The Vital Role of Whistleblower Scientists in Exposing Fraudulent Research During the Pandemic

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Pandemic presents perfect conditions for Research fraud

- Government has poured Billions of $$ into research grants to develop, manufacture & distribute COVID therapeutics (e.g. Operation Warp Speed for vaccines)
- Although DOJ has prioritized fighting COVID frauds, insufficient resources to oversee all the spending -- limited oversight

Cue the Whistleblower Watchdogs

- Surge in # of whistleblower reports during the pandemic (e.g., SEC tips increase 35%)
- Prototypical Whistleblower Insiders
  - Rebekah Jones: data scientist @ Florida Dept. Public Health, exposes DPH's manipulation of COVID data for political purposes
- Whistleblower Outsiders too
  - Science sleuths like Dr. Elisabeth Bik who use their expertise to review research & uncover fraud

False Claims Act: Rewards & Protects Research Whistleblowers

- WBs with info re: fraud in government-funded research projects are empowered to file qui tam lawsuit in government's name & receive % of gov't recovery as reward
- False Claims Act has anti-retaliation provision protecting whistleblowers from retaliation for speaking up

Types of Successful False Claims Act cases by Research Whistleblowers

- Falsified grant applications, progress reports or results.
  - Duke University paid DOJ $112M in qui tam case alleging Duke submitted to NIH & EPA grant applications & progress reports containing falsified research.
- Overcharging for time, costs and other grant-related expenses.
- Misuse of grant funds for unrelated or personal matters.
  - The Scripps Research Institute paid $10M in qui tam case alleging TSRI improperly charged NIH-funded grants for time spent on unrelated matters.
- Undisclosed or improper conflicts of interest (e.g., undisclosed grants from foreign governments).

Proposed Legislative Fix: Scientific Integrity Act of 2021

- Representative Paul Tonko introduced the Act on Feb. 4, 2021.

- Per the Union of Concerned Scientists, the **Act** "would protect federal science from political interference and make sure that the public can hear directly from scientists about the work they do. It will help us make sure that the decisions made by our leaders will be based on the best available evidence not the whims of ideologues or powerful lobby groups."

Disclosures Elisabeth Bik

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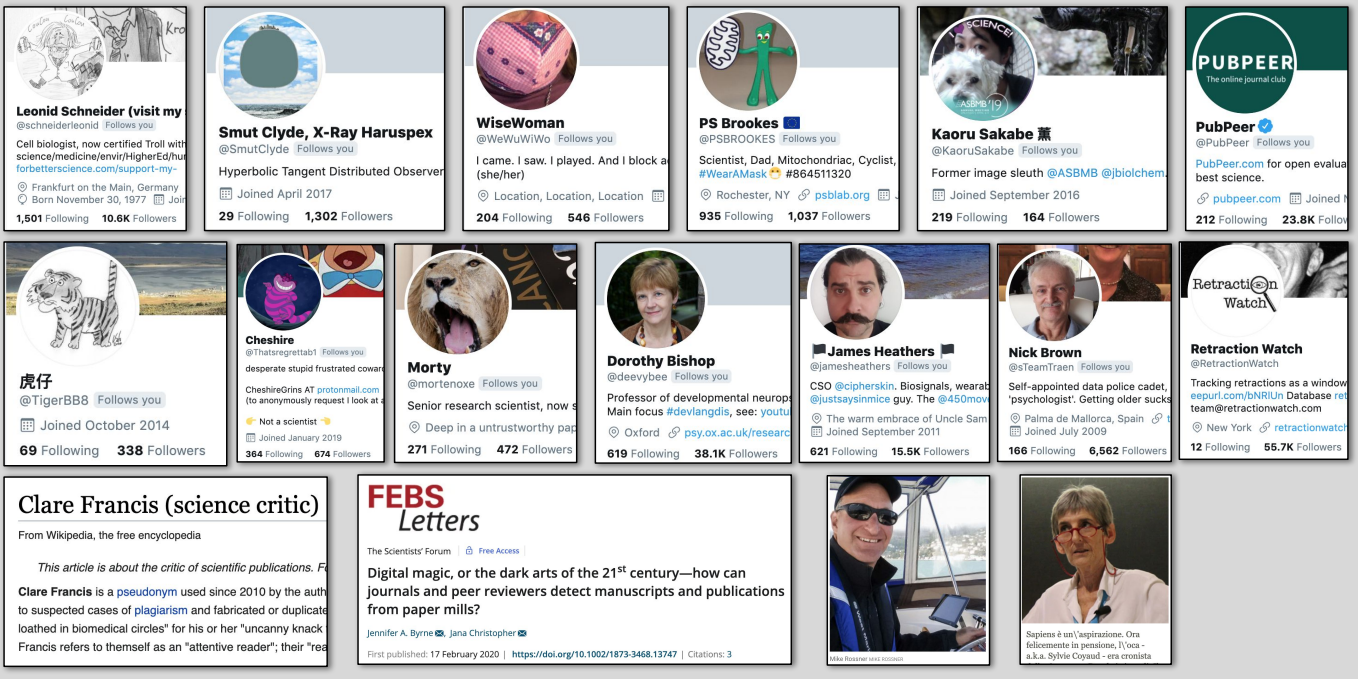
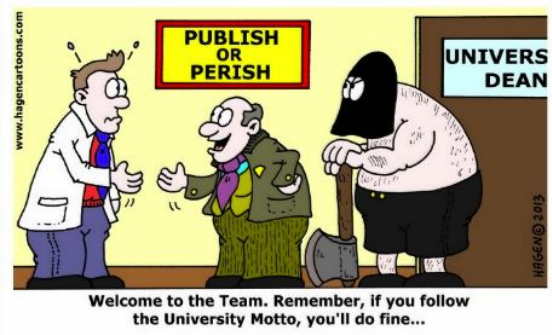
- Patreon account
  - https://www.patreon.com/elisabethbik

