# SOCIAL EFFECTS OF DIAZEPAM USE:
# A LONGITUDINAL FIELD STUDY*

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**Abstract**—A longitudinal panel study examined the effects of actual use of diazepam (Valium ") on subjective reports of life quality, affect, performance, stress, social support, control, coping and other variables related to mental health. Standardized interviews were conducted with 675 persons from the Detroit Metropolitan Area. Based on prescription records, diazepam users and nonusers were selected to represent a variety of sociodemographic characteristics rather than to be a completely random sample. Significant others in work and in personal life were also interviewed. Four interviews took place, one approximately every 6 weeks. Testing for social effects was conducted by within- and across-person analyses of 367 respondents who reported taking the medication at some time during the study and by comparisons with 308 respondents who did not report taking Valium. Users of Valium tended to take less Valium than prescribed. They also reported consuming less alcohol when using Valium than at other times and less than non-Valium users. Although there was a modest, positive cross-sectional relation between Valium use and distress, numerous multivariate analyses controlling for levels of stress and health indicated no notable effects of Valium use on any of the social or psychological indicators, including anxiety. Several interpretations of the results are examined including the possibility that the effects of Valium use were short-lived rather than long-term and that Valium may have been taken in anticipation of anxiety rather than after its occurrence.

## INTRODUCTION

A large body of clinical trial literature has demonstrated the anxiolytic properties of benzodiazepines (for an extensive review, see Greenblatt and Shader [1]). At the same time, there has been controversy regarding the social and psychological effects of minor tranquilizers as used in society [2–4]. Despite this controversy, there has been little systematic research on the social effects of *typical* use. This study addresses this controversy by examining typical use, rather than use in a clinical trial, and by focusing on long-term effects with a longitudinal panel design.

The study examines the consequences of tranquilizer use in people who were not participating in clinical trials. As necessary substitutes for the randomization and pre-experiment washout periods of formal clinical trials, the study uses multivariate statistical modeling techniques to capitalize on natural variation in tranquilizer use.

Previous large-scale survey research on psychosocial correlates of anxiolytic use has been cross-sectional [5, 6]. Such studies were not designed to distinguish among the antecedents, noncasual correlates and consequences of using minor tranquilizers. This study used a longitudinal survey design to search for consequent, relatively-enduring social effects such as changes in the ability to cope, in sense of control, and in the well-being of significant others such as a spouse. The study attempted to address social concerns about relatively permanent rather than transitory social effects of tranquilizer use [2–4], and so the design precluded detection of short-term effects such as relatively immediate (e.g. within hours) effects on affect, well-being or performance.

### Focus on Valium

In order to examine the correlates of variation in the pattern of tranquilizer use efficiently, a single brand of medication was studied. Diazepam (Valium ") served this purpose best because it was the most commonly prescribed tranquilizer in the United States [7], and is frequently mentioned as an example of a minor tranquilizer in the literature. Throughout the text, the proprietary name 'Valium' will be used because this is the way respondents referred to diazepam. No endorsement whatsoever is intended by this usage.

### Theoretical framework

Several basic hypotheses guided the study. One was that environmental stress, or demands and threats in personal and in work life, and the demands and threats of illness increase emotional strain such as anxiety [8]. Stress was also predicted to reduce life quality and performance. These hypotheses have been supported by numerous studies on how life

events as well as day-to-day events and conditions influence emotional well-being and behavior (e.g. [9, 11]).

It was further hypothesized that coping by changing how one viewed the problem, by expressing or controlling one's emotions, and by dealing directly with the cause of the problem could reduce stress, strain or the relation between them depending on the target of the coping. If Valium use alters the ability to cope, it could, in addition to having direct anxiolytic effects, indirectly influence all the above-mentioned effects of coping.

The study also examined whether the use of Valium influences the well-being of persons around the user. For example, the well-being of a spouse or a co-worker, and their ability to provide social support [16], might be influenced by the emotional state of the user and by any effects that Valium use might have on the ability of the user to cope with daily problems.

This framework suggested a variety of outome variables, referred to as potential social effects. These included sense of control, provision as well as elicitation of social support, affective states (anxiety, depression, anger), perceived quality of life (satisfaction), the use of alcohol, caffeine, and other drugs and ability to manage one's emotions and to perform responsible roles in work and personal life*. The well-being of significant others, noted above, also constituted an outcome variable. The study was not designed to examine drug dependence (e.g. [14]) or drug abuse.

Hypotheses were generated which considered direct and indirect effects of Valium use as well as interactive or moderator effects. As an example of a direct effect, one might hypothesize that Valium use would directly influence perceived quality of life by making the person feel good about life. As an example of an indirect effect, one might hypothesize that the effect of Valium use on quality of life might occur via the anxiety-reducing properties of the medication. As an example of a moderator effect, one might hypothesize that use of Valium reduces the effects of stresses on anxiety by making the user less concerned with the stresses. As another example of a moderator hypothesis, one might argue that Valium use effects performance or well-being only if the person takes the medication daily, for stress-related reasons (rather than for musculoskeletal problems), or has a high level of anxiety (e.g. [15]).

The hypotheses were examined in a two-tailed framework. For example, use of a minor tranquilizer might increase people's sense of control over their personal and work lives and over their emotions. It could also be argued, however, that Valium use might decrease this sense of control by making people feel dependent on their medication (e.g. [31]). To take another example, one could hypothesize that use of a minor tranquilizer could make people more agreeable and therefore increase the amount of social support which they received from others [16]. Conversely, tranquilizer use might reduce people's social responsiveness in interactions, making it less rewarding for others to be socially supportive, and thereby reduce rather than increase social support.

This study examined a large number of such hypotheses including the above examples. A large number of analyses were generated to test all the derived predictions. The text necessarily focuses on the main points of the methodology that was used and of the results that were produced†.

## METHOD

### Overview

In a panel survey design, 675 people, 17 years or older were interviewed four times, once every 6 weeks, covering a 6-month period. Of these persons, 367 reported using Valium at some time during the course of the study; the remaining 308 did not report using any tranquilizer during the course of the study. Characteristics of the respondents are presented below.

### Respondent selection

The Michigan Board of Pharmacy, under state law, reviewed the study protocol and authorized the investigators to obtain the names, addresses and telephone numbers of clients of pharmacies that agreed to participate in the study. The set of respondents was intended to include various demographic groups (to permit subgroup analyses) rather than to be representative of the population. Consequently the pharmacies were drawn from the greater Detroit metropolitan area in a random sample stratified to represent a broad range of neighborhoods with regard to sociodemographic characteristics. Males, females and members of different age groups were quota-sampled from the pharmacy records so as to have sufficient numbers for analyses within each subgroup.

