NURIA O'MAHONY
(HOLISTIC ACTION GROUP / MINDFREEDOM IRELAND)

EXECUTIVE REPORT FOR THE OIREACHTAS SUBCOMMITTEE FOR HEALTH

MAIN CONCERNS TO INVESTIGATE REGARDING THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY IN THE ISLAND OF IRELAND.

ABSTRACT

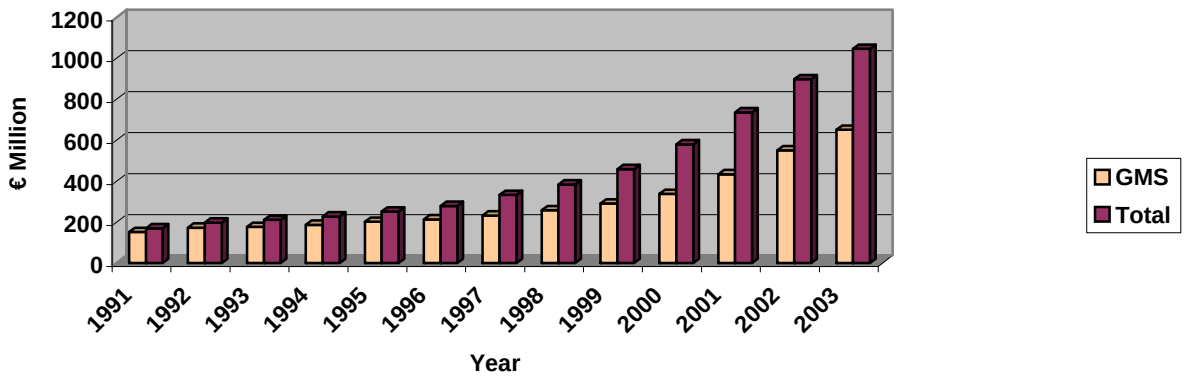
THE EXTENSIVE UNNECESSARY USE OF DRUGS IN THIS COUNTRY IS CAUSING MORE HARM THAN GOOD. THE "MEDICALISATION" OF SOCIETY IS NOT IN ITS BEST INTEREST & IT IS UNSUBSTAINABLE. THE BELIEF THAT EVERY PROBLEM REQUIRES MEDICAL TREATMENT IS FALSE. THIS OVERUSE CAN CAUSE DISTRESS, ILL-HEALTH, HOSPITALISATION AND EVEN DEATH. AN EFFECTIVE REGULATORY REGIME TO ENSURE THAT THE PHARMACEUTICAL INDUSTRY WORKS IN THE PUBLIC INTEREST IS ESSENTIAL. UNFORTUNATELY, THE PRESENT REGULATORY SYSTEM IS FAILING TO PROVIDE THIS. THE INTERESTS OF PHARMACEUTICAL COMPANIES AND THOSE OF THE PUBLIC, PATIENTS AND THE NHS OFTEN OVERLAP BUT THEY ARE NOT IDENTICAL. THE CONSEQUENCES OF LAX OVERSIGHT IS THAT THE INDUSTRY'S INFLUENCE HAS EXPANDED AND A NUMBER OF PRACTICES HAVE DEVELOPED WHICH ACT AGAINST THE PUBLIC INTEREST. INAPPROPRIATE PRESCRIPTION OF MEDICINES BY GENERAL PRACTIONERS IS OF PARTICULAR CONCERN.

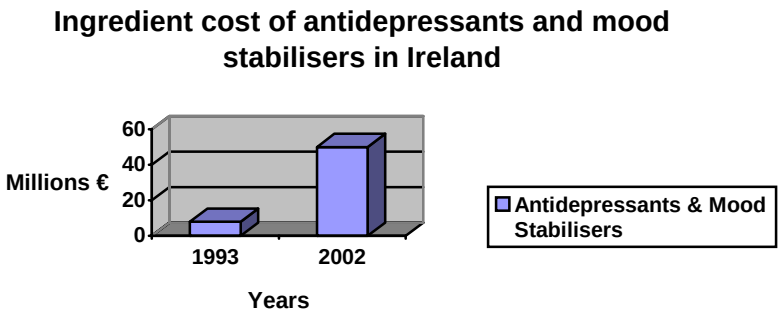
EXPENDITURE ON MEDICINES IN IRELAND

State expenditure on medicines in Ireland under the Community Drugs Schemes was approximately €943 million in 2003, a 15% increase as compared with the year 2002. The 15% increase in 2003 was the **7th consecutive year** with a double digit increase, a growth rate amongst the highest in Europe. The drug inflation in Ireland is running at 8 times the European average for the past 3 years (2001-2003). Expenditure on medicines in Ireland has increased over 4 fold during the 10 year period 1993 – 2003. Increased volume of prescribing, the prescribing of newer more expensive medicines and changes to the community drugs schemes have all contributed to this increase.

