscription
- Reviewers of manuscripts should focus on the most relevant issues, and limit requests for additional studies that are not necessary for the underlying theme of the study
- Appropriately severe punishment for investigators found guilty of research misconduct (eg, ban such scientists from obtaining government funding for research)
- Provide academic security for people who report unethical behavior (so-called whistle blowers)
- The principal investigator should be responsible for keeping track of data in real time, so that deviations from the so-called perfect story are noted early; the principal investigator should be held responsible for the integrity of all data, and for inclusion of all relevant studies, whether they are negative or positive
- Journals should welcome publications validating or refuting previous publications
- Published articles should not be convoluted and should have a clear message; dense articles are difficult to review, probably leading to suboptimal reviews and requests for irrelevant experiments
- Allow submission of negative data in response to primary reviews of manuscripts; the temptation to selectively report positive data is probably highest when a paper is under revision

\*Some have already been implemented.

2014

- Case Summary: Ahvazi, Bijan
- Case Summary: Chen, Li
- Case Summary: Cokonis, Melanie
- Case Summary: Deb, Kaushik
- Case Summary: Dzhura, Igor
- Case Summary: Freeman, Helen C.
- Case Summary: Fu, Jun
- Case Summary: Patel, Parag
- Case Summary: Suzuki, Makoto
- Case Summary: Takahashi, Takao
- Case Summary: Warne, James P.
- Case Summary: Xing, H. Rosie
- Case Summary: Zou, Zhihua



May, 2021

2015

- Case Summary: Anderson, David
- Case Summary: Asherin, Ryan
- Case Summary: Bitzegeio, Julia
- Case Summary: Blaylock, Brandi Lyn
- Case Summary: Briones, Teresita L.
- Case Summary: Dasmahapatra, Girija
- Case Summary: Fujita, Ryousuke
- Case Summary: Geraedts, Maria C.P.
- Case Summary: Kang, Bin
- Case Summary: Littlefield, Peter
- Case Summary: Massè, Julie
- Case Summary: Potti, Anil
- Case Summary: Reddy, Venkata J.
- Case Summary: Xiao, Dong

2016

- Case Summary: Cullinane, Andrew R.
- Case Summary: D'Souza, Karen M.
- Case Summary: Forbes, Meredyth M.
- Case Summary: Li, Zhiyu
- Case Summary: Malhotra, Ricky
- Case Summary: Pastorino, John G.
- Case Summary: Walker, Kenneth

2017

- Case Summary: Baughman, Brandi
- Case Summary: Chegini, Nasser
- Case Summary: Chetram, Mahandranauth
- Case Summary: El-Remessy, Azza
- Case Summary: Endo, Matthew
- Case Summary: Mirchandani, Alec
- Case Summary: Sauer, Frank

2018

- Case Summary: Baughman, Brandi M.
- Case Summary: Elqutub, Maria Cristina Miron
- Case Summary: Kadam, Rajendra
- Case Summary: Kreipke, Christian
- Case Summary: Murthy, Krishna H.M.
- Case Summary: Narayanan, Bhagavathi
- Case Summary: Rajamani, Uthra
- Case Summary: Ramadugu, Venkata Sudheer Kumar
- Case Summary: Santhanam, Srikanth
- Case Summary: Sen, Shiladitya
- Case Summary: Skau, Colleen T.
- Case Summary: Srivastava, Rakesh
- Case Summary: Wang, Li

2019

- Case Summary: Cruikshank, William W.
- Case Summary: Malhotra, Deepti
- Case Summary: Neumeister, Alexander
- Case Summary: Potts Kant, Erin N.
- Case Summary: Yakkanti, Sudhakar

2020

- Case Summary: Downs, Charles A.
- Case Summary: Fulford, Logan
- Case Summary: Jaiswal, Anil Kumar
- Case Summary: Jayant, Rahul Dev
- Case Summary: Kim, Shin-Hee
- Case Summary: Nemani, Prasadarao
- Case Summary: Panka, David
- Case Summary: Tataroglu, Ozgur
- Case Summary: Wan, Yihong
- Case Summary: Wang, Zhiwei

Are We Doing Enough to Punish Those Who Violate Our Trust?  
*What are the consequences of being found guilty of misconduct?*

# Most Common ORI Actions

- Retract paper(s)
  - Have research supervised for 3 yrs
  - No service on committees for 2-3 yrs
  - Most can still receive NIH funding
- For those found guilty of fraud, we must have a punishment that fits the crime.
  - What is the deterrent for such behavior?
  - Indeed, the entire system needs an overhaul, but let's start with making outright fraud something that can be deterred by tough punishment and prohibits this person from ever having the chance to do this again.
    - This is, of course, even more important for clinical fraud

# The Primary Inquiry Rests With Your NIH Funded Institution

## What the Office of Research Integrity Does

- Implements PHS regulations requiring institutions to respond to allegations of research misconduct
- Assures institutions requesting PHS funding have mechanisms in place to deal with allegations of research misconduct
- Provides assistance and guidance to institutions
- Can perform own investigation
- Leaves primary responsibility with the individual institutions
- Institutional Research Integrity Officer

-ML/ACC: W. Plunkett

**INHERENT CONFLICT OF INTEREST**



# Mechanism for Addressing Misconduct Is Institutional Dependent

- Allegations may be brought to Department Head, Division Head, or to the Provost and Executive Vice President (EVP)
- Provost & EVP and Res Integrity Officer (RIO) will assess the allegations
- Information-gathering and initial fact finding.
  - Conduct an Inquiry Panel of at least 3 faculty chosen by Provost & EVP and the Res Integrity Officer.

**INHERENT CONFLICT OF INTEREST**

If you trust no one at your own  
institute.....

- Most Universities (*or University systems*) have a website for abuse, fraud, and/or unethical behavior

“....you’ve uncovered a thorny problem in academia—selfishness. In moments of weakness or at the extremes, this creates an undertow away from integrity in science and public health. This is the single biggest limitation in our field,.....”

**We miss you, John!**  
**12/8/1980**

Lenna

GIVE ME SOME TRUTH

I'm sick and tired of reading <sup>hyper</sup>lines  
by seasick-narrow-minded-short-  
sighted-hypercritics,  
- all I want is the truth  
- just give me some truth

THE RIGHT TO  
SEARCH  
FOR TRUTH  
IMPLIES ALSO  
A DUTY;  
ONE MUST NOT  
CONCEAL ANY  
PART OF WHAT  
ONE HAS  
RECOGNIZED  
TO BE TRUE.

ALBERT EINSTEIN  
1879 - 1955



# Required Reading

- Websites/Twitter
  - Pubpeer
  - Retractionwatch.com
  - <https://ori.hhs.gov/>
  - For Better Science
  - Elisabeth Bik @MicrobiomDigest