Previous research had found that users of anxiolytics report more illnesses of all types compared to nonusers [6]. For this reason, it seemed best to draw nonusers as well as users of Valium from recent pharmacy records in order to reduce initial differences in health between the two groups (compared to what it might have been if nonusers had been sampled from the community). To this end, pharmacy clients were sampled if they had filled a prescription within the prior 6 weeks, either for Valium or for a nonpsychotropic drug. The 6-week period was required to obtain a sufficient number of Valium users in the sampled region. Persons were excluded from the nonuser (nonpsychotropic) group if they had received a prescription for other antianxiety agents, antidepresents, antipsychotics or, because of their CNS-depressant effects, antihistamines.

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*The study did not examine ergonomic aspects of performance nor basic elements of cognitive performance such as long- and short-term memory. Summaries of that research can be found elsewhere [12, 13]. Nor did the study examine personality characteristics, such as trait-anxiety, to see if personality conditioned the hypothesized social effects of Valium. Such analyses were beyond the scope of this study, given an already lengthy interview schedule.

†More complete detail is available from the Institute for Social Research, Publications Division [17].

Through this procedure, we drew 2070 names of persons 17 or older*. In addition, we drew a small number of names from other sources (e.g. business mailing lists) so the interviewers would not know from which source a prospective respondent was obtained.

It was possible to contact 1626 people. Of these, 784 (48%) agreed to make a 6-month commitment to participate on all four waves of the study and were interviewed at Wave 1†. At the second, third and fourth waves of the study, 91–98% of those interviewed at the preceding wave were reinterviewed successfully. Most analyses are based on the 675 persons who completed all four waves of interviews. Comparisons on the basis of numerous social-psychological and drug-related variables indicated no important differences at Wave 1 between the total set of 784 persons interviewed at Wave 1 and these 675 respondents.

### Analytic methods for addressing response rate bias

The response rate may have been influenced by the fact that the respondents came from a population of persons who were highly anxious or had health problems. Such persons, compared to people in the general population, may have been less likely to volunteer because the 6-month study represented an additional demand in their lives (participants were accepted only if they agreed to be interviewed four times)‡.

Given the response rate, replications are required to determine generalizability. Nevertheless, the re-

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*We considered a variety of other methods for obtaining respondents and rejected them all as too costly or infeasible. For example, if we had attempted to select users randomly from the population, the low point prevalence of use (estimated as only 2% on any one day and 12% annually) would have required the screening of thousands of persons to produce the required number of respondents for the study [18]. Pretesting indicated that recruitment at pharmacies was also unacceptable because it produced a highly selected group of respondents (usually persons from lower socioeconomic groups).

†Noncontacts included 305 persons who could not be located because of inaccurate addresses or who had moved and 62 persons who were on vacation. Seventy-seven persons were excluded because they were either foreign speaking, too ill, or too senile. It was not possible to compare the original 2070 persons with the final set of respondents on age or gender.

‡We were unable to compare the response rates for this study with those from recent nationwide random sample surveys of users and nonusers of Valium because such information was noncomparable or not reported. Mellinger and Balter [19] reported a response rate of 79% for a national random sample of users and nonusers of minor tranquilizers. This figure is for persons reporting any use in the past year. It is not possible to distinguish in those data between current users, as defined in this study, and past users of an anxiolytic medication, a category which must describe the large majority of respondents in such a study [18, 6]. Nor is it possible in those data to distinguish between respondents currently being treated for an illness, which was likely to characterize nonusers in this study, and respondents not being treated.

sults merit attention because this is the first study of its kind, and the findings and their interpretations may provide important guidance for future efforts. The Results section provides descriptive data on the similarity of these respondents to the U.S. population.

### Selection of significant others

Each respondent, hereafter referred to as a 'focal respondent', was asked to nominate a significant other person from personal life (e.g. a spouse or close friend or relative) and, if employed at least 15 hours a week, also to nominate a significant other from work life. Approximately 90% of the focal respondents provided a 'personal other' at each wave and 70% provided a 'work other'. The same personal and work others were used at all waves whenever possible.

### Data collection

Participation was voluntary and by informed consent. Respondents were contacted at their homes, after receiving an introductory letter, and usually were interviewed there for about 90 minutes at each wave. Focal respondents were paid $5 for each of the first three interviews and $10 for the final interview. Personal others and work others were usually interviewed by telephone and were not paid. All participants were told that the study dealt with stress and well-being in personal and work life. The personal and work others were never told anything about their focal respondents except that their focal respondents had nominated them as potential participants in the survey.

All respondents were interviewed by professional interviewers from the Survey Research Center of the Institute for Social Research who were trained for this study. The interviewers used structured questionnaires and a standardized interview protocol.

### Measurement

Multi-item indices of social and psychological variables were used to increase the reliability of measurements. These indices generally had coefficients of internal reliability (alpha) in the 0.70s and 0.80s. The reliabilities of the measures replicated in a variety of subgroups (e.g. males, females, Valium users and nonusers, high and low education) and across all four waves.

Unless noted otherwise, all interview questions referred to conditions during 'the last 7 days'. Anxiety, depression and somatic complaints were measured using relevant items from the Hopkins Symptom Checklist [20]. The Hopkins Checklist was used to assess changes in relative levels of anxiety symptomatology rather than to render a specific categorical diagnosis of anxiety.

Measures of quality of life [21] and of stress [11] were drawn from standard measures in the literature. Other measures of coping, control, performance and social support were developed and pretested for reliability prior to use in the study [22, 23]. The Appendix provides some examples of these measures, and the complete content of the indices is available elsewhere [17].

It was possible to examine the consensus between two observers because both the significant other and focal respondent reported on the focal respondent's performance, quality of life, social support, and social conflict. Data from Wave 1, which are typical, showed that there was good consensus in some domains and not in others. For example, the focal respondent's ratings of overall quality of life and of worklife were moderately to strongly correlated with ratings by the personal and work others (0.61 and 0.44 respectively). The focal respondent's ratings of technical and social performance in personal life correlated 0.18 and 0.25 with the respective ratings made by the personal life significant other. In the work life domain, the respective correlations were 0.09 and 0.30.

Given the generally good internal reliabilities for the measures from the focal respondent and the significant others, the low correlations between the two sets of respondents suggests that each type of person represents a different perspective. Each perspective perhaps is the product of particular bias and access to different information.

