

SITAB, Società Italiana di Tabaccologia, via G. Scalia 39, 00136 Roma. Tel.: 06-39722649, Fax: 06-233297645, 178-2215662. CF: 96403700584 Email presidenza: sitab.roma@tiscali.it - segreteria: sitab.milano@tiscali.it - internet: www.tabaccologia.org

More details on competing interests - BMJ

Rapid responses

20 May 2003 Martin McKee, Professor of European Public Health LSHTM, WC1E 7HT, UK, Pascal Diethelm martin.mckee@lshtm.ac.uk

Dear editor,

In an earlier rapid response, one of us called for clarification of certain aspects of Enstrom and Kabat's statement of competing interests. We are grateful to Professor Kabat for his clarification of involvement in an earlier paper with Professor Rylander mailto:[1mailto:] who, as we noted, has been shown to be a leading consultant for the tobacco industry mailto:[2mailto:].

However, in the light of the concerns that have been raised, it would also be helpful to be reassured that Professor Kabat was not involved in the work at the American Health Foundation funded by Philip Morris until 1991. This funding stream then funding ceased but was, however, followed by a substantial grant from Kraft, a member of the same industrial group as Philip Morris mailto:[3mailto:]. Interestingly, the letter from Kraft announcing the funding was copied to Steven Parrish, a senior executive at Philip Morris who has been active in their work on environmental tobacco smoke (ETS).

We also requested information on the nature of the funding awarded by CIAR, given that it funded two types of research, peer-reviewed and "special-reviewed", with the latter awarded directly by tobacco industry executives. As Barnes and Bero have shown mailto:[4mailto:], the special-reviewed projects were more likely than peer-reviewed projects to support the tobacco industry position and be used by the industry to argue against smoking bans in public places.

While awaiting a response we have undertaken our own research on the role played by CIAR using publicly available tobacco industry documents.

We note that, on 15 July 1996, Dr Enstrom, wrote to Dr Max Eisenberg, Executive Director of the CIAR, to introduce himself, stating that, "for the past three years I have done consulting and research on passive smoking for Jeffrey L. Furr of Womble Carlyle on behalf of RJ Reynolds and Philip Morris mailto:[5mailto:]." Womble Carlyle Sandridge & Rice is a law firm based in Winston-Salem, North Carolina, that was extensively involved on behalf of the tobacco industry in litigation in respect of the hazards of exposure to tobacco smoke indoors and Dr Enstrom had written reports on this topic for RJ Reynolds' legal department mailto:[6mailto:].

This was followed by a formal proposal to CIAR. The initial proposal, dated 28th June 1996 mailto:[7mailto:], set out a package of work that included reanalysis of three existing cohorts, including the CPS I study. The others were the NHANES I Epidemiologic Follow-up Study and the US Veterans Study.

We have obtained anonymous reviews which make it clear that the proposal was not highly regarded. One, by Dr J Oey, working at INBIFO, a facility in Germany owned by Philip Morris, noted that "The projects proposed are very large and diverse . for all these projects/studies the hypotheses or objectives are not stated" and "procedures are indeed very general and do not help one in determining the quality of the proposal" mailto:[8mailto:]. Another reviewer noted that such a reanalysis would "only add to the increasing number of imperfect studies" mailto:[9mailto:].

Despite these somewhat sceptical reviews, CIAR appears to have been willing to proceed further. The minutes of the meeting of the Board of Directors of the CIAR, on 15th May 1997 record that Dr Max Eisenberg, Executive Director of the CIAR, stated that he was in separate discussions with Drs Enstrom and Kabat about "the possibility of their collaboration" mailto:[10mailto:].

Richard Carchman, Vice President (Scientific Affairs) of Philip Morris then wrote to Dr Enstrom to confirm a meeting that would also be attended by Dr Eisenberg in Los Angeles, on 19th September 1997 mailto:[11mailto:]. Carchman had previous contact with Dr Enstrom, for example when he wrote on 25th April 1997 to notify him that he had been awarded a grant of \$150,000 by Philip Morris for research on "The relationship of low levels of active smoking to mortality" mailto:[12mailto:]. In his letter of 15th January accompanying that proposal mailto:[13mailto:] Dr Enstrom noted that "A level of trust must be developed based on my past research on passive smoking. A substantial research commitment on your part is necessary in order for me to effectively compete against the large mountain of epidemiologic data and opinions that already exist regarding the health effects of ETS and passive smoking". Charles Green, of RJ Reynolds, and convenor of the industry-wide ETS Task Force, a! nd who had taken a leading role in the industry campaign to undermine other work on the link between passive smoking and disease, was to have attended the meeting but was unable to. However Green did write to set up a follow-up meeting with Carchman on 9th October mailto:[14mailto:].

