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Conflict of interest: A tenacious ethical dilemma in public health policy, not only in clinical practice/research

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In addition to the ethical practice of individual health professionals, bioethical debate about conflict of interest (CoI) must include the institutional ethics of public policy-making, as failure to establish independence from powerful stakeholder influence may pervert public health goals. All involved in public policy processes are accountable for CoI, including experts, scientists, professionals, industry and government officials. The liquor industry in South Africa is presented as a case study. Generic principles of how to identify, manage and address CoI are discussed. We propose that health professionals and policy makers should avoid partnering with industries that are harmful to health. Regarding institutional CoI, we recommend that there should be effective policies, procedures and processes for governing public-private joint ventures with such industries. These include arms-length funding, maintaining the balance between contesting vested interests, and full disclosure of the identity and affiliations of all participants in structures and reports pertaining to public policy-making.

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The subject of conflict of interest (CoI) has long preoccupied bioethicists, particularly as a threat to clinical independence and quality of care[1,2] and as corrupting ethical practice in research.[1,3] For example, pharmaceutical companies' promotions and gifts act as inducements to influence doctors' prescribing practices, maintaining company profits at the possible expense of good-quality healthcare.[4,5] To address the practice of referring patients to services (including services provided as part of clinical trials) in which the practitioner has a financial interest – the so-called perverse incentives problem – the Health Professions Council of SA (HPCSA) has elaborated detailed guidance to avoid unethical practices.[6] Then there are the many documented examples of 'bent' science, where CoI has perverted the integrity of research. For example, researchers sponsored by the tobacco, asbestos and alcohol industries have often failed to declare their sources of funding when presenting findings that effectively exonerated these industries from producing hazardous products.[7-11]

We argue that bioethical debate should extend beyond the ethical practice of individual health professionals such as clinicians or researchers, to include the ethics of public policy-making. Opportunities for CoI arise when health sector policies, or those in other sectors that affect upstream health determinants, are poorly informed by an ethical perspective. Powerful elites, who stand to benefit directly from policy directions, may have influence not equally afforded to other affected parties, threatening the ethics of public policy formulation.

Policy making is inherently political, involving negotiation and compromise based on power and/or social consensus that is shaped by scientific evidence. To protect the integrity of the process, it is essential that experts and advisors behave ethically and professionally, particularly in their critical evaluation of evidence.

Conflict of interest involving experts, scientists and professionals and industry

Michaels[12] explores the problem of 'bent science' which underplays the risks of hazardous chemical and other exposures. He postulates that this process is essentially about the marketing of doubt. The scientific method cannot prove 100% that an exposure is safe nor that it is hazardous; at best it provides the basis for informed and considered judgements on the likelihood of its causing adverse health effects, and hence the ability to say that a product is not safe. Criteria for demonstrating a harmful effect include adducing cumulative evidence, showing consistency in multiple studies,

demonstrating dose/response effects, temporality and biological plausibility. However, while the requirement to meet these criteria may strengthen grounds for causality, it may also provide product defenders with latitude to sow doubt on findings of harm.

Furthermore, evidence may be overtly manipulated by inappropriate study design with insufficient power, to yield results that suggest the product has no effects. Under these circumstances, the absence of evidence may be misconstrued as evidence of the absence of any harmful effects. Skepticism is usually part of scientific method but tends to be selectively applied by vested interests to cast doubt on best estimates of risk, compiled honestly and comprehensively from the evidence at hand, with public safety in mind. The role of industry-funded scientists in producing and lending credibility to such bent science is well recognised.[13]

When such research is fed into the policy-making process, and where critical review is not provided, it can result in policies that insufficiently protect human health. This can be to the benefit of vested interests, particularly where protective policies may have negative economic effects for the state or where key political decision-makers also have vested interests in affected economic industries.

The World Health Organization (WHO) International Programme for Chemical Safety (IPCS) produces risk assessment documents entitled Environmental Health Criteria monographs. Its 1986 monograph on asbestos and other natural mineral fibres[14] concluded that all types of asbestos could cause lung cancer. The Canadian, Russian and Indian asbestos industries and other powerful stakeholders actively lobbied for using chrysotile (white) asbestos under controlled conditions and downplayed evidence for its toxicity. In 1993 the IPCS Workgoup's first draft of an updated monograph on chrysotile downgraded the carcinogenic risk associated with exposure to chrysotile asbestos.[7] This shocked the scientific community, which appreciated the evidence confirming carcinogenic risks associated with chrysotile asbestos. It emerged that members of the Workgroup were either in the employ of asbestos companies or were industry consultants, but had not declared this CoI in committee deliberations.

