

Statement Before the
FDA Advisory Committee On Anesthetics and Life Support Drugs
University of Maryland
Shady Grove Campus
Multi Purpose Room, Building 9630
Rockville, Maryland
September 13 & 14, 2001

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RESPONSIBILITY

In our society, absent any claim of incompetency, people are responsible for their own acts. Those who engage in irresponsible conduct should look first to themselves before searching elsewhere for blame.

Shortly after I received my license to practice pharmacy I had the following experience.

I lived in a small community that included a Veterans Administration facility which housed a small number of alcoholics. A few of these fellows were regularly surprised to realize early Sunday morning that the state liquor stores were not open. These 3 or 4 men would always be waiting for me to open the drug store for "Green Lizard", their pet name for Mennen Skin Bracer,

at 8:30 a.m. on Sunday. We did not know if this nickname was due to the product color or because they would see green lizards after consuming it. They followed me in the door and, in a regular ritual, would proceed to pick up all the Mennen Skin Bracer on the shelf while I turned the lights on. This "Green Lizard" apparently held them through the day. We would meet at the cash register for the transaction and they left while I proceeded to bring in the bundles of Sunday newspapers left in the morning darkness.

One weekend I decided to face this issue and removed all the Mennen Skin Bracer from the shelf on Saturday night. This would certainly preclude these wayward men from this detrimental habit and perhaps they would even end up in church that morning. The regular men were waiting the next day and followed me in the store. We met at the cash register and I was surprised that they had picked up all the bottles of Aqua Velva on the shelf.

That is when I learned that there are limits to controlling citizens' irresponsible behavior and restricting access does not necessarily have the desired effect.

The Food and Drug Administration has the responsibility to approve drugs for marketing after they have determined that the product is safe and effective within the dosage, duration and other conditions noted in the labeling. It is the obligation of prescribers and dispensers exercising professional judgment to guide consumers in using approved products as noted above. The whole

system then depends on the moral duty of patients to use prescription drugs appropriately.

Most, if not all, of the seriously detrimental results from controlled substances are due to irresponsible drug use. Intentional abuse and overdose are attributable to the consumer and not health professionals striving to help sick people.

I would draw an analogy to the United States monetary system. Nobody proposes penalizing merchants, banks or the Bureau of Printing and Engraving when citizens use money irresponsibly or counterfeiters pass out bogus currency with criminal intent. And I do not believe that we should penalize manufacturers who produce, physicians who prescribe or pharmacists who dispense FDA approved drugs which are then used recklessly or with criminal intent.

PERSPECTIVE

Over ten years ago a series of tragedies [one of which is recited in Chapter 4 of *The Great White Lie* by Walt Bogdanich, Simon & Schuster (1991)] in North Carolina produced a rule from the Pharmacy Board requiring the reporting of deaths due to drugs dispensed through pharmacies. After receiving reports for more than nine years a summary has been produced and it is Attachment 1 to this statement.

We do not claim this to be a precisely accurate research project but do present it for whatever value it may have. We know that not every death is reported but believe that the information has value at least as a representative reporting of deaths from drugs used in health care. This summary provides information on the drugs reported to have either caused or contributed to deaths during this nine-year period.

Certainly the most surprising fact is that controlled substances account for such a small proportion of these deaths. In fact these reports show that deaths are proportional to the use of controlled substances in health care. Between 10% and 15% of prescription orders are for controlled substances with an equivalent percentage of overall deaths.

We clearly need to pay more attention to prescription drugs that are not controlled substances when they account for 85-90% of deaths.

That is not to say that we should ignore controlled substances as abuse and addiction can be problems. But we need to recognize that abuse and addiction can be treated and success stories usually don't make the news. (See Attachment 2) The largest single category of drugs causing deaths are the anti-coagulants which account for less than 1% of all prescriptions yet cause almost 20% of deaths.

Some may find these statistics difficult to accept. I live in a community where research studies are more abundant than pine pollen in the spring. Massaging data from these projects has been known to distort results to support a predetermined position. That didn't occur in our case. Reports came from random sources that could not be controlled by Board staff and there is a clear delineation of drugs that are controlled or non-controlled.

In reviewing all of our reports over 9 years we note that a total of 3 deaths were reported involving OxyContin. Other drugs had much higher numbers. We are aware of 3 deaths in just one weekend at one hospital indicating that Tylenol consumed after alcohol is more dangerous than OxyContin, see Attachment 3.

Therefore if things are put in perspective other drugs are much more dangerous than OxyContin.

Pharmacy board statistics yielded one death in health care due to OxyContin and the State Medical Examiner reported that OxyContin caused or contributed to 21 deaths this year. During the same time period traffic accidents accounted for 1,563 deaths. *The New York Times* reports that over the last two years, OxyContin has been cited as a factor in more than 100 overdose deaths nationwide. Compare this to over 40,000 deaths each year by motor vehicles and the scope of the problem becomes more clear.

