

The good, the bad and the ugly about the Foundation for a Smoke-Free World

- Pr. Jean-François ETTER, PhD
- E-cigarette Summit, London
- November 17, 2017
- No competing interests
- I talked to Derek Yach in preparing this presentation
- I thank those who read preliminary versions and provided ideas

Context

- Disruptive technologies
- Rapid market transformation (IQOS=14% of all tobacco sold in Japan)
- New strategy of Philip Morris International (PMI):
 - product diversification, non-combustible products,
 - stated goal to eliminate combustion
- New products increase legal liability for Big Tobacco: cigarettes = defective
- Highly emotional debate

Foundation for a Smoke-Free World, Inc. (FSFW)

- Foundation was first announced by PMI CEO A. Calantzopoulos
- Launched in Sept 2017 at a tobacco-industry sponsored event (GTNF, NY)
- Funded by PMI, \$1 billion over 12 years,
= 80 million / year
= 1% of PMI's marketing budget
- Derek Yach: led the development of FCTC at WHO (1990s-2000s)
- Focus on **harm reduction**, new non-combustible products
- Aligns with PMI industrial strategy : product diversification
- Defense in product liability claims : they show they do all they can

Foundation for a Smoke-Free World, Inc. (FSFW)

- Bylaws, governance, US IRS registration documents, and agreement with PMI designed to prevent PMI influence
- Stated willingness of FSFW to act towards independence + transparency
- Objectives:
 - support research
 - provide directions and recommendations to reduce smoking
 - monitor industry activity
 - verify progress on elimination of smoking
 - help farmers find alternative income
 - create next generation of leaders and researchers

Reactions

- Many negative reactions, as could be expected
- Positive reactions too, according to FSFW
 - many researchers, institutions want to collaborate
 - provide ideas for research
 - requests for employment

Criticism 1)

FSFW not independent from PMI

- PMI provided initial funding
- Historical record of scientific misconduct from PMI, other PMI's scientific initiatives used to undermine tobacco control :
 - Whitecoat Project, INBIFO
- FSFW is seen as part of PMI's strategy to create doubt + controversies
- PMI may benefit from research results
- Director was selected by PMI and was paid by PMI (not anymore), and
- he led the process of selecting the board of directors
- Disingenuous: PMI should stop undermining anti-smoking laws and suing Govmt

Criticism 2) Reject harm reduction + new products

- Some critics of FSFW reject harm reduction as a tobacco control strategy
- They reject new reduced-risk products, in particular if sold by tobacco industry
- Cessation only
- Use traditional strategies instead (MPOWER)
- e.g. WHO FCTC Secretariat

Is there anything good about FSFW ?

Money = New talent, new countries

- Ambitious, well-funded for 12 years
- Currently, too little research capacity, too little money, too few researchers
- More research is needed on harm reduction and reduced-risk products
- FSFW intends to fill these gaps
- FSFW may attract new talent, researchers not yet involved in tobacco
= new methods, new perspectives, fewer pre-conceptions
- Fund research in **countries** where there is currently little research
- More diversity
- More global

Anything good ?

Potential for quality

- More money =
 - better equipment,
 - «definitive» studies in large samples,
 - replication studies
- FSFW grant applications will be competitive + peer-reviewed,
 - all studies will be published,
 - all original data will be made available

(but will studies and analyses be pre-registered ?)

Less tainted than research done directly by PMI

- PMI, BAT invest billions in R & D
- Broad range of studies
- Research done by PMI is already used by Gov agencies, policy makers
- e.g. FDA application to register IQOS as a reduced-risk product
FDA decision will be based almost entirely on PMI research
- FSFW-sponsored research may be less tainted than research done directly by PMI

Anything good ?

Harm reduction, new products

- WHO, FCTC COP are very negative about harm reduction, new products
- Some countries follow WHO lead and are reluctant to fund research
- FSFW = more research on harm reduction, on new products,
- However, USA and other countries fund research on reduced-risk products and new strategies

Should we participate, apply for grants or boycott FSFW ?

For boycott:

- PMI sells deadly products, engaged in scientific misconduct, opposes FCTC
- PMI may use FSFW output to challenge anti-smoking policies
- FSFW = public relation gains for PMI : «corporate responsibility»
- Any study funded by FSFW could be clouded by the suspicion of bias
- Avoid association with PMI and conflicts of interest
- Risk for career, reputation

Journals:

- Will journals that don't publish tobacco industry-funded research publish research funded by FSFW ? (*BMJ, Thorax, Heart, Tobacco Control*)

Against boycott

- Censorship approach
- Against basic scientific principles of open discussion between peers
- Discuss with all parties, in particular if you don't agree with them
- Boycott based on ideology rather than scientific principles
- Possible public relations benefits for PMI if public health rejects FSFW
- The FSFW is not PMI

If researchers don't apply or public health does not participate, then...

- Wasted money \$1 billion
- It may take longer to prove the effects of
 - reduced-risk products
 - harm reduction strategies
- Narrower range of research will be funded, in fewer countries, less diversity
- Most research on new products will be done by the industry itself

What more can FSFW do to be considered independent?

- Fulfill criteria for the acceptability of tobacco industry-funded research:
 - Transparency and independence
 - Governance, directorate
 - Protection against conflicts of interest
 - etc.
- J. Cohen, M. Zeller et al. *Tobacco Control*. 2009;18:228
- FSFW says it aims at meeting these criteria
- Use this framework to:
 - dialogue with FSFW,
 - hold FSFW accountable

What more can FSFW do to be considered independent?

Letter from Clive Bates and others to Derek Yach, November 16 :

- Donation should be irrevocable
- One-off payment, like an endowment
- Or if 12x, it should be no possible for PMI to withhold annual payments
- No repeated funding before after year 12

- Independent board of directors, modest honoraria
- Find other funding sources
- Accept the scrutiny of an *ad hoc* external oversight group

For some opponents, FSFW may never be acceptable whatever it does to prove its independence

What can researchers + public health people do ?

- Be aware that emotions can cloud rationality

Public health:

- Dialogue with FSFW to help them fulfill criteria for independence
- Participate in external oversight group
- Apply extensive scrutiny
- Hold FSFW accountable for its promises

Individual researchers may want to participate only after :

- FSFW's independence is more widely demonstrated
- Careful assessment of risks for career, reputation

Conclusions

- FSFW is a work in progress: not yet at the point where it can be considered independent, credible and acceptable
- Clarity needed on funding, governance, directorate, external oversight
- FSFW may have the potential to be useful if its independence from PMI can be demonstrated