After intense scrutiny and revision, the final report concluded there is no safe threshold of exposure for the carcinogenic risk of chrysotile, and recommended use of safer substitutes.[15] More significantly for the policy-making process, the WHO introduced a stringent policy requiring declaration of CoI for all its workgroups involved in policy making and standard setting.[7] This is an example of how governments (here a global 'government', the WHO) must ensure adequate balance of all vested and legitimate interests in their policy-making structures, and create tools to assure good public policy (e.g. CoI declarations and the balancing of vested interests).

Despite such noble intentions, it remains difficult to implement such safeguards against CoI in policy decisions, particularly where industry and governments have shared economic interests. The WHO came under severe pressure from the USA government to temper its 2003 report on the obesity epidemic, which argued for limiting the amount of sugar in diets to promote health. Acting at the behest of the powerful USA sugar industry, the USA government threatened to withdraw its financial contributions to the WHO unless the policy was altered.[16,17]

Elsewhere, civil society activists argued that the 2011 World Conference on Social Determinants of Health[18] would provide a platform for corporates with vested interests to limit the extent to which UN-recommended policies would threaten their profits. A civil society Statement of Concern[19] argued that the policy development process should not be 'compromised by obvious conflicts of interests associated with food, alcohol, beverage and other industries, that are primarily answerable to shareholders'. An alternative civil society declaration urged the WHO to adopt a code of conduct to ensure transparency in decision-making and appropriate management of CoI, particularly regarding organisations with commercial interests.[20]

As a result of this civil society pressure, the conference's final report made three references to 'safeguarding against conflict of interests'. This was directed at member states, but no reference was made to ensuring such safeguards apply to the WHO itself. Indeed, a commentary from the WHO Department of Ethics, Equity, Trade and Human Rights, released to coincide with the Rio Conference in October 2011, makes no mention of CoI in its discussion of action on social determinants needed to address non-communicable disease.[21] This illustrates the difficulties of implementing WHO CoI policy in practice.

While filling different senior executive positions at the WHO between 1995 and 2005, Derek Yach was responsible for some of the most influential public health promotion interventions on tobacco. In 2007 he became vice-president of food conglomerate Pepsico, with the stated intention of using his corporate base to advance a public health agenda and promote a key role for the food industry in stemming rising rates of nutrition-related chronic diseases.[22,23] However, detractors have criticised this attempt to influence corporate policy as irrevocably conflicted,[24] or as 'corporate capture' of public health.[25] Shah, conversely, viewed Yach's move positively, pointing to the increasing role of the private sector, whose resources dwarf those of public bodies (including the WHO), in funding and leading the global fight against disease.[26]

What is clear is that every individual or organisation participating in developing public policy must be required to declare potentially conflicting interests, as must the governance body (e.g. WHO or a national government). This will ensure a process that manages CoI by ensuring equality between participants, with and without vested interests.

The liquor industry as a case study of institutional CoI

The SA liquor industry deserves our critical attention.[27] National and provincial legislative reviews, together with public health research on alcohol's significant contribution to the burden of disease (BoD), have focused attention on alcohol policy. Research findings have highlighted premature mortality, increased morbidity, and damages/costs to the economy and the state sector.[28]

Alcohol is the third largest contributor[29] to the national BoD. It accounted for an estimated 6% of SA's burden of death and disability in 2004 (1.3 million years of life lost through dying prematurely from an alcohol-related cause, or years lived with an alcohol-related disability). Of this figure, 41% resulted from alcohol-related intentional and unintentional injuries; 32% from alcohol-related infectious diseases; 13% from alcohol-related non-communicable

diseases such as cardiovascular diseases, cancers and liver cirrhosis; and 12% from alcohol-related neuropsychiatric disorders.[30] It has been conservatively estimated that alcohol use cost the state sector (national and provincial) R17.2 billion in 2009.[28]

