

**All the texts on "Nicotine Replacement Therapy" ("NRT") in the WHO brochure "leave the pack behind" versus the actual facts.**

**EXPLANATION**

WHO/TFI's main message for the year 1999 was "Cessation".

"Cessation" is "a temporary or final ceasing (as of action): STOP [Middle French, from Latin cessatio, "delay, idleness", from cessare, "to delay, be idle"]; this is Webster's definition.

WHO/TFI's message was summarized in the brochure "leave the pack behind". The complete brochure in file-form is: ADVISORY.PDF, located in: FOLDER: WHOenglish.

WHO/TFI declared: "This project was supported by unrestricted grants from the International Federation of Pharmaceutical Manufacturers Association and the World Self-Medication Industry" (Source: "leave the pack behind", page 60 of the printed version, page 32 of the electronic version).

In TABLE 8 is described: Nearly all WHO/TFI-Statements concerning the substance "nicotine" and the "Nicotine Replacement Therapy" are false.

**TABLE 8**

| <i>ORIGINAL WHO/TFI TEXT ("leave the pack behind"; typographical elements same as in the brochure)</i>   | <i>NOTES on this by Maes</i>  |
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| <p><b>Text on page 4</b></p> <p>Today we know that successful and cost-effective treatments exist. Nicotine replacement medicines such as nicotine gum, patches, nasal spray and inhalers as well as non-nicotine medicines such as bupropion can double people's chances of succeeding.</p> | <p><b>In the 1st paragraph of her introduction, WHO Director General Dr. Brundtland already praises the products of the manufacturer associations that are allied with the WHO/TFI, as well as Bupropion (trade name: "Zyban"), which is made by the firm Glaxo-Wellcome.</b></p> |

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| <p><b>Text on page 19</b></p> <p>Nicotine has effects on brain dopamine reward systems similar to those of drugs such as heroin, amphetamine and cocaine. In a ranking of the addictiveness of psychoactive drugs, nicotine was determined to be more addictive than heroin, cocaine, alcohol, caffeine, and marijuana.</p>               | <p><b>Nicotine is described as a drug that is <i>more addictive</i> than heroin, cocaine, etc.</b></p> <p>No source is indicated.</p> <p>This classification is not in line with the current state of knowledge, not even with that contained in other WHO announcements.</p> <p>The history of the terms "addiction" and "dependence" and their use by WHO is described in the book "W+D Nachsicht: "Passive Smoking". The accompanying CD contains relevant WHO-materials (Facsimiles of "Technical Reports" etc.). More in: Folder: PURCHASE.</p>  |
| <p><b>Text on page 46</b></p> <p><b>Nicotine replacement therapies have been shown to be twice as effective in successful cessation attempts as those attempts without them.</b> For many quitters, nicotine replacement therapy eases withdrawal symptoms and is a psychological, as well as physical, aid to the cessation process.</p> | <p>There are no studies that prove in a generalizable manner that cessation attempts are twice as effective.</p> <p>Apart from a few exceptions, studies relate to observation periods of up to one year after the beginning of the measure. Catamnyses on withdrawal procedures in the case of "hard drugs" measure results after several years.</p> <p>General remarks:</p> <p>1. There are hardly any studies on nicotine replacement therapy that meet the minimum standards used in work on "classic addictions". The WHO did not start calling nicotine a "dependence-producing drug" until the 10th revision of the "International Classification of Diseases" came into force in 1993 [see W+D Nachsicht: Passive Smoking, pp. 137ff. on this subject and certain inconsistencies].</p> |
| <p><b>Text on page 46</b></p> <p>For many quitters, nicotine replacement therapy eases withdrawal symptoms and is a psychological, as well as physical, aid to the cessation process.</p>   | <p>2. There are only very few studies on nicotine replacement therapy.</p> <p>On January 3, 2001, "Medline" registered only 163 studies on "Nicotine Replacement Therapy", but 5.905 studies on "Smoking Cessation". In APPENDIX 2 all bibliographical data related with "Smoking Cessation" are listed; in APPENDIX 3 all on "NRT".</p>  |

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| <p><b><i>Text on page 46</i></b></p> <p><b>Non-nicotine pharmacological therapy, such as bupropion, functions through different pathways than nicotine replacement, and has also been proven to be twice as effective in helping smokers achieve successful cessation attempts. Behavioural therapy can help the smoker overcome the social and psychological motivations for smoking.</b></p>   | <p>On January 3, 2001, "Medline" registered 13 studies on "Zyban"; a complete listing in: APPENDIX 4.</p> <p>The most well-known study used only 244 test persons for Bupropion, 244 for patch, 245 for the combination of Bupropion and patch, and 160 test persons for the placebo. This work is the "most significant" on "Zyban" [Jorenby et al, A Controlled Trial of Sustained-Release Bupropion, a Nicotine Patch or Both for Smoking Cessation, New England Journal of Medicine 1999; 340: 685-69]</p> <p>Most serious descriptions of NRT products in general state that they <i>could</i> be helpful. There is certainly no mention of definite success (as claimed by the WHO in its statement "<i>has also been proven to be twice as effective</i>").</p> |
| <p><b><i>Text on page 48</i></b></p> <p><b>Perhaps the most important precursor to successful quitting is acknowledgement by smokers that they themselves have to take control of changing.</b> But that being said, there are now pharmacological aids which make a real difference to smokers' chances of succeeding in a serious quit attempt. Extensive and rigorous scientific research over the past two decades has shown that nicotine itself, the addictive drug underlying smoking behaviour, can be exploited as an effective aid to treatment, and evidence for the efficacy of new non-nicotine drugs has recently begun to emerge.</p> | <p>Further praise for nicotine replacement therapy.</p> <p>The reference to "extensive and rigorous scientific research" is false.</p> <p>Both "nicotine as an addictive drug" and "nicotine replacement therapy" have only played a marginal role in research.</p>  |
| <p><b><i>Text on page 49</i></b></p> <p><b>Numerous experimental and clinical studies have shown that NRT reliably attenuates the severity of withdrawal, thereby making it easier for would-be ex-smokers to cope with abstinence while unlearning the deeply ingrained habit elements of smoking.</b></p>  | <p>As already described: nicotine replacement therapy was rarely involved.</p> <p>None of the studies led to generalizable statements in the sense implied by the WHO/TFI text. As already described, only comparatively very few studies have been conducted at all.</p>  |