A detailed history of drug use in the prior 6-weeks was obtained, as was some information regarding use in the prior year. Particular detail was pursued with regard to consumption of frequently used medications which have either CNS-stimulant or -depressant effects. Seventy-five percent of the data regarding prescribed dosages of medications was recorded from medicine bottle labels; the remainder was based on respondents' memories. Distinctions were made in the coding and analyses of these data between 'use as needed' (PRN) prescriptions and fixed schedules.

In addition, respondents were asked for retrospections about use of Valium, anxiety, and quality of life for each of the 6 weeks preceding each interview. At Waves 2–4 they were also asked for retrospections regarding the seventh prior week, which was the week of the preceding interview; this allowed checks on the accuracy of retrospection. These weekly data on Valium-taking, anxiety, and life quality were obtained on a form that resembled a calendar; they are referred to below as 'calendar measures'.

These retrospective calendar measures were found to be reasonably accurate. Restrospections at Waves 2, 3 or 4 correlated on the average with matched data collected at the previous wave in the range from 0.5 for anxiety to 0.8 for Valium-taking. Recall may have been good for two reasons: (a) the phenomena may be relatively stable and (b) we worked at improving recall by first asking respondents to recall an event that stood out in their lives for each week.

### Characteristics of respondents

As noted, the intent was not to draw a random sample of the population. Nevertheless, comparisons with the 1979 U.S. Census Data [24] indicated that the respondents were similar to the U.S. population with respect to the distributions on sex, age and education. The mean age for the respondents was 46. Average education was 12 years. Average family income was in the range of $15,000 to $24,999 per year. Fifty-four percent of the respondents took Valium at some time during the study.

To provide sufficient numbers of both sexes among the Valium users, the proportions of male and female users in this study (39 and $61^{\circ}{}_{0}$, respectively, at Time 1) were more equal than those found in national sample surveys [6, 19]. Among nonusers, $46^{\circ}{}_{0}$ were male, $54^{\circ}{}_{0}$ were female. The higher proportion of Blacks ($21^{\circ}{}_{0}$) than found nationally ($10^{\circ}{}_{0}$ [24]) reflects the demography of the Detroit metropolitan area.

Valium users tended to be slightly older, less educated and have less income compared to non-users. Valium users also reported lower subjective quality of health, higher anxiety, higher depression, and lower subjective quality of life. Such differences reflect the association between distress and use of anxiolytic drugs found in random sample surveys of the U.S. population [5, 6].

Comparisons with nationwide prescription surveys [25] showed that, as in the country as a whole, respondents in this study were prescribed Valium most often by physicians in general practice or in internal medicine; osteopaths and psychiatrists were the next most likely to prescribe this medication. With regard to physical health, users of Valium in this study were similar to those in a recent national random sample [6]. Users were four times as likely to report some health problem as nonusers in this study even though the nonusers were pharmacy clients too. Users in this study, like those found in the national sample, were more likely to report chronic illnesses such as high blood pressure and arthritis whereas nonusers were more likely to report acute medical problems.

The major potential difference between re-spondents on this study and in national random-sample cross-sectional surveys [5, 6] is the percentage of persons in this study who reported taking Valium daily or nearly every day. At Wave 1, $48^{\circ}{}_{0}$ of those taking Valium reported such use (the percentages at Waves 2–4 were similar). Mellinger and colleagues reported that 21% of those who took Valium daily took it for as long as 4–84 months [6]. These two studies' methods of measurement of Valium use are not directly comparable. Consequently, the data only suggest that daily users were overrepresented in this study. Measures of use incorporated in our study need to be used in a random sample survey to determine the generalizability of the descriptive statistics regarding patterns and levels of use reported here. To deal with the possible overrepresentation in daily usage patterns, analyses examined the social effects of daily Valium use separately from those of other patterns of use. Within-group analyses were also performed separately for males and females, blacks and whites, high and low dosage users, and many other subgroups to determine if the results might differ from one group to the other. Where appropriate, comparisons of results were made before and after controlling statistically for stress-related variables such as health patterns, negative life events [10] and social conflict.

### RESULTS

#### Overview of Valium use

Anxiety, tension, keeping calm or keeping relaxed were mentioned by $70^{\circ}{}_{0}$ of the respondents as reasons

for taking Valium; insomnia was mentioned by 17%; and the only commonly mentioned physical reason was a pulled back or sore muscles (9%). Note that these were respondent reports rather than diagnoses from medical records.

The most commonly prescribed doses of Valium ranged from 10 to 20 mg per day. Fewer than 9% of prescriptions were for 30 mg or more per day. Patients prescribed specific regimens (i.e. not PRN) tended to take less rather than more milligrams than prescribed, replicating prior research on compliance with anxiolytic treatment [26]. The most commonly reported actual usages ranged between 2 and 15 mg per day (88%), a range within guidelines described by the Valium package insert [27]. Only two persons reported taking more than 40 mg per day at Wave 1.

The large majority (83%) of persons taking Valium within the 6 weeks preceding each interview also reported taking the medication within the seven days prior to each interview. The majority of Valium users (59%) took some Valium during all four of the 6-week periods prior to each interview. Nevertheless, there were considerable ranges of doses and patterns of use across and within the 6-week periods between interviews. During the 6 weeks preceding the Time 1 interview, 33% of the users of Valium reported taking the medication 'only once in a while', almost half (47%) reported taking it 'every day or every other day the whole time' and the remainder took it either 'some weeks almost every day, other weeks not at all' (11%) or at more evenly spaced intervals which were less frequent ('at least once a week the whole time'; 9%). The distributions of pattern of use at Times 2–4 were similar to that at Time 1.

The number of drinks of alcohol consumed by Valium users compared to nonusers was about the same (e.g. at Wave 1, the respective means were 5.7 and 6.1 drinks per week; the respective standard deviations were 14.2 and 11.9). (Although comparable national sample data are not available, a 1979 survey [37] showed that 33% of the population were nondrinkers, and among the drinkers, 'heavier' drinkers were classified as consuming more than 40 drinks per week. The averages in this study fall well below that level.) Persons who took Valium daily were less likely to consume alcohol than nonusers (e.g. 48% compared to 66% of the nonusers at Wave 1, $P < 0.01$), but among those who drank any alcohol at all during this period, there was no difference in the amount of alcohol consumed. The design of the study does not allow one to determine the extent to which the differences in the percentage of drinkers among daily Valium users and nonusers was due to self-selection, substitution of Valium with alcohol (and vice-versa) or compliance with physician recommendations regarding the use of alcohol and Valium simultaneously. Valium users also tended to smoke more cigarettes than nonusers, but Valium users and nonusers did not differ with regard to use of caffeine or street drugs. Street drug use was very low among all respondents, and there was no evidence that Valium use led to use of street drugs. Valium users tended to take more prescribed nonpsychotropic drugs than did nonusers.