Subsequently, an amended proposal, dated 20th October 1997, now jointly with Dr Kabat and with Drs Lawrence Garfinkel and Clark Heath, from the American Cancer Society, was entitled "Environmental tobacco smoke and mortality among CPS I" mailto:[15mailto:].

Again, a review was unfavourable mailto:[16mailto:], noting:

- . "the proposal appears to have multiple, mixed goals"
- . "the proposal fails to distinguish between "ETS exposure" and "living with a spouse who smokes, makes light of the substantial loss-to-follow-up expected in this cohort, freely assumes adequate adjustment can be made for the non-representativeness of the initial cohort, underplays the import of smoking cessation on the analyses, and is uncritical of positions established by the non-smoking community"
- . "the proposal fails to clearly define the analyses planned and hypotheses to be tested for ETS exposure"
- . "the proposal fails to clearly define the data upon which the planned analyses will be based."

However the reviewer does note that "The list of consulting authors (Heath, Kabat, Garfinkel) is impressive and should add credibility to interpretation of results".

A memorandum from Dr Eisenberg, dated 3rd November 1997, then makes clear that Dr Enstrom's "proposed research on passive smoking" was to be considered by CIAR under its directed studies (or special reviewed) programme mailto:[17mailto:], which has elsewhere been found to mean that it would be undertaken under industry direction. Its special status seems to be confirmed in the minutes of the meeting of CIAR's Board of Directors on 19/20th November 1997. This listed 20 proposals that had been recommended for consideration by CIAR's Scientific Advisory Board. Dr Enstrom's proposal was taken separately and it was decided to fund it with (unspecified) modifications mailto:[18mailto:].

Since then, Dr Enstrom appears to have maintained his links with the tobacco industry, for example, speaking at a symposia and workshops, with tobacco industry representatives nominating him as an "appropriate" (sic) expert, along with others who are well known to be consultants to the industry mailto:[19mailto:]. These links extended to a meeting organised by Philip Morris staff in June 2000 with Peter Lee, a leading consultant to the tobacco industry, to "discuss the results of the CPS I and CPS II studies and develop possible approaches to analysing the data" mailto:[20mailto:].

Dr Enstrom reported that "In recent years mailto:[hemailto:] has received funds originating from the tobacco industry for his tobacco related epidemiological research because it has been impossible for him to obtain equivalent funds from other sources." Given the controversy that this paper has generated we hope that this account will clarify the nature of this relationship.

Martin McKee

London School of Hygiene and Tropical Medicine, London, UK

Pascal Diethelm

OxyGenève, Geneva, Switzerland

## References

1 Koo LC, Kabat GC, Rylander R, Tominaga S, Kato I, Ho JH. Dietary and lifestyle correlates of passive smoking in Hong Kong, Japan, Sweden, and the U.S.A. Soc Sci Med 1997; 45: 159-69.

2 http://www.prevention.ch/rylanderpm.htm mailto:[accessed 14 May 2003mailto:]

3 McVicker RG. Letter to Wynder E. Dated 3 May 1991. Bates Number: 2046988682; Master Document Id Range: 2046988682/8684.