Analysis of the GMS scheme demonstrates the number of eligible persons has fallen by 9% from 1,274,621 (35.77% population) in 1993 to 1,158,143 (29.57% population) in 2003. However the **32.2 million prescription items issued in 2003** (GMS only figure) represents an approximate 2 fold increase over the 10 years. Despite the price freeze on medications since 1993 the influence of product mix is seen as the cost per item prescribed also increased by 2 fold over the decade. Total prescriptions items issued in 2003 (GMS, DP & LTI schemes…not including hospitals prescriptions) were **43.15 million** with the **overall cost** to the government and consumers of **€1.326 billion in 2003.** *The ingredient cost for antidepressants and mood stabilisers in Ireland in 2002 was* ***€50 million,*** *an increase of* ***€42 million*** *since 1993 (in 9 years* ***an increase of 84%!!!****).*

Drug Expenditure under the Community Drugs Schemes in Ireland from 1991-2003

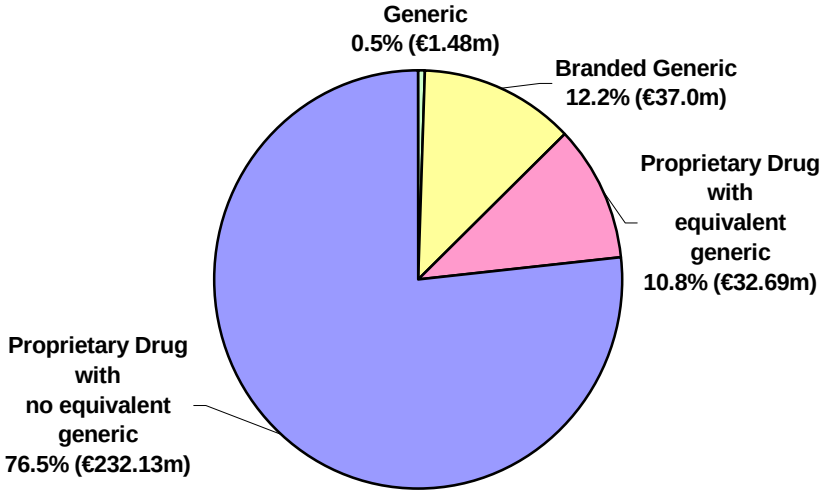




Scale of fees payable to participating pharmacists under the DPS as at 31/12/2003

Standard dispensing fee	€2.59
+	
Ingredient Cost of drug e.g. pravastatin 40mg/day x 28days	€54.29
+	
50% mark up on ingredient cost	**€27.15**

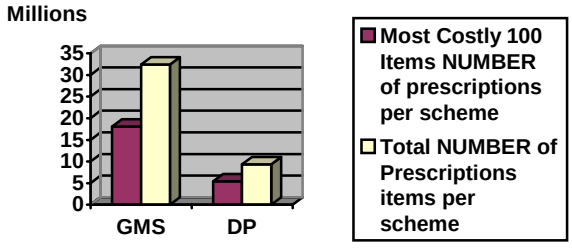
The percentage of the ingredient cost spent on generic items on the GMS in 2001

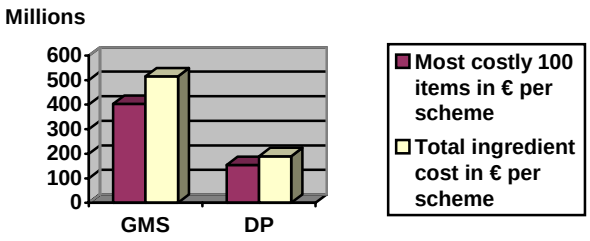


Estimated savings from substitution of omeprazole and simvastatin in 2003 on the GMS scheme

	Cheapest generic equivalent	Potential savings from generic substitution
Omeprazole	Lopraz ®	€6.8 million
Simvastatin	Simzor®	€0.88 million

From the GMS top 100 most costly items list: 1-Clinical Nutritional Products 2-Pravastatin 17-Citalopram 26-Paroxetine 29-Sertraline 33-Fluoxetine. From the GMS top 100 most prescribed items list: 1-Aspirin 13-**Diazepam** 34-**Temazepam** 42-Citalopram 62-Paroxetine 68-Fluoxetine 98-Sertraline. From the DP top 100 most costly items list: 1-Atorvastatin 14-Citalopram 15-Sertraline 16-Paroxetine 25-Fluoxetine. From the DP top 100 most prescribed items list: 1-Aspirin 22-Citalopram 31-Paroxetine 33-**Diazepam** 39-Fluoxetine 45-Sertraline. Making the SSRI antidepressants more commonly prescribed in the Drug Payment scheme than the General Medical Services scheme in 2003. The **SSRIs** (excluding Fluvoxamine –not available figures- and including Venlafaxine) total items **1.075 Million** at an ingredient cost of **€38.274 Millions** for 2003. The second **HIGHEST** cost category was drugs acting on the nervous system **€189.59 Million** in 2003. The most costly 100 items in the GMS scheme ingredient cost in 2003 was €402.50 Millions (78.28% of total cost) and only represented 55.72% of all prescriptions for that scheme. The most costly 100 items in the DP scheme ingredient cost in 2003 was €154.59 Millions (81.35% of total cost) and only represented 58.35% of all prescriptions for that scheme. The World Health Organisation **ESSENTIAL DRUGS CONCEPT** implied that a **RELATIVELY SMALL NUMBER of IMPORTANT, OFF-PATENT DRUGS could MEET VIRTUALLY ALL HEALTH NEEDS**.





