**SUBMISSION TO FSANZ ON INITIAL ASSESSMENT REPORT FOR APPLICATION 576 LABELLING OF ALCOHOLIC BEVERAGES WITH A PREGNANCY HEALTH ADVISORY LABEL**

Drug Awareness (NSW) submits the following response to the questions in the IAR:

**Q.1: Other strategies or programs (initiated by industry, public health, government and consumer groups) to advise women of childbearing age of the risk of consuming alcohol when pregnant, or if planning a pregnancy.**

**1. Strategies by Industry**

a) Organisations funded by the liquor industry, such as DrinkWise claim to "aim to maximise any benefits and minimise the harm from alcohol consumption..(which) involves pursuing an effective means ofaddressing irresponsible drinking, while maximising the positive health and social impacts of responsible drinking"[1] . The alcohol advertising code states that alcohol must be marketed in a mature and responsible way.

b) However, there is continuous, unrelenting pressure by advertising and other means, on **all sectors** of society, to imbibe alcohol. TV and other media have fostered the belief that drinking alcohol is a rite of passage to adulthood, and that non-drinkers are tame and dull . Some of them have acquired the taste from alcohol-flavoured biscuits or chocolates. All of them hate being left out, so many drink, even if they don't really want to.

• In 1995 a series of **new alcoholic drinks** - "alcopops"- directly targeted young people, with ads and brightly-coloured bottles. "An alcohol company insider admits the industry deliberately targets young people by sweetening ready-to-drink alcopops to mask the taste of alcohol. Mat Baxter, a marketing executive behind vodka-based drink Absolut Cut, a premixed, stubby-sized, vodka-and-citrus drink (5.5% alcohol). said the market was booming for high strength, pre-mixed spirits that 'get young people drunk faster'"...**Alcohol companies had till then consistently denied that they targeted younger-age drinkers.** [2]

• "A beer ad was scrapped following complaints, for breaching the alcohol industry's advertising code **by linking sexual success with drinking**, though it had passed a vetting process.[3] Some drinking houses blatantly exploit men's sexual urges, and **encourage male patrons to get a woman drunk.** In one road-stop bar a prominently-displayed wall poster showed the picture of an attractive young woman and the caption: 'If at first you don't succeed, buy her another drink'"[4] .

Whatever the industry's code may say about "mature and responsible" marketing, **its practices belie its profession.** Liquor companies admit that they know that binge drinkers are using alcopops to get drunk fast. They also know that **many females of childbearing age** are among these drinkers, and often end up having an abortion, but they have not taken alcopops off the market, or warned about the dangers of drinking during pregnancy, for the aim of their strategies is not to protect pregnant women or their infants, but to increase sales by exploiting the immaturity of many young women who think that their self-respect depends on having a boyfriend. In a 1992 survey carried out by *Girlfriend* magazine, nearly 25% of the readers who responded said they first had sex because they were drunk and didn't know what they were doing, or because they wanted to satisfy their boyfriends.

c) Co-operation by the **media and advertising industry** is easily bought. Gossip magazines and websites that repeatedly publish photos glamourising the wild behaviour of figures such as Paris Hilton, Britney Spears, Lindsay Lohan and Nicole Richie, have turned these women into role models, although they have all been arrested and tried, even jailed, for drink driving offences, one of them while pregnant. Young girls are seduced into using alcohol and other drugs, heedless of the consequences of combining alcohol with sexual licence. [5]

**d) The liquor industry opposes warning labels, diverting attention from the risk** of FASD, addiction and and cancers, etc., by constantly promoting the supposed health benefits of a small quantity each day (Cf. Attachment A)

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[1] www.drinkwise.com.au/About/WhatisDrinkwise.aspx - 15k -.

[2] *The Age,* 6 Aug. 2007

[3] *idem.*

[4] Ashton & Laura *Uncorked! The Hidden Hazards ol Alcohol,* Signs Publishing Co. 2004, p.50

[5] From "A Christian Voice in Politics", by Gordon Moyes, 23/8/07

**2. Strategies by Governments**

**a)Australian Local Government:** Alcohol Harm Minimisation Projects A good practice guide, a report prepared by Turning Point Alcohol and Drug Centre, Melbourne 2003. Trevor King and Jennifer Richards, for the National Drug Strategy Local Government Subcommittee, a partnership between the Intergovernmental Committee on Drugs, Council of Capital City Lord Mayors, and Australian Local Government Association

This report stresses "moderate, responsible consumption of alcohol", but by perpetuating the unfounded belief that there may be health benefits, and failing to mention FASD either among the alcohol-related problems listed, or in the Family Interventions, it does nothing to discourage alcohol consumption during pregnancy.

However, 'social influence strategies' to inform students about peer and media influence on alcohol and other drug use and provide strategies for resisting this influence (p.19) could help some girls to resist pressure to drink during pregnancy - **if warning labels were placed on all alcoholic beverages, and the warning labels were backed up by appropriate information in the project.** The girls could point to the label and say "I'm not supposed to drink. I don't want a brain-damaged baby".

Messages designed to increase fear and anxiety by dramatising the risks associated with alcohol and other drug use are said in the report to have proved to be ineffective, particularly when the message contradicts the experience of the students. But how much information about people with FASD have they been given? Do they realise that ".. the deleterious effects of alcohol on the brain, such as ADHD, can occur at any time during pregnancy" and remain undiagnosed and untreated for years, while problems mount?[6] .A good sample of actual case stories (e.g., from Professor Ann Streissguth's book *Fetal Alcohol Syndrome: a Guide for Families and Communities* 1997) could remove some of their scepticism. School visits by parents and foster-parents to give first-hand information of the daily problems of raising children with FASD would be even more effective - someone like Elizabeth Russell, who knows the problems only too well:

Elizabeth's son Seth has FAS. **"He was diagnosed by a Canadian expert because I couldn't find anyone over here** who could help me", she explains. Seth was not diagnosed until 17 years old. "It was very late in the scheme of things. The earlier the diagnosis, the better the strategies that can be put into place to help people...He was diagnosed with ADHD when he was 13, but I believe that many of the people that I did go to see to seek help from thought I was being a neurotic mum, and that it was just behaviour that he'd grow out of. I don't remember ever becoming intoxicated. I do remember drinking two or three drinks every couple of nights....I remember **when I had an amniocentesis, the doctor told me to go to the pub and have a few drinks to stave off labour. So I thought then that obviously alcohol wasn't a problem.** I stopped smoking, I took all the right vitamins, I prepared as well as I thought for a pregnancy, but I didn't have any indication anywhere that alcohol was going to be the problem it was. **There are very few specific services in Australia...**We can go to the existing mental health services, and the existing addiction services, but none of them understand the implications of someone having FAS as well.... There are an estimated 200,000 people with this condition in Australia. Last week I spoke to a friend of mine who's pregnant. She said her doctor said it was okay to have a few drinks. **There's no consistent message...**While we're not saying a couple of drinks won't be okay, we can say **that there is damage at a cellular level with any amount of alcohol."**

"All we want to do is to advise mums that alcohol is a teratogen, which is a substance that causes birth defects, and that no alcohol equals no risk. Believe me, if you could see what Seth has to cope with in his daily life you wouldn't want to run the risk in any way, shape or form, of having this condition...If something is poisonous to the fetus, then you wouldn't even want to take any of it. I can see the damage, I can see him everyday, and I would never want to risk that again."[7]

**b) The NSW Government campaign "Be Part of it, not out of it"**[8] targets "young males between the ages of 14 and 29". There is no mention of the dangers of getting girlfriends to drink alcohol and have sex, although Community Drug Action Team in Hornsby has reportedly developed a peer education resource for young women on the harms of **binge** drinking. But **CDAT and other government programs actually encourage alcohol consumption by talking about "responsible drinking"**, instead of encouraging total abstinence, at least until their twenties,

[6] *Effect of Prental Exposure to Alcohol Across the Life Span.* Paul D. Connor, Ph.D And Ann P. Streissguth, Ph.D. NIAAA Research Grant AA01455-01-23 to A.P. Streissguth

[7] **On-linel warning for mothers-to-be**
http://www.abc.net.au/southqld/stories/s2109441.htm?backyard December 4, 2007

[8] Alcohol - Key Achievements, paper received from NSW Health, 20/11/07

when their brains are more able to withstand the harm caused by alcohol.

**c)** A valuable government strategy would be legislation to ban products like alcopops or alcohol-flavoured biscuits/chocolates, which, by popularising alcohol among young women, increase the risk of addiction, making it more difficult to stop before becoming pregnant, and more likely that they will conceive at a time when they have been drinking.

## Q.2 "What information (from industry, public health, government and consumer groups) is available to women planning a pregnancy, or pregnant women, about the risk of consuming alcohol?"

**1. Warnings by AMA:**

**a)** AMA President, Dr Mukesh Haikerwahl, in a press release, reiterated a call made Dec.2004 for the NHMRC to revise its guidelines on alcohol consumption during pregnancy, and to recommend abstinence. The US has done this since 1989, as well as putting health warning labels on alcohol packaging.