Valium users reported that their prescribing physicians were generally supportive, a finding counter to

the criticism that tranquilizer prescribing indicates some physicians' relative inattention to the psychosocial needs of patients [28]. Lastly, Valium users reported that the medication helped them control their lives, although there was no statistical relation between the amount of Valium taken and users' scores on various measures of control.

### Social effects of Valium use: primary analyses

Results of bivariate analyses are described first. They are followed by results of multivariate analyses that introduce various statistical and subgroup controls.

Correlational, lagged analyses. Using the weekly retrospective calendar data, it was possible to examine how ratings of quality of life and anxiety correlated with Valium use when Valium use and these other variables were measured simultaneously, and when Valium use was measured before (i.e. 1–24 weeks before) and after (i.e. 1–24 weeks after) quality of life and anxiety. The measure of Valium use employed in these and most other analyses reflected the total number of milligrams taken each week. Figure 1(a) and (b) summarize the results separately for the total set of respondents (users plus nonusers) and for persons who took some Valium during the 6-week period preceding each interview. None of the relations was very strong. Regardless of the lag, anxiety was always positively (although weakly) correlated with use of Valium, the average zero lag
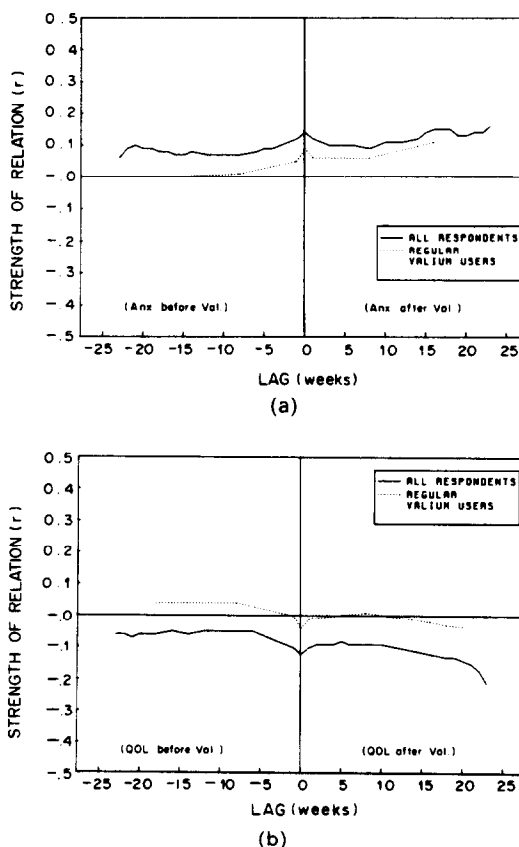


(a)



(b)

Fig. 1. (a) Relation between Valium-taking and anxiety at various lags. (b) Relation between Valium-taking and quality of life at various lags.

correlation being about 0.14. Conversely, the average zero-lag correlation was about $-0.12$ between Valium-taking and quality of life, and the correlation was always negative regardless of the lag—i.e. poor quality of life was associated with the use of Valium. For both quality of life and anxiety, the simultaneous relation with Valium-taking tended to be slightly stronger than most of the lagged relations. The correlation between quality of life and anxiety was $-0.52$ at lag 0 and decreased by weeks 4–6 in the range $-0.1$ to $-0.2$. The relation declined only slightly more with lags beyond 6 weeks. These results suggest that if causal relations existed, they were more likely to occur within the 7-day span of the measures rather than across longer intervals.

Lagged relations were also examined using data from the other portions of the interview, referring to levels of Valium use, anxiety, quality of life, and other social-psychological variables in 'the last 7 days' prior to each of the four interviews. Analyses examined the relations between these variables measured with simultaneous, 6-, 12- and 18-week lags. Again, use of Valium and anxiety (here measured by the Hopkins Symptom Checklist) were always positively cor-

related regardless of the length and direction of the lag, and the relation was strongest for the simultaneous corrections (maximum $r = 0.30$). Similarly, regardless of the specific lag examined, Valium-taking tended to be weakly associated with poor quality of life, poor performance in work and personal life, low social support, perceived lack of internal control, poor perceived health and high levels of stress (maximum $r = 0.28$). Over 1000 such relations were examined. This general positive association between stress and use of minor tranquilizers is like that in national-sample cross-sectional survey results obtained by other investigators [5, 6].

The structural modelling described below, provides a summary of the main findings from the cross-sectional as well as longitudinal analyses, in a compact manner.

*Change score analyses.* Although change scores have some psychometric disadvantages, such as reduced reliability [29], they have the advantage of canceling out certain systematic response errors from each wave. Analyses using change scores did not alter the basic pattern of findings described above. In general, the relations between changes in Valium use and changes in the indicators of stress, performance and well-being were weak $(r < 0.2)$ regardless of whether the changes occurred simultaneously or the changes in Valium use preceded or followed changes in the indicators of social effects.

*Structural modeling.* Traditional methods of hypothesis testing (such as analysis of variance or multiple regression) examine relations among *measures* of the constructs in the hypotheses. Such analytic methods provide imperfect tests to the extent that the measures of the variables are not good representations of the constructs. In contrast, structural modeling (e.g. LISREL IV, see [30]) allows one, with certain assumptions, to estimate relations among the *constructs*. These estimates are made possible by the use of statistical controls for random errors of measurement, for correlated measurement errors (e.g. when a predictor and a dependent variable are correlated because they are measured with the same procedure), and for potentially confounding variables, including the differences between users and nonusers of Valium in initial levels of anxiety, perceived stress, and perceived physical health. We believe the modeling approach provides the best available estimates of the effects of Valium use because of these controls*.

Using this approach, the investigator specifies a set of hypotheses, referred to as the model, and tests how well the data conform to the model†. The model in Fig. 2 was the best of several models in terms of its ability to describe the actual relations in the data, the theoretical reasonableness of the parameter values, and the theoretical reasonableness of the obtained structure‡.

For example, health was modeled as increasing stress, and both stress and health were modeled as increasing anxiety. Anxiety, in turn, was modeled as leading to the comsumption of Valium and to decrements in performance in personal life. And poor health, high stress amd anxiety, and low performance were, in turn, modeled as producing a decrease in perceived quality of life as a whole. Valium was

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*Three features allowed this analysis to control statistically for imperfections in the measures: (a) two methodological factors were included that reflect response styles or biases in answering the retrospective calendar measures. One factor represented the calendar measurement of quality of life and anxiety; the other represented the calendar measurement of Valium use. We presumed that the effect of each methodological factor on its measures would be equal and hence constrained the analyses to reflect this. (b) The model included a residual input to each questionnaire measure. This residual represents other factors, unrelated to the methodological factors and the primary construct, that might influence the measure. For example, the residual input for Anxiety is 0.23 at Time 2 and 0.19 at Time 3. (c) For the non-calendar measures, allowance was made for the possibility that the residual inputs to any particular measure assessed at one wave might covary with the residual inputs to that measure assessed at another wave. If one failed to take into account such covariation in these residuals, one could err in estimating the between-wave links among the primary factors. (Illustration of these covariations has been omitted from Fig. 2 to simplify the schematic although they were estimated as part of the model.)