By changing the way GPs prescribe could save millions on NECESSARY drugs and reduce the overuse of UNNECESSARY drugs that in turn would save on their cost and the prevented drug-induced harm to those patients. No figures for the economic burden of drug-induced illness yet exist, but it is feared that it could amount to VASTS amounts. €800 million costs the State of Ireland for the suicides that took place in 2003 (By international measures of the loss of production as a result of a suicide, the potential future contribution to the economy of the person who dies and the human cost the individuals place on their lives) and €40 million annually for self-harm (Daniel Neville TD, Suicide Prevention Dáil statements / debate June 2005). So the overall cost of all drug-induced harm can be MASSIVE and most of it preventable. Drug reactions in hospitals **only**, may constitute either the **4th** or the **6th** leading cause of death behind heart disease, cancer & stroke (Lazarou et al, 1998).

ECONOMIC FACTORS

Ireland is the biggest pharmaceutical exporter in the world (€33 billion on 2003, 36% of total exports), GSK profit margin in 2000 = 56% sales $ 22209.5 millions 7% of global market, the pharmaceutical industry is responsible for 35% of the economic growth in Ireland, 19 pharmaceutical plants in Cork, 72 plants in Ireland, Ireland has the lowest corporate tax in the whole of the EU (figures obtain in 2004). Pfizer's Ringaskiddy complex in Cork is the largest Pfizer's production facility plant outside the USA. 1/3 of pharmaceutical companies budgets are spent on MARKETING, much higher than their RESEARCH & DEVELOPMENT allocation in the pharmaceutical budgets. Although the pharmaceuticals justify the high cost of their drugs on the cost of the research & development of new drugs, but they fail to mention the larger cost of the MARKETING of those drugs being responsible for such a high cost for their drugs. This needs to be limited as it is costing huge amounts of money and also it is causing huge amounts of unnecessary harm as a result.

The pharmaceutical industry continually complains about tougher regulation and competitive pressure, yet global sales of prescription drugs grew by 7% in 2004 toping $500 billion for the first time. Antidepressant medications rank **THIRD** in pharmaceutical sales worldwide, with $13.4 billion in sales last year alone. This represents 4.2% of all pharmaceutical sales globally. Antipsychotic medications generated $6.5 billion in revenue. This industry that employs 17000 people in Ireland (2005) accounts for €34 billion of the country's annual exports.

PHARMACEUTICAL INDUSTRY, DEPRESSION AND GP'S

Prime time programme survey in Ireland: over 30% of GPs believe they are not influenced by corporate hospitality but 60% believe their colleagues are influenced ("not me syndrome"). 22% increase on antidepressants sales a year between 2000 & 2002, 1.5 times as fast as the global growth over the same period. 1 in 10 adults were taking antidepressants in Ireland in 2002 (estimate 300000), 300000 people were claimed depressed in Ireland in 2002. These figures indicate that Ireland has nothing less than a hidden epidemic. Doctors (GPs and Psychiatrists) are not trained in psychotherapy/counselling. Even without knowing the full facts 70% of GPs had some concern about side effects. Although that did not prevent them from prescribing them, according to the Prime Time survey to a **new** patient complaining of 2 months of unhappiness, inability to enjoy everyday activities and a lack of energy (3 out of 5) against the NICE and WHO guidelines for the

treatment of depression. 14/15 GPs prescribed antidepressants and 1 prescribed an herbal preparation. Then the same patient went to another 15 GPs complaining of feeling down for 2 weeks. 8/15 prescribed antidepressants and 1 prescribed an anti-anxiety. To then let this patient walk out their surgery not to be seen again. UNACCEPTABLE!!!!!!!! Those medications were not required in the first place, the patients were not aware of the potential of the possible consequences of the adverse effects of these drugs, nor their families. The **unfamiliar** GPs have put them at risk of drug-induced harm, UNNECESSARILY, to then have NO FOLLOW UP WHATSOEVER.

