May 17, 1949. M. R. FIELDS 2,470,297

INHALATOR

Filed Sept. 4, 1947

Fig. 1.

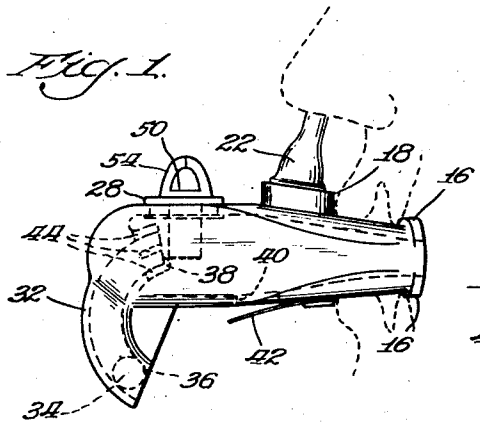
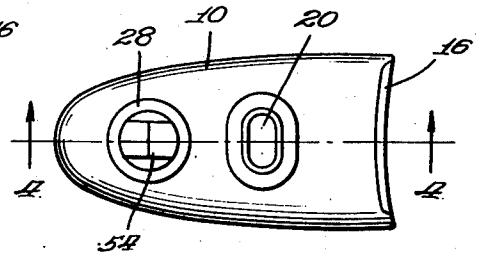
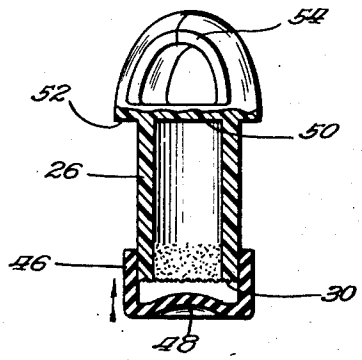


Fig. 2.





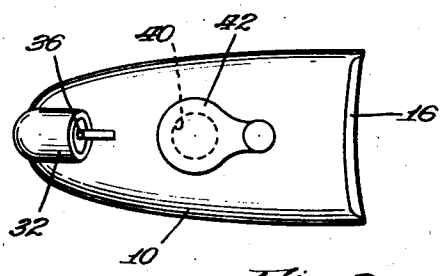
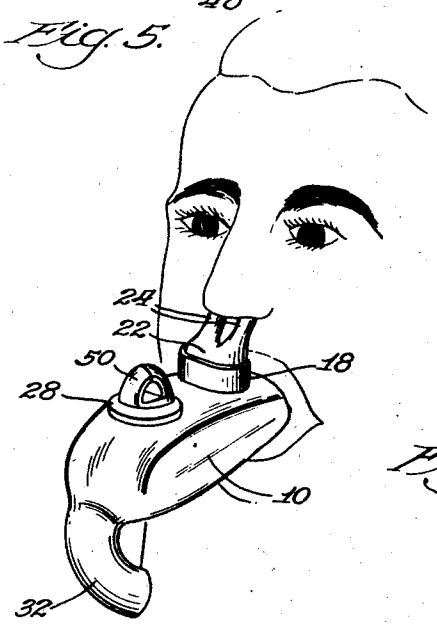


Fig. 3.

Fig. 5.



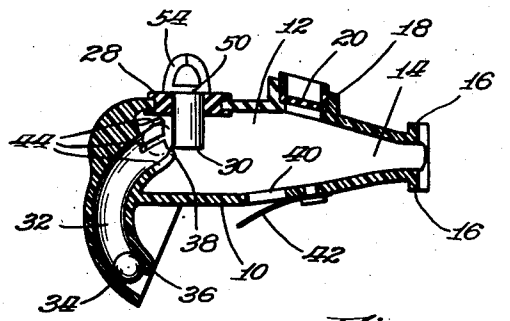


Fig. 4.

Fig. 6.

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INHALATOR

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3 Claims. (Cl. 128—266)

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My invention relates to therapeutic medication and includes among its objects and advantages increased convenience in medication with dry medicaments in powder form, especially with respect to accuracy of dosage and accurate placement of the material.