'External' whistleblowers in science



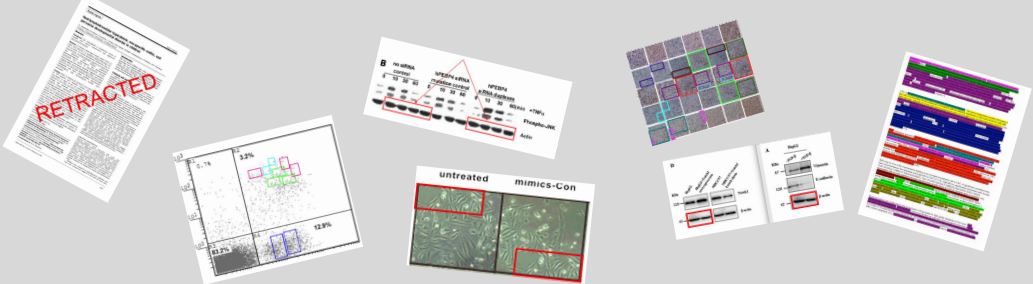
Why do scientists cheat?

- Scientists need to publish
- Positive findings are more attractive than negative results
- Built on trust: Most scientists are honest and hard-working
- Science is not immune to fraud
- Science misconduct: plagiarism, falsification, fabrication



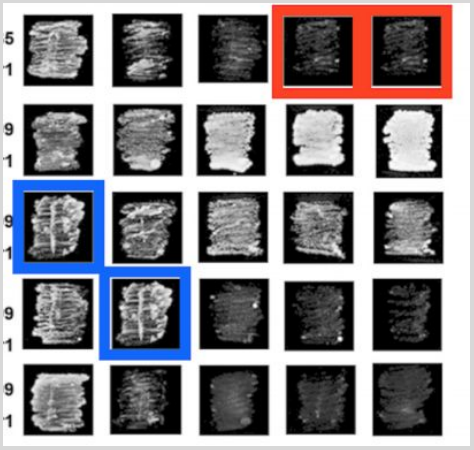
Concerns about scientific papers

- Study set-up problems (e.g. control vs treatment group)
- Misinterpretation of results
- Errors in statistics, calculations
- Unexpectedly small error bars
- Undisclosed conflicts of interest (patents, company stock)
- Animal or human subject ethics (approval, lack of consent)
- Excessive self-citations
- Plagiarism
- Peer review concerns
- **Duplicated or altered photographic figures**