In Ireland GPs are over-prescribing these tablets contravening the WHO/NICE guidelines for treatment of depression, especially mild depressions. When those same GPs have been kept in the dark of the full adverse effects of these drugs by the pharmaceuticals, which are the primary source of information for 50% of GPs. Pharmaceuticals are significant players in the continuing education of Doctors (dangerous). In the absence of Independent pharmacological information to doctors there is a need in my opinion to **STOP** the marketing of prescription drugs to doctors altogether or severely limit the quantity of material prescribers receive, particularly in the first six months after drug's launch. Less experienced and non-specialised doctors are ill-equipped to cope effectively with the promotional material and those people are the ones targeted in the first place. Stricter controls are needed in respect of drug company representatives' promotion of their products to junior doctors and to nurses or pharmacists with POTENTIAL prescribing powers in the near future. Corporate hospitality to Doctors is nothing else than bribery, both sides are naïve or even worse if they think it is not influential in both their lives. You only need to have a look at the expenditure of drugs in this country stated above and some of the figures for drug-induced harm. It is extraordinary that there are stricter controls on hospital specialists prescribing than on GPs. **The pharmaceutical industry has produced unrealistic inflated expectations about the benefits of their life-style medicines and other prescription drugs to reach mass markets for profit making, regardless of safety and playing down & dismissing the risks.** The Business practices of **ALL companies should RESPECT HUMAN RIGHTS** and not give rise to **INJUSTICE or SUFFERING…or even DEATH**.

The changing of the way GPs prescribe is detrimental and I do not accept that this is a difficult task to undertake. Pharmaceutical sales representatives have no problem changing the way MOST GPs prescribe THEIR drugs very fast indeed once the drug comes to the market. Education is the way and incentives (even a single pen does the trick for the reps!!!) to encourage change are essential. 70% of GPs are visited by pharmaceutical sales representatives several times a week in Ireland. 15% of GPs have attended purely social events sponsored by the pharmaceutical industry. This contravenes the rule of the medical council code of conduct that all pharmaceutical hospitality needs to be REASONABLE and SECONDARY to the main PURPOSE of the event for doctors (i.e. Educational). The limiting of the pharmaceutical industry influence on GPs in the form of sales reps must take place within other measures to achieve greater transparency so that medical practitioners, experts and the public can make an **independent assessment** of the evidence. The prescribing of drugs should be a LAST RESORT in most medical cases, not A FIRST CHOICE. The government needs to draw a clear line between industry and medicine to give back medicine the integrity that is required to be therapeutical, truthful and trust worthy beyond any vested interests and bribes. Essential ingredients for good medicine, if the medical organisations are not prepared to sacrifice this "hospitality and other incentives, including financial" in the interest of public health, the government should. This is not only limited to medical practitioners please examine the UK parliamentary report for more details. It also includes medical journals, patient groups, experts, associations, universities…and the list goes on unfortunately.

On the UK Health Committee Parliamentary report on the influence of the pharmaceutical industry in 2004-5, they heard allegations that clinical trials were not adequately designed –that they could be designed to show the new drug in the best light- and sometimes **fail** to indicate **the true effects** of a medicine on health outcomes relevant to the patient. They were informed of several

high-profile cases of **suppression of trial results**. They also heard of **selective publication strategies and ghost-writing**. The suppression of negative clinical trials findings leads to **a body of evidence that does not reflect the true risk:benefit profile** of the medicine in question. Guidance produced by NICE and others rely on the published evidence. If all the evidence is not published, or if negative findings are hidden, **accurate guidance cannot be issued and prescribers cannot make truly evidence-based decisions**.

Also looking into the recently released (-2006-, 5 years later) sealed psychiatric expert report by Dr. Peter Breggin written for Lacuzong v GSK lawsuit and signed as an affidavit in California in July 21, **2001**, this report documents how "the company SYSTEMATICALLY hid and manipulated data concerning Paxil/Seroxat/Paroxetine-induced suicidality in depressed **ADULTS**. It also documents how GSK hid the incidence of Paxil/Seroxat/Paroxetine-induced akathisia and stimulation. Akathisia and stimulation are risks factors for suicidality and violence. GSK failed to release its complete data concerning rates of suicidality on Paxil/Seroxat/Paroxetine. In the information that was originally provided to the FDA, **the number of suicide attempts on Paxil/Seroxat was UNDER-REPORTED** and **the number of suicide attempts on placebo was INFLATED**. The company also hid the stimulating effects of the drug that pose a potential risk for causing violence". Among the documented findings in Dr. Breggin's report " In a 9/6/94 letter from Sherry Danese to Michael Brennen at SKB, the company's promotional materials are again heavily criticized. This letter is particularly important because it demonstrates a SPECIFIC attempt on the part of SKB to **MISLEAD doctors** concerning the stimulant effects of Paxil. This directly relevant to the issue of murder and suicide, both of which can be related to the stimulating, agitating effects of antidepressants. From this material alone it can be concluded that SKB attempted to hide the dangers of Paxil in regard to stimulation and its adverse consequences of murder and suicide". In the letter, according to the FDA's criticism, SKB made the following statement: "Effective in treating anxiety and agitation associated with depression without inducing symptoms of arousal" This statement suggests that Paxil is not associated with side effects that might aggravate anxiety or agitation. To the contrary, **Paxil is ASSOCIATED with an 8.3% incidence of tremor, a 5.2% incidence of nervousness, a 13.3% incidence of insomnia, a 5.0% incidence of anxiety, and a 2.1% incidence of agitation**. Therefore this statement is **FALSE and MISLEADING**". Importantly, the FDA analysis also establishes the rudiments of a stimulant profile for Paxil, including the following symptoms: Tremor, nervousness, insomnia, anxiety and agitation. It also establishes that **Paxil can *CAUSE* or *WORSEN* "anxiety and agitation associated with depression"**. Note that **the rate for suicide attempts on Paroxetine approaches 1%** (table 1), which the FDA considers ***FREQUENT***. Also note that the rate for suicide attempts on paroxetine is **3.8 times HIGHER than for placebo** and **3.6 times higher than for the comparison antidepressants (tricyclics)**. Dr. Breggin stated: "The drug companies settle almost all legal cases brought against them in order to **SEAL incriminating scientific data**. *This deprives the FDA, medical profession and public of critical information on drug safety and efficacy.* The publication of a previously sealed medical expert report is a rare event –the first in my experience. The law should be changed to require drug companies to **PUBLISH ALL of the safety and efficacy data they generate in regard to their drug products**". See report for further details:

www.breggin.com/breggin%20paxil%20lacuzong%20report%20filed%20with%20court.pdf and www.breggin.com/courtfiling.pbreggin.2006.pdf

The fact is, the pharmaceutical industry giants –with tacit complicity by the government oversight regulatory body that has lost its way- are able to **CONCEAL the most damaging facts** about the products the IMB approves for wide marketing without so much as **FULL** disclosure of the hazardous risks. **Only the court provide a mechanism for getting at the truth, even though current laws allow defendant companies to keep documents sealed. It is strictly in the**

PUBLIC INTEREST to CHANGE THE LAW and open the documents to public scrutiny. By sealing relevant documents, a symbiotic relationship is formed: companies can **CONTINUE to engage in fraudulent marketing resulting in PREVENTABLE HUMAN TRAGEDIES**, and lawyers can get rich by suing multiple times for the same violations.

It is long past time for these companies who have become extremely **WEALTHY** at **OUR EXPENSE** to start **PAYING** their own way and **ACCOUNTING** for their **MISTAKES / RESPONSIBILITIES / FRAUD / NEGLIGENCE/HARM** (a very good example is the US pharmaceutical companies that contaminated lots of haemophiliacs -Hepatitis, HIV- in this country with their products KNOWINGLY and the minister for health is not holding them to account in the courts, although is costing the Irish Tax payer lots of money to look after these people and they continue to die with no justice being done). There is no doubt that if this were the case we would see **FAR FEWER** of these **DEADLY MIND ALTERING, BEHAVIOUR ALTERING, ADDICTIVE, CONTAMINATED DRUGS/PRODUCTS ON THE MARKET**. "Never before Prozac has a medication been so MISREPRESENTED by SO MANY PEOPLE for SO LONG in the ABSENCE of ADEQUATE DATA" (Dewan & Masand, 1991). From approval to October 1993 (6 years), 28623 complaints of adverse effects had been filed with the FDA (a figure higher than ANY OTHER DRUG in the history of the FDA), including 1885 suicide attempts and 1349 deaths and these figures represent anywhere from 1-10% of the actual figures as you are well aware (only around 1-6% are reported). No other drug, even the benzodiazepines in 20 years had the figures of ADRs as Prozac in 6 years only. But Prozac remains in the market with inappropriate warnings and used indiscriminately causing harm. I wonder what the figures are today including the rest of the SSRIs. Prozac has the distinction of having the most ADRs of any drug in history (Blake Tracy, 1994).

DEPRESSION, MEDICATION AND SUICIDES

The increase of these drugs goes side by side with the increase on psychiatric admissions to hospital (1/3 of them with depression) and the increase of length of stay per episode. Incidence of suicide and the prescription of antidepressants are increasing almost on parallel (Dr. D.Walsh, Primetime). The community population, free from depression, is at certain risk of suicide (certainly is not ZERO). Most of the depressions suffered in the community do not increase this risk of suicide because the only intrinsic risk of depression induced suicide is only applicable to the SEVERE depressions and according to the MHRA (General Practice Research Database) (Martinez, C 2005) that accounts for 3% of all the community depressions in the UK. The EXAGGERATED potential risk of suicide for ALL depressions has only one objective to make people afraid not to take treatment, that is medication, even though those medications have not been proved to reduce or prevent suicides, quite the contrary there are strong suspicions that may even increase this risk on all people who take them. On the seroxat patient leaflet you will find: *If it is not treated, your condition may not go away and may become more serious and more difficult to treat.* ***My comment: Your condition may spontaneously resolve as most of the time they do, especially in MILD to MODERATE DEPRESSION. "Affective disorders have a VERY HIGH RATE OF SPONTANEOUS REMISSION, provided SUFFICIENT TIME PASSES" (Baldessarini, 1980). Today, the impulse to prescribe is REINFORCED by a climate of FEAR; the nature and strength of it can be felt in the FEARSOME SIZE of the ESTIMATES made of the DANGERS of DEPRESSION.***

The unproven hypothesis of the serotonin imbalance in the brain causing depression came about from levels tested in **some** cadavers (dead brains) and blenderised **rat brains**. Although, the EMEA has come out with the difference between the live brain of a teenager, the live brain of an adult up to