"FAS has been found in babies born to mothers who drink 4~5 drinks/day, or who go on binges...Effects vary widely: some babies seem to escape harm, while others are severely damaged due to the effects of even small amounts of alcohol.

"There is compelling international evidence that mothers who drink even small amounts of alcohol during pregnancy could unwittingly harm their unborn children...**It's been shown that possibly just one and a half drinks a week is enough to cause harm.** The effect of these low levels of alcohol may be very subtle, with slightly lower IQ or poorer motor skills than normal. Because alcohol affects so many sites in the brain, researchers believe that it is far worse for the developing brain than any other abused drug."[9]

**b) AMA Victoria, 1/9/05**:

Dr Duncan said there was no known safe level of alcohol consumption during pregnancy. "Less alcohol is better, but **no alcohol is the best and safest option.**.FASD is preventable. The public need to be aware of the dangers associated with excessive alcohol consumption during pregnancy. A woman who chooses to drink should not exceed the NHMRC guidelines and restrict her intake of alcohol to no more than two standard drinks per day and ensure she has at least two alcohol-free days per week. Binge drinking is not recommended for any woman, pregnant or not. It's dangerous for your health and safety," she said.

"[Children with FASD] may experience learning problems such as delay in starting to talk, or difficulties at school....In most cases having a few drinks in the early weeks does not cause harm, but heavy drinking during that time can cause problems for the baby, especially if other drugs are also used. Babies are more vulnerable to alcohol in the early weeks of pregnancy, with the highest risk being between two and eight weeks. Many pregnancies are not planned and women often **don't know they are pregnant until about the sixth week of the pregnancy or later."**

Warning labels are needed.

2. **NHMRC Guidelines.**

**a)** InMarch 2006, the Federal Government released national guidelines which reiterated the 2001 NHMRC guidelines advising pregnant women to have less than seven standard drinks per week and no more than two standard drinks per day.

Dr John Whitehall, Director of Neonatology at Townsville Hospital, said current alcohol-in-pregnancy advice left no margin for safety and put unborn infants at risk.It was out-of-step with the views of many Australian experts as well as US health authorities, who urge abstinence during pregnancy because of the effect of alcohol on intricate neurological function. Exposure to alcohol at the recommended levels had been shown to affect brain development and certain behaviours in animals.

Dr Christine Tippet, President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, supported the 2006 guidelines, saying "Information should not create an environment of fear" [10]. **But health professionals need to look past this fear to the safety and health of the child, and the lifelong burden of care for those affected by FASD.**

**b)** If the **Draft Guidelines** released December 2007 are adopted, they will give much clearer guidance for health professionals and pregnant women about the risk of consuming alcohol:

[9] AMA Press Release 1/09/05.

[10] *Medical Journal Of Australia* 2007:186:35~37

"For women who are pregnant, are planning a pregnancy, or are breastfeeding, not drinking is the safest option".

It is up to industry and governments to act without further procrastination.

**c) Actual dissemination of this knowledge, and implementation of policies** on alcohol and pregnancy **is very uneven,** as shown by:

**i)** *Review of policies on alcohol use during pregnancy in Australia and other English-speaking countries 2006,* by Colleen O'Leary, Louise Heuzenroeder, Elizabeth Elliott and Carol Brewer[11].

Some health professionals advise abstinence, others advise occasional small amounts. It reflects the problem of ignorance about FASD, and reluctance to antagonise clients, by either warning against drinking, or giving a diagnosis of FASD. FASD is sometimes found in more than one child in the family, a tragedy that could have been avoided in some cases **if diagnosis and warning had been given. But:**

- doctors and other health professionals don't know how to diagnose FAS – let alone the other conditions in the spectrum. (BMA study shows only 4~5% of children born to women who consumed large amounts of alcohol during pregnancy are affected by the **full** syndrome presentation. Without the facial dysmorphology, diagnosis can be difficult.)
- They are worried about stigmatising the child and family;
- they don't know where to refer children and are not sure whether treatments are available;
- some communities, such as rural, remote or indigenous communities, are poorly served by paediatricians who are generally the health professionals to make the diagnosis.

**ii)**"A study from WA investigating the knowledge and practice of health professionals suggests that health professionals lack knowledge on diagnosis and management of FAS"[12].

**iii)** This "lack of knowledge" was strongly confirmed in a further postal survey of 1143 WA health professionals by the same authors in July 2005, which found:

- only 12% identified all four essential diagnostic features of FAS;
- 53% said the diagnosis might be stigmatising;
- only 2% felt very prepared to deal with FAS, and most wanted information;
- only 44.5% "routinely ask about alcohol use in pregnancy". (GPs were the best, at 67%);
- only 24.7% (15.9% of obstetricians) routinely provide information on the consequences of alcohol use in pregnancy.

"A better understanding about the importance of correct diagnosis to the child and their family would assist health professionals to **look past the stigma** and focus on interventions to improve the health and well-being of children with FAS"[13]

### 3. On-linel warning for mothers-to-be

"FAS is a disorder of the brain's development", says Dr Joanna Holt, a paediatric consultant. "Those babies have lifelong effects which include a lower IQ than the average, developmental delays, and an increase risk of behaviour and mental health problems later in life..There actually isn't evidence to tell women how much is safe or not. There is not clear clinical evidence that small amounts of alcohol, perhaps one drink a night, or less than seven drinks a week, cause FAS. **But neither can we tell mothers that it doesn't.** There is clear evidence that more than six or seven drinks a week, or more than two or three drinks a night, becoming inebriated, does cause FAS in some mothers and babies"[14].

### 4. Community Groups

**a)The Salvation Army** booklet on alcohol: *The Facts – Binge Drinking & Alcohol Abuse*:

i) Warns about FAS/FAE in the section on pregnancy, p.12 (but unfortunately, not in the earlier section about binge drinking by young women).

ii) Warns on the danger of breast cancer (p.11), which is very relevant for all women, but especially those who are pregnant or planning a pregnancy. (Cf. Attachments.)

iii) Quotes Dr Rod Jackson, University of Auckland, to refute the notion that because alcohol is good for the heart, "pregnant women should not be deprived of this benefit".(p.13)

[11] *MJA* Vol.186 No.9 7 May 2007

[12] FAS Report 2002~03, by Prof. Carol Bower, Assoc.Prof.Elizabeth Elliott, Prof.Eric Hahn, Ms Jan Payne.

[13] *ANZ JPH*, 2005; 29.6, p.563.

[14] Alcohol warning for mothers-to-be
http://www.abc.net.au/southqld/stories/s2109441.htm?backyard December 4, 2007

**b) Woman's Christian Temperance Union** has been producing literature warning about FAS/E since it was first identified.

## Q.3 What published and unpublished information is available that may provide answers to the risk assessment questions (1~3 below) regarding FASD to be addressed in the Draft Assessment?

1. What is the strength of evidence that intake of alcohol at less than 2 standard drinks/day causes fetal developmental effects?
2. Does the scientific evidence identify a threshold of alcohol intake for pregnant women above which fetal harm is likely to occur? What is the quality of this evidence?
3. What factors are likely to affect the impact of alcohol consumption on the fetus, including:
   a) binge drinking compared with smaller drinks
   b) genetic differences
   c) susceptible populations, e.g. people with diabetes?

**1~2.**

**a)"It's been shown that possibly just one and a half drinks a week is enough to cause harm" (AMA press release Sept.2005).**

**b) Dr John Whitehall, Neonatal Unit Townsville Hospital**[15]

Exposure to alcohol at the recommended levels has been shown to affect brain development and certain behaviours in animals. Most women don't realise that because their fetus' liver is not mature enough to metabolise alcohol at the same rate as they do, and because the amniotic fluid acts as a reservoir for ethanol (the fetus urinates into the amniotic fluid which it drinks), the BAC in the fetus can be even higher than that of the mother's, during the 2nd and 3rd hours after drinking

**At a BAC of 0.014,** alcohol causes damage to the cell itself, the intricacies of the cell communication network, and the mobility mechanism. This causes apoptosis, and impairment of executive function.

**One** standard drink gives a **BAC of 0.02~0.05,** depending on body size, genetics, etc. When considering the toxicity of materials, the advice is that the dose [used in animal experiments] be reduced to 1 tenth, to allow for interspecies variations, and if, for instance, a child's life is at stake, the level should be reduced by a further factor of 10 or 20... Therefore no alcohol in pregnancy is the safest level.

**c) Report on Prenatal Exposure to Alcohol by Professor Peter Hepper of Belfast, Ireland** [16]

Maternal alcohol consumption during pregnancy influences infant habituation at 5 months of age. The behavioural effects observed indicate maternal alcohol consumption has influenced, possibly permanently, the functioning of the brain and CNS of the fetus and infant These effects are observed at **low levels** of maternal alcohol consumption (5-6 units per week; [1 unit = 10 ml of ethanol]) and this raises questions regarding the 'safe' level of alcohol during pregnancy

An examination of new-born and infant habituation, using a visual attention task, was also conducted in order to evaluate the permanency of the neurobehavioural effects observed *in utero.* There was no effect of maternal alcohol consumption in the new-born period. There was a highly significant effect of maternal alcohol consumption during pregnancy on the infant's habituation response at 5 months of age. Infants exposed to maternal alcohol *in utero* habituated much faster than infants not exposed to maternal alcohol *in utero.*

**d)** The *Review of policies on alcohol use during pregnancy in Australia and other English-speaking countries, 2006*[17] concluded that "the amount of alcohol necessary for fetal damage is unclear, and it **remains debatable whether there is a threshold level** below which alcohol does not harm the fetus".(p.466), but "identifies the need for more definitive research" (p.470).