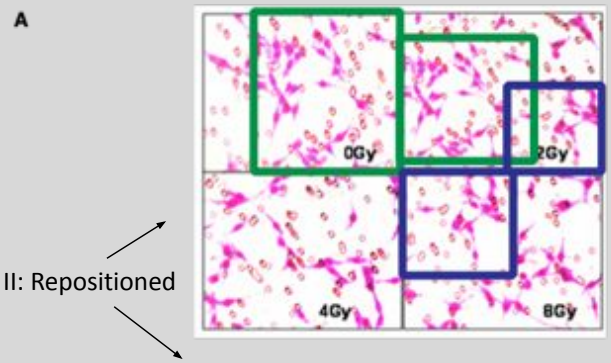


Inappropriate image duplication

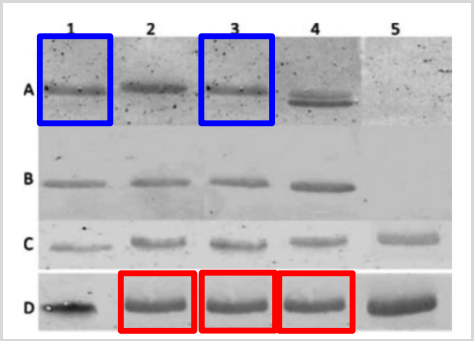
I: Simple

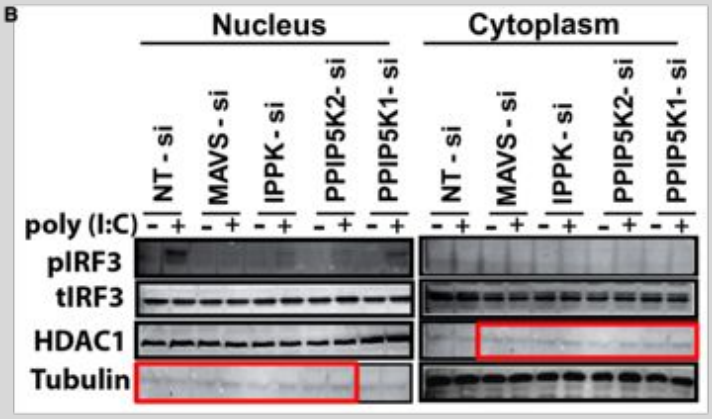


II: Repositioned



III: Alteration





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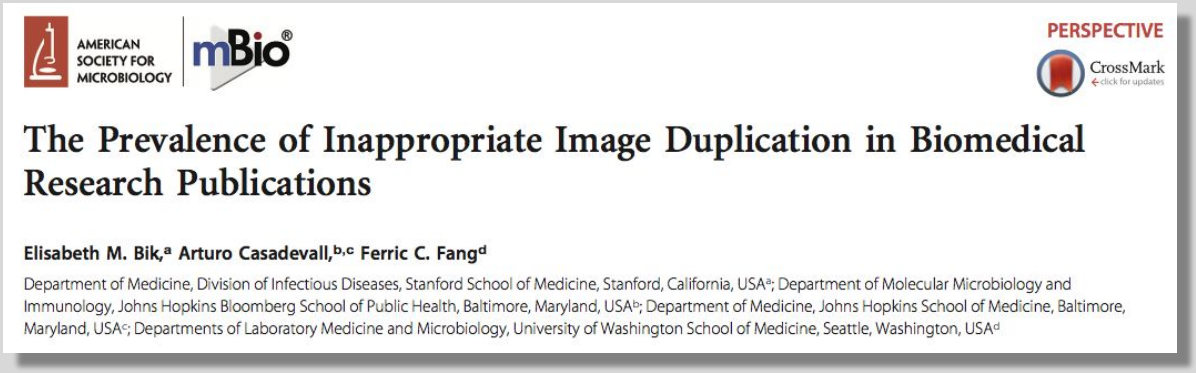

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PERSPECTIVE

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The Prevalence of Inappropriate Image Duplication in Biomedical Research Publications

Elisabeth M. Bik,[a] Arturo Casadevall,[b,c] Ferric C. Fang[d]

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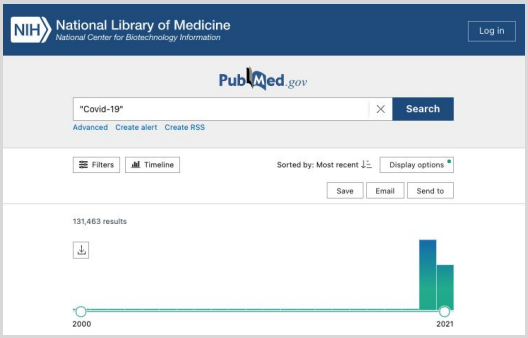
- 20,621 papers from 1995-2014 - by eye
- 40 journals from 14 publishers
- ~ 800 papers with duplicated figures (4%)
- 3 types: Simple - Repositioned - Altered
- Not all are misconduct! About half intentional: 2%
- Alteration in other data types much harder to detect