30 and the live brain of an adult after 30 when it comes to Seroxat/Paroxetine adverse effects. The EMEA warning says if you are over 30 in Europe: "Tough! The powers that be have decided that YOU developed an immunity to neurotoxic adverse effects of meds at the stroke of midnight on your 30th birthday. This miraculous neurophysiological transformation was very recently believed by those governments and medicines regulatories bodies to have taken place on your 18th birthday. Prior to that again, and still not very long ago, governments believed (alongside the persuasive pharmaceutical industry) that there was no need whatsoever to invent any birthday miracle at all as this medication was SAFE and BENEFICIAL. So the current situation is that any akathisia and increased suicidal risk experienced only while on an SSRI (or in withdrawal from it) from the age 30 upwards has to be caused by something else...Under 30? Its the SSRI induced akathisia/agitation/suicidality, over 30 its....what?" It can only get better as the FDA and Health Canada warning covers all ages using a precautionary management rather than a risk management to protect their citizens from the dangers of SSRIs. Maybe we should consider doing the same in Ireland.

After the CLEAR FDA & Health Canada warnings regarding the increased risk of suicide in the ADULT population taking certain antidepressants including SSRIs, the article "Efficacy of antidepressants in adults" by Joanna Monchieff + Irving Kirsch in the British Medical Journal in July 2005 that concluded "*Recent meta-analyses show SSRIs have NO CLINICALLY MEANINGFUL ADVANTAGE OVER PLACEBO, Claims that antidepressants are more effective in more severe conditions have LITTLE evidence to support them, Methodological artefacts may account for the SMALL degree of superiority shown over placebo, Antidepressants have not been convincingly shown to affect the long-term outcome of depression or SUICIDE RATES and Given doubt about their BENEFITS and CONCERN about their RISKS, current recommendations for prescribing antidepressants SHOULD be RECONSIDERED"* & the latest study published on the 22/8/05 "Suicide attempts in clinical trials with paroxetine randomised against placebo" by Ivar Aursnes et al. that concluded "*PATIENTS AND DOCTORS SHOULD BE WARNED THAT THE INCREASED SUICIDAL ACTIVITY OBSERVED IN CHILDREN AND ADOLESCENTS TAKING CERTAIN ANTIDEPRESSANT DRUGS MAY ALSO BE PRESENT IN ADULTS. The data STRONGLY SUGGEST that the use of SSRIs is CONNECTED with an increased intensity of suicide attempts per year. The two meta-analyses and our contribution taken together make a strong case for the conclusion, at least with a short time perspective, that adults taking antidepressants have an increased risk of suicide attempts. We also conclude that the recommendation of restrictions on the use of paroxetine for children and adolescents recently conveyed by regulatory agencies* ***SHOULD BE EXTENDED TO INCLUDE USAGE BY ADULTS***".

All these studies, independent reports and Regulatory warnings leave us with no doubt that the present warning about paroxetine and the SSRIs dangers for the adult population in Ireland/EU is INAPROPRIATE. Also questions need to be asked about the way DEPRESSION is treated at the present time in the Island of Ireland and the consequences of those treatments to our people's health.

REGULATORS

The interest of Public Health is a declared benchmark for industry and regulators. Definition of Bias: Pattern of Technical inconsistencies consistent with one set of interest (INDUSTRY) rather than another (PUBLIC HEALTH).

Irish Medicines Board: Corporatist relations with industry, Improved communications with industry, Board member is an industry representative Anne Nolan CEO of IPHA, Reduced backlog and accelerated the licensing process to 45 weeks mean time for licensing new products, 6 staff out of 100 working in pharmacovigilance, not accountable to public, secrecy paramount, transparency none existent, first chairman Chief executive of IPHA, last CEO left for industry, present CEO comes from industry, 100% funded by industry (fee payment).

The present chief executive officer Pat O'Mahony has a background of past managerial posts in the pharmaceutical industry here and the UK, the past chief executive officer Professor Frank Hallinan left to the pharmaceutical industry (Wyeth Biopharma) this is a well known trend. Anne Nolan is an industry representative member (CEO of IPHA) out of 9 members…I am still awaiting representation in this board of management by my consumer representative member Breda Dooley.

The reality of drug testing and regulation:

1. Primary function of IMB = Licensing. *45 weeks for new product authorisations.*

2. Regulatory advisers may hold consultancies/shares in pharmaceutical companies.

3. The IMB is 100% funded by industry.

4. Tendency to accept practices that fall below established efficacy standards.

5. Tendency to erect very rigorous standard of causal inference regarding unfavourable post-marketing ADR data. *In Drug cases where commercial & health interests clash, regulatory agencies award the benefit of the scientific doubt to the manufacturer.*

6. Uneven reception of scientific papers.

7. Omissions and commissions of 'labelling'.

8. Permissive approach to conflict of interest of expert advisors to regulatory agencies. *Industry representative IMB member.*

9. Secrecy and lack of public accountability for regulatory decision-making.

10. Drug testing conducted/organised by institutions with commercial interests (75%).

11. Pharmaceutical companies frequently do not publish all their scientific studies.

12. Tendency to extrapolate positive efficacy, but not positive toxicity findings in animals to humans.

13. Tendency not to search for the most rigorous clinical safety testing regimes.

14. Tendency to question/deny the causal significance of unfavourable clinical trials data.

15. Re-writing of manuscripts prior to publication.

16. Secrecy provides a first line of defence for companies.

A regulatory agency, which began with the declared intention to regulate private industry in the public interest, it has come to serve the interests of the regulated industry instead.