Many useful medicaments, and especially penicillin and related antibiotics, are subject to substantial or, in some instances, complete alteration by the stomach juices when administered orally. Different patients vary widely in the condition of the alimentary canal and the extent to which oral dosages will be impaired in effectiveness. In fact, the same patient will react differently to the same dosage at different times, because the condition of the patient's alimentary canal varies from time to time.

On this account, precision in treatment has only been attainable in the past with oral doseages supplemented by checking blood samples to ascertain how much medicament has found its way to the blood stream, or by parenteral administration. Both such methods of treatment require hospitalization or attendance in a clinic.

It has been discovered that the air-borne ingestion of powdered penicillin and many other water-soluble medicaments available in the form of fine powders, can result in effective blood levels of the medicament when the material is inhaled into the lungs. It is also possible to combine the general treatment thus resulting with high local concentration of the same medicament in whatever body cavity is utilized, including the lungs, and the throat.

In addition to water-soluble anti-biotics, solid inhalation therapy is of value in connection with certain vasoconstrictors, and is indicated for at least some of the known anti-histamine drugs. Illustrative examples of vaso-constrictors are: epinephrine hydrochloride, isopropyl epinephrin and 2-aminoheptane.. Illustrative examples of anti-histamine agents are: N-(alpha-pyridyl)-N-(alpha-thenyl)-N',-N'-dimethylethylenediamine hydrochloride, and N-(alpha-pyridyl)-N-(benzyl)-N',N'-dimethylethylenediamine hydrochloride.

Data available so far do not support any reliable generalizations. More particularly, the mere fact that a drug is ineffective or toxic when administered orally affords no indication that it is suitable for solid inhalation therapy. Many such therapeutic agents which are water soluble, will be found effective by solid inhalation, but both the effect and the degree of effectiveness need to be establishd by spcific test in connection with each substance.

However, especially when the local application is in the lungs, a wide variability in the proportion of powdered material that comes to rest in the nose and in the bronchial tubes and in

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the actual lung itself can only be avoided by a substantial constancy in the method of inhalation.

According to the invention, I succeed in obtaining such constancy by providing apparatus which is to be utilized by the patient by breathing in and out in a simple, substantially normal way. I utilize the energy of the patient's breathing to deliver into each charge of air inhaled a small substantially constant charge of powdered medicament, which charge is delivered quickly, shortly after inhalation begins, and finds its way to the depth of the cavity long before inhalation is finished. Thus the apparatus itself and the nose and bronchial tubes are thoroughly swept and scavenged with pure air during a major portion of the breathing-in process. I have found that administration in this way not only contributes to deep penetration of the medicament, but that it becomes unnecessary to pulverize or micronize the medicament into a true smoke. The use of larger particles tends to increase the reliability with which a uniform fraction of the material will pass on through the nose and bronchial tubes without getting caught on the moist walls.

Whereas other methods of administration by inhalation known to me are objectionable because the apparatus is expensive or complicated, or because the amount of medicament rendered effective for therapeutic purposes varies uncontrollably over a range of several hundred per cent, or both, it is possible according to the invention to work out dependable procedures which do not require hospitalization or the repeated checking of blood samples.

In the accompanying drawing:

Figure 1 is a side elevation of an inhalator according to the invention:

Figure 2 is a plan view of the same inhalator from above;

Figure 3 is a plan view of the same inhalator from below;

Figure 4 is a section as on line 4—4 of Figure 2;

Figure 5 is a longitudinal section of the capsule before it is assembled with the inhalator; and

Figure 6 is a perspective of the device in use.