**e) Research by National Scientific Council on the Developing Child**[18]

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[15] Summary of presentation to 1st FASD National Conference, June 2007.

[16] FINAL REPORT Grant Title: Maternal alcohol consumption and the behaviour of the fetus Grant Holder: Peter Hepper Grant reference: R8/94 . Grant period: Feb 1995-Feb 1998

[17] Colleen O'Leary, Louise Heuzenroeder, Elizabeth Elliott and Carol Bower, *MJA* 186/9 7/5/07

[18] *Early Exposure to Toxic Substances Damages Brain Architecture:* p.7, 2,4..SWAT - NOFASARD research (Spring 2006)National Scientific Council on the Developing Child.

"It is generally assumed that the determination of a dangerous level of exposure to a potentially neurotoxic substance is a straightforward scientific question. In fact, this can present a complicated challenge because the developing brain of a young child is typically more susceptible to damage than the mature brain of an adult, and the immature nervous system of an embryo or fetus is even more vulnerable to toxic exposures than is that of an infant. Therefore, **there is no credible way to determine a safe level of exposure to a potentially toxic substance** without explicit research that differentiates its impact on adults from the greater likelihood of its adverse influences on the developing brain during pregnancy and early childhood."

**f)** As noted in the IAR, in June 2007, the **British Medical Association** published *Fetal Alcohol Spectrum Disorders - a guide for healthcare professionals*, in which it advises women who are pregnant, or who are considering a pregnancy, not to consume any alcohol, recognising that "FAS, although not a common condition, is nevertheless regarded as the leading known cause of non-genetic intellectual disability in the Western world."

- (p.7 ) "There is currently no consensus on the level of risk or whether there is a clear **threshold** below which alcohol is non-teratogenic. A 2006 review of the existing evidence on the effects of alcohol on the developing embryo, fetus and child conducted by the National Perinatal Epidemiology Unit (NPEU) found there to be no consistent evidence of adverse health effects from low-to-moderate prenatal alcohol exposure."

However, as noted in the IAR, "It is worth noting that the current evidence is not robust enough to exclude any risk from low-to-moderate levels, and that **evidence is continuing to emerge as to the possible effects of prenatal alcohol exposure at these levels**. Evidence from animal experiments suggests that damage to the CNS may occur at low levels of alcohol exposure. Moreover, a prospective study of 501 mother-child dyads found that the child's behaviour at **age six to seven** was adversely related to **low-to-moderate** levels of prenatal alcohol exposure. A dose-response relationship between the level of alcohol ccnsumed and the behaviour exhibited was also found. Studies examining the effects of alcohol on the fetus have shown that exposure at low-to-moderate levels can alter fetal behaviour .. These studies have consistently shown that acute exposure to **one to two units of alcohol** rapidly suppresses fetal behaviour through a rapid decrease in fetal breathing.

Studies examining the effects of **chronic consumption** indicate that **low-to-moderate levels of exposure** (two to five units per week) elicit a developmental delay in the functioning of the fetus's nervous system and may result in a permanent effect. It is not currently clear what effect these changes in behaviour have on fetal development and the health outcomes of pregnancy. A recent large prospective study has found that **occasional low-to-moderate drinking** during the first trimester may have a negative and persistent effect on children's mental health".[19]

"**There is considerable debate as to the adverse effects of maternal alcohol consumption at low-to-moderate levels of drinking.** This may be explained by the variability in the definitions of consumption levels, differences in the way drinking behaviour is characterised, methodological problems in the design and analysis of relevant studies, and in determining the relative effect of confounding factors (eg genetic predisposition)."

**g)** In *BJOG* 114:3, **Henderson et al**[20]. review studies on the effects of low to moderate PAE for the following outcomes: "miscarriage, stillbirth, intrauterine growth restriction, prematurity, birthweight, small for gestational age at birth and birth defects including FAS". They and the Health Council of the Netherlands concluded that while there is "no convincing evidence of adverse effects of PAE at low to moderate levels of exposure"pregnant women should be advised against drinking during pregnancy, for the review had not included studies examining cognitive or neurological effects of PAE (*sequelae* believed to be more common than full FAS), and animal studies have shown that even transient, low levels of PAE can cause negative neurological effects.

**h) Willford JA, Richardson GA, Leech SL, Day NL. *Verbal and visuospatial learning and memory function in children with moderate prenatal alcohol exposure.***[21]

Effects of **moderate PAE** on learning and memory in 14-year-old adolescents: Prenatal alcohol exposure during the first trimester predicted deficits in learning, short-term memory, and long-

[19] 41 Riley EP & McGee CL (2005) Fetal alcohol spectrum disorders: an overview with emphasis on changes in brain and behaviour. *Experimental Biology and Medicine* 230: 357-65.

[20] Henderson J, Gray R, Brocklehurst P. Systematic review of effects of low-moderate prenatal alcohol exposure on pregnancy outcome. *BJOG* 2007;114:243–52.

[21] *Alcohol Clin Exp Res*28(3):497-507, 2004 Mar.Affiliation: Department of Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA.

term memory, specifically in the verbal domain. Deficits in performance were specific to learning and memory of word-pairs. In addition, deficits in memory were mediated by learning performance. CONCLUSIONS: Results demonstrated that **PAE leads to deficits** in encoding processes as indicated by deficits in verbal learning. Initial deficits in acquisition were responsible for deficits in immediate and delayed recall of verbal information in children who were exposed to alcohol during pregnancy but did not have FAS. ("Moderate" not defined in the Abstract.)

**i) Huizink AC; Mulder EJH. Maternal smoking, drinking or cannabis use during pregnancy and neurobehavioral and cognitive functioning in human offspring (review)**[22] .

An overview of studies of neurobehavioral and cognitive teratogenic findings beyond the early ages, resulting from **low or moderate levels** of exposure to these substances.... It is concluded that prenatal exposure to either maternal smoking, alcohol or cannabis use is related to some common neurobehavioral and cognitive outcomes, including symptoms of ADHD (inattention, impulsivity), increased externalizing behavior, decreased general cognitive functioning, and deficits in learning and memory tasks.

**j) Mattson et al.** 1998[23] noted that problems in maintaining attention have long been associated with FAS and are quite common, affecting 60% of children and adolescents with the syndrome. **Deficits in attention also have been reported for children exposed to relatively low levels of alcohol before birth.** Various studies indicate, however, that the attention disruption associated with prenatal alcohol exposure differs from that arising from other disorders, such as ADHD, which could have important implications for diagnosing and treating attention disorders.

**k)** A study examining exposure during the first trimester to an **average daily volume of one drink** found there were significant effects in verbal learning and memory as measured by the Wide Range Assessment of Memory and Learning (Richardson *et al.*, 2002)[24]

## Q.3 question 3: factors affecting impact of alcohol

**a) NSCDC research** [cf. Q.1(e) p.6] notes the following factors:

**i)** "the **immaturity** of the fetal brain, and lack of a protective barrier of cells to restrict the entry of chemicals into the bloodstream, makes it most vulnerable to disruption of brain architecture...**Of all the recreational neurotoxins studied to date, alcohol produces the most devastating disruptions of early brain development",** especially in the structure of cell membranes, that contain the proteins responsible for the ability of growth factors and neurotransmitters to perform their normal functions. "The adverse impacts of alcohol are so powerful that they also can interfere with the development of organs that often are spared by other toxic exposures, including those of the cardiovascular, digestive, and musculoskeletal systems."[25]

**ii) Multiple exposures,** such as to cocaine, cigarettes and alcohol;

**iii)** physiological effects of **environmental** stresses facing children whose parents have a substance abuse problem, both of which can harm the developing brain. (Cf. **b.i)** below.)

Despite these confounding factors, "there is abundant scientific evidence that exposure to dangerous levels of neurotoxins at particularly **sensitive times** in the developmental process can disrupt the architecture of the brain.[26]

**b) (BMA** *FASD guide for HPs):* Data about FASD are continuing to emerge and it is clear that **some populations** are more likely to have children affected by these disorders.

**i)** The most **at risk populations** are those that experience high degrees of social deprivation and poverty such as indigenous or native populations This also affects individuals' perceptions of their level of drinking and how much they think is safe to drink.

**ii)** The damage caused by alcohol on the developing fetus is dependent on the **level** of maternal alcohol consumption, the **pattern** of alcohol exposure and the **stage of pregnancy** during which

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[22] *Neuroscience and Biobehavioral Reviews* 30(1): 24-41, 2006. (155 refs.)

