

Open letter to the EU Commissioner of Health & Food Safety Mr. Vytenis Andriukaitis.

### **Executive summary.**

When EU politicians and civil servants are to take decisions on dental health issues it is of paramount importance to know what Conflicts of Interest (CoI) they are up against.

The industrial involvement in dental scientific organizations is high and accelerating. It includes monetary support as well as memberships. Industrial sectors involved ranges from the dental materials industry (including mercury fillings manufacturers) to the sugar industry. Organizations affected ranges from global dental scientific organizations, global general dental organizations to global dental educational organizations.

New documents reveal that in the 1970-ies the US sugar industry initiated an accelerated use of fluoride instead of sugar consumption restrictions by dominating a national caries program run by NIDR, the dental branch of the National Institutes of Health, NIH.

Dental scientific journals requesting authors to reveal any perceived or actual Conflicts of Interest are owned by organisations themselves engaged in severe Conflicts of Interest.

It is asked whether the fact that no regulation on permissible emission of mercury vapour from fillings exist and that the absence of any requirement for full disclosure of ingredients in dental materials is a result of this industrial – dental symbiosis. From June 1<sup>st</sup> no list of ingredients in dental materials what so ever will be available since the new CLP requirements on classifications and labelling exempts medical devices from that regulation. Cosmetics used outside the body is better regulated by the EU than dental materials used inside the body.

It is not possible for EU politicians or any other decision makers anywhere to reach well founded decisions on any dental healthcare issues unless these extensive CoI relations between the dental and industrial communities are fully understood.

An independent and transparent EU initiated investigation into these severe CoI issues is proposed.

### **CoI issues in the dental community**

The entire field of dental care in a wide sense is affected ranging from questions related to single dental products via oral health care in general to the education of future dentists and connections to the sugar industry. To my knowledge no field of medicine shows such deep industrial collaborations and organizational connections as dentistry does. The situation is extreme and could be regarded as a symbiosis.

The foundation for political decisions regarding this entire field cannot be solid without the full knowledge about this substantial industrial involvement. Industrial membership and monetary support indicate that advice given by the dental community may not be free and independent.

Unfortunately the Conflicts of Interests under investigation affecting some of the SCENIHR WG Amalgam members is just an example indicating a much bigger problem affecting the dental community as a whole (1).

Almost any problem with dental materials is refuted by dental organizations despite the fact that their education is not a specialty of the adverse effects experienced – that calls for a totally different set of skills. The dental manufacturers responsible for the biocompatibility of their products are hardly ever confronted with these questions. They are instead almost exclusively handled by the dental organizations resulting in a “gatekeeper effect.”

### **General dental organizations.**

#### FDI

FDI World Dental Federation organizes the national dental associations around the world and claim to represent more than 1 million dentists (2). They have partners and members from the dental industry. These are organized as Corporate Partners and Supporting Members (3, 4). In fact developing industrial collaborations is one of the goals set out in the current FDI Strategic Plan:

*“Develop relations and partnership with the industry, and also with international foundations and philanthropic organisations.”* (5).

Supporting members must not be for profit entities. This is solved by accepting industrial umbrella organizations as members. These are not for profit organizations but their industry members are very much so:

*“International Dental Manufacturers, IDM,  
Association des Dépôts Dentaires Européens  
Australian Dental Industry Association (ADIA)  
British Dental Trade Association  
Dental Trade Alliance (USA)  
Federation of the European Dental Industry  
Japan Dental Trade Association”* (6)

The dental industry is allowed to have their say about the countries and cities chosen for the AWDC. This event can be coordinated with marketing activities of the Corporate Partners.

One further sign of the close ties between FDI and the industry is the fact that the bottom of all pages of the International Dental Manufacturers (IDM) site carries the FDI logotype (8). IDM is the global umbrella organization for the dental manufacturing industry.

FDI and IDM have regular annual meetings twice a year at the FDI: s AWDC and alternating between the Chicago Dental Society Midwinter Meeting in the US and Internationale Dental-Schau (IDS) in Cologne, Germany.

FDI have a section for its members who are chief dental officers with substantial power in governments around the world, the Chief Dental Officer/Public Health Section (9). This

means that FDI and its members and partners have channels directly into the governments of many countries.

The fact that FDI work with GlaxoSmithKline sales representatives training modules might serve as a recent example of close cooperation with the industry (10). FDI has a special Associate Director Business Development & Corporate Relations handling corporate contacts (11).

IDM: s executive director Friedrich Herbst has held a position as consultant within the FDI for many years. He has just recently announced his retirement. If the new executive director will take up the job as consultant within the FDI is presently unknown (12).