The WHO has passed various resolutions on alcohol at the World Health Assembly since 2006 which, alongside the activities of the WHO Secretariat, has focused attention in SA on the need to address harmful alcohol use. In May 2010 the WHO approved the *Global Strategy to Reduce the Harmful Use of Alcohol,*[31] which makes a clear case for countries to consider implementing evidence-based strategies to reduce the occurrence of heavy drinking episodes and the prevalence of alcohol use disorders. These strategies include regulating the availability and price of alcohol to reduce accessibility, stricter controls on alcohol marketing, as well as strengthening the capacity of health services to screen for risk and conduct brief interventions for hazardous and harmful drinking at primary healthcare and other settings.[32-34]

Alcohol policy in SA: Prevention of harm and industry advocacy

However, policy developments in SA have been uneven. In 2003 the ANC government[35] introduced the first legislation to provide for liquor legislation at provincial and national level. Then, in 2007, the ANC-led Western Cape Provincial Government passed the Western Cape Liquor Bill, and advertised its intention to remove zoning restrictions under the Land Use Planning Ordinance (Number 15 of 1985) throughout the province. The aim was to encourage black entrepreneurs, as set out in the preamble to the Bill (see Annex 1), by allowing small tavern owners in the informal sector to operate legally within residential areas. This ordinance would have regularised the *de facto* liquor distribution networks set up by the South African Breweries (SAB) for unlicensed shebeens. But in 2008 a government change in the Western Cape aborted this legitimisation of informal alcohol distribution, and provided opportunities to strengthen controls over the liquor industry.

More recently, the ministries and departments of health, social development and transport, acting on a mandate from cabinet, and the Western Cape and Gauteng provincial governments have signalled their intention to take stronger action to reduce harmful use of alcohol. In March 2011 the President and eight cabinet members attended the Second Biennial Substance Abuse Summit, which tabled several resolutions addressing substance abuse in SA that included raising the drinking age, not allowing any drinking and driving, and banning alcohol advertising.[36] Notably, however, some national government ministries and departments, in particular the Department of Trade and Industry (DTI), have shown greater ambivalence toward taking more decisive action on harmful alcohol use.

Recognising the imminent policy changes the liquor industry, in particular its major player, SAB, has made an unprecedented effort to influence alcohol policy. SABMiller, headquartered in the UK, is the world's second largest brewing company with substantial resources for lobbying. A key component of its alcohol strategy in SA is to channel more resources into building partnerships with government, which includes supporting 'regulators in building capacity and capability'.[37] We believe SAB is entering or seeking to enter into partnerships with government departments to influence the policy debate, by selectively promoting policy options that would protect their profits.

The industry has sought to present themselves to government as socially responsible, and to deflect attention from the widespread misuse of their products by a broad spectrum of consumers, by framing misuse as a problem within a few high-risk sub-groups. Despite the evidence that SA has extremely high rates of problem drinking,[38] industry arguments perpetuate the myth that it is a 'relatively small percentage of South Africans' who abuse alcohol, and whose actions have 'a disproportionately negative impact on South African society'.[39] Claiming to exercise its 'responsibility to lead the attack on alcohol abuse,'[39] industry argues that what is needed is not more regulation or legislative change but better enforcement of existing laws, more public education and greater scope for self-regulation in areas such as alcohol advertising.

SAB has sought out highly visible partnerships with government. In October 2010 the CEO of SAB and the National Minister of Social Development sent a joint invitation to a broad grouping of stakeholders to attend a two-day strategic planning workshop on fetal alcohol syndrome (FAS). Although purportedly a joint initiative, the meeting was driven by SAB, with the department playing a minor role. Concerned that SAB's role constituted a clear CoI, public health academics, researchers and others lobbied their colleagues not to attend. Moreover, the focus on FAS potentially reframes a social problem with systemic roots into a behavioural problem of individuals (women who drink during pregnancy). While FAS prevention merits specific attention, the risk of focusing only on pregnant women as a risk group draws attention away from upstream interventions which may threaten sales and corporate profits.

The meeting went ahead and, despite fewer participants than expected and a shortened programme, SAB achieved good publicity, with a laudatory newspaper headline claiming 'SAB helps with alcohol syndrome'.[40] Thus, despite questionable programmatic value, and lukewarm scientific reception, the initiative promoted the brand of a company whose products contribute to the problem that was supposedly being addressed.