†Once such a model is specified, the magnitudes of its effects are estimated (i.e. the magnitudes of the links among constructs, between constructs and measures and among measures) so as best to account for the observed relations in the data. The closer the estimated magnitudes of the relations to the observed data (summarized by the chi-square-per-degrees-of-freedom ratio, by the mean absolute residual, and by Hoelter's CN statistic [31]), and the more theoretically reasonable the estimates (e.g. positive effects where expected, negative effects where expected, small or large effects as expected), the more adequate the hypothesized model. Based on the fit statistics presented with Fig. 2, it is clear that this model reproduces the observed relations quite well.

‡Alternative models allowed, for example, for direct effects of Valium use on performance in personal life and on quality of life rather than for indirect effects via changes in anxiety.

modeled as having effects on performance and quality of life-as-a-whole via the effects of Valium on anxiety. And most of the concepts were modeled to allow for direct effects on themselves at later times.

In Fig. 2, the constructs are represented by ovals. The measures of the constructs are represented by rectangles. The subscipt within each oval or rectangle represents the particular wave of data collection. Arrows between ovals represent estimates of the strength of relations between constructs after controlling for measurement error (e.g. at Wave 2, the strength of the relation between health and anxiety is −0.44). The arrows from ovals to the rectangles represent the effects of each construct on how people answer the questions about the construct; hence, they reflect the validity of the questions (e.g. anxiety is reflected at Wave 1 in the calendar measure with a validity of 0.58 and in the Hopkins measure with a validity of 0.79).

In this particular model, the data at Waves 2–4 merit the closest attention because they take into account prior (i.e. from the previous interview) levels of stress, health. Valium use, performance and quality of life. The model shows a number of reasonable relations within the last three waves. For example, and as expected, poor health and stress preceded increased anxiety (coefficients ranged from −0.18 to −0.44 and from 0.67 to 0.82, respectively). Anxiety had negative effects on performance in personal life (−0.20 to −0.27) and on quality of life as a whole (−0.44 to −0.55). Performance had a positive effect on quality of life (0.33–0.39). Health and stress were generally unrelated.

The current levels of anxiety and of life quality in this model were attributed mainly to the *current* levels of the other constructs, with little or no direct effects from six weeks earlier. Although the model allowed for the possibility that Valium-taking would have an effect on anxiety 6 weeks later, and, through anxiety, on performance and life quality, these links were zero or near zero*.

These results provide one of the more important findings of the study—an explanation for the positive relation between Valium use and psychic distress found in cross-sectional studies [5, 6], as well as in this study's bivariate analyses (see above). Once prior levels of anxiety, health and stress were controlled, there was no relation between Valium use and anxiety either cross-sectionally or over time.

These controls also led to the near-zero effect of anxiety on Valium-taking at Waves 2–4. This finding suggests the following interpretations: Whereas a high level of anxiety may lead to a prescription for Valium (or any other anxiolytic), continued use may not be triggered by anxiety under the following conditions: when the person (a) uses the medication daily because of instructions from the physician or

based on habit, including the habit of preventive or anticipatory use or (b) uses the medication nondaily for the management of anxiety that lasts only for a brief period such as a day. With regard to the first condition, although almost 50% of the users of Valium were daily users at each of the waves, the study was not designed to examine preventive or anticipatory use. With regard to the second condition, the measures of Valium use and of other variables were not designed to detect the effects of such highly transitory use, but, rather, were designed to summarize time periods of at least 7 days. Further research will be required to evaluate the validities of these potential interpretations.

### Social effects of Valium use: supporting analyses

*Subgroup analyses.* Although there was no evidence of either harmful or beneficial social effects of Valium use when all study participants were analyzed together, it was possible that some social effects might appear for specific subgroups of respondents. Subgroups were formed in a number of ways: by whether Valium had been taken for anxiety or for other reasons, the amount of social support the person reported receiving from the Valium-prescribing physician and others, gender, daily use versus other patterns of Valium use, use of other medications, perceived internal control, attitudes towards tranquilizers, demographic variables, use of coping techniques, health, and other stressors of life. Over 6000 analyses examining various lags were performed across the several waves of data. No evidence was found for subgroup effects beyond those due to chance.

Another search examined the extent to which Valium use either buffered (reduced) or exacerbated (increased) the relations between stresses and quality of life or other outcomes, such as anxiety, depression, performance and perceived control. Although there was a slight tendency for Valium use to buffer such relations, the magnitude of the effect was generally weak, did not replicate well across waves, and was offset by some instances in which Valium use seemed to exacerbate effects of stress on other outcomes.

*Analysis of covariance.* This set of analyses, like the structural modeling analyses, controlled for the higher levels of perceived stress and poorer health among users of Valium. Some of these analyses selected small subsets of both users and nonusers of Valium who had high initial levels of anxiety on the Hopkins Checklist—levels typical of those found at the start of treatment in clinical trials. Three separate sets of analyses were performed: (1) for *daily* users (highly anxious persons who reported taking Valium daily or nearly daily during the 6 weeks prior to Wave 1 through Wave 2—a period of about 12 weeks), (2) for *new* users (persons who reported taking Valium for the first time during the 6-week period prior to Wave 1) and (3) for highly anxious nonusers. With these restrictions, the number of new users was only 19, and the number of cases for the other two groups was about 50 (the sample size varied depending on the variables analyzed).