We are puzzled as to the comparison of our results to what is happening in the United States. The fact is that there are no reliable statistics and not any prospect for that in the near future.

I was astounded to learn in an article in the New Yorker "Final Cut", March 19, 2001, Attachment 4, that the National Center for Health Statistics stopped collecting autopsy and toxicology information 6 years ago. Before we rush to judgment on controlled substances or specific products which, from our data, do not seem to be a particular problem in health care, we should know results from the entire population. Without such information we are merely comparing anecdotes which are likely to be misleading.

Having had a recent experience in my family for the need for pain relief I can say that it is an essential humanitarian activity. After extremely painful surgery followed by radiation and chemotherapy my spouse had need for a thorough and effective pain treatment and Oxycodone filled that bill. The dosage was Oxycodone 5 mg., 1 or 2 every 4 hours as needed for severe pain in conjunction with OxyContin, 20 mg. CR every 12 hours as needed. Very few doses were consumed but the legitimate need was there.

In conclusion it needs to be said that there is a legitimate need for Oxycodone/OxyContin and the government response to reckless use should not interfere with treating those in real need.

NORTH CAROLINA DRUG RELATED DEATH REPORTS

4-17-01

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In 1992, the North Carolina Board of Pharmacy enacted a rule that required pharmacy managers to report drug related deaths that occur at their location to the Board. Since that time, 228 drug related deaths have been reported North Carolina. This is approximately the number of prescriptions filled in one day at your local pharmacy.

Approximately 75% of these reports came from the hospital setting, while only 14% occurred in the community setting. The remaining 11% occurred in other locations such as home health or nursing homes. Since the most critically ill of patients are in the hospital setting, these figures are understandable.

Of the 228 drug related deaths, 37 were associated with controlled substances. Controlled substances are those drugs earmarked by the DEA as potentially addictive substances. There is more accountability for these drugs than for other prescription substances. The vast majority of deaths, 191, were associated with non-controlled prescription drugs.

These figures make sense since controlled substances consist of approximately 10% of the prescription volume in the retail community setting and would constitute a greater percentage of prescription volume in the hospital setting. Most institutions prescription volume majority is associated with these non-controlled substances.

The majority of drug related deaths, approximately 84%, were related to the non-controlled prescription substances. These are drugs that are not considered to be addictive, but need to be taken under the guidance of a physician. This category includes familiar drugs such as Penicillin, Zocor and Celebrex.

The highest death rates were associated with blood modification products used to adjust a patient's blood thickness. These accounted for over 19% of all drug related deaths. This category includes such agents as Coumadin and Heparin.

This is followed by the controlled substances, which account for 16% of the drug related deaths. Only 10.5 % of all reported drug related deaths in North Carolina in the past 9 years were associated with schedule II controlled substances, which have the highest level of scrutiny imposed upon them by the DEA. This class is reserved for the most addictive drugs on the market, and includes compounds such as morphine and

oxycodone. About 60% of the deaths associated with controlled substances were due to patient related causes, such as overdose, suicide, or polypharmacy.

Another category of concern was the narrow therapeutic agents. These are drugs in which the level associated with therapeutic benefits is very close to the level associated with toxicity. This can result in negative effects if not closely monitored by health care associates. Narrow therapeutic agents accounted for 10% of the deaths.

Narrow Therapeutic Drugs in North Carolina:

Carbamazepine
Cyclosporine
Digoxin
Ethosuximide
Levothyroxine
Lithium
Phenytoin
Procainamide
Theophylline
Warfarin

Antibiotics accounted for 9% of deaths. These deaths were primarily due to allergic reactions by the patient. Other categories of concern included antiarrhythmics, antidepressants, and antihypertensives.

Upon receiving these reports, inspectors at the Board of Pharmacy investigate the cases to determine the cause of the death. It appears that of the 228 drug related deaths, 86 were due to a combination of adverse effects of the medications and already compromised patient health. In 21 cases, anaphylaxis or severe allergy was the cause of the deaths. These were common in the antibiotic and radio contrast media categories. Eight patient deaths were the result of fatal drug interactions.

Health professional error accounted for 20 of the drug related deaths. Two patients misinterpreted medication labels. In addition, there were 24 overdoses and suicides. Of the remaining 67 deaths, 11 causes were inconclusive, 20 were determined that the drug did not contribute to the cause of death, and others are still under investigation by the board.

The Board's rule on death reporting was a direct result of deaths that occurred in hospitals in two different cities over ten years ago. A description of the events in Charlotte can be found in *The Great White Lie* by Walt Bogdanich (Simon & Schuster), 1991. North Carolina is the only state that requires pharmacists to report such deaths.

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