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| <p><b>Text on page 49</b></p> <p>Nicotine replacement products are available in a number of forms, including gum, transdermal patch, nasal spray, lozenge and inhaler. The various forms of NRT differ in terms of route of administration and speed of absorption, as well as in the extent to which they offer a situational response to craving and a behavioral ritual to replace the rituals of cigarette smoking.</p>   | <p>This is the WHO/TFI's description of the different preparation forms.</p> <p>What is striking is that the WHO/TFI only lists the product range of its sponsors. Other preparations are used as "replacement therapy", but - in line with the strictly correct definition of the term - do not contain nicotine, but other substances.</p> <p>The products ignored by the WHO/TFI are by no means insignificant. They are mentioned as a matter of course in serious, objective accounts by other institutions.</p>   |
| <p><b>Text on page 50</b></p> <p><b>Randomised trials have established that all forms of NRT are effective aids to cessation, on average close to doubling the chances of a quit attempt succeeding.</b> There is currently no reliable evidence that any one form of NRT stands out as more effective than the others, which means that choice of product will depend more on features such as ease of compliance with recommended dosing (the skin patch has a particular advantage here) and on availability. The efficacy of NRT appears to be largely independent of other elements of treatment: although absolute success rates are higher with more intensive behavioural support, the effect of NRT in doubling the chance of quitting is found in brief interventions and over-the-counter settings as well as in specialised smokers' clinics. This feature gives NRT an important role in public health approaches aimed at reaching the bulk of the smoking population with simple, brief interventions.</p> | <p>The statement by the WHO/TFI that all forms of nicotine replacement therapy are equally effective - i.e. in doubling the chances of "quit attempts" - is wrong. The findings of the studies show that neither the different forms nor the variations within a form - e.g. 7 mg, 14 mg and 21 mg nicotine patches - produce <i>same</i> results. There have been no generalizable "randomized trials" in which the products have been tested against each other.</p> <p>One of the WHO's fundamental mistakes is that it does not differentiate. Unlike the WHO, serious studies on NRT discuss sex-specific, social and other factors (which is normal practice if a study claims to be scientific).</p> <p>Similarly, the WHO's statement on the success rate in connection with behavioral therapy (BT) is incorrect. NRT studies have also tested procedures against each other - BT versus NRT - in which BT apparently achieved better results.</p> |

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| <p><b>Text on page 52</b></p> <p>There are very few instances in which the use of NRT is contraindicated, and recent clinical practice guidelines have suggested that NRT should be part of the core treatment package offered to all smokers. Even in those instances where there has been understandable caution to advocate NRT use, such as pregnancy and advanced heart disease, rational arguments based on efficacy and safety suggest it would be preferable to the likely alternative of continued cigarette smoking.</p> | <p>The WHO's statement on contraindications is dangerously false.</p> <p>The WHO creates the impression that all NRT products are relatively safe. In actual fact, the indication spectrum is much narrower than the WHO claims. Even non-experts can understand the arguments involved:</p> <p>Comprehensive information on medicines recently made accessible online in the USA by the "National Institutes of Health" contains many detailed warnings on nicotine replacement therapy products. They are aimed at people with the following illnesses:</p> <p><i>Asthma and other problems of the respiratory tract, heart or circulatory diseases, high blood pressure, liver illnesses, thyroid overactivity, gastric ulcers, diabetes.</i></p> <p>The NRT nicotine can aggravate the condition when such (and other) illnesses are present.</p> <p>NRT studies to which the WHO refers in a general way have expressly warned against administration in the case of heart diseases and pregnancy. This was justified, among other things, by the observation that smokers had taken NRT products in addition to smoking. The studies and accompanying editorials contain warnings on the cumulative effects of cigarette smoking plus NRT. Guidelines also exclude the use of the products in the case of heart disease and pregnancy.</p> |
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| <p><b>Text on page 53</b></p> <p><b>Clinical trials, among nondepressed smokers, have shown clear evidence of efficacy, and in a study recently published in the New England Journal of Medicine, bupropion and the nicotine skin patch appeared to have additive effects in enhancing outcomes.</b></p> <p>Bupropion has a positive impact on weight in that smokers who used bupropion gained less weight than smokers who received placebo. This effect has also been observed in some trials of NRT, but the weightgain suppressant effect of pharmacological treatment may not be maintained after cessation of therapy. In most countries bupropion is not yet available, but it is of considerable interest because of the light it may throw on brain mechanisms of nicotine addiction and for its potential in adding to the therapeutic effects of NRT.</p> | <p>Here the WHO/TFI is advertising Bupropion ("Zyban"). As said above: nothing in the quoted study can be generalized.</p> <p>The WHO's Director General Dr. Brundtland has supported NRT products in a very unusual way, as described in the following text of the study.</p> <p>This is surprising, especially taken into account the lack of evidence.</p> |
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