These analyses examined the effects of Valium use on performance, anxiety, depression, the well-being of the personal other, and many other variables. No

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*The effect of Valium use on subsequent level of quality of life can be computed by multiplying the coefficients along each causal path that links Valium use to quality of life and summing the products. The same procedures can be followed for computing the link between Valium use and performance. These products are all very small because the Valium-anxiety link is weak.
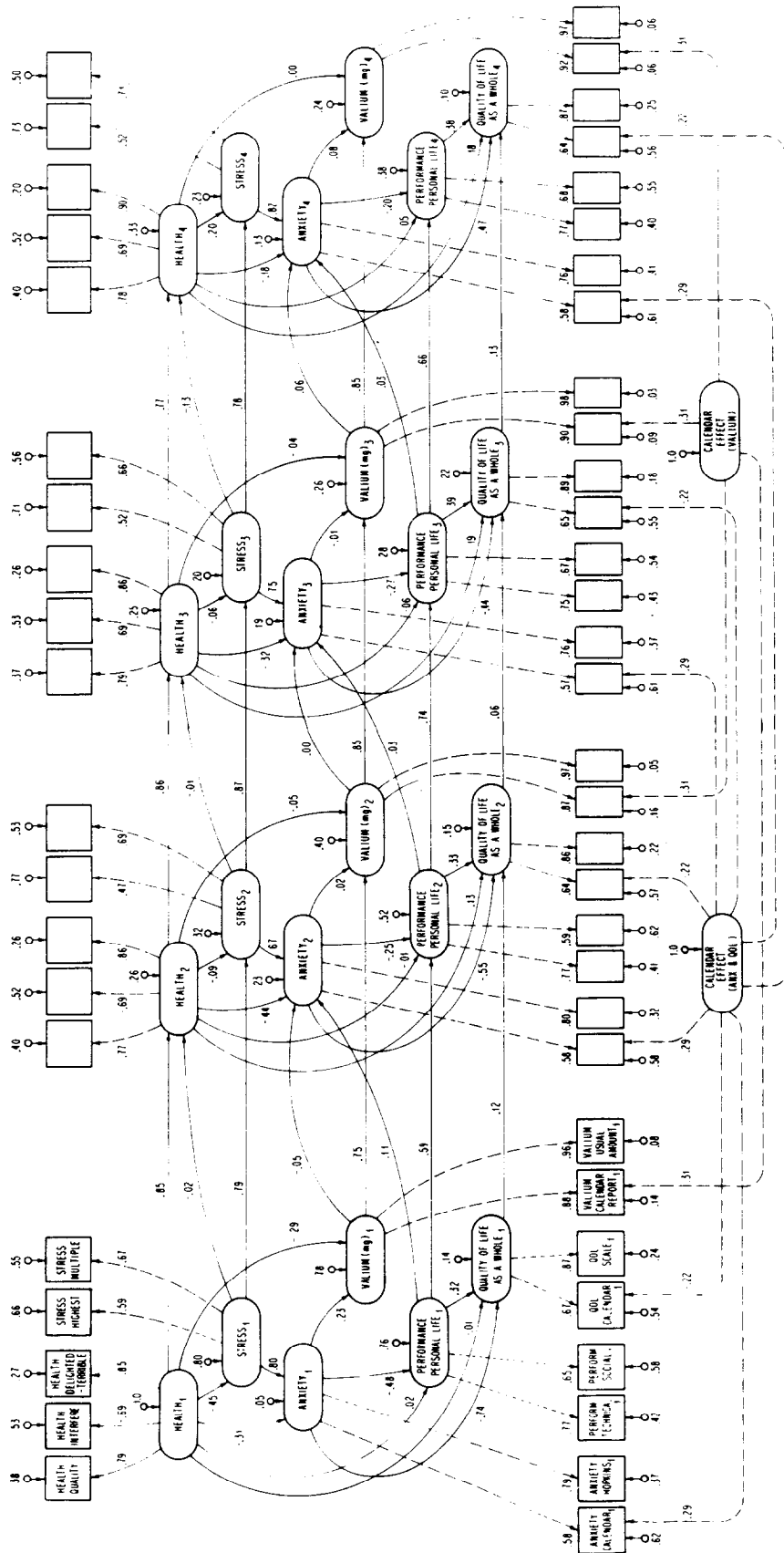
Fig. 2. Estimated causal effects among health, stress, anxiety, Valium-taking, quality of life, and performance. $N = 660$, d.f. $= 1176$, $\chi^2 = 3469.3$, $\chi^2/\text{d.f.} = 2.95$, maximum residual $= 0.246$, mean absolute residual $= 0.041$, CN $= 242.6$. Constructs are indicated by ovals; items measuring the constructs are indicated by rectangles. For ease of interpretation, an arbitrary standardization has been incorporated such that each variable represented in an oval or rectangle has a variance equal to 1.0.

notable evidence of any differences was found among the three groups. Overall there was no evidence of any long-term social effects.

*Within-person analyses.* Whereas the preceding analyses all examined the social effects of Valium use between persons but within and across waves of the study, the next two types of analyses examined these relations *person-by-person* (within persons, across time). The first type of analysis used the retrospective, 24 weeks of calendar data to examine, person-by-person, weekly changes in anxiety and quality of life before and after use of Valium. Anxiety tended to decrease and quality of life to increase after Valium use. Similar changes were observed, however, when the same individials experienced an increase in anxiety but did not use Valium. Nonusers showed a similar pattern of increase and subsequent decrease in anxiety. With similar results, these analyses were repeated separately for new users, for intermittent users (persons who started taking Valium after a period of at least 6 weeks of not taking the medication) and for several other groups of users. The findings provided no clear evidence that Valium use uniquely influenced either anxiety or quality of life over a period of at least a week.

There was a possibility that some persons might show positive, others negative, and others no correlation between Valium use and anxiety or quality of life. Such variation might be due to differential responsiveness to Valium. This possibility was explored in the second type of analysis by using the 24 weekly points of the calendar data to compute separate correlations for each individual to determine how Valium-taking varied with anxiety or quality of life across time but within persons. For each person, correlations were computed separately for relations based on simultaneous measures as well as lags of 1, 3, 6 and 9 weeks (the lags included those where Valium use preceded as well as followed the anxiety and quality of life ratings). These correlations were then related to 82 other variables, including stress, social support, coping, control, performance, use of medications and other substances, quality of life, and demographic variables. Significant notable negative or positive within-person correlations between Valium use and either quality of life or anxiety occurred with such infrequency as to represent only chance.

### Other findings dealing with social effects

Elsewhere it has been suggested that the use of minor tranquilizers may dull the user's sense of the external environment and its stresses and may numb normal emotional reactions so that users are not able to report their feelings to others [32]. The data from this study do not support these conjectures. The statistical relations between stress and emotion for users and nonusers were generally the same across most waves. Furthermore, changes in stress and in emotion over the four waves of the study among the nonusers were paralleled by similar changes for the users of Valium (stress declined in personal life and in work life, and emotional states improved for both groups with no statistical differences between the groups after controlling for initial levels). Among users of Valium, the higher levels of stress, including poor health, were accompanied by higher levels of negative affect—a normal emotional response in the sense that nonusers of Valium also showed similar response sensitivities.

