issue," he ignores the fact that two vastly different issues are involved and that I was addressing myself to only one of these. My editorial (Chest 69:331-332, 1976) is concerned only with "freedom-of-choice" privileges of the American clinician and the relationship of this concept to the distribution of worthless compounds. Governmental prohibition of drugs whose efficacy has never been tested by scientifically sound investigations cannot be compared to policies concerned with the evaluation of new, therapeutically active agents.

Even the Food and Drug Administration (FDA) has conceded that changes should be made in that agency's continued evaluation of new therapeutic compounds. Recently, Dr. J. Richard Crout, Director of the FDA's Bureau of Drugs, described serious administrative problems which the FDA has experienced in the past decade. Small wonder then that major errors of omission and commission occurred during that turbulent period. Dr. Crout noted, however, that many of these deficiencies have been corrected following a massive shake-up by top management. Undoubtedly, further changes will be effected, stimulated perhaps by such items as a recent national survey of physicians' attitudes towards government. The results of the poll indicated that clinicians believe that monitoring and licensing of the use of new drugs is handled poorly by the FDA. Seventy percent of the 2,100 physicians who answered the questionnaire stated that the FDA was "too cautious" in its handling of procedures for approval of new drugs (Roth R: The mood in medicine: Disillusionment and pessimism. Modern Medicine, May 1, 1976).

We must exercise the responsibility of constantly evaluating the procedures for approval of new drugs by the FDA. We should be critical of such episodes as the undue delay in the licensing of propranolol for the therapy of angina pectoris; however, it is very destructive to equate this issue with the FDA's bitter battle against the promotion of nostrums such as Laetrile. All individuals in the FDA (as well as those outside of that agency) who combat the devious methods involved in the promotion of Laetrile deserve the enthusiastic and grateful support of the medical profession. Let no one use the false issue of "freedom of choice" as a cloak to disguise the real dangers inherent in the distribution of "worthless but harmless drugs."

Alfred Soffer, M.D.
Editor-in-Chief

To the Editor:

Your editorial entitled "'Worthless but Harmless' Drugs Can Be Deadly" in the March issue (Chest 69: 331-332, 1976) is timely. The simplistic conclusions of well-meaning laymen in the media represent a danger toward which we must maintain a constant alert.

Medicine acknowledges the existence of iatrogenic disorders. One wonders whether or not the sponsors of "disorders of ignorance" ever come to realize how much more—how very much more—they contribute to the totality of human suffering.

Sanford M. Lewis, M.D., F.C.C.P.
East Orange, NJ

Treatment for Malignant Pleural Effusions

To the Editor:

I have read with interest the report of Wallach entitled "Intrapleural Tetracycline for Malignant Pleural Effusions" (Chest 68:510-512, 1975).

We have been working in this field during the last three years and have treated 15 patients with pleural effusion secondary to breast carcinoma by using a combination of pleural tube drainage, x-ray films to evaluate lung reexpansibility, and immediate instillation of 20 ml of a 0.5-percent solution of sodium hydroxide.

If the lung was not trapped with a peel, success was achieved in 100 percent, without recurrence of effusion from 6 to 18 months of follow up (except for one case of recurrence after five months, which was successfully treated with a second drainage and instillation). Local pleuritic pain lasted two or three minutes, ending spontaneously. Drainage after instillation was minimal. The tube was removed at 24 to 72 hours, and patients could be discharged on the third to fifth day.

In spite of evident metastatic pulmonary involvement, it has been difficult to find neoplastic cells.

We agree with Wallach about the nonspecific irritative action of this type of agent, but we believe, as Thorsrud,1 that it is necessary to produce a violent reaction of the visceral pleura to overwhelm the pleural defense mechanism and to damage both the visceral and parietal surfaces, which results in definite concrescence, as our clinical experience seems to prove.

