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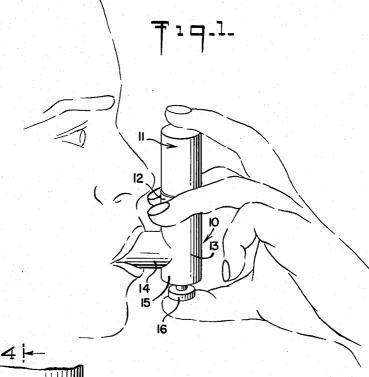
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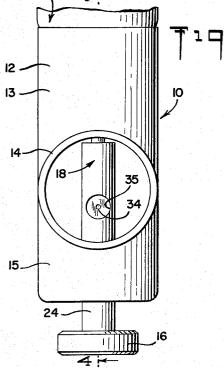
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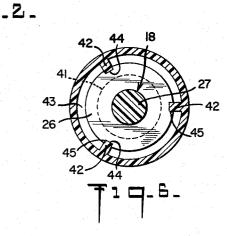
DEVICE FOR INHALATION AEROSOL

Filed June 25, 1962

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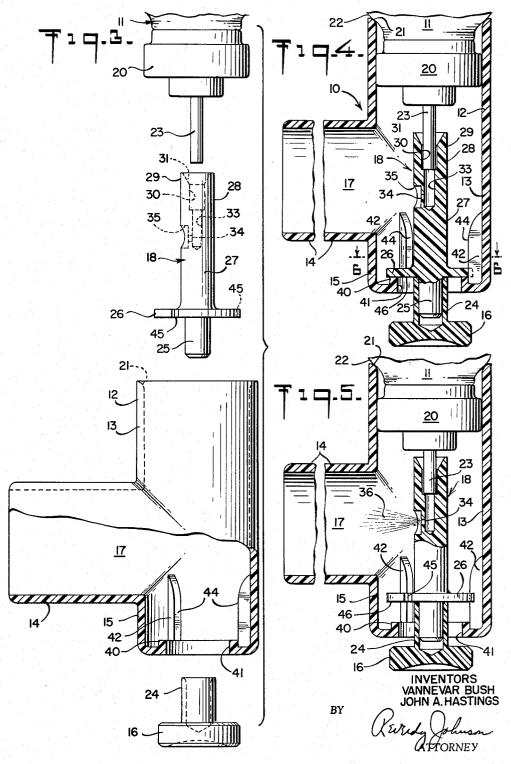
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DEVICE FOR INHALATION AEROSOL

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DEVICE FOR INHALATION AEROSOL Vannevar Bush, Belmont, and John A. Hastings, Bass River, Mass., assignors to Merck & Co., Inc., Rahway, N.J., a corporation of New Jersey Filed June 25, 1962, Ser. No. 204,913 6 Claims. (Cl. 128–208)

This invention relates to a device for use in inhalation therapy with aerosols. More particularly, the invention 10 relates to a simple, inexpensive device to be attached to an aerosol container of medication which, upon proper actuation, provides exceptionally deep penetration of the medication into the lung cavities.

Other features of the invention will become apparent $_{15}$ as the description proceeds.

In the drawings:

FIGURE 1 is a view, in perspective, of the inhalation device and attached aerosol container and showing the manner of their use;

FIGURE 2 is a vertical elevation of the inhalation device alone, looking into the mouth end of the inhalation tube;

FIGURE 3 is an exploded side elevation view of the inhalation device and attached aerosol container;

FIGURE 4 is a vertical sectional view of the inhalation device taken along the line 4-4 of FIGURE 2, showing also the aerosol container in position at the top of the device;

FIGURE 5 is a view similar to FIGURE 4 showing the 30 positions of the parts when the actuating thumb button is pushed upwardly; and

FIGURE 6 is a transverse sectional view of the lower part of the inhalation device taken along the line 6-6 of FIGURE 4.