COVID-19 papers: Fast & Furious

- Enormous amounts of COVID-19 preprints/papers
- Many opinion/editorial pieces
- Hastily written and peer-reviewed
- Retractions (n=110)
- Erodes trust of public in science



Duplicated panels in medRxiv preprint

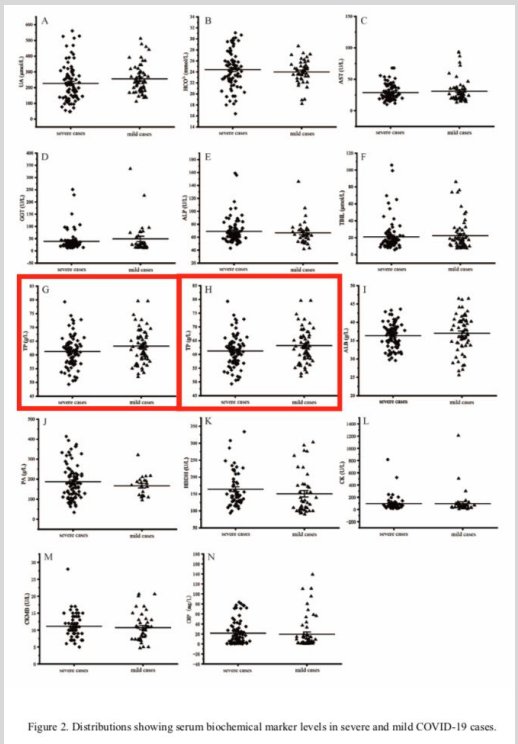
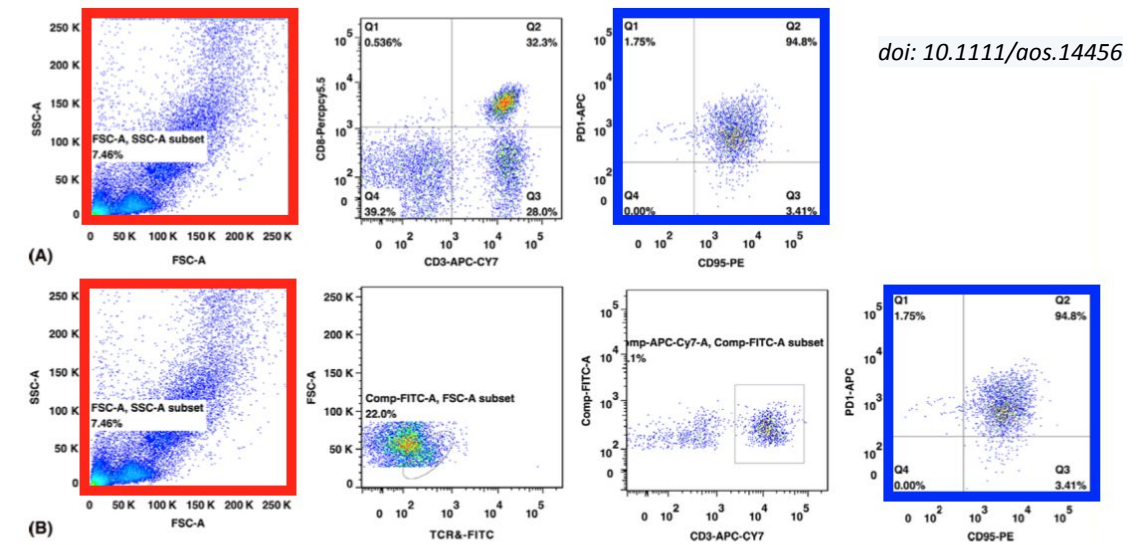


Figure 2. Distributions showing serum biochemical marker levels in severe and mild COVID-19 cases.

- Preprint posted on March 23, 2020
- PubPeer comment posted on March 25, 2020
- Authors never replied, no correction
- Paper was never published