[23] In Prenatal Exposure to Alcohol *Alcohol Research and Health,* Vol 24 No.1, 2000 p.35

[24] STATE OF THE SCIENCE REPORT ON THE EFFECTS OF MODERATE DRINKING:NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM NATIONAL INSTITUTES OF HEALTH DEPT OF HEALTH AND HUMAN SERVICES DEC.19. 03

[25] American Academy of Pediatrics, Committee on Environmental Health:Elk Grove Village, IL.)

[26] Quoting from Stanwood GD and P.Levitt, Drug exposure early in life: Functional repercussions of changing neuropharmocology during sensitive periods of brain development. *Current Opinion in Pharmocology, 2004,* 4:p.65~71.

alcohol is consumed.[27]

- Women who **binge** drink are much more likely to have children with facial dysmorphology, cardiac anomalies or cognitive impairment than women who drink the same total amount of alcohol over an extended period of time.
- The stage of pregnancy during which alcohol is consumed determines how and which cells of the developing fetus are affected.
- Evidence from animal experiments suggests these critical periods of exposure occur during the first and third trimesters in humans. Studies in mice have found the very early stages of embryogenesis to be critical periods for damage to the developing brain and induction of alcohol-induced craniofacial alterations.
- PAE during the third trimester is highly related to damage to the cerebellum, hippocampus and prefrontal cortex. A small-scale study examining children with school problems who had been prenatally exposed to alcohol found that damage to the cerebellum can also occur following heavy maternal alcohol consumption during the first trimester of pregnancy.
- The occurrence of PFAS, ARBD and ARND is not fully understood. It has been postulated that the anomalies characteristic of PFAS, ARBD and ARND result from exposure to heavy doses of alcohol intake on specific days of fetal development, and that exposure to heavy doses throughout pregnancy results in the development of the pattern of anomalies found in FAS.

**iii)** This is confounded by a number of other risk factors including the genetic makeup of the mother and the fetus, the nutritional status of the mother, hormonal interactions, polydrug use (including tobacco use), general health of the mother, stress, maternal age and low socio-economic status. For example, research to identify specific genetic factors contributing to FASD has found that polymorphisms of the gene for the alcohol dehydrogenase enzyme ADH1B in both the mother and the fetus, can contribute to FASD vulnerability.

**c) Willford JA; Leech SL; Day NL. Moderate prenatal alcohol exposure and cognitive status of children at age 10.[28]**

The objective of this study was to assess the association between moderate PAE and cognitive ability in children at age 10 controlling for other prenatal and birth factors, maternal and child psychosocial factors, and environmental characteristics

A significant relation was found between alcohol exposure during the first and second trimesters and the composite score of the Stanford-Binet for **African American** children at age 10. Significant relations were also found for the verbal, abstract/visual, and quantitative subscales. Additional predictors of IQ at age 10 included mother's IQ, home environment, and child's report of depression. There is a significant association between PAE and cognitive ability at age 10 **among African American offspring.** There was no relation between PAE and scores on the Stanford-Binet scales among the Caucasian offspring.

## Q.4. "What other data are available regarding alcohol consumption by women of childbearing age and during pregnancy in Australia and New Zealand?"

The need for more effective measures in Australia to reduce alcohol consumption by women, especially those of childbearing age, is shown by the following:

1. One major study of **women in Australia**[29] indicated that 87% of women surveyed had at some time drunk alcohol. **Over 33%** of them were "hazardous drinkers", while 4% were "drinking harmfully" and 1% were "dependent".

- The **highest proportion of hazardous/harmful drinkers was among women aged 17-24;**
- they are increasingly participating in **binge** drinking (5 or more standard drinks/ occasion);
- teenage drinking is starting earlier among girls and includes a binge drink pattern of heavy intake and consumption of mixed drinks with high alcohol content;
- 94% of the drinkers usually drank less than weekly or 1-2 days per week,
- 33% usually have 3-4 drinks on a drinking day,
- another 33% have 5 or more drinks on a drinking day.

[27] 41 Riley EP & McGee CL (2005) Fetal alcohol spectrum disorders: an overview with emphasis on changes in brain and behaviour. *Experimental Biology and Medicine* 230: 357-65.

[28] *Alcoholism: Clinical and Experimental Research* 30(6): 1051-1059, 2006. (49 refs.)

[29] *Patterns of Alcohol Consumption in Young Australian Women.* H. Jonas, A. Dobson and W. Brown Australian and New Zealand Journal of Public Health 2000 (24), 2: 185-191

• 53% reported drinking five or more drinks per occasion (binge drinking) about monthly or less often; and 17%, weekly or more often.

**2. National Health Survey**. 2004~05 showed:
• 13% (approx. 2m) drank at a risky/high risk level (5 or more standard drinks for females)
• The proportion of people drinking at a risky/high risk level **has increased** over the past 3 surveys:(after adjusting for age differences):
8.2% in 1995
10.8% in 2001
13.4% in 2004-05.
Of these: among people aged **18 years and over, in the last 12 months:**
30% of females had consumed alcohol at risky/high risk levels in the short term **at least once;**
4% of females had consumed alcohol at risky levels in the short term **at least once a week.**
Among people **18~24yrs:**
11% of females had consumed alcohol at risky levels in the short term **at least once a week.**
Among people aged **14 years and over,**
31% of females consumed alcohol at risky/high risk levels in the short term. [NDSHS, AIHW 2005a)].
The increase in those drinking at a risky/high risk level since 1995 **has been greater for women (6.2% to 11.7%) than for men** (10.3% to 15.2%).

**3. The Australian Longitudinal Study on Women's Health (Young and Powers 2005),** reveals that 18% of women aged 18-23 (mainly Australian born women and those of English speaking backgrounds), drank at risky or high-risk levels at least weekly. While risk drinking among women of this age group occurred more often among "women who were not or had never been pregnant" indicating that at least some women reduced their drinking levels once they realised they were pregnant, a lot of damage can be done to the embryonic brain during the first six weeks before the discovery.
Other groups drinking alcohol at risky levels seem to be using it to forget their sorrows:
-- those separated, divorced and widowed, or having difficulty managing finances,
-- current smokers, illicit drug users,
-- women who repeated self-harm,
-- women who had more sexual partners.

25% females aged in their 20s drink at high risk levels for short-term harm at least once per month and 85% of the total alcohol consumed by 14-17 year old females was drunk at risky/high risk levels for short-term harm.
The reasons for drinking amongst teenagers were reported to include social perspective, living with peers at home or on the streets, peer pressure, relief from stress, a remedy from boredom.

**4. The 2006 Salvation Army survey data** (Roy Morgan research estimates):
• 754,000 14-24 year old males drink irresponsibly (ie. 6 or more drinks in any one session).
• **14-17 year old females** are also drinking more. The number drinking 7 drinks or more in a session has jumped from 11% in 2005 to 16% in 2006.
• **41% 18-24 year old women now binge drink regularly** (7 or more drinks on one occasion - up 4% on the 2005 figure).

**5. A survey by the National Drug and Alcohol Research Centre** suggests nearly half of pregnant and breastfeeding women are drinking alcohol. (This tallies with the "47%" reported by NDSHS.)

## Q.5 Are there any other data available on the incidence of FAS/FASD in Australia or NZ?

Lack of diagnostic skills, and fear of stigmatising by recording a diagnosis of FAS, have contributed to under-reporting of its occurrence and underestimation of the problem, as well as to failure to advise against drinking durng pregnancy. Research (Q2.2(c)) has confirmed several reasons for under-diagnosis (and hence, apparent low prevalence):

**1. National FAS Workshop Report (Australian National Council on Drugs 2002).**
a) ADAC SA noted (p.4):
• it was believed that major hospitals in South Australia were not diagnosing the condition

satisfactorily. There was a discrepancy between [extremely low] numbers of FAS cases being reported in Australia [0.005/1000] compared with overseas numbers [1/100];
• need for simpler NHMRC guidelines, training for alcohol screening by health professionals, and national guidelines for screening for alcohol use in pregnancy.

Difficulties assessing the true incidence of FAS and related disorders in Australia are due to:
• lack of data links between perinatal services, outreach services and drug and alcohol services;
• patchy and variable data collection, *ad hoc* and under-reporting;
• APSU covers only paediatricians, who see referrals only;
• difficulty of diagnosis at birth - no uniform diagnostic criteria, lack resources and training,
• reluctance of some health professionals to make diagnosis, for fear of stigmatising family,

Difficulties also arise in quantifying maternal alcohol consumption due to:
• reluctance of some health workers to take drinking history,
• lack of screening tools and instruments appropriate for some populations,
• inaccurate self-reporting of alcohol consumption and recall bias,
• limited linkage of ante-natal and post-natal data collections;
• incomplete wholesale alcohol sales data collection;
• lack of adequate documentation of drinking patterns in Indigenous communities.

**2.** ***FAS in Australia: Fact or Fiction?*** **(2004) by E.J.Elliott and G.Bower[30] reiterates the same** difficulties still being experienced in ascertaining the incidence of FAS in Australia: poor recording of detailed clinical data and alcohol consumption, lack of access to services in rural and poorer communities, difficulty of diagnosis.

**3. BMA** *Fetal Alcohol Spectrum Disorders - a guide for healthcare professionals.* The most at risk populations are those that experience high degrees of social deprivation and poverty such as indigenous or native populations.