In November 2010, SAB made a similar attempt to partner with the Western Cape Department of Health to address alcohol-related gender violence, drunk driving, underage drinking and FAS. The launch was aborted after public health practitioners and researchers lobbied the Premier's office, arguing that the proposed programmes were not evidence-based, did not address the major alcohol-related harms and, consistent with the WHO recommendations, that it was not in government's interests to partner with the liquor industry.

In September 2011, SAB invited stakeholders to a meeting to inform them about a planned underage drinking initiative in partnership with DTI. The invitation claimed that the organisers had 'considered local and international best practice in order to create a programme with highest possible efficacy', yet they primarily proposed an educational/information campaign comprising school road shows, ambassadors in schools, workshops to educate the community and teachers, posters in taverns surrounding schools, township murals and exhibitions in shopping centres. There is little evidence that such interventions are effective, particularly compared with reducing

access to alcohol. SAB's seeming concern about underage drinking has not extended to interventions that have been shown to be effective, particularly restricting advertisement of alcohol products where there is likely to be high youth exposure (e.g. on billboards near schools, universities or on routes to and from schools; or on radio and TV before 9 pm, at sporting events or on social media sites).[32,33]

In February 2012, SAB invited stakeholders to a launch in Phoenix, KZN, of another initiative to curb underage drinking. The invitation was sent in the name of the KZN MEC for Education and SAB's executive director for corporate affairs and transformation. An SAB media release on the day referred to the partnership between itself, the DTI and the National Youth Development Agency.[41] In response, a broad grouping of stakeholders wrote to the Inter-Ministerial Committee on Substance Abuse (IMC), raising concerns about the liquor industry's involvement in joint events co-hosted with government, and pointing out the attendant CoI. No response was received from the IMC, but an article in *Business Day*[42] quoted a spokeswoman for the Department of Social Development who indicated that the department was finalising a cabinet memo to all national and provincial government departments to regulate and restrict their interaction with the liquor industry.

The article referred to a 2011 letter from the Minister of Social Development instructing all provincial premiers not to 'partner with any company in the liquor industry, even in programmes that the industry describes as part of their own initiatives to reduce alcohol-related harm.' The minister indicated that government would 'engage with the liquor industry as a key stakeholder [to] develop policy and legislation to reduce alcohol-related harm,' but warned that 'when government partners with industry it tends to improve the brand image of the industry and by association the products it produces and markets.' This was particularly true when it came to 'responsible drinking' messages aimed at adolescents and youth[42].

In another case of CoI, the Global Fund for Tuberculosis, AIDS and Malaria (GFTAM) awarded SAB funding for a speculative HIV prevention intervention targeting male perpetrators of violence in shebeens, an intervention with little evidence of effectiveness. In response to allegations of complicity in corporate capture, the GFTAM asserted that, far from acting irregularly, they had only supported the SAB proposal based on approval from the national co-ordinating mechanism – viz. the South African Department of Health.[44] If true, this is a case of a government department supporting an untested intervention, run by a private corporation whose massive profits irrevocably depend on alcohol sales. It is another worrying example of industry influence over state decision-making on alcohol policy.

Provincial governments have been signing on to partnerships in SAB's Responsible Trading Programme, previously known as the *Mahlashedi* programme. Initiated by SAB in 2002, the programme aims to normalise the retail liquor sector by helping and motivating owners of unlicensed liquor outlets (primarily shebeens) to enter the regulated sector.[45] SAB has four strategies: (*i*) providing assistance with licensing (free consultancy and lodgement services for applicants) and licensing workshops; (*ii*) lobbying regarding provincial legislation; (*iii*) business skills training for taverners; and (*iv*) securing funding for taverners. The project had positive outcomes for participants, including a 30% increase in average turnover, and substantial increases in profits,[45] but no reports were found of its impact on alcohol abuse or alcohol-related harms. In 2010, SAB partnered with the Gauteng Department of Economic Development on this project; and in 2011 the Western Cape Department of Economic Development followed suit, despite protests from public health experts.

Public health versus private profit

We argue that the conflicting interests of the alcohol industry and the public health sector constitute an irreconcilable culture clash well described by Munro and de Wever.[46] As a private corporation, SAB's obligation to its shareholders is to increase sales of its products and the profit margins of its operations. Its investment in social responsibility activities typically comprises a small fraction of profits.