- 4 Barnes DE, Bero LA. Industry-funded research and conflict of interest: an analysis of research sponsored by the tobacco industry through the Center for Indoor Air Research. J Health Polit Policy Law 1996; 21: 515-42.
- 5 Enstrom JE. Proposed research on passive smoking. 15 July 1996. Bates Number: 2502317161; Master Document Id Range: 2502317161/7179.
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- 9 Comments to proposed research on passive smoking. 30 Oct 1996. Bates Number: 2502317159/7160
- 10 CIAR. Minutes of meeting of the board of directors. 15 May 1997. Bates Number: 517578187/8188
- 11 Carchman RA. Letter to Enstrom J dated 15th Sept 1997. Bates Number: 2063610773.
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- 13 Enstrom JE. Proposed research on the relationship of low levels of active smoking to mortality. 15th Jan 1997. Bates Number: 2075873003; Master Document Id Range: 2075873001/3021.
- 14 Green C. Memo to M. Opocensky. Undated. Bates Number: 2063635713.
- 15 Enstrom JE, Garfinkel L, Heath CW, Kabat G. Proposed research on passive smoking environmental tobacco smoke and mortality among CPS I. Bates Number: 2076979240/9270; Master Document Id Range: 2076979214/9270
- 16 Comments on proposal, environmental tobacco smoke and mortality among CPS I. Undated. Bates Number: 566943526.
- 17 Eisenberg M. CIAR PROPOSALS. Dated 3 Nov 1997. Bates Number: 2076979214; Master Document Id Range: 2076979214/9270.
- 18 Eisenberg M. Center for Indoor Air Research. Board of Directors' meeting. 19/20 November 1997. Bates Number: 522077990/7993
- 19 Carchman R. Letter to B Rikert. 7 May 1998.
- 20 Sanders T. Tobacco smoke lung cancer histological types and analysis of major databases. Bates Number: 2505540920

Competing interests: As editor of the European Journal of Public Health, MM published another paper by authors funded by the Center for Indoor Air Research. This publication was the centre of a long-running dispute between the journal and the authors concerning undeclared conflicts of interest. It led to his involvement as a witness in a lengthy legal dispute that has recently been resolved. PD successfully defended a charge of libel in the same case. OxyGenève is an organisation involved in tobacco control. Both have received funding for work on tobacco control.

http://bmj.com/cgi/eletters/326/7398/1057#32472

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Science as PR - BMJ 20 May 2003 Gene Borio, Webmaster, Tobacco.org 10012 gborio@mindspring.com This letter questions the presentation of this study as if the British Medical Journal were an arm of Burson Marsteller. It examines how this presentation fits into the industry's 15-year crusade against secondhand smoke research. It questions the role of study author James Enstrom in that crusade. And it criticizes the seemingly inadequate due diligence by the BMJ.

I believe ignoring or minimizing these issues represents a significant failure of nerve by the BMJ. Science's inability to safeguard its castle from Trojan Horses leads inevitably to the distrust of all science by the public, and, of course, an absence of scientific trust is a win for the industry.

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I'm very troubled by the BMJ's overt politicization of this study.

It's my understanding that reputable scientists and journals are very careful about calling any single study definitive-especially when it contradicts a large body of previous studies. I also understand that a null-result study is rarely newsworthy. In addition, I have seen that scientific professionals often take care to minimize the impact a misunderstood study might have. A study on the health benefits of alcohol, for example, is likely to couch its conclusions in moderate terms, for fear of spawning headlines in the popular press like, "Drink up, me maties!"

But this study not only got the cover, it got a politically inflammatory cover at that. "Passive smoking may not kill" is coupled with a picture of a California building's toxic substances advisory. Many will infer -- as at least one "FORCES" site 1 featuring the cover has -- that a larger point is being made beyond the study itself: an implication that this study is so accurate and so powerful that it may invalidate communities' smoking bans.

But this study did find something: an increase in COPD diseases. Yet the COPD result is downplayed, and the null result trumpeted on the cover. The New York Post itself couldn't have hailed this study with more glee. I wonder how many previous covers the BMJ has done heralding null results.

Such a cover practically invites headlines like:

"Study denies link between secondhand smoke, disease" (Baltimore Sun)

- -- "2nd Study Confirms 2nd Hand Smoke Harmless" (Rush Limbaugh site)
- -- "Passive smoking is innocent, says controversial study" (AFP)
- -- "Passive smoke 'not bad'" (The Sun)
- -- "Passive smoking may not be harmful, says study" (online.ie)
- -- "Secondhand Theory Blows Smoke: Study" (NY Post)
- -- "Passive smoking may not damage your health after all, says research" (Daily Telegraph)
- -- "Passive smoking risks in doubt, study says" (London Times).