Duplicated panels in published paper

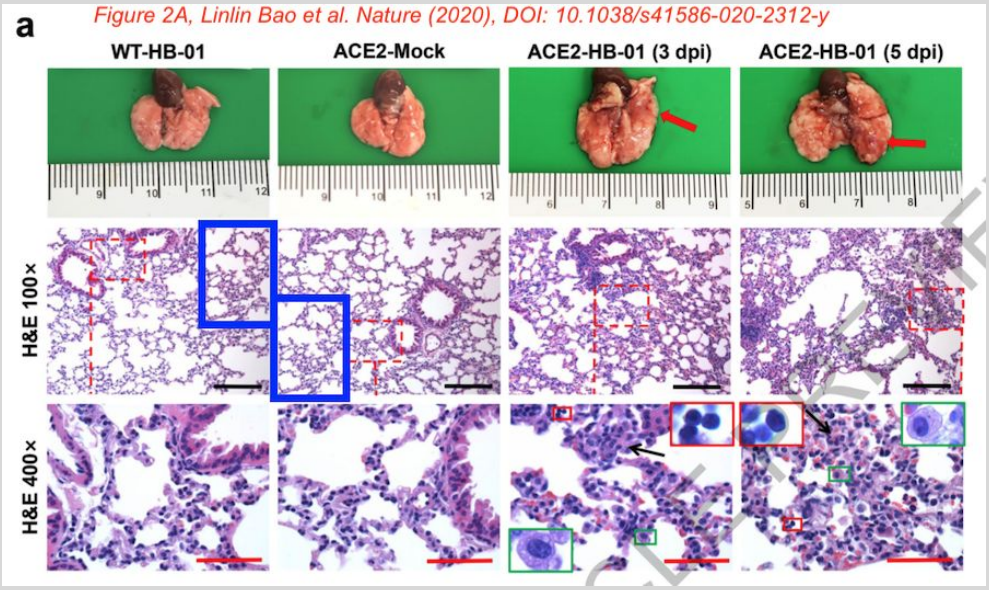


doi: 10.1111/aos.14456

Fig. 3. Flow cytometry results of lymphocyte subsets: (A) PD-1$^+$ CD95$^+$ cells were accounting for 94.8% in CD3$^+$ CD8$^+$ T subset and (B) for 94.8% in CD3$^+$ TCRγδ$^+$ T subset.

- Paper published on 14 May 2020
- PubPeer comment posted on 15 May 2020
- Authors never replied, no correction

Overlapping photos in a Nature paper



- Paper published on 7 May 2020
- PubPeer comment posted on 11 May 2020
- Figure silently corrected sometime after that

Hydroxychloroquine: A game changer?

International Journal of Antimicrobial Agents

Available online 20 March 2020, 105949

In Press, Journal Pre-proof

Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

Philippe Gautret [a, b, $], Jean-Christophe Lagier [a, c, $], Philippe Parola [a, b], Van Thuan Hoang [a, b, d], Line Meddeb [a], Morgane Mailhe [a], Barbara Doudier [a], Johan Courjon [e, f, g], Valérie Giordanengo [h], Vera Esteves Vieira [a], Hervé Tissot Dupont [a, c], Stéphane Honoré [i, j], Philippe Colson [a, c], Eric Chabrière [a, c], Bernard La Scola [a, c], Jean-Marc Rolain [a, c], Philippe Brouqui [a, c], Didier Raoult [a, c, *]

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https://doi.org/10.1016/j.ijantimicag.2020.105949

Donald J. Trump
@realDonaldTrump

HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....

7:13 AM · Mar 21, 2020 · Twitter for iPhone

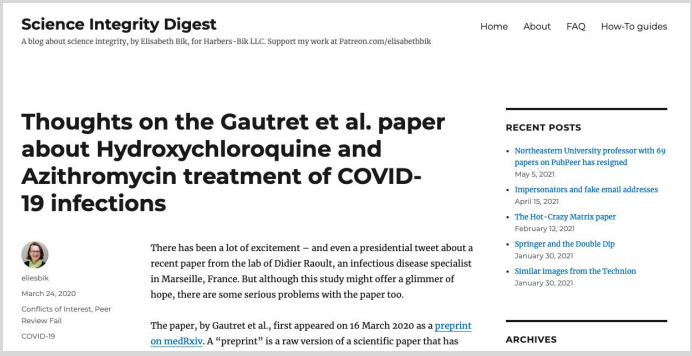
103.3K Retweets **386.8K** Likes

Didier Raoult has complained about the "dictatorship of the methodologists" who insist on randomization and control groups in clinical trials. MOURA/ANDBZ/ABACA/SIPA VIA AP IMAGES

Science, 9 April 2020

A critical review

- Ethical issues: study may have started before ethical approval
- Differences between control and treatment groups
  - Age - Hospital - Different PCR tests - Not randomized
- Six treated patients left out of study (1 died, 3 went to ICU)
- Peer review in 24h
- Editor in Chief of journal is an author



Science Integrity Digest

A blog about science integrity, by Elisabeth Bik, for Harbers-Bik LLC. Support my work at Patreon.com/elisabethbik

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Thoughts on the Gautret et al. paper about Hydroxychloroquine and Azithromycin treatment of COVID-19 infections

elisebik

March 24, 2020

Conflicts of Interest, Peer Review Fail

COVID-19

There has been a lot of excitement – and even a presidential tweet about a recent paper from the lab of Didier Raoult, an infectious disease specialist in Marseille, France. But although this study might offer a glimmer of hope, there are some serious problems with the paper too.