Referring to FIGURES 1 and 2 of the drawings, the inhalation device generally designated 10 has attached thereto an aerosol container generally designated 11. When the device is in position for use, as shown, the aerosol container 11 is in inverted position and closely 40 fitted within the upper portion 12 of the vertical tube 13 of the device 10. The horizontal tube 14 of the device 10 serves as the gas expansion chamber and mouthpiece. A thumb button 16, by which the device is actuated, extends downwardly from the lower portion 15 of the vertical tube 13.

When using the device, it is grasped in the hand and positioned so that the open end of the horizontal tube 14 is grasped firmly by the mouth, with the tube 13 positioned vertically and the thumb under the thumb button 16. The 50 index finger is placed over the top of the aerosol container, which, since the container is in inverted position, is the base of the container. The first and third fingers are conveniently on opposite sides of the vertical tube 13. The user then exhales fully, releasing his mouth grasp of 55the horizontal tube 14 to do so, after which the user regrasps the horizontal tube 14 with his mouth and attempts to inhale or suck in his breath. Because there is then no passageway from inside the device 10 to the atmosphere (as will be explained later), a subnormal pressure or a vacuum is created within the device 10. After this vacuum is created the user pushes thumb button 16 upwardly, and this causes a metered amount of medicament and propellant to be discharged from the aerosol container 11 into the horizontal tube 14 and thence into 65 the breathing apparatus and lungs of the user.

Referring now to the other figures (i.e., FIGURES 3, 4, 5 and 6) in addition to FIGURES 1 and 2, the inhalation device 10 consists of three main parts. These are (1) the T-shaped chamber, generally designated 17, 70 formed by the horizontal tube 14 and the vertical tube 13 intersecting therewith so that part of the vertical tube 13 2

is above the horizontal tube 14 and part is below the horizontal tube 14; (2) the main stem generally designated 18; and (3) the thumb button 16 and its associated parts.

The interior of the upper portion 12 of vertical tube 13 fits closely around the circular perimeter of the metal closure and sealing cap 20 of the aerosol container 11. Preferably also, the tip end 21 of the upper tube portion 12 engages the outer surface of the neck 22 of the aerosol container 11. The end result of this construction is that there is a substantially air-tight attachment of the aerosol container 11 to the inhalation device 10, so that no air can leak into the upper portion 12 of vertical tube 13 from the exterior.

Projecting downwardly through the center of the closure and sealing cap 20 of the aerosol container 11 is the hollow discharge valve stem 23 of the aerosol container. When this stem 23 is moved axially upwardly from its normal position as shown, the valve of the container is actuated to cause a discharge of propellant and active ingredient downwardly out of the hollow valve stem 23. The detailed construction of the aerosol valve is not part of this invention, and so is not shown.. Preferably, however, the aerosol valve is of the type known as a metering valve, by means of which a measured quantity of the propellant and active ingredient mixture in the aerosol container is discharged to form a single burst of aerosol mist. To effect discharge of more of this mixture, the aerosol valve stem must be returned to its normal position and then reactuated to the discharge position.

Thumb button 16 projecting below the lower portion 15 of tube 13 is the part of the inhalation device that is manually operated by the user of the device to actuate the aerosol valve stem 23. Thumb button 16 has a cylindrical piece 24 extending upwardly therefrom. The upper end of this piece 24 is hollow so as to fit tightly about the lower cylindrical portion 25 of the main stem 18. This main stem 18 also includes, in the following order from bottom to top, a flange portion 26, a solid portion 27, a hollow portion 28, and a valve stem receiving portion 29. This last portion 29 of main stem 18 has a cylindrical recess 30 therein, the annular wall of which fits closely, but not tightly, about the lower end of the aerosol discharge valve stem 23, with the base of the recess 30 abutting the end of the stem 23. The upper end of recess 30 may be tapered outwardly, as at 31, so as to guide the aerosol valve stem 23 into the recess 30 when the aerosol container 11 is operatively assembled with the inhalation device 10.