In Australian aboriginal populations the incidence of FASD is estimated as 4.7 per 1,000 live births, while the incidence in the Western Cape Province of South Africa has been reported to be as high as 68.0 to 89.2 per 1,000 children. The incidence of FASD in Italy has been estimated to be 20.3 to 40.5 per 1,000 children. In Canada, FASD are reported to affect 10 in every 1,000 live births. It has been estimated that in Western countries as many as 9 per 1,000 live births involve children affected by FAS, PFAS or ARND. Of the children concerned, 10~15% are affected by FAS, 30~40% by PFAS, and nearly half by ARND.

## Q.6. Are there any other data available relating to the level of awareness amonst women of childbearing age of the risk of consuming alcohol when planning to become pregnant and during pregnancy in Australia and New Zealand?

Women's awareness of risk is greatly influenced by the health professionals they see during pregnancy. **The following surveys** confirm the need (Q.5.1) for more education, not only of mothers-to-be, but also of health professionals, about the effects of alcohol, and diagnosis of FASD:

**1.** ***Health Professionals' knowledge, practice and opinions about fetal alcohol syndrome and alcohol consumption in pregnancy.***[31]

Of 1,143 health professionals, (87 Aboriginal health workers, 286 allied health professionals, 537 community nurses, 170 GPs, 63 obstetricians),
12% identified all 4 essential diagnostic features of FAS.
95% had never diagnosed FAS,
82% believed that making a diagnosis would improve treatment plans,
53% said diagnosis might be stigmatising,
2% felt very prepared to treat FAS; most wanted information for themselves and clients,

Of the 659 HPs caring for pregnant women, only
45% routinely ask about alcohol use in pregnancy,
25% routinely provide information on the consequences of alcohol use in pregnancy,

[30] *J. Paediatrics and Child Health* (2004) 40:8~10
[31] Jan Payne, Elizabeth Elliott, Heather D'Antoine, Colleen O'Leary, Anne Mahony, *Australian and New Zealand Journal of Public Health* 2005 Vol29 ,No.6, pp 558~64

13% provide advice consistent with NHMRC Guidelines.
Implications: "FAS is likely to be under-ascertained in Australia due to a lack of knowledge of FAS by HPs.Until this lack of knowledge is addressed, opportunities for diagnosis and prevention of FAS will be limited."(Jan Payne)

*2. A survey of paediatricians' knowledge, attitudes and practice*[32]
Postal survey of paediatricians in Western Australia in 2004. Of 179 eligible paediatricians, 132 (73.7%) responded (90 consultant paediatricians and 42 paediatric trainees).
**Results**
Of the 132 respondents,
- 18.9% identified all four essential diagnostic features for FAS.
- 49.2% had previously diagnosed FAS (range 1–30 cases) but 91.7% had seen children diagnosed by others.
- 76.5% had suspected but not diagnosed FAS;
- 12.1% had been convinced of but not recorded the diagnosis;
- 31.8% had referred children for diagnostic confirmation.
- 79.6% agreed early diagnosis might be advantageous, but 69.6% said diagnosis might be stigmatising and 36.4% thought parents might resist referral for assessment and treatment.
- 78.2% agreed avoiding binge drinking may reduce FAS, but only 43.9% believed women should abstain from using alcohol in pregnancy.
- 4.5% felt very prepared to deal with a patient with FAS: 69.7% wanted educational materials for themselves and child carers;
- **23.3% routinely ask about alcohol use when taking a pregnancy history**
- **4.2%** routinely provide information on the consequences of alcohol use.
- 11.4% had read the current NHMRC Guideline regarding alcohol consumption in pregnancy; 9.1% provided advice consistent with the guideline.

The failure by many HPs to inform women about the dangers of alcohol during pregnancy, and to diagnose FASD, has been illustrated by the case of Elizabeth Russell (reported under Q.1.2). :

## Q.7. Do you think a health advisory statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy on all alcoholic beverage containers should be required? Why?/why not?

**1. Health advisory statements are necessary, and part of the duty of care to all citizens.**
**a)** Consumers rightfully expect to be warned on the label of possible harm from chemicals or prescription medicines. If, as the AMA has come to recognise, there is no known safe level of alcohol consumption during pregnancy, people need to know this, and it is unfair to withhold the information. The liquor industry and the Government know the risks because bottles exported to the US must carry labels warning against drinking during pregnancy. Should not the Government protect its own citizens?
**b)** The Australian Associated Brewers Inc., in opposing Application A359 for warning labels, wrote "Warning labels may discourage drinking among moderate consumers of alcohol, and thus deprive them of protection against the most common cause of death in Australia, cardiovascular disease".and goes on to quote the claim of reduced mortality among moderate drinkers.
**Doubts about the research underlying this claim** are acknowledged in NHMRC Draft Guidelines Dec.2007(p.45: Fillmore *et al.),* and as a result, Australia's winemakers are concerned that the new guidelines do not recommend alcohol in moderation as a protective health measure[33]
The following comment by WHO (Press Release Nov.1.1994) has been vindicated by subsequent research (cf..Attachments), and would be worth quoting in explanatory leaflets similar to those given with prescription drugs:
"The publicity given to the use of moderate consumption of alcohol for heart disease

[32] *Journal of Paediatrics and Child Health* **May 2006,** by Elizabeth J Elliott, Jan Payne Eric Haan and Carol Bower Discipline of Paediatrics and Child Health University of Sydney, The Children's Hospital at Westmead, The Australian Paediatric Surveillance Unit, Sydney, Telethon Institute for Child Health Research, Centre for Child Health Research, The University of Western Australia, Perth, Department of Genetic Medicine, Women's and Children's Hospital and Department of Paediatrics, University of Adelaide, Birth Defects Registry of Western Australia, Women's and Children's Health Service, Perth
[33] .The Age .com.au

prevention is not the result of rigorous scientific research but is to a large extent inspired by commercial purposes".

**c)** How can women make an informed choice unless there is a warning label, as there is on other toxins? As pointed out under Q2 and Q3, advice given by health professionals is inconsistent and. many of them have failed to warn about drinking during pregnancy and breastfeeding.

**d)** "Not drinking is the safest option" is a new guideline, and without warning labels it could take much longer to advertise the change and prevent more brain damage.

**e)** Particularly in rural areas, where there is a higher rate of teenage pregnancies, but less information about FASD,[34] and inadequate health services, warning labels are essential.

**f)** The burden of care for those affected by prenatal exposure to alcohol is onerous, expensive and lifelong. The liquor industry should bear part of this burden by providing warning labels.

**2 . Health advisory statements can be effective**

**a)** To be effectiv e and known to all consumers, this information needs to be on every package. **Warning labels give advice at the critical time and place of choice.**

**b)** Application A359 was rejected on the grounds that "they may result in an increase in the undesirable behaviour in some 'at risk' groups."[35] Dr Ian Walpole argues that **prohibition** advice "probably leads to greater fetal mortality ... because many women terminate a pregnancy following a party, and their anxiety and precipitous decisions are exacerbated by a prohibition program, whose preventive effect is likely to be minimal"[36]. But this is not a "prohibition program" (abstinence imposed by the State), but strong encouragement to **voluntary abstinence** for the sake of the child, its family (especially the mother!) and the community.

The same objection about effectiveness could be made about "Poison" labels on chemicals, and about traffic warning signs. No one is suggesting that warning labels alone are **sufficient,** or effective in all cases, but they are **necessary,** and can be effective as either a spearhead or a back-up for other strategies.

**c)**Many (including young people) do heed warnings[37] , and the wise should not be deprived of their benefit for the sake of the heedless. This has been shown in USA, where the number of women reporting any alcohol use during pregnancy dropped from 80% in 1974/75 (time of first survey) to 42% in 1980/81[38], even though their later warning labels were designed to fail

**d)** If women who terminated their pregnancies had been advised by health professionals before becoming pregnant, to abstain from alcohol, some of them would have remembered the warning when confronted with a conspicuous, well-designed warning label. Those who did not heed it, and their carers, should be helped to raise the damaged child, and to nurture a sense of responsibility for themselves and their children.

**e)** Although warning labels and other measures may not have immediate effect on all "at-risk" groups, a rotation of graphic warnings will, over time, penetrate people's consciousness (not just women, but partners and parents also), and help to reduce the numbers of those who find it difficult to stop drinking before they become pregnant.

## Q. 8 and 10. What further evidence is available about the use and /or effectiveness of a health advisory statement on alcoholic beverage containers regarding the risk of consuming alcohol when planning to become pregnant and during pregnancy? Wording of statement?

## Q.11. What are the advantages and disadvantages of a written statement compared to a pictorial image...?

Written statements can convey more detailed information, but pictorial images are eye-catching, and transcend language barriers. Written statements need to be translated into a number of languages, and the mix of target languages in Australia changes over time.