The paper, by Gautret et al., first appeared on 16 March 2020 as a preprint on medRxiv. A "preprint" is a raw version of a scientific paper that has

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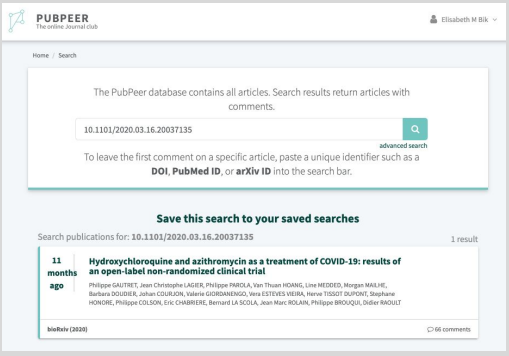

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10.1101/2020.03.16.20037135

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11 months ago

Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial

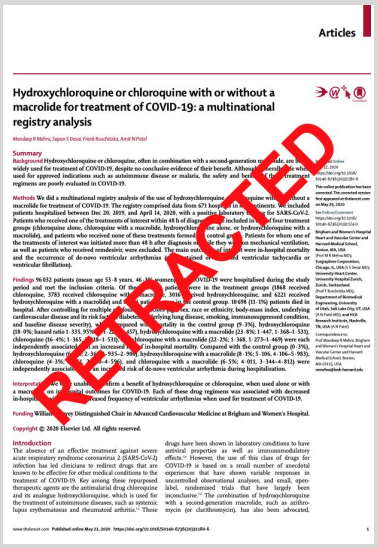
Philippe GAUTRET, Jean Christophe LAGIER, Philippe PAROLA, Van Thuan HOANG, Line MEDDEB, Morgan MAILHE, Barbara DOUDIER, Johan COURJON, Valerie GIORDANENGO, Vera ESTEVES VIEIRA, Herve TISSOT DUPONT, Stephane HONORE, Philippe COLSON, Eric CHABRIERE, Bernard LA SCOLA, Jean Marc ROLAIN, Philippe BROUQUI, Didier RAOULT

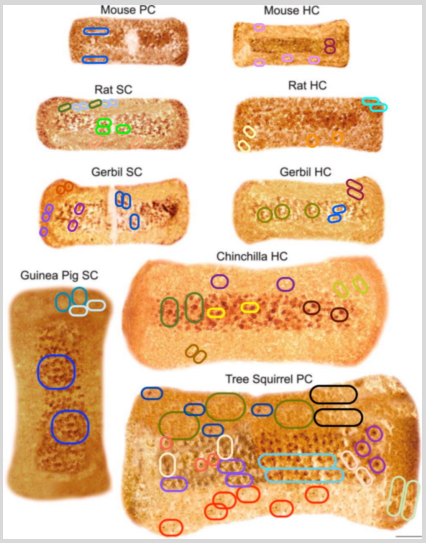
bioRxiv (2020)

66 comments

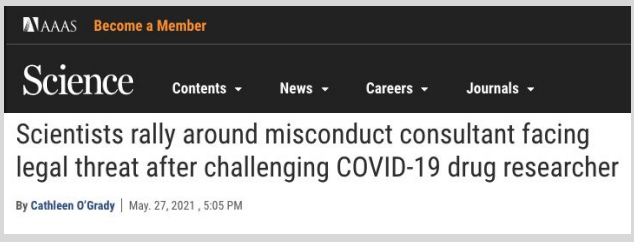
Hydroxychloroquine: does it not work?

- Lancet / NEJM papers, now both retracted
- 96,000 COVID-19 patients from 671 hospitals
- Data provided by Surgisphere
- Surgisphere founder: photos of concern in 2005 PhD paper





Legal threats for science whistleblowers



Science Misconduct: Discussion

- What is the percentage of science misconduct?
- Why do people commit science misconduct?
- Conflicts of interest *(publishers, institutions)*?
- Legal protection for whistleblowers?
- Tremendous cost of science misconduct *(scientists, science)*
- @MicrobiomDigest #ImageForensics

James MacLeod, University of Evansville, IN

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."