

Point 3, its advantages to people who cannot tolerate aspirin. There I presume at least 80 percent is used by people who cannot take aspirin.

Commissioner KENNEDY. That is correct.

Senator LEVIN. And you do not know whether the other 20 percent who take it alone can tolerate aspirin. Certainly, 20 percent take it for that purpose alone.

Commissioner KENNEDY. Very much less.

Senator LEVIN. Can you estimate what percent of the people who take Darvon get relief or can get relief from aspirin and can take aspirin?

Commissioner KENNEDY. You have moved us to the real world again and it is people who are taking Darvon in a particular therapy setting and asking them to change not only their drug but their behavior and I think that is a very difficult question to answer.

Senator LEVIN. From the studies, though, the objective studies putting aside the psychological implication questions, would you state it is over 80 percent putting aside the psychological aspects of having the prescribed drug instead of buying it at the supermarket counter?

Commissioner KENNEDY. Yes; if one were able to eliminate those entirely, perhaps over 90 percent.

Senator LEVIN. What it really comes down to is the biggest advantage of Darvon is that it is prescribed.

Commissioner KENNEDY. Well, there are some others. I mean compared with other things it really does, if used alone, have lower side effects and so forth, but I think if you take into account that 80 percent is prescribed in combination and so forth, then I would think a major advantage of it is that it is prescribed.

Senator LEVIN. Thank you.

Senator BAUCUS. No. 1, in listening to your testimony here the question arises in my mind is the degree to which you consider psychological amplification, I guess my point is—a drug which obviously does not safely test for some reasons has tremendous psychological implications. Do you weigh that or do you not weigh that?

Commissioner KENNEDY. I would be very unhappy to be in that position, Senator, but I fortunately think I never will be because the absolute essential property that the drug must have if it is to yield that kind of physiological amplification is if it is generally thought that the amplification is psychological instead of physiological. It is to be thought of as something else and I guess at the front end of an approval process, it would not occur to me I think to consider the psychological effect of a drug as an important part of the efficiency criteria given, however, that 35 million prescriptions a year are written for it and it is out there it seems to me that I would have to take that very much into account.

Senator BAUCUS. How do you measure psychological applications?

Commissioner KENNEDY. Well, you would experimentally get people to report their pain and to report their pain after having been given a physiological active analgesic and having been given something known not to contain any physiological active principal and then ask the question under circumstances where a certain percentage of people show placebo response, experience pain relief in response to placebo without some other kind of intervention and you then ask