At the 2010 Chicago Dental Society Midwinter Meeting FDI declares that it offers its Corporate Partners to help shaping policy and to be “a voice at the table” (13):



Feature	Benefit
Federation of over 200 Associations	Global Reach Access to dental professionals world
Annual World Dental Congress	Track record in all types of markets Corporate-sponsored Symposia Congress sponsorships
Committees and Strategic Partners Partnerships	Shaping policy, 'voice at the table' Access to NDAs and other member Trusted partner Vision toward oral health Corporate Social Programs
Publications	Peer-reviewed supplement(s)
Education Programmes	Global Reach Access to dental professionals
Corporate Partners Programme	First to know about health

The FDI has launched a project called the Global Caries Initiative. This has been done with the industry as founding sponsors (14).

The FDI also has connections to the sugar industry, see separate section below.

### IADR

International Association for Dental Research, IADR, is an association for dental researchers worldwide. The biggest section is the American Association for Dental Research, AADR. According to the bylaws of both associations industries are accepted as members and placed in a special Corporate Section (15, 16)

IADR's first formed specialty group and one of the biggest and most influential ones is the Dental Materials Group (17). It has many members from the dental industries, sometimes in such high positions as Vice Presidents. One of its main goals is to facilitate collaboration between IADR/AADR industrial members and other parts of the society:

*“To promote cooperation in research on dental materials among the dental profession, schools, industry, governmental agencies, and other professional societies.” (18).*

IADR owns the highest ranking scientific journal in dentistry, Journal of Dental Research. Authors must adhere to the following: *“Any perceived or actual conflicts of interest need to be identified in the acknowledgments section.” (19).* The owners themselves are in severe Conflicts of Interest having multiple dental industries as members.

Connections to the sugar industry, see below.

## **The educational sector**

### IFDEA and ADEE

Another area with heavy industrial involvement is the educational sector. In 2007 International Federation of Dental Educators and Associations, IFDEA, held a global congress on dental education and the launch of a network related to this. In this Dublin meeting the dental industry took center stage. A number of working groups was formed and it was concluded that it is essential with very close connections between the educational sector and the dental industry to make IFDEA a major player in dental education worldwide. In fact one working group with many members from the dental industry had the task of exploring such possibilities. Some quotes:

*“Robust partnerships linking dental industry and dental education have existed over long periods for mutual advancement and benefit.”*

*“Certain discretionary, or opportunistic funds may be available to support other academic activities in line with corporate objectives.”*

*“An active corporate involvement would have considerable mutual benefits that far exceed financial support” (20).*

In Europe dental educators are organized by a Regional Association of IFDEA, Association for Dental Education in Europe, ADEE (21). This organization has a number of dental industrial companies as Corporate Partners (22). ADEE states that:

*“ADEE relies heavily on the support of our Partners to enable our activities on an operational and strategic level. ADEE very much appreciates our PLATINUM partners support as they are a key provider of funding for ADEE activities’. ADEE is aware of the challenges faced by our corporate partners as they respond to increasing demands for transparency and accountability within their philanthropic, sponsorship and membership activities. ADEE understands the need to demonstrate a return for such support that is appropriate and tailored to the particular organisation.*

*ADEE has therefore devised a new benefit to ADEE PLATINUM Partnership (Corporate Membership), the ADEE PLATINUM Peer review programme.” (23).*

ADEE owns the European Journal of Dental Education. This scientific journal requests authors to disclose any Conflicts of Interest (7). The mother organization is however affected of severe Conflicts of Interest.

### **Connections to the sugar industry**

Another quite unexpected fact is the connection between dental scientific organizations and the sugar industry. Dental science and the sugar industry alike holds the position that sugar is a contributing factor to dental caries. One explanation for the sugar industry’s interest in close collaboration with dental organizations is given in a new scientific paper published on Mars 10 this year (24).

Here Kearns, Glantz and Schmidt reveals previously unknown papers on the sugar industry’s successful attempt to avoid restrictions on the use of sugar. This was achieved through collaboration with the National Institute of Dental Research, NIDR (now NIDCR), the dental part of the National Institutes of Health, NIH. The restrictions on sugar intake was replaced by increased fluoride delivery and unsuccessful research on a caries vaccine. One of the authors, Prof. Stanton Glantz is a giant in the field of tobacco research and the tobacco industry’s lobbying (25).

This new paper gives an indication of the benefits for the sugar industry to have close ties to the dental community – a possibility to indirectly influence the sugar policy. Politicians and other decision makers are mostly unaware of the close ties between the sugar industry and the dental community. What is in it for the dental organizations then? Monetary support could be one explanation.

One door opener for the sugar industry into the dental community is the introduction of sugar free chewing gum said to reduce the incidence of caries. Most of these products are manufactured by the confectionary industry. It is not uncommon for dental clinics to advice their patients to use xylitol chewing gum or pastilles. Even national dental organizations and national health authorities are known to have such recommendations (Sweden). In a recent Cochrane review of the effects of xylitol containing products it is concluded that the evidence for the caries reducing effects of these products is lacking (26). Cochrane reviews is regarded as a “gold standard” when it comes to evidence based medicine and dentistry.