While attempting to partner with government on alcohol harm reduction programmes and to burnish its social responsibility image, SAB simultaneously launched its 'Bigger is better' campaign to promote its 750 ml bottles of Black Label beer. The advertisement (Fig. 1) depicts a 340 ml bottle hiding behind the 750 ml one, and implies that a '*grootman*' (big shot) drinks from the larger bottle while the smaller one is for a '*laaitie*' (youngster). This advertisement targeted young drinkers and contravened the industry's own advertising code by encouraging customers to drink more, illustrating the weakness of relying on industry self-regulation. SAB withdrew the advert only after widespread protests and a complaint lodged with the Advertising Standards Authority.

Fig. 1. SAB beer billboard.

Partnerships with the alcohol industry are thus highly fraught – industry gains considerable public relations and marketing benefit while the impact of its alcohol-related harm-reduction programmes is limited. SAB acted to profit from alcohol sales, particularly targeting young people, while simultaneously seeking credibility as part of the solution to the problems to which its products contribute. This CoI, in which industry uses social responsibility selectively, while campaigning against proven effective interventions, is widely recognised.[47,48] Therefore the WHO has proposed arms-length engagement and dialogue rather than partnership as the appropriate mode of interaction with the alcohol industry.[31]

Why should health professionals and policy makers consider partnership with the alcohol industry off limits?

Jahiel and Babor[49] highlight the alcohol industry's role in sustaining an industrial disease epidemic, in which corporations and their allies promote products that are also disease agents. Corporations and Health Watch (CHW) includes the alcohol industry alongside five others that significantly affect public health through the commercialisation of hazardous products (alongside the tobacco, drugs, food, firearms and auto industries). They provide rules of thumb that public health and not-for-profit organisations should apply before partnering with industry,[50] each of which places the alcohol industry off-limits in SA.

CHW maintain that industries should 'provide independent public health professionals and community representatives: a) access to corporate records, facilities, workers, research reports, health promotion budgets, and communications to conduct independent audits of the corporation's health promotion, environmental, worker health and safety programs and human rights activities, and b) the right to immediately provide an independent written report to the public'.

A review[51] of the alcohol industry's social responsibility investment (SRI) programmes found little formal evaluation in peer-reviewed publications to support evidence for effectiveness, but only opaque marketing materials (see, for example, http://www.sab.co.za/sablimited/content/en/responsible-trader-programme; http://www.sab.co.za/sablimited/content/en/alcohol-responsibility-drunk-driving-programme; http://www.sab.co.za/sablimited/content/en/underage-drinking-programme). Total alcohol sales data by volume, a key determinant of the alcohol burden, are not made readily available, except by the wine industry. The only data available are on profits derived from alcohol sales, and estimates of drinking need derived from population-based surveys.

CHW suggests industries should 'fund independently developed health promotion publicity campaigns in amounts equivalent to the corporation's advertising budget'. But the alcohol industry has resisted an initiative by public health and other social interest groups to establish an independent health promotion foundation to counter harmful messaging. They channel their SRI funding through an industry-funded Association for Responsible Alcohol use (ARA) that focuses its messaging on selected harms – FAS, drunk driving and underage drinking – and omits the main alcohol-related harms in South Africa.. These are popular targets for industry bodies internationally, perhaps because interventions are largely behavioural programmes aimed at individuals and, whether effective or not, are unlikely to reduce population-level drinking and therefore profits.

CHW maintains that industries should 'keep all corporate health promotion and health education programs and activities free of corporate logos, the corporation's name, products, symbols, figures, etc.' In SA, liquor companies use their logos widely in their SRI campaigns. The liquor industry is a prominent funder of several NGOs, and recognised for co-funding initiatives in partnership with government. The SAB logo is prominent in the invitation regarding its initiative on underage drinking in partnership with the KZN government. (Fig. 2).

Fig. 2. Partnerships: use of an industry logo on a state programme to reduce alcohol-related harm.

Industries are also expected to 'not make any contributions to election campaigns to political parties, political action committees, independent campaign advocacy organisations or lobbyists, or on ballot referenda or amendments'. Whether this happens in SA is difficult to ascertain because of the lack of regulations ensuring transparency of funding for political parties."

