

Mr. STURGES. As for data lag, virtually all of the numbers for the quarters involved are higher in the April to June report than they were in the January to March report, which goes to the point that information continues to roll in for 6 months, and even up to 2 years, after the reporting period.

Mr. DURRIN. That is correct, the numbers continue to increase, and we update as I said on a monthly basis.

You can draw no conclusion whatsoever from the 1978 figures at this point.

As I said, the first 3 months of 1978 are probably pretty much entirely in, indicating the deaths are continuing at about the same level as previously.

Senator LEVIN. The clear and convincing evidence test you have referred to is that what the law provides, or is that by regulation?

Mr. MILLER. Our regulations and the Administrative Procedures Act requires only substantive evidence, as distinguished from beyond a reasonable doubt, or by preponderance.

We only have to show there is substantial evidence, which is a whole lot less difficult to prove.

However, when we go into an administrative hearing, in making a determination as to whether propoxyphene should be moved from schedule IV to schedule II, we are in a full-fledged rulemaking area, and the data that is going to be submitted will have to be weighed through with witnesses, and statistics, and whatever information we may have, and, finally, it comes down to is there a substantial amount of evidence that the drug has a high potential for abuse; and secondly, does it have a severe dependence-producing liability.

That will be exceedingly difficult to do in an administrative area, because it will take a long time to do, and I can tell you that in case you do not know it, it took us nearly 7 years to control the tranquilizers.

We were tied up in hearings that never ended; we went through the court procedures and the difficulty in doing this administratively. If you have a drug that is very difficult to fit within the criteria within the Controlled Substances Act, and Congress sees that there is a need to control it quickly, and not take months and years, then the Congress will have to act. I can assure you, it will not be a simple case of the Government acquiring sufficient data that will constitute a certainty or substantial evidence that propoxyphene has a high potential for abuse, as distinguished from one that has a low potential for abuse. Meeting the criteria for schedule III and schedule IV as to whether or not it has a severe dependence-producing liability is not clear because all those schedules say dependence-producing liability relative to the higher schedule. Then drop down a schedule, and it says as less than that scheduled above, and you get down to another schedule, and you say dependence-producing liability relative to the other schedule, so the criteria are uncertain. All I am saying is that unless we get a great deal more information, that convinces us we can safely go into a hearing, it will take a long, long time to control it.

Senator NELSON. Thank you very much for taking the time to come to testify.

The committee will recess until tomorrow morning at 10.

[Whereupon, the committee was in recess until 10 a.m.]

[The prepared statement and supplemental information of Mr. Dur-
rin follow:]