In a summary of 120 different Cochrane Systemic Reviews (CSR) on as many different dental procedures used in every day dentistry Faggion concludes that:

*“On the basis of CSRs, the overall quality of evidence can be regarded as low or nonexistent for most of the dental procedures assessed.” (27).*

The European Organization for Caries Research, ORCA, is a European based organization for caries researchers. Its activities is however reaching far beyond Europe. It is surprising to see that several sugar industries/organizations and dental materials industries are members of ORCA. Here we find Sugar Nutrition UK, funded by UK sugar manufacturers, Wrigley Inc. a manufacturer of candy owned by Mars Inc. and Cloetta a major candy manufacturer on the European market based in Sweden. Up until 2011 the Coca-Cola Company was a member. Annual fees ranges from 20 000 € to 3 500 €. This fee gives the corporations voting rights within ORCA and a lot of other benefits to the member company (28, 29). The organization owns a scientific journal, Caries Research. This is as far as I know the only scientific journal dealing only with caries. The journal has strict rules for Conflicts of Interest when it comes to the authors (30). The owner organization itself however, suffers from severe Conflicts of Interest.

#### IADR

*"U.S.-based Mars Inc is the third biggest confectionery business globally behind Nestle SA and Mondelez International, the maker of Cadbury, according to Euromonitor International"* (31).

At least two of these have close connections to IADR. M&M Mars paid for parts of the IADR headquarters building, (32). Montadelez International is a Corporate Member of IADR (33). The company owns the British confectionary Cadbury. The vice president of Cadbury hold a position as Institutional Section Councilor in IADR: s Regional Development Committee (34). Her responsibilities within the company is Regulatory Affairs & Emerging Science (35).

Wrigley Inc. a manufacturer of ordinary candy and sugar free gum, owned by Mars Inc. It is an IADR Corporate Contributor (36).

#### FDI

As stated above FDI has initiated the Global Caries Initiative. Wrigley Inc. is one of the founding sponsors (37).

In 2010 "Ambassadors" from MARS Inc. one of the world's largest confectionary manufacturers developed advocacy materials for national dental associations at FDI. They met with high FDI officials (38). Among these were the Chairman of the FDI Public Health Section, a section organizing Chief Dental Officers from governments around the world (39).

This meeting and other collaborations with the sugar industry takes place despite the fact that the FDI Ethical Guidelines says: *"Relationships with any entity working against the FDI's public health policies (i.e. tobacco or sugar industry) are not permitted."* (40).

#### **Results from industrial – dental symbiosis?**

A major concern regarding health effects from mercury fillings has been linked to its emission of mercury vapour which is absorbed to approx. 80%. Despite this fact no limit for this emission has been set in formal regulations/laws. In fact mercury fillings can emit any amount of vapour without being removed from the market. No standardized method for measuring vapour emission from mercury fillings has been developed.

The ingredients in most dental materials are not fully declared. It is very hard to understand this fact if not taking the symbiosis between the dental community and the dental materials industry into consideration. Every chemical product must have a Materials Safety Data Sheet, MSDS, as stated in the REACH regulation. This document lists ingredients posing risk during handling, transport, storage and in the case of fire. Even though this is a most insufficient list of ingredients it was the only indication of content dentists, governmental agencies and patients had. On June 1<sup>st</sup> the new rules for classifications and labelling set out in the CLP regulation kicks in. Here medical devices are exempt from these rules leaving the dental community and patients without any information what so ever on the ingredients of dental materials. In a personal communication from a Swedish dental materials manufacturer these ingredients will be treated as trade secrets by the dental industry from now on.

The only dental organization touching upon this that I have come across is the Council of European Dentists. This is however only made as a recommendation to dentists not using dental materials lacking full declaration of ingredients (40).

It is very hard to imagine the medical profession accepting the use of drugs of unknown composition. If the dental community had been serious about this they should have been working for this matter to be formally regulated. One gets the impression that the dental community actively works against any formal regulations of the dental sector in matters related to dental materials.

### **A truly independent investigation of CoI-issues in the dental community is called for.**

If the EU will be able to steer clear of CoI-issues affecting dental policy decisions in the future it is essential with an investigation into the collaboration and partnerships between dental organizations and industry. These connections are extreme and affect the entire dental community ranging from scientific organizations via the educational sector to general dental organisations organizing dental personnel worldwide. It is absolutely essential that EU politicians and other decisions makers have an understanding of these organizational and economic connections in order to reach well founded decisions affecting dental care within the EU.

I suggest a truly free and independent EU initiated investigation to fully reveal the severe CoI issues mentioned above in order to pave a solid ground for future EU decisions related to the field of dental care. Checking the accuracy of the facts revealed above would give such a work a head start.