From the base of recess 30 in the main stem 18 is a vertical passageway 33 of a diameter smaller than that of recess 30 and extending downwardly along the axis of the stem 18 to just below the axis of horizontal tube 14. At a point about opposite the axis of tube 14 this vertical passageway 33 connects with a horizontal passageway 34 that is quite small and that extends radially outwardly in the direction of the mouth of horizontal tube 14. This passageway 34 serves as an orifice, and for better control of the orifice characteristics, the length of the passageway 34 is reduced by substantially enlarging the diameter of the passageway nearest the surface of hollow portion 28 of main stem 18, as indicated at 35.

Hence, it is evident that when thumb button 16 is pushed upwardly (as shown in FIGURE 5), the main stem 18 is moved upwardly, and with it the aerosol valve stem 23 is moved upwardly, to effect a discharge of the measured quantity of propellant and active ingredient mixture in the aerosol container. This mixture is discharged down the vertical passageway 33 and out through the orifice, formed by horizontal passageway 34, into the horizontal tube 14, as indicated at 36. The bottom end of the lower portion of the vertical tube 13 is partially closed by an inwardly projecting wall 40 forming an an-

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nular wall having a circular opening 41 therein. The upwardly extending cylindrical portion 24 of thumb button 16 passes through this opening 41, with an appreciable radial clearance therebetween.

The lower portion 15 of vertical tube 13 has three inwardly projecting ridges 42 formed on the inside of the tube. These ridges 42 extend axially upward from the wall 40 to about the lowest point of intersection of the horizontal tube 14 with the vertical tube 13.

The diameter of flange portion 26 of main stem 18 is 10 somewhat less than the inside diameter of the lower portion 15 of vertical tube 13, thereby providing a clearance 43 between the periphery of the flange portion 26 and the inside of the lower portion 15 of vertical tube 13. However, the diameter of flange portion 26 is larger than 15 the diameter of the circle tangent to the inner faces 44 of the ridges 42 at the bottom of tube 13 (i.e., at annular wall 40). Flange portion 26 is provided with three slots 45 in its periphery which fit about the respective ridges 42 and permit the flange portion 26 to be moved downwardly 20 until its bottom surface 46 is in engagement with the inner surface of annular wall 40.

As a result of the above described construction at the bottom of vertical tube 13, the main stem 18 is always oriented so that its orifice 34 discharges the aerosol mixture parallel to the axis of horizontal tube 14 and in the direction of the open end of horizontal tube 14.

Also as a result of the above described construction at the bottom of vertical tube 13, the flange 26 acts to seal the lower portion 15 of vertical tube 13 against the passage 30 of air into the tube 13 from outside the tube while the aerosol container 11 and its metering valve are in normal, unactuated position, as shown in FIGURE 4.

This sealing action is accomplished by the engagement of the bottom surface 46 of flange portion 26 of the main stem 18 against the inner surface of annular wall 40 at the bottom of the lower portion 15 of vertical tube 13. To effect this engagement, the vertical tube 13 is moved up onto the aerosol container 11 as far as it will go, with the main stem 18 in position engaging the areosol discharge valve stem 23 and with the lower end of that stem seated against the base of recess 30 in the main stem 18. The frictional fit of the inside of the vertical tube 13 about the perimeter of the closure and sealing cap 20 of the aerosol container 11, and the action of the 45spring (not shown) of the metering valve within the aerosol container 11 that tends to maintain the aerosol discharge valve stem 23 in its fully extended position (i.e., lowermost position as the inhalation device is viewed in these drawings) maintains this air sealing engagement $\,{}^{50}$ of the parts at the lower end of vertical tube 13.

Hence, when the user of this device places the open or mouthpiece end of horizontal tube 14 in his mouth, as shown in FIGURE 1, and attempts to inhale or suck in, there is no passageway anywhere in the device for air to enter the interior of the device (i.e., chamber 17). It cannot enter from the upper end of vertical tube 13, due to the air-tight attachment of the aerosol container to the upper portion 12 of vertical tube 13. Air cannot enter from the lower end of vertical tube 13, due to the air-sealing action of flange portion 26 of main stem 18, as described. Elsewhere the vertical tube 13 and horizontal tube 14 are without openings or vents.