This politicization of a scientific study is especially disturbing when one considers the study's funding history, the BMJ's foolish excuse for paying little attention to such funding, the article's vague and minimalist description of the authors' tobacco work, the number of industry consultants listed in the References, and, as topping to the political cake, Enstrom's crucial role in the decade-long industry campaign to characterize the 1993 US EPA report as junk science.

More specifically:

- 1. The authors write, "In recent years JEE has received funds originating from the tobacco industry for his tobacco related epidemiological research because it has been impossible for him to obtain equivalent funds from other sources."
- a. That is a shame. But isn't this the same excuse for accepting tobacco money given by dance companies, battered women shelters, teen smoking prevention programs, and certain University Corporate Responsibility Centers?

This very rationalization is eminently useful by the tobacco industry in a multitude of venues. It is used by recipient organizations in testimony against community smoking bans. It is used to extol tobacco companies' essential benevolence in society, helping the business end continue quietly and profitably. It is used to exonerate tobacco companies in litigation. An obscene amount of money can take one very far indeed.

b. Doesn't the BMJ get suspicious as to why only the industry would fund this study? The clear pattern of industry funding for 40 years--in fact, its very goal, according to what we read in the secret documents-- appears to be to protect the industry's profits. This study certainly fits right in with that goal. Why does this raise no red flag at all at the BMJ?

c. How long, exactly, is Dr. Enstrom's "recent years." This seems coy indeed. W are not told exactly how many tobacco organizations Mr. Enstrom has worked with, in what capacity, or for how long. Surely, considering the industry's history and stated goals in these matters, this is vital knowledge. CIAR, yes, Philip Morris, yes, for this particular study. What about earlier documents linking Enstrom to RJR, and to its law firm Womble Carlyle, which helped RJR fight the Butler secondhand smoke suit.

What of this proposal, dated 1992 and attributed in the Bliley documents to Dr. Enstrom? It is entitled, "Report Concerning Smoking and Health Issues Prepared by Consultants Engaged by RJR for the Purpose of Assisting Attorneys in Connection with Ongoing Litigation Transmitted to RJR in-House Legal Counsel":

"The mortality changes among nonsmokers must be due to factors other than cigarette smoking and these changes mean that factors other than personal smoking have had a major impact on mortality rates that has not been fully considered when evaluating the impact of cigarette smoking. These changes have a direct bearing on the interpretation of the death rate changes that have occurred among the population as a whole, presumably due to changes in smoking. Also, these changes affect the interpretation of the number of U. S. deaths "due to" cigarette smoking . . . " 1

And what of this 1996 letter, from J. Furr of Womble Carlyle?

"Re: EPA Litigation -- Enstrom Publication

"Dear Dan, Jim and Jim:

"Enclosed please find a copy of the analysis of the Fontham study that Dr. Enstrom has submitted for publication in JAMA I will keep you apprised of the status of Dr. Enstrom's submission.

"I also will be calling to discuss meeting with Dr. Enstrom regarding additional work that he has proposed." 3

c. And what of Dr. Enstrom's role in the fight against the EPA's 1993 report? Enstrom was liberally quoted in several influential if not seminal articles that found fault with the report -- one by Michael Fumento and two by Jacob Sullum.

In 1994, Sullum's articles were reprinted in full-page ads nationwide by Philip Morris and RJR. RJR's run was headlined, "If we said it, you wouldn't believe it."

If indeed Dr. Enstrom was being funded by the industry at this time, this PR seems patently dishonest -- the industry funds a person it likes (to put the most naive face on it), then touts his opinions proclaiming, "We didn't say it, he (presumably, a disinterested scientist totally unaligned with the industry) did!"

Deployed for political and business goals, such a manufactured and circular citation ill becomes a scientist who would partake in the deception simply by his silence. It is certainly unbefitting a scientist who should be published in-and excused by-the British Medical Journal.

Did the journal know of this history? Did it think it irrelevant? Did it even ask? Unless the BMJ has investigated these issues thoroughly in light of these documents and Enstrom's history, I believe the vague "recent years" admission cum excuse is far too weak a descriptor to constitute a full disclosure of conflicting interests.