In the embodiment of apparatus selected for illustration, the main housing 10 is of transparent plastic, molded in two halves cemented together on the plane of the section of Figure 4. The body defines a chamber 12 having an outlet opening 14 for the discharge of air into the mouth of the patient. Flanges 16 assist the patient in holding the device in place with the teeth as partially indicated in dotted lines in Figure 1. The top opening 18 is closed by a plug 20 when it happens that medication through the mouth only is desired. Normally, it will receive a lower end of a bifurcated nose connector piece 22. This is of flexible ma-

terial with its lower end fitted into the opening 18 and the two tips 24 entered in the nostrils of the patient. With a suitable grade of rubber the bottom portion may advantageously have a wall thickness of about 68 thousandths of an inch, which will secure a satisfactory grip in the opening, and the wall may taper to about 30 thousandths of an inch at the end of the tip so that the tips 24 will be soft and comfortable to the user's nostrils.

Means are provided for discharging a predetermined amount of powdered medicament small enough in quantity to be carried into the air-filled cavity receiving it during a first and preferably minor fraction of each breathing in, or inhalation. By making the energy requirement for the discharge of the medicament extremely low, it is possible to make this discharge, and the timing of the discharge, completely automatic, and to energize it by the energy supplied by the patient in inhaling without imposing enough burden on the muscular strength of the patient to cause any material labor or annoyance. I have illustrated a capsule 26 inserted into place in a rubber grommet 28 set in the upper wall of the body 10. The capsule, when in use, has an open lower end obstructed by a fine screen 30. Suitable results have been obtained with screens from about 40 to 80 mesh. To jar, or agitate, the capsule with the right force at the right time, I provide an inlet tube 32 in which lies a ball 34 freely movable from one end of the tube to the other but restrained from falling out by a lug 36 and from falling into the chamber by a lug 38. Upon reference to Figure 4, it will be observed that the parts are so proportioned that the ball 24 may strike the capsule 28 at the end of its inward movement and thus deliver a blow to discharge powder through the screen 30.

The chamber 12 has another inlet 40 in its bottom controlled by the simple flap check valve 42. It will be apparent that at the beginning of each inhalation the flap 42 closes immediately and the suction exerted by the patient then throws the ball 34 quickly from the bottom of the tube 32 up into contact with the capsule 28. A simple steel ball functions very well in this connection, but with a ball of aluminum the parts may be designed to secure a slightly better mechanical action.

The inner end of the tube 32 is provided with four slots 44 extending down the tube far enough so that the ball uncovers and opens them when it moves to the upper end of its path. Thus, the user does not experience any material restriction on his breathing.

The capsule 26 is filled and sealed at the place of manufacture. It may advantageously be shipped with its lower end covered with a rubber cap 46, which, in undistorted condition, has its bottom dished upward as indicated at 48 in Figure 5 so that pushing the cap home on the lower end of the capsule will stress the bottom 48 and cause it to remain gently pressed upward against the screen 30 until the cap is removed preparatory to using the capsule.

The upper portion of the capsule is shaped for convenient handling by the user. I have illustrated a plastic capsule which may be formed initially with a middle diaphragm 50 at the top of the capsule proper 26, and substantially arcuate closed wall sections rising above the diaphragm 50 and of slightly larger diameter than that of the capsule proper 26 to define an abutment shoulder 52 to engage the grommet 28. The

segmental upper portions may then be heated slightly and gently pressed over to define an open-ended arch 54, the ends of which may conveniently be engaged by the finger tips of the user when inserting or withdrawing the capsule.

I prefer to curve the passage 32 in a generally arcuate path down and in toward the user to reduce the overall length of the device.

By varying the fineness of the powder and the mesh of the screen 30 various powdered medicaments can be administered at various rates. With sodium penicillin I prefer to use a screen of about 60 mesh and it is not hard to granulate the powder by trial and error to a grain size such that an administration of 100,000 units is easily accomplished by normal breathing, in from three to six minutes. I have also found that smoother and more accurate mechanical action can be secured by mixing the penicillin with at least a little other material intended to function as a diluent or vehicle. Specifically, 100,000 units of graular penicillin represents about 90 milligrams of material and the addition to the charge of about 25 milligrams of sulfanilamide makes up into a combined powder that secures materially better and more accurate mechanical functioning. A patient inhaling such a charge will receive a full normal dose of penicillin but only about 10% of a normal dose of sulfanilamide. It will be obvious that the charge may include various combinations of medicaments with or without completely inert vehicles.

