To the Editorial Board of *Addiction*

Request for Retraction of Journal Article

24 May 2015

This is a request for the journal *Addiction* to retract the article: Methylphenidate for ADHD and Drug Relapse in Criminal Offenders with Substance Dependence: A 24-week Randomized Placebo-controlled Trial, by Franck, Konstenius, *et al.* 2014, [1].

The potentially disastrous consequences of the *misrepresentation* of the actual study results—as presented in the journal article—can be exemplified by the following:

> The Swedish National Board of Health and Welfare has worked to produce guidelines for the treatment and support in cases of drug addiction and dependence. In the area of treatment recommendations for persons with ADHD and concomitant amphetamine dependence, the preliminary recommendations, March 2014, became: "In amphetamine dependence and concurrent adhd *methylphenidate* can be used to treat the amphetamine dependence, as it seems to have an effect on *a drug-free condition*." [Emphasis here.]
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> Upon questioning the project leader (Branting) told that the conclusion was reached from above mentioned study by Franck and Konstenius (and a smaller, more failed pilot study). Further questions about the research data available for the National Board of Health and Welfare in its analysis gave this answer: "Our expert had no other data to work with than the two published articles …"
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> And so the (distorted) presentation of the study results in the Journal Addiction was about to result in national guidelines recommending a high dose of methylphenidate for the treatment of amphetamine addiction, as it seemed to bring about a "drug-free condition"!
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> However, as *I* had access to *the needed underlying study results* I could explain to the Board that it was about to issue guidelines based on misleading data about what actually happened in the study. The end result was that the recommendations were changed in this area: The study by Franck and Konstenius, did *not* show that methylphenidate "seems to have an effect on a drug-free condition". The Board did however use the easy way out. Instead of telling *what* the study really showed, it was said that the drop-out rate in the study was such that an assessment could not be done. It was excluded. And the treatment recommendation was dropped.

From this example we can see how unscientific journal articles, presenting a misleading picture of the actual research results, can have disastrous consequences for the treatment recommendations on a *national* basis.

We can also see why it is important to retract the article by, Franck/Konstenius: Other countries may well issue unscientific guidelines, influenced by the results presented in *Addiction.*

Part of the definition of research fraud is "misrepresentation of the research process … for example through incorrect use of methodology, dishonest inclusion or exclusion of data, deceptive analysis of data that intentionally misrepresents their interpretation …"
(http://www.codex.uu.se/en/etik6.shtml)

And in the study by Franck/Konstenius, which first of all was misrepresented as a "double-blind study", data about what happened with the persons receiving the study drug (Concerta) were *deliberately* excluded to such an extent that it was impossible to understand even for the most careful reader.

Let's look at some of the *real* results for the **Concerta group**—which emerged when the underlying documents for the study finally were released, after vivid requests using the Swedish Freedom of Information Act. We could then see that:

- 7 of the 27 subjects in the Concerta group (26%) relapsed into addiction – had actual positive urines – *the first week* of release from prison; the same week when most of them reached the maximum dose of 180 mg of the legally prescribed stimulant drug (Concerta).

- 11 persons (41%) relapsed in the first *two* weeks after release.

- 20 persons (74%) relapsed during the study – did leave *actual* positive urines (5 dropped out without leaving positive tests, 2 completed with no relapses).

- 7 of the 9 persons who *completed* the study, who were present at week 22 in freedom, had relapsed into addiction. The 7 subjects had 2, 3, 9, 9, 10, 12, 23 relapses – in average 10.

- 18 persons (67%) dropped out of the study before it was over.

None of the *crucial* results above (with the exception of the drop-out rate) are presented in the article in *Addiction.* If they had been, it would, for all serious readers, be clear that conclusions about positive effects of the study drug could not be done.

I can of course, as needed, assist with presenting the underlying data to the results above.

I hope the Editorial Board of the Journal welcomes the above data and request that the article, with its false and misleading presentation and conclusions, is retracted.

Kind Regards,

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[1] Konstenius, M., Jayaram-Lindström, N., Guterstam, J., Beck, O., Philips, B., Franck, J., Methylphenidate for ADHD and Drug Relapse in Criminal Offenders with Substance Dependence: A 24-week Randomized Placebo-controlled Trial, *Addiction*. 2014; 109(3):440-9) http://onlinelibrary.wiley.com/doi/10.1111/add.12369/pdf
[2] The National Board of Health and Welfare, Guidelines for the treatment and support in cases of drug addiction and dependence, 2015, http://www.socialstyrelsen.se/publikationer2015/2015-4-2/Sidor/default.aspx