( I certainly was comforted, however, by the authors' ultra-scientific disclosure that they are "both lifelong non-smokers" -- almost as comforted as when I read a similar avowal by John Luik in his Bostonia magazine article "Pandora's Box." Objective gentlemen, all!)

2. To what is Prof. Smith referring when he says, "the controversy still persists?" I know of exactly two non-tobacco-funded scientists who dispute some aspects of the secondhand smoke literature. Two scientists hardly make a controversy. To this day, Jacob Sullum continues to cite Enstrom as proof of a "controversy" about secondhand smoke--as if there are simply too few non-tobacco-funded sources available to maintain his claim of a controversy. (It's certainly striking how many tobacco-funded scientists are cited in this study's references.)

The only controversy I have seen in this matter is tobacco-funded, just like this study, which Prof. Smith says will "continue the controversy." It's as if Prof. Smith is in dutiful lockstep with the Philip Morris' 1988 strategy to "keep the controversy alive." 4

- 3. The BMJ's justification of tobacco industry funding seems to be based on the scientifically-accurate but unuseful adage that even a stopped clock is right twice a day. Even so, I believe this policy should be reworked in the case of the tobacco industry. After all, the industry's outsize PR capability can make a stopped clock's 2 seconds appear more important than a running clock's 86,400. When a funding source has such a nefarious history, and has demonstrably used science for its own political and business goals, I believe the BMJ must formally adopt strict rules governing the examination of that source's submissions, authors and provenance--a due diligence that goes as far beyond the usual as the industry's historic depredations have gone.
- 4. If the BMJ did know of Enstrom's history, and the history of the tobacco industry's massive and variegated war against the science of a) primary smoking and b) secondhand smoke, then why did the BMJ create -- so boldly, so baldly -- a presentation of this study that any industry PR flack would be proud of? Before trumpeting a study that finds the industry's stopped clock is right more often than the medical world's 2-minutes-fast clock, some editorial caveats would seem to be in order. It's singularly unbecoming for the British Medical Journal to act as an arm of Burson-Marsteller.

If the BMJ can be this lax about safeguarding against manipulation by the industry, what does this say to lesser journals? How big a flood of tobacco industry studies polluting the literature may we look forward to?

This can destroy the integrity of not just the BMJ, but of the public's faith in the scientific establishment. If science is incapable of policing itself--in fact, if it deliberately lends itself to a study funders' political goals--then all trust is lost

Which, of course, would be just fine for a multitude of commercial interests. If trust in science dies, PR, ignorance and deceit will rule in its place.

The industry certainly got its money's worth on this study.

"Those who cannot remember the past are condemned to repeat it." -- George Santayana

- 1. "The secondhand smoke myth goes up in smoke," http://www.forcesduluth.com/ Downloaded May 18, 2003
- 2. "Report Concerning Smoking and Health Issues Prepared by Consultants Engaged by RJR for the Purpose of Assisting Attorneys in Connection with Ongoing Litigation Transmitted to RJR in-House Legal Counsel": http://tobaccodocuments.org/bliley\_rjr/515814425-4435 .html, accessed May 16, 2003
- 3. "Epa Litigation -- Enstrom Publication." 09 May 1996. http://tobaccodocuments.org/rjr/515638685-8685.html, accessed May 17, 2003
- 4. "Note on a special meeting of the UK Industry on Environmental Tobacco Smoke, London, February 17th, 1988" http://www.ash.org.uk/papers/401247331.pdf, http://tobaccodocuments.org/youth/EtPrPMI19880217.M m.html, accessed May 17, 2003

Competing interests: Tobacco.org, a news-tracking website that posts all tobacco news without censorship, is currently funded by TTAC, which was established in 2001 through a grant from the American Cancer Society, the American Legacy Foundation, and The Robert Wood Johnson Foundation. As on the website, I speak only for myself.

http://bmj.com/cgi/eletters/326/7398/1057#32434	

Apology Requested - BMJ 21 May 2003

William T Godshall, Director, Smokefree Pennsylvania Pittsburgh, PA 15217 USA bill@smokescreen.org

To begin atoning for publishing and promoting "Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-98" by James E. Enstrom and Geoffrey C Kabat, BMJ editors are urged to publish at least as bold of apologies on the front cover, in an editorial and in the promotional press release of a forthcoming BMJ issue.