The need for a mix of pictorial images as well as written statements has been shown in several countries:

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[34] Policy research paper by NRWC, Feb.2005, pp 5~6.
[35] ANZFA Report 2000.
[36] National FAS Workshop Report (2002), p.22.
[37] A recent survey by NRMA found that 90% of young respondents stated they used designated non-drinking drivers (*The Post, 9/1/08).*
[38] Ann Streissguth: The Seattle Prospective Longitudinal Study, June.2007, p.98.

**1.** In **the USA**, a number of specific universal strategies aimed at preventing FASD have been used. These have focused on media advertising campaigns, school and community-based programmes, warning posters, and labelling of alcohol beverages. There has been relatively little research into the effectiveness of universal FASD prevention strategies in the USA, with the exception of alcohol beverage warning labels:

**a) Hankin JR (2002)** ***Fetal alcohol syndrome prevention research.***[39]
Analysis of the impact of alcohol beverage warning labels found there to be an increase in awareness and knowledge. Alcohol beverage warning labels were introduced in the USA in 1989 following implementation of the Alcoholic Beverage Warning Label Act 1988.[40]

**b) Argo, Jennifer J. and Kelley J. Main (2004), Meta-Analyses of the Effectiveness of Warning Labels**[41]
Five separate meta-analyses, one for each dimension of warning label effectiveness, indicated:
- warning labels are effective in attracting consumers' attention;
- when warning labels include certain characteristics such as **color or symbols**, the likelihood of noticing the label is further increased;
- . where consumers do perceive hazards with a product, these perceptions are more likely to be associated with products that are purchased less frequently (e.g., appliances) as opposed to products purchased more often (e.g., cigarettes). [This highlights the need to change the warnings regularly.]
- In the fifth meta-analysis, results indicate that **warning labels do appear to positively influence consumer behavior.** The tendency to comply with the warning label was highest when the cost of doing so (i.e., how difficult it would be) was low. Consumers were also more willing to comply when they were familiar with a product, than when they were unfamiliar with it.

**c)** In **"Do Warning Labels on Alcoholic Beverages Deter Alcohol Abuse?",** Ruth C. Engs, Dept. of Applied Health Science, Indiana University, asks: "How frequently do unbuckled drivers read the sign and then buckle up? Regardless of state law or seat belt warning signals, less than 15% of all drivers use seat belts ". But despite this seeming ineffectiveness, there has not been any campaign to remove traffic warning signs.
Studies of **prescription inserts** to inform consumers of the dangers and proper use of a drug, a practice that may be more analogous to alcohol warning labels, find that most patients read the information provided with the prescription and show an increased knowledge about the side effects and the dangers. In 1971, the U.S. FDA required patient package inserts in oral contraceptives, and in 1977 the agency required them for many other drugs. Morris found sales of a particular brand of estrogen dropped sharply after media reports were broadcast linking estrogens to cancer. Sales declines continued following the mandatory insertion of information sheets a few years later.

**d)** Comparison with tobacco warning labels is also relevant, for both alcohol and nicotine are addictive, and tobacco used to be as socially acceptable as alcohol. More evidence is available about their effectiveness, for the simple reason that they have been tried:

**Larger Labels With Pictures -- As in Other Countries -- May Make Smokers Think Twice**
By Miranda Hitti WebMD Medical News Reviewed By Louise Chang, MD February 06, 2007[42]
**Key finding:** The U.S. labels, which were the smallest and least detailed, were also the least effective. The U.K. revised its cigarette warning label in late 2002, adding 10 written warnings (such as "Smoking when pregnant harms your baby") for a total of 16 written warnings on the front and back of the package. The warning text was also enlarged at that time.

**e)** The major barrier to effectiveness of US warning statements is, that they are hard to read[43] . "Congress passed the Alcohol Beverage Labeling Act of 1988 to inform the American public and alcohol consumers of serious risks related to alcohol consumption. BATF [Bureau of Alcohol,

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[39] Alcohol Research and Health 26: 58-65.
[40] *Fetal alcohol spectrum disorders – a guide for healthcare professionals* (BMA) P.12
[41] *Journal of Public Policy & Marketing*, 23(2), 193-208. 2004 Association for Consumer Research. All rights reserved.
[42] *American Journal of Preventive Medicine,* March 2007.
[43] Alcohol Healthwatch Briefing Paper (NZ 2003).

Tobacco and Firearms] has failed to carry out Congress' intent."[44]

**2.** In **Israel**: Pregnancy damage, driving impairment and health problem components of the warning label serve more as a reminder than as a tool for initially informing the public of new information. The warning label should serve as a clear, non-confusing reminder of health hazards. Furthermore, it was argued that warning labels are most effective in situations where consumers are being reminded of hazards they already know exist, as opposed to messages intended to educate or persuade [45].

**3.** In **Australia**: The 2006 survey conducted by Roy Morgan for the Salvation Army showed that 69% of the public would support warning labels on alcohol; 68% of those surveyed said if there were health warnings on bottles or cans that they would still buy as much alcohol, with 12% saying they would buy less alcohol if warnings were on products. (Most of the remainder do not drink or do not buy alcohol).

However, the fact that in 2006 the alcohol industry again opposed the immediate imposition of warning labels as too hasty could indicate that it regards them as too effective. Would all those 68% really be indifferent to the prospect of giving birth to a brain-damaged baby?

**4. In Canada** the experience with tobacco warning labels is again instructive[46] .

**a)** Survey on Effectiveness of Graphic Canadian Cigarette Warning Labels reports:

"One year after Canada required **large, picture-based health warnings** on cigarette packs that depict the devastating effects of tobacco use on the human body, a new national survey released today by the Canadian Cancer Society shows that **the new warnings are highly effective at discouraging smoking.** The effectiveness of Canada's graphic warnings underscores the woeful inadequacy of the current cigarette health warnings in the United States....**Each cigarette package must depict one of 16 rotated, full-color, picture-based warnings.** The graphic pictures include a diseased mouth, a lung tumor, a brain after a stroke, a damaged heart and a limp cigarette as part of an impotence warning. Inside the package, one of 16 additional rotated messages are required, nine of which contain tips on quitting. As a result, Canadians receive detailed, highly visible information about both the magnitude of the health risks they face and the practical steps they can take to quit."

"The survey (by Institute of Cancer Research of the Canadian Institutes of Health Research), conducted Sep. 19~Oct 10, 2001, found that 90% of Canadian smokers had noticed the new warnings (compared to 49% of non-smokers), and 43% of smokers said they are more concerned about the health effects of smoking because of the warnings. 44% of smokers said the new warnings increased their motivation to quit smoking, and of those who attempted to quit, 38% said the warnings were a motivating factor...". In contrast, " in the United States [warning labels] are having virtually no effect on smoking prevalence. Studies indicate that fewer than 5% of U.S. smokers even see the warnings...[which] are weak, outdated, incomplete, and not nearly as graphic and prominent as they should be".

**b) Presentation to the Standing Committee on Health on Bill C-206, an Act to Amend the Food and Drugs Act . Michel Perron, CEO Canadian Centre on Substance Abuse 21-3-05:**

In 1996, there was conditional support for mandatory alcohol warning labels: Despite the lack of effectiveness in bringing about changes in problematic drinking behaviour, it was thought likely that over the long term they may help create an environment in which other controls can develop more easily.

"The most compelling argument in favour of mandatory warnings" was thought to be that "consumer products that have a proven potential for causing harm should be appropriately labelled. **Alcohol should not be exempted from labelling requirements demanded of other potentially toxic substances.".** However warning labels did not emerge as a viable policy in the final recommendations for action "due to the lack of evidence regarding their effectiveness". There was no explanation, but **industry pressure was thought to be not unlikely.** "The context of a comprehensive drug and alcohol strategy" is usually a "harm minimisation policy, which aims to protect the alcohol industry, while appearing to take action".

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[44] The Center for Science in the Public Interest (CSPI), a nonprofit health-advocacy group based in Washington, D.C., that focuses on alcohol policies, nutrition, and other issues. It led efforts to obtain the warning label on alcoholic beverages and nutrition labels on foods.

[45] Letho and Miller, 1988: Alcohol & Alcoholism Vol. 32, No. 3, pp. 251-257, 1997 Israeli Arab and Jewish Youth Knowledge and Opinion about Alcohol Warning Labels.

[46] Statement by Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Jan. 9, 2002

There was no suggestion that pictorial images be tried.

**It is not unreasonable to expect that a rotation of well-designed, graphic warnings about the effects of alcohol during pregnancy could be effective in Australia.**

**Q.9. "What wording ...would be appropriate..to raise awareness in pregnant women..?**

- Alcohol is toxic to your unborn child.
- Heavy drinking during pregnancy may cause a miscarriage, or organ damage..
- Even one or two drinks during pregnancy can cause brain damage.
- You don't know what damage alcohol will cause to *your* baby. Every person is different.
- Damage to the unborn caused by alcohol lasts a lifetime.
- Alcohol can damage your child's brain before it's born.
- What's so cool about a brain-damaged baby?
- 60% of ADHD is caused by alcohol damage to the brain before birth.
- Alcohol enters the breastmilk. It can reduce your milk supply, and make your baby irritable..[47]

(Although Application A576 is for warnings about drinking during pregnancy, a warning to nursing mothers is a legitimate extension of this, in line with Draft NHMRC Guidelines.)