In turn, CHW advocates that no corporate officials accept employment or appointment to government regulatory agencies, boards or committees that have authority for any part of their industry'. Government has been a refuge for several influential alcohol industry directors, most notably Meyer Kahn, who was seconded from SAB to chief executive of the SA Police Service, before returning as chairman of South African Breweries plc upon its listing on the London Stock Exchange in 1999.

Industries should also 'pay the full statutory federal corporate tax rate'. Given the difficulty in obtaining primary data, it is difficult to assess the alcohol industry's *bona fides* in SA. Nevertheless, SABMiller, the dominant company in SA and Africa, has been accused of a chequered tax record in low- and middle-income countries. For example, a detailed analysis of the behaviour of an SAB subsidiary in Ghana demonstrated extensive use of tax evasion strategies to boost corporate profit.[52] SAB is also currently on a determined path of opening up the African low-income and traditional drink market on a continent where state regulation is weak.

What should be done about institutional CoI more generally?

Health and other professionals must think twice about the ethics of serving on industry-created bodies that use their presence to leverage public policy credibility. For example, the Foundation for Alcohol Research (ABMRF), set up as a partnership between academia and industry, lists 6 industry members on its board of trustees alongside a number of prominent academics. Similarly, the International Council on Alcohol Policies (ICAP) regularly commissions academics to write chapters in books they publish that promote an industry agenda.[53] ICAP is funded by SABMiller and other liquor companies.

In finance-constrained economies, public institutions are increasingly pursuing public-private initiatives or partnerships. They need policies and systems to govern these partnerships,

particularly in the case of industries producing socially harmful products.[31] In a policy-making institution, CoI should be managed by an explicit code of ethics and set of procedures, which bind all participants whether they be professionals or elected or appointed officials. Representation of economic and social interests should be equally balanced, and policies affecting multiple government departments with conflicting interests should be developed by inter-sectoral bodies, not individual departments. In policy making and implementation, the permissible roles and boundaries of vested industrial interests should be clear.

Public transparency should characterise the policy-making process, including declarations of CoI by all participants. Further, private industry should not be integral to the policy-making process through, for example, establishing partnerships. Rather, it should have the opportunity to engage with government. Should industry wish to contribute funding to any public policy-related process, this should take place via an arms-length relationship and industry should not decide its allocation or use.

All evidence used in policy making should be in the public domain. Where products such as reports are collectively authored, all contributors should be named together with their affiliations and whether or not they were supported indirectly or directly by industries with vested interests. This information should be monitored by the public institution concerned and by relevant regulatory bodies. For example, the HPCSA could incorporate such provisions into its guidelines for managing perverse incentives[6] as a basis for overseeing professional behaviour related to policy-making.

Stakeholders, including the Medical Research Council, have proposed an independent Health Promotion Foundation (HPF),[54] funded by a levy on alcohol and tobacco manufacturing. This levy will be used to pay for preventive interventions, including high-priority research that is free from the influence of vested industry interests. Such an independent foundation will be able to act without fear or favour to promote activities aimed at increasing responsible drinking and reducing harmful alcohol use, by funding research and counter-advertising, stimulating alternative income-generation activities to wean small entrepreneurs off alcohol retailing, and supporting upstream interventions to reduce access to alcohol. An independent HPF should also monitor the liquor industry's activities, particularly in the context of public-private ventures.

Conclusion

CoI is not inherently problematic if openly declared, and where evidence presented to support a policy can be subjected to peer review and critique. Problems arise when CoI is not declared or when informal channels of insider influence and reputation steer policy-makers; or when evidence is misrepresented, deliberately misinterpreted, or hidden.

While this article has focused on the example of the liquor industry, we believe the principles of how to identify, manage and address CoI are generic and can be extended to other areas where vested interest influences public policy processes that affect health. The interests of government and industry should be transparent and clearly differentiated in respect of the public good and the pursuit of profit. Where these interests overlap or co-exist (government may depend on product taxes, and the industry may wish to support a social responsibility programme geared to its product) there should be effective policies, procedures and processes for governing public-private joint ventures. These should involve arms-length funding, maintenance of balance between contesting vested interests, and full disclosure of the identity and affiliations of all individual participants in structures and reports pertaining to public health policy-making.

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