The golden rule: Those who have the gold make the rules.

After trying very hard to obtain the following statistics, **the *ACCURATE* Number of Scripts, The Net Ingredient cost, and the Quantity of Medication (i.e. number of pills/millilitres) from the year of drug introduction in Ireland to 2004 for each dose concentration (20mg, 30mg, 40mg and liquid drug in mls in case of paroxetine...etc) and supplier for the following substances :- Paroxetine, Fluoxetine and Sertraline,** in the last year. Dr. Davida De La Harpe –Assistant Director of Population Heath- Health Intelligence in the Health Service Executive has confirmed to me in writing that the quantity of medication data is not available in this country. How can you regulate something (PRESCRIPTION DRUGS) when you cannot even trace them to find out how many people are taking them in the first place in this country???? Never mind tracing how many people are affected by their adverse effects to inform of the dangers on these drugs!!!! (Remember doctors report only 1-6% of adverse reactions).

3 questions spring to mind about the Irish Medicines Board (IMB):

1) What evidence does the Irish Medicines Board / Department of Health have that Irish doctors alone in the world diligently report 90- 100% of possible adverse and lethal effects of the drugs that they prescribe, when all other doctors in the world only bother to report between ZERO and 6% of adverse effects? This is acknowledged by all medical associations and is cited in medical articles worldwide.

2) If the Irish Medicines Board / Department of Health does not believe that Irish doctors behave much more responsibly than their colleagues worldwide, what pro-active steps has the Irish Medicines Board taken over the last 30 years to deliberately seek out the missing feedback that

would enable the Irish Medicines Board / Department for Health to make the correct regulatory safety decisions about drugs that induce lethal and serious adverse effects?

3) If the Irish Medicines Board / Department of Health does not know **how many people have ever taken a given prescription drug in Ireland** and if the Irish Medicines Board / Department of Health **does not proactively seek and demand feedback response from GPs** then it is evident that the **Irish Medicines Board / Department for Health has no idea of the extent of harm caused by the drug**. Therefore the Irish Medicines Board / Department for Health are incapable of any scientific evaluation of the drug safety. Therefore because drug usage and outcome is unmonitored in Ireland how on earth can the Irish Medicines Board / Department for Health conclude that any drug is safe?

The Irish Medicines Board **lack of transparency, accountability and lack of regulatory ACTION is obvious. After the scandals regarding MAJOR SAFETY PROBLEMS** –The SSRIs and Seroxat in particular & The COX 2 Inhibitors and VIOXX in particular- **I have to focus not only on the drugs involved, but also on the quality of the regulatory system and its relationship with the pharmaceutical industry.**

Consideration should be given to the establishment of post-marketing surveillance and drug safety monitoring systems **INDEPENDENTLY** of the licensing authority. As it could be a conflict of interest arising when the same agency is responsible for both pre- and post-marketing drug evaluation: if problems arise once a drug is on the market (highly likely), it might indicate flaws in the original assessment and require the regulators to examine **THEIR OWN EARLIER FAILINGS**. **A public inquiry should take place whenever a drug is withdrawn on health grounds** because of such cases typically leave behind victims injured by the drug or bereaved relatives of people who suffered **FATAL** reactions to the drug. The Federal Aviation Administration (FAA) in the US establishes the standards by which airplanes are built, licensed, and flown but when one plane crashes, a DIFFERENT organisation, INDEPENDENT of the FAA, steps in to investigate. The need for OBJECTIVITY demands it. Unfortunately, this is not the case with the regulators of medicines. In fact, not only does the same agencies conduct the investigations of adverse drug reactions….OFTEN the same individuals who APPROVED the drugs LEAD the investigations.

THE MEDICAL PROFESSION

"Trust me…. I'm a doctor"

Divinity, law and medicine. From the Middle Ages, they were the sacrosanct professions upon which universities were founded and reputations were made. For those who attained the elevated status graduation afforded, prestige, prosperity and, most abundantly, POWER, were guaranteed. In recent times, the not-so-divine sides to the holy men have been exposed and lawyers are beginning, albeit slowly, to feel a backlash against the money machine their services have become.

The medics, however, were always that bit extra special. They hold lives in their hands and nobody wants those hands to shake. Trust me, I'm a doctor, the profession commanded. And trust they were given.