The wording needs to be in large, bold type, and in sharp contrast with the background colour, in a large framed inset.

**Q.12. What % by volume should be used to determine which alcoholic beverages are to carry an advisory statement, if required?**

As there is no known threshold for harm, any amount of alcohol should carry a warning.

**Q.13~14. What is the likely impact..if the *status quo* is maintained/if an advisory statement is required?**

1. a) If the *status quo* is maintained, the liquor trade will continue to flourish at the expense of an increasing number of brain/organ-damaged children and adults in our society...Our hospital crisis will be aggravated, as will the problems of DoCS, and education and other services.

b) Failure to warn pregnant women of the dangers of alcohol could leave the industry open to legal challenge by parents of FASD children, as is happening in Europe.

2. If well-designed advisory statements are implemented,

**a) the consumers' "right to know"** will be partially met, and many children and their families will be spared the costs, pain and frustration of FASD. Considering the enormous harm caused by alcohol, including harm to the unborn, requiring the labelling of alcoholic beverages with warning statements is actually **in perfect accord with "objectives for standard-making"** listed in Section 10 of the Australia New Zealand Food Authority Act 1991: "the protection of public health and safety; provision of adequate information relating to food, to enable consumers to make informed choices and prevent fraud and deception...".

The "fraud and deception" in this case lies in advertising health benefits which, even if real, can be obtained more safely from fruits, vegetables and exercise, and in the failure to warn that alcohol, even at moderate levels, can cause FASD, cancers, high blood pressure, cirrhosis and addiction.

**b)** As pointed out in the IAR, all consumers could see the labels, and this may foster discussion of the issue in the broader community. This would be a highly desirable outcome, especially if more parents discouraged teenage daughters from drinking, and at least some boys desisted from luring girls to drink alcohol in order to have sex.

Warning statements alone may not be effective in reducing risky consumption, but they do influence waverers, especially if as part of a broader strategy promoting the benefits of a lifestyle free of alcohol and other artificial stimulants. With children as young as 10 being admitted to the Odyssey House rehabilitation program for alcohol dependence, and the average age at which they first try drugs (particularly alcohol and cannabis) down to 12~13 years, it is clear that they are needed to help steer **people of all ages** away from alcohol, which is not only harmful in itself, but is also the pathway to other drugs.[48]

**c) Warning labels** would be more effective if advertising of alcohol were banned, "harm

[47] from NDARC website - Pregnant women ignoring drink dangers. 12/02/2007. ABC News Online http://www.abc.net.au/news/newsitems/200702/s1845510.htm)

[48] *Sydney Morning Herald,* p.1, 18/12/07

minimisation" gave way to zero tolerance for underage drinking and illicit drugs, and "responsible drinkers" acknowledged that their example was an encouragement to resort to artificial stimulants. In its booklet *"Our Strongest Defence Against the Drug Problem"*, the Commonwealth Government advises parents to "acknowledge that illicit drugs are dangerous" and to tell them that they would not use them now (p.13). Why not acknowledge also that use of the legal drugs (alcohol and tobacco) causes the most harm, misery and death?

**d) Impact on industry and trade:**

**i)** In its Final Report on A359, ANZFA stated "The costs to industry of labelling alcoholic beverages are not expected to be high". The cost of re-labelling existing stock would be a tiny fraction of profits.

**ii)** The wine industry would do well to promote the production and sale of non-alcoholic grape juice - especially purple grape juice with the seeds and skins, which has been shown to be an effective anti-coagulant [49] but at present has to be imported from USA, and is often unavailable.

**iii)** Australia is laggiing in its responsibility to warn overseas consumers, and should not seek to improve its balance of trade at the expense.of their health. Health advisory statements would improve our reputation for fair trade, but failure to adopt them could leave the industry open to legal challenge, as in the tobacco industry.

**iv)** Has WTO challenged USA over its warning labels? Has Australia ever challenged USA?No. Has any international crisis ensued from the adoption of labels by France?

In view of the following report from the UK News Group, European countries are not likely to challenge Australia, should warning labels be adopted, even if the EU Commission fails to take the initiative:

"According to WHO, some 600,000 Europeans die every year from alcohol-related problems. This costs EU members €200 billion (US$253 billion) annually. However, Europe is about to turn a corner in its alcohol policy. Since Master spoke of the need for governments to warn their citizens of the destructive effects of alcohol (January 2006, Magazine 164), the European Community has called on its member states to consider imposing health warning labels.

A report released in June by the Institute of Alcohol Studies declared that all alcoholic products should carry health warnings. This report was funded by the European Commission in order to analyze alcohol's effect on the social, economic, and physical well-being of Europe. It says that **the harmful effects of alcohol should be described on the labels of alcoholic products.** Also, product packaging, labeling, and advertising should be regulated to avoid false impressions of the physiological effects of alcoholic beverages. Reducing drinking through early education and public awareness programs are recommended. The report also argues that a decline in the consumption of alcohol will not necessarily lead to job losses, and may not even lead to drastic changes in affected sectors such as restaurants and bars. These positive recommendations will be taken into consideration by the EU Commission in September, when it develops a new alcohol policy in its Communication on Alcohol and Health."

## Q.15 Relative Cost-effectiveness

Warning labels, designed to catch the eye and maintain interest with a changing stream of informative messages on the effects of prenatal exposure to alcohol, would be by far the most cost-effective single measure, but certainly need to be backed up by information in the school curriculum and media messages.

The cost would and should be borne by the industry that produces the harm and makes the profits. Any resultant rise in the price of alcoholic beverages may help to reduce demand, which would be a further benefit for our society.

[49] 1. Durak I, et al. Comparison of antioxidant potentials of red wine, white wine, grape juice and alcohol. Current Medical Research and Opinion, 1999; 15(4):316-20. 2. Increase in Antioxidants, Decrease in Free Radicals Identified as Likely New Mechanism of Action for Purple Grape Juice Benefits. Science Daily, June 14, 2001. Available online at: http://www.sciencedaily.com/ releases/2001/06/ 010612065525.htm. Accessed February 9, 2006. See also Attachment A(f).

## CONCLUSION

Research has well established, and the Initial Assessment Report by FSANZ recognises, that heavy prenatal alcohol exposure leads to neurobehavioral impairment, and can cause full FAS. While the effects of lower levels of alcohol exposure are not as clear, **many of the problems linked to FAS also seem to exist in children whose mothers drank moderate amounts of alcohol when pregnant.** These problems include deficits in general intellectual functioning, visual-spatial reasoning, attention, and academic achievement on all memory tasks evaluated.

These conclusions, should be enough for anyone who cares about the welfare of unborn children, to abstain from alcohol when pregnant, or from offering alcohol to anyone who is, or could soon become pregnant. "Dangerous levels" are not always defined, but **in the absence of a clear threshold**, it is the clear duty of FSANZ to warn potential mothers (and fathers) of the burdens they can lay on the child, and on themselves and society, if they indulge in alcohol during pregnancy.

Drug Awareness (N.S.W.) therefore urges the Board of FSANZ to endorse the ALAC Application A576, and **adopt Option 2: "Amend the Code to require a health advisory label on alcoholic beverage containers, advising of the risk of consuming alcohol when planning to become pregnant and during pregnancy".**

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ATTACHMENTS

A. ALCOHOL AND HEART DISEASE

The liquor industry opposes warning labels, saying that pregnant women should not be deprived of the "proven" health benefits of a glass/day of red wine or beer, to get the antioxidants that prevent coronary heart and vascular disease, although these antioxidants are not in the alcohol but in the grape skins and seeds, or in the barley, as well as in tea, fruit, vegetables and whole grains. **They ignore the damage to the cardiovascular system and other organs:**

**1.** In an extensive review of the effects of alcohol on the cardiovascular system, Freidman (1998) concluded that the ingestion of **one to two drinks** can affect heart rate, blood pressure, cardiac output, myocardial contractibility, and regional blood flow. He noted that although these actions generally are not considered to be clinically important, **in the presence of cardiovascular disease they might result in transient unfavourable changes in haemodynamics.**[50]

**2)** In 3.2, p.29 of NHMRC Draft Guidelines, Dec.2007, it says: **"low levels of alcohol raise HDL and reduce plaque accumulations in arteries.**, and in Additional Health Advice and Precautions (p.70) it says: "it also has a mild anti-coagulating effect..." However, the President of the NSW Heart Foundation, cardiologist Lynne Pressley, is reported to have said that while alcohol's anti-clotting properties might explain why even light drinkers had a lower risk of heart attack than teetotallers, **alcohol's impact on cholesterol levels (and therefore, plaque) "only kicks in at higher levels of consumption.** Heart patients who had not previously used alcohol should not start drinking".[51]

**3)** "Health benefits" - especially for CHD - have been consistently presented as "proven". But according to **Dr Gerald Shaper**, Emeritus Professor of the Royal Free and University College Medical School, London, **"there ought to be a debunking of the 'benefits' of alcohol.** [Doctors] should be very careful of advising people to start drinking 'because it is good for them'. The popular wisdom that moderate drinking, particularly of red wine, can help people's overall health, interferes with the message about the risks of alcohol".