### **References**

1/ <http://www.ombudsman.europa.eu/en/cases/caseopened.faces;jsessionid=F4996A1E68142F84B684CBC29ACD9DD4> .

2/ <http://www.fdiworldental.org/home.aspx>

- 3/ <http://www.fdiworldental.org/fdi-at-work/working-with-corporates/corporate-partnerships.aspx>
- 4/ <http://www.fdiworldental.org/members/member-benefits/types-of-membership.aspx>
- 5/ [http://www.fdiworldental.org/media/63116/strategic\\_plan\\_2014-2017.pdf](http://www.fdiworldental.org/media/63116/strategic_plan_2014-2017.pdf)
- 6/ <https://web.archive.org/web/20120924215921/http://www.fdiworldental.org:8080/content/supporting-members>
- 7/ [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1600-0579/homepage/ForAuthors.html](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1600-0579/homepage/ForAuthors.html) 8/ <http://www.idm-vox.org/>
- 9/ <http://www.fdiworldental.org/about-fdi/governance/sections.aspx?id=6>
- 10/ [http://www.dental-tribune.com/articles/news/asiapacific/19940\\_interview\\_optimal\\_oral\\_health\\_for\\_the\\_worlds\\_population.html](http://www.dental-tribune.com/articles/news/asiapacific/19940_interview_optimal_oral_health_for_the_worlds_population.html)
- 11/ <https://ch.linkedin.com/in/emmanuelchevron>
- 12/ <http://www.zoominfo.com/p/Friedrich-Herbst/522610800>
- 13/ [http://www.idm-vox.org/images/slideshows/slides\\_mar2010/fdi\\_executives\\_at\\_ga\\_4.jpg](http://www.idm-vox.org/images/slideshows/slides_mar2010/fdi_executives_at_ga_4.jpg)
- 14/ <http://www.global-caries-initiative.org/website/Founding-Sponsors.html>
- 15/ <http://www.iadr.org/i4a/pages/index.cfm?pageid=3284#.VTXNX03ECUk>
- 16/ <http://www.aadronline.org/i4a/pages/index.cfm?pageid=3459#.VTcc-U3ECUk>
- 17/ <http://www-personal.umich.edu/~sbayne/DMG/000-Index-Files/index-DMG-frames.htm>
- 18/ <http://www-personal.umich.edu/~sbayne/DMG/DMG-Governance/DMG-Constitution-and-ByLaws/DMG-CBL-2014-Proposed.HTM>
- 19/ <http://www.iadr.org/files/public/JDRInstructionstoAuthors.pdf>
- 20/ European Journal of Dental Education 2008 12 (Suppl. 1), 64–73.
- 21/ <http://www.ifdea.org/associations/Pages/default.aspx>
- 22/ <http://www.adee.org/about/corporate-partners.html>
- 23/ <http://www.adee.org/about/ADEE-membership-benefits-platinum-peer-review.pdf>
- 24/ <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001798>
- 25/ <https://tobacco.ucsf.edu/users/sglantz>
- 26/ <http://www.ncbi.nlm.nih.gov/pubmed/25809586>
- 27/ <http://www.ncbi.nlm.nih.gov/pubmed/22935276>



- 28/ <http://www.orca-caries-research.org/membership/corporate.html>
- 29/ [http://www.orca-caries-research.org/membership/ORCA\\_Corporate\\_Membership\\_Layout.pdf](http://www.orca-caries-research.org/membership/ORCA_Corporate_Membership_Layout.pdf)
- 30/ <http://www.karger.com/Journal/Guidelines/224219>
- 31/ <http://news.yahoo.com/mars-inc-set-open-first-chocolate-factory-india-215318473--sector.html>
- 32/ <http://www.iadr.com/i4a/pages/index.cfm?pageid=3748#.VRoeME3ECUk>
- 33/ <http://www.iadr.com/i4a/pages/index.cfm?pageid=4445#.VTh2AU3ECUk>
- 34/ [www.iadr.org/files/public/1314IAComm.pdf](http://www.iadr.org/files/public/1314IAComm.pdf)
- 35/ <https://www.linkedin.com/pub/doris-tancredi/5/9a0/ba1>
- 36/ <http://www.iadr.org/files/AnnualReports/14IADR.pdf>
- 37/ <http://www.global-caries-initiative.org/website/Founding-Sponsors.html>
- 38/ Worldental Communiqué. 2010, issue 5 Nov/Dec.
- 39/ <http://www.fdiworldental.org/about-fdi/governance/sections.aspx?id=6>
- 40/ FDI Handbook - Chapter11. Ethical Guidelines Manual. 2006, page 3.
- 40/ <http://www.eudental.eu/component/attachments/attachments.html?id=483>

Sincerely

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This document is not connected to my work at LiU.