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and Department of Surgery, School of Medicine
 Universidad de Chile
 Valparaíso, Chile

REFERENCE

To the Editor:

At the Washington Hospital Center, others have begun to use instillation of tetracycline for malignant pleural effusions. Of the six additional patients who have been treated (two with carcinoma of the lung and four with breast carcinoma), all have had a good result, with no recurrence of effusion. Four of these patients were not treated with alphaprodine hydrochloride (Nisentil) but only with morphine sulfate one hour
before instillation. Three patients did not have the severe local “burning” pain that occurred with our original group of patients. It is our belief that if the alphaprodine is not routinely given, it should be at the bedside and be given immediately to those who do complain of pain. Caution should be observed in the dosages of both the morphine sulfate and the alphaprodine hydrochloride in patients with known metastatic hepatic involvement or with cirrhosis. One patient with metastatic hepatic disease and cirrhosis needed naloxone hydrochloride (NARCAN) to reverse a respiratory arrest which occurred after the alphaprodine was given. So I suggest that in these patients a smaller dose of morphine sulfate be given and the alphaprodine not be given routinely. If it is given, then a narcotic antagonist should be readily available.

Howard W. Wallach, M.D.
Chief Medical Resident
Washington Hospital Center, Washington, DC

Pacemaker Rate Increase

To the Editor:

The early complete analysis of certain data in a pacemaker clinic has identified an excessive increase in rate in a significant number of Medtronic unipolar pacemakers (model 5951; Xytron).  

METHODS

A schedule of follow-up clinic visits was established. This included physiological examination and electrocardiographic and oscillographic wave-form analysis.

RESULTS

Wave-form analysis was performed at each clinic visit

<p>| Table 1—Patients’ Characteristics and Rate Increase at Time of Each Evaluation |
|-----------------------------|-----------------------------|-----------------------------|</p>
<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr), Race, Sex</th>
<th>Follow-up, weeks</th>
<th>Rate Change, beats per minute (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>70, W, F</td>
<td>18</td>
<td>2 (3)</td>
</tr>
<tr>
<td>2</td>
<td>12, W, M</td>
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<td>1 (1)</td>
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<td></td>
<td></td>
<td>24</td>
<td>4 (6)</td>
</tr>
<tr>
<td>3</td>
<td>75, W, F</td>
<td>12</td>
<td>4 (6)</td>
</tr>
<tr>
<td>4</td>
<td>89, B, M</td>
<td>18</td>
<td>2 (3)</td>
</tr>
<tr>
<td>5</td>
<td>37, W, F</td>
<td>16</td>
<td>2 (3)</td>
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<tr>
<td>6</td>
<td>56, W, F</td>
<td>12</td>
<td>7 (10)</td>
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<tr>
<td></td>
<td></td>
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<td>6 (8)</td>
</tr>
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<td></td>
<td></td>
<td>15</td>
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<td></td>
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<td>3 (4)</td>
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<td>72, B, F</td>
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<td>18, B, F</td>
<td>5</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

and revealed no deviation from the manufacturer’s specifications. Duration was 0.50 to 0.52 msec, and amplitude was from 100 to 250 mv in each case. These remained constant even though the rate changed (patients 2 and 6).

Significant (greater than 3 percent) increases in pacing rate occurred in 50 percent (six) of these 12 pacemakers within six months of the date of implantation, and five of the six exhibited these changes at the time of the first follow-up visit at four months. One patient showed an increase from 74 beats per minute at 12 weeks to 77 beats per minute at 24 weeks. All of the remaining patients have shown an increase in rate of approximately 2 beats per minute (3 percent). After the initial clinic visit, one patient died of related cardiac disease. Table 1 shows the increase in rate for each patient. Patient 6 became symptomatic with chest pain while her rate was 78 to 79 beats per minute. The discomfort subsided spontaneously as the rate decreased.

DISCUSSION

Unexpected changes in rate can occur with alarming consequences if one is not fully aware of all of the methods now available for clinical surveillance of pacemakers. The current model of Medtronic pacemaker (5951) is designed to exhibit a decrease in rate, prolongation of pulse duration, and drop in amplitude with battery failure. Because of the absence of these factors, we believed that we were dealing with an exaggerated rate drift and that replacement was not necessary. It is obvious that a downward drift to the level present at implantation would represent a change of significant magnitude and indicate prompt pacemaker replacement unless one is aware of an initial rate increase. Many variables must be utilized in making the decision for pacemaker change to ensure maximal efficiency, avoid unnecessary surgery, and particularly avoid unexpected pacemaker failure or exhaustion.

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