Prof.Shaper **questioned whether even the reduced risk of heart disease was due to alcohol**. Men who moved from not drinking, or taking the occasional drink, to more regular drinking in middle age tended to have had better lifestyles when younger. The research is reported in the medical journal *Heart*.

**"Alcohol inhibits blood clots only at high levels in the blood - high enough to cause intoxication"**, according to Jane Freedman M.D, Asst. Prof. of Medicine and Pharmacology. "In addition, platelets in **purple grape juice** released 55% less superoxide...a free radical...which quickly inactivates the beneficial effects of nitric oxide." Grape juice also contains the flavonoid Quercetin, which inhibits platelet activity. Table grapes can be as good as wine for the heart. Purple grape juice concentrate was declared to have this effect at the American Heart Association's 71st Scientific Sessions in 2002.

**4)** After an extensive review of the research literature pertaining to alcohol and heart health, researchers at Heidelberg University, recently warned that a regular daily administration of alcohol should **not** be recommended and that educating the public that alcohol be used as a coronary therapeutic agent would create more damage than benefit. They concluded that any recommendation for alcohol to be used as protection against heart attack and ischemic stroke has the potential to cause damaging effects on various other organs.[52]

**B. Low~moderate Prenatal Alcohol Exposure (PAE) Surveys**

**1. Avaria MD; Mills JL; Kleinsteuber K; Aros S; Conley MR; Cox C et al. Peripheral nerve conduction abnormalities in children exposed to alcohol in utero.** [53] Objective: We performed a longitudinal study of nerve conduction velocity to determine the effect of prenatal alcohol exposure on the peripheral nervous system. Study design: We studied 17 children exposed **to >2 oz** of absolute alcohol/day prenatally and 13 unexposed children, identified prospectively from a cohort of pregnant women screened during prenatal care. Nerve conduction assessment was done

[50] Single et.al: Evidence Re Low-Risk Al Consumption 1999.

[51] *SMH* 17-11-05.

[52] Meier P. and Seitz HK, 2006, "Effects of alcohol. Besides its harmful health impact, are there any positive aspects of chronic alcohol consumption?" Med Klin Munich, Nov.15;101(11): pp891-7.

[53] *Journal of Pediatrics* 144(3): 338-343, 2004. (14 refs.)

on the median, ulnar, peroneal and tibial nerves during the newborn period and between 12 and 14 months of age. **Results** At both assessments the alcohol-exposed subjects had significantly slower ulnar motor nerve velocity (P =.007), smaller proximal (P =.018) and distal amplitude (P =.051). They also showed reduced tibial nerve velocity (P =.06) and a decrease in distal amplitude. Conclusions: This study demonstrates that prenatal alcohol exposure is associated with abnormalities in nerve electrical properties, and that the pattern is different from that.seen in adults. Electrophysiologic abnormalities in peripheral nerves should be added to the problems found in children of alcohol abusing mothers.

**2. Huizink AC; Mulder EJH. Maternal smoking, drinking or cannabis use during pregnancy and neurobehavioral and cognitive functioning in human offspring (review).**[54] Teratological investigations have demonstrated that agents that are relatively harmless to the mother may have significant negative consequences to the fetus. Among these agents, prenatal alcohol, nicotine or cannabis exposure have been related, to adverse offspring outcomes. Most studies have focused on prenatal exposure to heavy levels of smoking, drinking or cannabis use. Few recent studies have paid attention to **low or moderate levels of exposure to these substances. This review** endeavors to provide an overview of such studies, and includes animal findings and potential mechanisms that may explain the mostly subtle effects found on neurobehavioral and cognitive outcomes. It is concluded that prenatal exposure to either maternal smoking, alcohol or cannabis use is related to some common neurobehavioral and cognitive outcomes, including symptoms of ADHD (inattention, impulsivity), increased externalizing behavior, decreased general cognitive functioning, and deficits in learning and memory tasks.

**3. Willford JA; Leech SL; Day NL. Moderate prenatal alcohol exposure and cognitive status of children at age 10.** [55]

Deficits in general intellectual ability in children with **low to moderate PAE are less well understood**.[than with heavy exposure]. The objective of this study was to assess the association between moderate PAE and cognitive ability in children at age 10 controlling for other prenatal and birth factors, maternal and child psychosocial factors, and environmental characteristics. Data were collected as part of the Maternal Health Practices and Child Development Project, a prospective study of prenatal substance use with 636 mother-child pairs. Women were assessed during each trimester of pregnancy and with their children at birth, 8 and 18 months, and 3, 6, and 10 years. Each phase included an evaluation of growth, development, cognitive, and psychological functioning. At age 10, cognitive ability was assessed using the composite score and verbal, abstract/visual, quantitative, and short-term memory area scores of the Stanford-Binet Intelligence Test, fourth edition. Maternal intellectual ability, maternal prenatal and current drug use, maternal and child psychosocial characteristics, demographics, and home environment were included in the analysis. A significant relation was found between alcohol exposure during the first and second trimesters and the composite score of the Stanford-Binet for African American children at age 10. Significant relations were also found for the verbal, abstract/visual, and quantitative subscales. Additional predictors of IQ at age 10 included mother's IQ, home environment, and child's report of depression. **There is a significant association between PAE and cognitive ability at age 10 among African American offspring.** There was no relation between PAE and scores on the Stanford-Binet scales among the Caucasian offspring.

**4. Willford JA; Richardson GA; Leech SL; Day NL. Verbal and visuospatial learning and memory function in children with moderate prenatal alcohol exposure.** [56]

This study investigated the effects of moderate PAE on learning and memory in 14-year-old adolescents. The Children's Memory Scale was used to assess learning and memory function in the verbal/auditory and visual/spatial domains. In addition, both short- and long-term memory function were assessed. Methods: Data were collected as part of the Maternal Health Practices and Child Development Project, a longitudinal study including 580 children and their mothers. Women were assessed during each trimester of pregnancy and with their children from birth to 16 years of age. At age 14, memory function was evaluated using the Children's Memory Scale, an assessment tool that measures learning and immediate and delayed memory function in the verbal

[54] *Neuroscience and Biobehavioral Reviews* 30(1): 24-41, 2006. (155 refs.)

[55] *Alcoholism: Clinical and Experimental Research* 30(6): 1051-1059, 2006.(Copyright 2006, Research Society on Alcoholism.)

[56] *Alcoholism: Clinical and Experimental Research* 28(3): 497-507, 2004.Copyright 2004, Research Society on Alcoholism.

and visual-spatial domains. Results: PAE during the first trimester predicted deficits in learning, short-term memory, and long-term memory, specifically in the verbal domain. **Conclusions:** Results demonstrated that PAE led to deficits in encoding processes as indicated by deficits in verbal learning. Initial deficits in acquisition were responsible for deficits in immediate and delayed recall of verbal information in children who were exposed to alcohol during pregnancy but did not have FAS.

**5. Offspring Effects of Prenatal Alcohol Exposure from Birth to 25 Years: The Seattle Prospective Longitudinal Study** Ann Streissguth Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine. **Published online:** 30 June 2007. Approximately **500 offspring exposed to a range of alcohol levels** were examined on 11 occasions between day 1 and 25 years. Neuropsychological and neurobehavioral performance measures are correlated with prenatal alcohol dose, without substantial confounding by socio-demographic or rearing conditions, smoking, nutrition, or other drugs. Deficits in attention, arithmetic skill, spatial-visual memory, and IQ, as well as increased alcohol problems and psychiatric disorders are among offspring outcomes correlated at several ages with maternal drinking during and before pregnancy recognition.

**C. Alcohol and Cancer**

**1**.The Salvation Army booklet on alcohol: *The Facts – Binge Drinking & Alcohol Abuse* warns on the danger of breast cancer, which is particularly relevant for women who are pregnant or planning a pregnancy. 1 drink/day associated with 11% increase in breast cancer (1994 study); higher risk than with tobacco . 30~40% higher risk with 30 gm/day (NSW Cancer Council).

**2** In 2006 the International Agency for Research on Cancer estimated that worldwide, there were about 389,000 cases of cancer attributed to drinking alcohol each year, resulting in around 233,000 deaths. Among women, breast cancer comprised 60% of alcohol-attributable cancers[57] .

**3. Drinking during pregnancy has been linked to childhood leukemia.** Researchers in France have found a significant association between any maternal use of any alcoholic beverage, versus abstinence, with childhood acute lymphoid leukemia, and acute non-lymphoid leukemia. Maternal **smoking** is not significantly associated with childhood leukemia (Richard Saitz, MD MPH, and Rosanna Guerriero MPH, Boston University Medical Campus, May-June 2006). (Experiments on rats. also indicate that women who drink moderate to high quantities of alcohol during pregnancy could be contributing to an increased risk of cancer in their daughters (AARC News Release, alcoholism.about.com, Apr.2004).

[57] Boffetta P, Hashibe M, La Vecchia C, Zatonski W, Rehm J.,2006, . "The burden of cancer attributable to alcohol drinking." *Int J Cancer*. 2006 Aug 15;119(4): pp 884-87