According to the article's competing interests, "In recent years JEE has received funds originating from the tobacco industry for his tobacco related epidemiological research because it has been impossible for him to obtain equivalent fund from other sources." But a quick search of tobacco industry documents reveals a long term mutually beneficial relationship between JEE and the tobacco industry (chronologically listed below).

1975: http://legacy.library.ucsf.edu/tid/ldi79c00 Enstrom writes to the tobacco industry funded and controlled Council for Tobacco Research (CTR) requesting funds.

1975: http://legacy.library.ucsf.edu/tid/qdi79c00 Enstrom writes again to CTR asking for money.

1976: http://legacy.library.ucsf.edu/tid/quk2aa00 Enstrom writes to Tobacco Institute asking for help in getting CTR money.

1976: http://legacy.library.ucsf.edu/tid/guk2aa00 Enstrom writes to CTR about his grant application.

1978: http://legacy.library.ucsf.edu/tid/hgi89c00 Enstrom writes to CTR to ask for money again.

1979: http://legacy.library.ucsf.edu/tid/gov10f00 Enstrom's research finds that lung cancer rates are rising in nonsmokers, leading him to conclude that numerous lung cancers are due to something other than cigarette smoking.

1990: http://legacy.library.ucsf.edu/tid/xoj52d00 Enstrom writes to Philip Morris asking for money "My epidemiological research does not deal directly with the issue of environmental tobacco smoke...However my research does deal extensively with cancer and other diseases among nonsmokers."

1991: http://legacy.library.ucsf.edu/tid/aix89c00 Enstrom applies for more CTR money.

1992: http://legacy.library.ucsf.edu/tid/xix89c00 CTR gives Enstrom a three year grant; goal of research: answer "questions regarding the among of current mortality that can be considered directly due to cigarette smoking and the amount of current mortality that can be prevented by smoking cessation".

1993: http://legacy.library.ucsf.edu/tid/iix89c00 Enstrom gets \$34,500 of CTR money.

1994: http://legacy.library.ucsf.edu/tid/mix89c00 Enstrom gets another \$34,500 of CTR money.

1995: http://legacy.library.ucsf.edu/tid/gjx89c00 Enstrom gets another \$35,000 of CTR money.

1996: http://legacy.library.ucsf.edu/tid/jkx89c00 Enstrom applies for more CTR money.

1997: http://legacy.library.ucsf.edu/tid/elx89c00 CTR offers Enstrom more money.

1997: http://legacy.library.ucsf.edu/tid/lkx89c00 Enstrom gets another \$35,000 of CTR money.

1997: http://legacy.library.ucsf.edu/tid/oxw91d00 Enstrom applies to the tobacco industry funded and controlled Center for Indoor Air Research for \$425,000 to research passive smoking, which appears to be the funding for his article in last week's BMJ.

1997: http://legacy.library.ucsf.edu/tid/tww91d00 Enstrom's cover letter for the grant application: "For the past three years I have done consulting and research on passive smoking for Jeffrey. L. Furr of Womble Carlyle on behalf of R J Reynolds and Philip Morris." The bait: "This research has found a number of results that raise serous questions about several published findings on the relationship of passive smoking to lung cancer and other diseases".

1997: http://legacy.library.ucsf.edu/tid/imf37d00 Enstrom's grant application to "Philip Morris Research Center".

1997: http://legacy.library.ucsf.edu/tid/cmr29c00 Internal industry review of Enstrom's proposal doesn't consider it important, but notes he "seems to have good connections/resources which might be useful in the future for other issues." This is the same document that has been cited recently by other health groups.

1998: http://legacy.library.ucsf.edu/tid/mjc36d00 Enstrom writes to CTR asking for more money or time (?)

In short, Enstrom's 25 years of requesting money from the tobacco industry aren't consistent with his claim that he's just "received" money and just "in recent years". And during the past decade, Enstrom has received more than half a million dollars from the tobacco industry. In return, it appears he has delivered a study amazingly useful to his sponsor.

The tobacco industry documents cited in this letter were obtained and summarized by Jon Krueger.

Once again, to help regain its previous scientific and public health integrity, the BMJ should publish and promote apologies to its readers and to the media as soon as possible.

Competing interests: None declared

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