Little wonder the Lourdes Inquiry report into the activities of obstetrician Michael Neary at Our Lady of Lourdes Hospital, Drogheda described the maternity unit there as "caught in a time warp". "We found an incredibly PERVASIVE culture of ACCEPTANCE and ACQUIESCENCE of

consultant activity. To ask WHY, or to COMMENT, was not a part of everyday practice. To consider that things could change seemed UNIMAGINABLE". It was against that backdrop that Neary got away with performing needless hysterectomies on scores of unsuspecting women, inflicting deep scars, both psychological and surgical, without anyone around him blinking an eyelid for 25 years. But this wasn't a dusty episode from the dark ages. This was in the 1970s, 1980s and, incredibly, the 1990s when the fallibility of the medical profession was obvious.

The Finlay and Lindsay tribunals would go on to hear of the mistakes and misjudgements that left mothers battling hepatitis C and haemophiliacs dying of AIDS. Since 1998, when Michael Neary was suspended from practice, the organ retention scandal has revealed post-mortem practices that were almost ghoulish in their clinical application and callous disregard for the respect of human remains and the feelings of grieving families. Also taking into account the selling of organs (placentas, gallbladders, pituitary glands, etc…) to the pharmaceutical / cosmetic industries by the hospitals who did so without consent.

The recent histories of Monaghan General and Cavan General Hospitals are riddled with difficulties and deficiencies, and staff who kept their heads down to avoid the worst of the crises even if it meant diverting their eyes from the patients in their care.

The Leas Cross controversy showed how vulnerable elderly citizens could suffer neglect and abuse in a State-approved nursing home that was supposed to afford them safety, comfort and medical care. Tellingly, an Oireachtas Committee during the first week of March was told that Mary Harney's recent, much-publicised survey on hand hygiene quizzed nurses, caterers and cleaners about their hygiene practices, but not CONSULTANTS. So is it still the case that the medical profession is all about the medics who control it and not about the patients who depend on it?

The comments of the president of the Medical Council, Dr. John Hillery were "There are issues of an **ETHICAL** nature as regards our **responsibilities** to patients and our **duties** to the profession that need to be addressed immediately". I would like to emphasize the use of his words….medics have *responsibilities* to patients and *duties* to the profession. I think their priorities are misplaced to say the least. As it showed when Dr. Neary was investigated by the Medical Council (by 3 Irish Consultants Obstetricians) and he was cleared from doing anything WRONG, even worse he was praised treating the victims in a manner that the same council had to apologise for, after a UK Consultant had to raise the alarm on Dr. Neary's practices.

Self-regulation does not work. It does not work for the Gardai force, it does not work for the pharmaceutical industry, it does not work for the Irish Medicines Board, it does not work for the alcohol drinks industry, it did not work for the catholic church in this country, it does not work either for the medical profession, Dr. Neary's case being a very good example. For the medical profession's integrity to be restored, we have the responsibility to uphold TRUTH and TRUST. This should include **full and honest disclosure** and investigation. This will support **unguarded and thorough knowledge regarding prescription drugs and their side effects, vital changes in law**, and a climate wherein patients, doctors, and pharmaceutical companies have reason to trust and respect each other. This is not the case today causing HARM.

All positions of POWER should be transparent, open to independent scrutiny, honest, truthful and trustworthy. In medicine is even more important as they hold lives in their hands, medicine will lose integrity and its therapeutic relationship with their patients if truth and trust is not paramount. It should be a privilege to hold such position in society and any abuse of that very special POWER

should be highlighted and dealt with publicly, and in a fast manner in the interest of the most important person here the PATIENT.

There is a crisis in which the innocent lives of patients have been and are still being lost due to:

1. The suppression of vital information and proper doctor and patient education, and the reckless marketing on the part of the pharmaceutical industry.

2. The ignorance, the lack of independent study and investigation, and the practice of giving "quick fix", thoughtless prescriptions demonstrated by many doctors (conflicts of interest and bribery, should not be tolerated within the profession).

3. The lack of consumer study regarding drugs and their side effects and the ingestion of drugs in a manner contrary to doctor's instructions.

CONCLUSION

I believe that the Health Committee should make recommendations to the Government similar to the ones drawn up by the UK Parliamentary Health Committee in their report on the influence of the pharmaceutical industry last year to improve this awful situation TODAY.

Auditing should take place regarding the prescription patterns of GPs today. Irresponsible, unnecessary, expensive (patent) prescription practices should be curtailed regardless of the reasons for them as it is causing more harm than good to the people of Ireland. I believe independent pharmacists can play a major role in doing so as part of a nationwide programme to improve the way we use prescription drugs today in Ireland, this is in the best interest of the patient and it would encourage best practice in prescribing medicines when necessary.

Informed consent is vital and fundamental in any part of health care where the patient's health is at stake & therefore the patient should be **fully** involved in any decision that affects their health. To do so we need to inform our doctors/health care professionals/patients and the pharmaceuticals need to release **all** information to enable **INFORMED CONSENT** to take place. The IMB should be demanding nothing less from the industry and if those companies do not comply they should be reprimanded heavily. If we do not make those responsibilities mandatory we have no way of checking that any drug is safe in a community setting or forewarn of any possible adverse reactions in the clinical setting until the HARM is overwhelming.

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