### DISCUSSION

Overall, this study found little evidence that use of the minor tranquilizer Valium had any social effects, either harmful or beneficial. Although there were small, positive cross-sectional relations between indicators of distress and use of Valium, these relations were near zero over time when statistical controls were introduced for prior conditions of stress and health. A lesson of these analyses is that it is important to consider the stabilities and the antecedent effects of variables which are likely to influence the use of anxiolytics *and* potential outcomes of anxiolytic use such as anxiety and quality of life.

It was conceivable that the findings might have been an artifact of a particular statistical method of analysis. For this reason, multiple techniques were used for examining the data across as well as within persons. Each analytic method allowed us to take a different perspective on the data. The results were similar across all of the methods.

With regard to other social issues, users of Valium perceived their prescribing physicians as socially supportive rather than unsupportive. There was no evidence that Valium use numbed emotional responsiveness: the relations between social stresses (e.g. role conflict at work) and emotions (e.g. anger) were the same for users and nonusers of anxiolytics.

Although the study was not designed to examine drug abuse, it was evident that there was little use of street drugs among these respondents as a whole, no difference between users and nonusers of Valium with regard to the use of such drugs, and a tendency for users of Valium to take less rather than more than the amount of Valium prescribed. This tendency toward undermedication with minor tranquilizers has also been noted in clinical trials [33].

### Interpreting the longitudinal findings

This study was designed chiefly to examine social effects of the use of Valium. The fact that no major social effects were detected requires explanation.

It was hypothesized that social effects might occur either directly or indirectly as the result of Valium use. If brought about indirectly, such effects might have been the secondary result of a reduction in anxiety, which is typically found in clinical trials [1]. Thus, this study's finding of no major social effects might be explained by its corresponding finding of no lasting effects of Valium use on anxiety. Consequently, it is worth examining why the study detected no anxiolytic effects of Valium use.

One possible reason why Valium use was not found to reduce anxiety is that the Valium users in the study may not have taken sufficient doses of the medication. However, although users of Valium did tend to take less Valium than prescribed, the amounts they took are considered adequate to produce anxiolytic effects and fall within the recommended doses described in the package insert. Nevertheless, we conducted separate analyses for persons who took

different doses or had different patterns of use (e.g. daily vs intermittent) and the findings remained basically unchanged. Thus, low dose does not provide an explanation. What other factors might account for the lack of any detectable anxiolytic or social effects?

As noted at the outset, this study was designed to search for long-term rather than transitory (e.g. those that might occur only for a day or so after taking the medication) anxiolytic and social effects. The rationale was that most of the social issues raised regarding the use of tranquilizers dealt with long-term changes. If people took Valium to manage very brief episodes of anxiety (much like taking an aspirin for a headache), both the anxiolytic and social effects might be short-lived. Consequently, it is possible that, any anxiolytic effects might have been too short-lived to detect in this study. This is plausible because the strongest associations among use of Valium, anxiety, and quality of life occurred at lag zero and tended to decrease as the lags increased to one or more weeks. (Although clinical trials suggest that Valium's anxiolytic effects occur in as little as one week [15], most trials focus on interventions of 1–6 weeks rather than period's shorter than that. The package insert [27] does not indicate a specific minimum period of recommended anxiolytic use.)

The other side of this concern might be that if there were any social effects of Valium use, they might take longer to develop than the 6-month time span of this study. However, the lagged data described above indicated no such trend. Indeed, the magnitude of effects examined in this study decreased, rather than increased, with the passage of time.

It is also possible that, if there were any social or anxiolytic effects, they might have occurred prior to when people entered the study. Only prior measurement could have resolved this issue. However, new users of Valium and users who started and stopped taking Valium during the course of the study provided one opportunity to look at anxiety and social effects over a relatively short period of new or renewed use. Analyses of the small number of new users and of intermittent users did not alter the basic findings*.

No association between use of Valium and either anxiety or social effects would be likely to occur, even over the short run, if people took the medication prophylactically. If people took Valium in anticipation of events that they perceived as potentially anxiety-provoking, then one might expect anxiety to be low both before and after taking Valium; other social effect outcomes also might be relatively unchanged. This study lacks the data required to evaluate this explanation, and we are not aware of any other study which assessed the incidence and prevalence of prophylactic use.

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*Another possible explanation of the results is that Valium use was effective in improving quality of life, but no more so than anything else. This interpretation derives from case-by-case analyses of the data. Those analyses showed that, after an increase in anxiety, anxiety generally decreased and quality of life generally increased. but no more so when Valium was taken than when it was not. Only a placebo trial can determine the validity of such an explanation.

Similarly, no association between Valium use and anxiety or social effects would be detected if people were using alcohol and Valium in a complementary fashion to manage anxiety continuously. However, when those taking alcohol (or other CNS stimulant or depressant drugs) were examined separately from those who were not taking such drugs, the overall results were unchanged.

A lack of association might also occur if users of Valium had levels of anxiety and depression that were not clinically responsive to the effects of a minor tranquilizer [34, 35]. However, analyses of subgroups with different initial levels of anxiety and with different initial combinations of anxiety and depression did not alter the basic findings.

There is the possibility that social and anxiolytic effects were not detected because the measures were unreliable or invalid. This is refuted by the rigorous criteria that were used in developing the measures. Internal reliability was demonstrated in a variety of key subgroups including users and nonusers of Valium. Validity of the measures was demonstrated by bivariate and multivariate analyses which showed that measures of the stresses, social support, performance, subjective health, anxiety, and quality of life were related to one another in marked, statistically significant and theoretically meaningful ways [36]. Furthermore, the simple, cross-sectional correlations between use of Valium and measures of distress were similar to those found in national random-sample surveys of the United States [5, 6].

Finally, the lack of association between Valium use and the various measures of well-being might be valid only for the respondents in this study; the effects might be different for the larger population of Valium users. Although the results should be replicated on a random sample of users and nonusers of Valium (or of other minor tranquilizers), we find no specific reason for predicting that the resulting relations reported here would be different.

*Links to clinical trials and implications for future research*

For most competing explanations, we conducted subgroup analyses or made use of other statistical techniques to control for potential artifacts. In each case the basic findings of the study were unchanged— Valium use did not appear to have any effects on anxiety or on many other social psychological variables when the minimum time frame for measuring use of the medication and level of the effects was seven days and when the maximum interval was 6 months. In view of the numerous clinical trials demonstrating the anxiolytic effects of Valium and similar benzodiazepines, the most probable conclusion is that Valium has no long-term social effects, either harmful of beneficial, within the time frames and range of social effects examined in this study.

