

Dear Dr von Eschenbach

We are the Swedish couple - drs Ulf and Birgitta Jonasson – “experts on Propoxyphene” - and we are two of four signers of the Public Citizens petition to FDA about banning Darvon. We would like to add some more information and background about Propoxyphene or Dextropropoxyphene (DXP) as we call the substance in Europe.

Our background: We have written and published eight scientific articles about (DXP) . After that, we wrote and defended two doctoral dissertations – in 2000 and 2001. To get the academic results known outside the academic world we wrote a popular science version of our research. The book was also translated into English and the title was “ Fatalities due to use or misuse of painkiller”.

Main results: Our main-result was that 200 persons were poisoned to death every year during the investigated years **1992-1999 (eight years)** – where DXP caused or contributed to the death. During these years the population of Sweden was about 9 million inhabitants. There were 1 572 fatal deaths in the medico legal world during 1992-1999 where DXP caused or contributed to the death during the 8 years. During the years **1992-1996 (five years)** there were 956 fatalities due to DXP and the manner of death was recorded as **accident** in 49 cases (**5 %**), **suicidal** in 542 cases (**57%**) and **undetermined** in 365 cases (**38 %**).

We also publish a follow up study. You will find a summary here <http://www.rmv.se/pdf/dxp-summary.pdf> and the report: <http://www.rmv.se/pdf/dxp-report.pdf> The follow up-report was about the years 2000-2002 and was published 2004. The report was written on behalf of National Board of Forensic Medicine, Medical Product Agency in co-operation with National Social Insurance Board and Swedish Poisons Information Service – all in Sweden.

Consumption of DXP. Thanks to INCB - The International Narcotic Control Board in Vienna – we have figures on the consumption of DXP since 1982 for some countries; US, UK, France – they are big consumers - and Sweden, Norway and Denmark – all three have restrictions when DXP is to be prescribed. We have all the countries in the world from 1995 – 2003 http://www.incb.org/pdf/e/tr/nar/2004/narcotics_part4_tables.pdf (US-figures at page 219, or nr 60 of 116 are from 1999 to 2003, the rest of the figures I have from a special e-mail)

The US figures are as follows: From 1982 – 2003 (22 years) US consumed **1 921 915** kg DXP. It makes **87 360** kg/year. If we compare – with Sweden - the years 1982 - 2003, the consumption was **47 170** kg, that makes **2 144** kg every year.

Some “**Golden standards**” for Sweden: According to our research 1 592 persons were poisoned to death - where DXP caused or contributed to the death - during the investigated years 1992-1999 (**eight years**). That makes 199 fatalities per year. During the same years the consumption of DXP in Sweden was totally **19 154** kg, that is **2 394** kg every year. If you say that these **2 394** kg/year caused **199** fatalities, it “took”**12,03** kg for every fatalities.

If it “took” 12 kg of DXP for every fatalities in Sweden, maybe it also “took” 12 kg DXP for every fatalities in the US. The consumption – during the years 1982-2003 was **1 921 915** kg, and we divide that with 12 kg = **160 160** persons. That is 7 280 persons every year that were poisoned to death. Do you know anything that would contradict this statement? I think the American people and the Swedish people in many ways are quite the same. If we use the Swedish figures as “**Golden standards**” and compare them with some other countries you will get some interesting figures: This time I compare the years 1996-2000. You get the quota = DXP kg (the average consumption during the years 1996-2000)/population x 100.

Sweden – average consumption in kg – **2 847** kg, quota – **32.0** and **fatal deaths per year 200**. Norway – 394 kg – 9,0 – 28 fatal deaths, Denmark – 349 kg – 6,6 – 24 fatal deaths, UK –

49 641 kg – 100,7 – 3 452 fatal deaths, France – 44 940 kg – 76,4 – 3 151 fatal deaths and finally **US 101 687 kg, 37,1- and 7 136 fatal deaths**. There are different ways to estimate the fatal poisonings in different countries. We have all figures for Sweden, and we have two figures for the other countries. It needs a simple equation to get the third number.

More US-figures: In the case above mentioned, I have figures from the years 1982 – 2003. I do know that the consumption of Propoxyphene probably was the highest during the mid 60th, but I do not have those figures . During these years Propoxyphene drugs were the most sold in the whole of US.

In the report **Propoxyphene – Oversight**, Hearing before the Subcommittee on health and the environment of the Committee on Interstate and Foreign Commerce House of Representatives, ninety-sixth congress, May 21, 1980. Serial No.96-80. In this hearing Dr Sid Wolfe from Public Citizen was one witness and he mentioned among other things that 11 000 death in the US since 1972 (to 1979 or 1980). 11 000 fatal deaths in 8 or 9 years, that makes 1200 – 1350 every year. In 1982 the consumption of DXP in the US was 47 812 kg, and that increased to 110 041 kg in 2002, 2,3 times more. Maybe the fatalities could be 2,3 more – 2760- 3100 per year.

There are quite different medico legal systems comparing Swedento US. How could we trust the Swedish figures and not the American in this research.

The most important thing is the organisation of the medico legal system in Sweden compared with US. We have fresh, updated data in Sweden, we have studied the problem since 1993, nobody has studied in the way we do in the US. I have been told there are no data at all from the last years about propoxyphene in your country. The circumstances are not there to find important data in your country.

In Sweden we have just **one law for the whole medico legal organisation**. And this includes all the **four branches** of the medico legal world; the forensic medicine, the forensic toxicology, the forensic psychiatric medicine and the forensic genetic medicine. In the forensic medicine world in Sweden all doctors are MDs, almost everyone has a PhD, and to be a specialist in medico legal medicine you have to have 3-5 years of special training.

When a person dies - so to say outside the hospital - or the cause of death is unknown, you will be transported to one of the six medico legal stations in the country – and an autopsy will be done. Even more important is that **a blood sample is taken** on 95 per cent of the dead persons – and this blood-sample **screens for all legal drugs** – like propoxyphene - and even illegal drugs if the police or the district attorney wants that. This is why we find DXP in Sweden. It is quite simple with one law for the whole medico legal things.

In US you have two different systems – as you well know, the **coroner system** and the **medical examiner system**. There are about 60 per cent with the coroner system, and the coroners are more like investigators – no MDs. With all respect for all skilled medical examiners, they are MDs, but most of them are not PhDs and just some of them have special training for medico legal purposes.

The coroner system and the medical system in US are based on State-laws, that differs a lot between many states, and the most import thing is that the power to test a blood samples is decided on county-level and there are some 3 200 counties in US. And **if** you by some reason take a blood sample, you are mostly not looking for propoxyphene. Of the states with a coroner system, they are elected in 21 states, only 4 states requires the coroner to be a physician, 7 requires certain limited training. Today only 300-400 forensic pathologists employs full time in the US today. Only about 30 are specialists in forensic pathology. Today 38 states have some form of medical examiners system in state, county or district

In this special DXP-case, I think that the Swedish – and partly even Norway and Denmark –

have a very good organisation of the medico legal systems. In our system we find lots of things in the blood samples-that you do not find in your country.

To put it short. We am quite convinced that you don't find the problem - propoxyphene in the blood samples – in your country and that's very sad. If we look at the consumption - figures from INCB – that is an organisation within the WHO, it is easy the see what this drug does to people I do hope you will get some more understanding to the Swedich data that we present, and we do hope this will help you to a decision about banning propoxyphene.

Kind regards

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