The user, while continuing to suck and breathe in, then pushes thumb button 16 upwardly, so that the parts are in the position as shown in FIGURE 5. This action causes a burst of propellant and medication to be discharged out of the orifice 34 into the horizontal tube 14, where it mixes with air released into the device at the bottom of vertical tube 13 by the raising of flange 26 away from engagement with the annular wall 40 of the tube.

The air mixes with the propellant and medication to one end of a substantially horizontal tube, the upform an aerosol mist in the horizontal tube 14. This mist 75 per end of the vertical tube being attached in a rela-

is carried deep into the breathing apparatus and lungs of the user by virtue of the relatively significant initial subnormal pressure, or vacuum, created in the breathing apparatus and lungs just prior to the actuation of the thumb button 16, and the sudden release of that vacuum when the thumb button 16 is actuated to produce the formation of

the aerosol mist in the horizontal tube of the device. Hence, the inhalation device described is a simple and inexpensive device that enables the medication within the aerosol container to be administered very deep in the lung cavities. This depth of administration is greater than can be effected by presently known or available small-size, pocket-type, manually-actuated aerosol inhalation devices. What is claimed is:

1. An aerosol inhalation device for administering to the lung cavities a medication stored with a propellant under pressure in an aerosol container having a hollow discharge valve stem projecting from a sealing closure, said device comprising: (a) a closed chamber effected by having an inlet opening adapted to fit in a substantially air-tight manner about the sealing closure of the aerosol container with the aerosol discharge valve inside the chamber, said closed chamber also having an outlet tube adapted to be grasped by the lips of the user 25and through which an aerosol mist, when it is formed in the closed chamber, passes into the mouth of the user, said closed chamber also having vent means, which, when actuated to open position, admits air from the exterior of said closed chamber to the interior of said closed chamber; (b) mechanism positioned within said closed chamber adapted to engage said aerosol discharge valve stem and, when displaced, moving said aerosol valve stem to discharge a propellant-medication mixture from the aerosol container into said closed chamber and in the direction of the outlet tube; (c) an aerosol actuating button positioned outside said closed chamber; and (d) connecting means mechanically connecting said actuating button with said mechanism and responsive to the actuation of said mechanism for opening said vent means to admit air into said closed chamber from the exterior thereof when the mechanism is actuated to effect a discharge of the propellant-medication mixture from the aerosol container into the closed chamber.

2. An aerosol inhalation device as set forth in claim 1, in which said connecting means (d) includes a rod that is secured at one end to said actuating button (c) and that is secured at the other end to said aerosol valve moving mechanism (b), with said vent means including said rod extending through an aperture in said closed chamber (a) that is substantially larger than the exterior of said rod, so that air can pass into said chamber through said aperture, said rod having a washer-like flange portion positioned thereon just inside the closed chamber and engaging the inner wall thereof in the vicinity of the aperture through which the rod passes into the closed chamber and serving to close off such aperture when the aerosol actuating button (c) and the aerosol valve moving mechanism (b) are in non-actuated position, but with said washer-like flange portion moved away from engagement with the inner wall of said closed chamber, and thereby automatically opening said aperture through which said rod passes to enable the passage of air into said closed chamber, when the user moves the aerosol actuating button (c) into aerosol-actuated position.