Rigorous clinical trials are designed to rule out the many artifactual and competing explanations that we have just addressed. On the other hand, such trials introduce conditions which are antithetical to a study of actual, nonexperimental use. Hence we suggest that clinical trials might be used in the post-market surveillance period to confirm findings which have been identified through field surveys. In this way,

clinical trials, with their increased precision, and field surveys, with their advantages of breath and economy in examining large numbers of patients in natural settings, could be combined to generate a basic and complementary set of findings regarding the issue of the social effects of anxiolytic drug use.

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## APPENDIX

### Selected Measures

*Up to three* items are presented as illustration. Standard measures that are found elsewhere, such as the Hopkins Symptom Checklist [20], are not presented here. Where appropriate, an estimate of Cronbach's alpha ($\alpha$) is provided. As there were multiple estimates available based on the four waves of data collection and various subgroups, a summary is given. Many of the measures are derived from,

but not identical to, indices developed by other investigators. Those details as well as the full content of the measures are available elsewhere [17]. Also available are the details of the calendar measures of Valium use, quality of life, and anxiety which were used to obtain retrospective data and the details of the protocol for assessing medication use. These procedures are too complex to present here and require special materials.

### Potential indicators of strain

*Anger* ($\alpha$ *in the 0.80s*). In the last 7 days, how much have you felt...(1) furiously angry, (2) mad at someone, (3) so angry that you felt like hitting someone? *Response scale:* 1 = not at all, 2 = a little bit, 3 = quite a bit and 4 = extremely.

*Alcohol consumption.* (1) I would like to ask you about alcoholic beverages—i.e. wine, beer and liquor. Again, think back over the *last 7 days*. On how many of those days did you drink *any* alcoholic beverages? (2) *In the last 7 days*, on the days that you drank alcoholic beverages, how many drinks did you *usually* have? By drink I mean shot or glass. (3) (Asked of persons who reported no drinks in the last 7 days) In the last *month*...(text continued as in items 1 and 2 above).

*Quality of life: health* ($\alpha$ *in the 0.80s and 0.90s*). (1) How would you rate your health at present?—excellent, good, fair, or poor? *Response scale:* (implicit in item).

(2) In the last 7 days, how much has your physical health kept you from doing the things you want to do? Would you say it interfered *not at all, just a little, some,* or *a great deal? Response scale:* (implicit in item).

*Quality of life: various sub-indices* ($\alpha$ *generally in the 0.80s and 0.90s*). (1) How do you feel about the way you handle problems that come up in your life? (2) How do you feel about your physical appearance, the way you look to others? (3)...what you are accomplishing in your life? *Response scale:* 1 = terrible, 2 = unhappy, 3 = mostly dissatisfied, 4 = mixed (about equally satisfied and dissatisfied), 5 = mostly satisfied, 6 = pleased and 7 = delighted.

### Social conflict, social support, control and stresses

*Social conflict* ($\alpha$ *generally in the 0.70s–0.90s*). In the last 7 days, how much did some one person...(1) *misunderstand* the way you think and feel about things? (2) ...get on your nerves, (3) ...show that he or she disliked you? *Response scale:* 1 = not at all, 2 = just a little, 3 = some, 4 = quite a bit, and 5 = a great deal.

*Social support* ($\alpha$ *generally in the 0.70s and 0.80s*). In the last 7 days, how much did some one person...(1)...be a source of encouragement and reassurance? (2)...treat you with respect? (3)...show that he or she *cared* about you as a person? *Response scale:* (same as social conflict items).

*Social support from physician* ($\alpha$ *generally in the 0.60s and 0.70s*). (1) When you visit your (KIND OF DOCTOR), how much time is there to discuss with him or her *all* the things you want to talk about? *Response scale:* (same as social conflict items except 1 = none or very little).

(2) Would you say your (KIND OF DOCTOR) is very cold towards people, somewhat cold towards people, neither cold nor warm, somewhat warm, or very warm towards people? *Response scale:* (implicit in item).

*Control* ($\alpha$ *generally in the 0.60s and 0.70s*). (1) In the last 7 days, how much of what has happened in your personal life depended on what *you* said and did? (2) ...depended on what *others* said and did? (Note: items assessed control by self, by others, and by chance or luck, over the domains of personal life and of emotions. *Response scale:* (same as social conflict items).

*Stress: Role ambiguity* ($\alpha$ *in the 0.70s and 0.80s*). In the last 7 days, how *sure* or *unsure* were you about...(1)...whether the people in your personal life would *approve* of the way you were doing things? (2)...what others expected of you? *Response scale:* 1 = very sure, 2 = fairly sure, 3 = neither sure nor unsure, 4 = fairly unsure, and 5 = very unsure.

### Performance ($\alpha$ generally in the 0.60s–0.80s)

In the last 7 days, how *well* were you doing at...(1)...handling the responsibilities and daily demands of your personal life? (2)...getting along with others in your personal life? (3)...making the *right* decisions? *Response scale:* 1 = very poorly, 2 = not very well, 3 = all right, 4 = very well and 5 = exceptionally well.

### Perceived helpfulness of Valium and perceived influence on control ($\alpha$ in the 0.70s and 0.80s)

(1) Think about how (MEDICATION) affects your control over your emotions. Does it *increase* your control, *decrease* it, or not really affect it at all? IF THE PERSON REPLIED 'INCREASE'. Does it increase your control a lot or only a little? IF THE PERSON REPLIED 'DECREASE'. Does it decrease it a lot or only a little?

(2) Think about how it affects your ability to deal with the problems in your life. Does it *increase* your ability to deal with them *decrease* it, or not really affect it at all? (Follow-up questions were like those in the preceding item).

(3) How helpful do you find (MEDICATION)? *Response scale:* 1 = not at all, 2 = just a little, 3 = somewhat, 4 = very, 5 = extremely.

### Attitudes toward tranquilizer use ($\alpha$ in the 0.70s and 0.80s)

(1) Based on what you know about tranquilizers, do you generally *approve* or generally *disapprove* of the present use of them, or are you undecided? *Response scale:* (implicit in item).

(2) I'm going to read you some statements about tranquilizers. After I read each one, I want you to tell me how much you agree or disagree with the statement. (a) Using tranquilizers just prevents people from working out their problems for themselves. (b) It is better to use will power to solve problems than it is to use tranquilizers. *Response scale:* 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree and 5 = strongly agree.

### Measures of the significant others ($\alpha$ generally in the 0.70s and 0.80s)

Measures obtained from the significant other in personal life and at work were generally similar to those described above. For example, significant others in personal life completed self-administered measures of the Hopkins Symptom Checklist and provided performance ratings with wordings identical to those illustrated above for the focal respondent.