Because the energy of the user's breath actuates the timed discharge, there is no other instrumentality with which any synchronism needs to be maintained. Further, because there is no extraneous power imposed on the ingoing air stream, the patient's natural and normal lung movements are not disturbed and upset by being pushed or pulled in a way that is always uncomfortable and frequently unexpected and bad for the morale of the patient.

Others may readily adapt the invention for use under various conditions of service by employing one or more of the novel features involved, or equivalents thereof. As at present advised with respect to the apparent scope of my invention, I desire to claim the following subject matter.

I claim:

1. Equipment for introducing an air-borne powdered medicament into body cavities, which comprises: a rigid transparent plastic body defining a chamber; said chamber being formed with one end outlet shaped to be gripped between the teeth of the user; said chamber having a lateral outlet positioned below the user's nostrils when said first outlet is gripped by the user's teeth; a flexible branched conduit having a single lower opening fitting said second chamber outlet, and double upper openings of a size to fit into the nostrils of the user; said upper openings being defined by flexible material; a tubular inlet at the end of the chamber opposite said first outlet; a ball of diameter sufficient to substantially close said tubular inlet; said tubular inlet being inclined so that the ball normally resides at the intake end of said inlet; an obstruction at the intake end of said inlet end to prevent egress of said ball; an obstruction at the discharge end of said tubular inlet to prevent discharge of said ball into said chamber; said tubular inlet having lateral vent opening adjacent its discharge end positioned to be uncovered by said ball; a removable container for medicament;

socket means in the wall of said chamber for receiving and holding said container in a position to be struck by said ball at the end of its inward movement; said container having a foraminated bottom; and a charge of powdered medicament in said container of grain size small enough to deliver an increment of medicament through said foraminated bottom each time said ball strikes said container at the beginning of inhalation; a return flow discharge opening in said chamber, and a quick-acting check valve permitting gas to issue from said chamber during exhalation but closing at the beginning of inhalation to compel the air inhaled to enter through said tubular inlet.

2. Equipment for introducing an air-borne medicament into body cavities, which comprises: a rigid transparent plastic body defining a chamber; said chamber being formed with one end outlet shaped to deliver fluid to the mouth of the user; said chamber having a lateral outlet positioned below the user's nostrils when said first outlet is gripped by the user's teeth; a conduit means for delivering gas from said second chamber outlet into the nostrils of the user; a tubular inlet at the end of the chamber opposite said first outlet; a ball of diameter sufficient to substantially close said tubular inlet; said tubular inlet being inclined so that the ball normally resides at the intake end of said inlet; an obstruction at the intake end of said inlet end to prevent egress of said ball; an obstruction at the discharge end of said tubular inlet to prevent discharge of said ball into said chamber; said tubular inlet having lateral vent openings adjacent its discharge end positioned to be uncovered by said ball; a removable container for medicament; socket means in the wall of said chamber for receiving said container in a position to be struck by said ball at the end of its

inward movement; said container having a foraminated bottom; and a charge of powdered medicament in said container of grain size small enough to deliver an increment of medicament through said foraminated bottom each time said ball strikes said container at the beginning of inhalation; a return flow discharge opening in said chamber; and a quick-acting check valve permitting gas to issue from said chamber during exhalation but closing at the beginning of inhalation to compel the air inhaled to enter through said tubular inlet.

3. Equipment for introducing an airborne powdered medicament into body cavities, which comprises: a body defining a chamber; said chamber being formed with an outlet shaped to deliver fluid to the person of the user; an inlet to said chamber; a medicament container in said chamber having a foraminated wall; means actuated by the initial flow of inhaled gas through said inlet, for jolting said container to release an increment of medicament through said foraminated wall; said chamber being provided with an additional outlet for the exit of gas during exhalation; and an automatic check valve in said additional outlet to prevent inward flow.

MACK R. FIELDS.

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