3. The combination of (i) an aerosol container having a hollow discharge valve stem projecting from a sealing closure, said container containing a medication for administration to the lung cavities and a propellant for the medication, said propellant being under pressure in said container, and (ii) an aerosol inhalation device for administering the medication through the mouth to the lung cavities, said device comprising: (a) a substantially vertical tube intersected between its ends by one end of a substantially horizontal tube, the upper end of the vertical tube being attached in a relaverted position so that the aerosol discharge valve stem is positioned inside said vertical tube and projects downwardly therein, the lower end of the vertical tube having an annular wall partially closing the vertical tube at that end and leaving an opening at that end, and the other end of the horizontal tube being open for insertion in the user's mouth and grasping between the lips of the user; (b) an actuating button positioned just below the lower end of the vertical tube and outside the an- 10 nular wall thereat, said button having a member extending up into the lower end of the vertical tube through the opening formed by the annular wall thereat, the size of said member being smaller than said opening so that air may readily pass into the vertical tube via the space be- 15 tween the member and the inner edge of the annular wall; and (c) means positioned inside said vertical tube mechanically connecting the portion of said member inside said vertical tube with the aerosol discharge valve stem and responsive to the upward movement of the actuating 20 button for actuating the aerosol discharge valve stem to effect the discharge of propellant and medication mixture from the aerosol container through its discharge valve into the aerosol inhalation device in the area where the horizontal tube intersects the vertical tube, with the dis- 25 charge directed toward the end of the horizontal tube in the user's mouth, said means including a flange positioned inside the vertical tube and overlying the opening in the annular wall and normally in engagement with the interior surface of the annular wall to prevent the passage 30 of air into the vertical tube via the space between the member and the inner edge of the annular wall, said flange being smaller in diameter than the inside diameter of the vertical tube at the lower end thereof so that air may readily pass between the outer edge of the flange 35 and the inside wall of the vertical tube, and said flange being raised out of engagement with the interior surface of the annular wall when the actuating button is moved upwardly to actuate the aerosol discharge valve stem, thereby automatically opening a vent for the admission 40 of air to the lower end of the vertical tube when the actuating button is moved upwardly to effect a discharge of propellant and medication into the user's throat and lungs.

4. The combination as set forth in claim 3, in which 45 the connecting means is a substantially vertical rod having a cylindrical recess at the top into which the lower end of the aerosol discharge valve stem fits, said rod having a passageway smaller in diameter than the base of said cylindrical recess and extending from said base down- 50 wardly to just below the axis of the horizontal tube, said rod also having an aperture from said passageway at right angles to the axis of the rod and serving as an orifice for the discharge of the propellant and medication mixture from the aerosol container into the area where the hori- 55 zontal tube intersects the vertical tube, with the orifice directed to discharge such mixture toward the end of the

horizontal tube in the user's mouth, the bottom end of said rod being attached to the upwardly extending member of the actuating button and having affixed thereto, just inside the lower end of the vertical tube, the flange that overlays the opening in the annular wall and normally is in engagement with the interior surface of the annular wall.

5. The combination as claimed in claim 4 in which the lower inside portion of the vertical tube has at least one inwardly projecting ridge extending vertically up the inside wall thereof from the annular wall at the bottom of the vertical tube for at least a distance equal to the amount of vertical movement imparted to the vertical rod when the actuating button is moved upwardly to effect a discharge of propellant and medication mixture from the aerosol container, said flange having as many slots in its periphery as there are ridges, each slot fitting about its corresponding ridge without hindering the vertical movement of said flange and rod but preventing the rotation of said flange and rod about its vertical axis, thereby maintaining the orifice in the rod oriented in the direction of the mouth end of the horizontal tube.

6. The improved method of administering to the throat and lungs a medication contained in an aerosol mist derived from a propellant and medication mixture in an aerosol container that is discharged into a mixing chamber where it mixes with air to form the aerosol mist that is directed to a mouth tube and from there sucked into the throat and lungs, and wherein the user manually actuates a button to effect the discharge from the aerosol container, said improvement comprising: initially creating a vacuum in said mixing chamber by sucking action of the user on the mouth tube, said mixing chamber being closed to the atmosphere and ventless at the time so that a significant vacuum can be created therein by the user; and then venting said mixing chamber to admit air thereto simultaneously with, and in response to, the manual actuation of the aerosol actuating button.

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