1983; and Slatopolsky *et al.*, "Calcium Carbonate as a Phosphate Binder in Patients with Chronic Renal Failure Undergoing Dialysis," New Engl. J. Med. 315:157-161, 1986). Thus, an analog of 1,25-$(OH)_2D_3$ that can suppress PTH with minor effects on calcium and phosphate metabolism would be an ideal tool for the control and treatment of secondary hyperparathyroidism.

[00017] Another vitamin D analog, namely, 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 (referred to in the literature as "2MD") is also known to suppress PTH production. (*See* U.S. Published Application No. 2011/0034426A1). Although it would therefore appear to be a candidate for treating secondary hyperparathyroidism, it is also well known from U.S. Patent No. 5,843,928 that 2MD has very potent calcemic activity. 2MD significantly increases bone calcium mobilization activity to a level likely to be 10-100 times that of 1α,25-$(OH)_2D_3$ while also exhibiting a modest increase in intestinal calcium transport activity. Due to this highly selective activity for the mobilization of calcium from bone, the compound 2MD was never seriously considered as a pharmaceutical agent for treating secondary hyperparathyroidism, until now.

SUMMARY

[00018] In one aspect there is provided a use of 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 or pharmaceutically acceptable salts thereof in the manufacture of a medicament for treating or preventing secondary hyperparathyroidism or the symptoms ~~thereof~~ of secondary hyperparathyroidism in a subject having or at risk for developing secondary hyperparathyroidism ~~or the symptoms thereof~~ without inducing hypercalcemia in the subject.

[00018a] It has now been discovered that the vitamin D analog 2MD has the ability to treat secondary hyperparathyroidism as well as symptoms of secondary hyperparathyroidism when administered under well-controlled conditions to a subject in need thereof. It also now been discovered that the vitamin D analog 2MD has the ability to prevent secondary hyperparathyroidism as well as symptoms of secondary hyperparathyroidism when administered under well-controlled conditions to a subject in need thereof.

[00019] In one embodiment, the present disclosure provides a novel method of treating secondary hyperparathyroidism by administering a therapeutically effective amount of a composition comprising 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 (2MD) or pharmaceutically acceptable salts thereof as the active agent to a subject

CLAIMS

We claim:

1. Use of 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 or pharmaceutically acceptable salts thereof in the manufacture of a medicament for treating or preventing secondary hyperparathyroidism or the symptoms ~~thereof~~ of secondary hyperparathyroidism in a subject having or at risk for developing secondary hyperparathyroidism ~~or the symptoms thereof~~ without inducing hypercalcemia in the subject.

2. The use of claim 1, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in an oral, topical, transdermal, parenteral, injection or infusion dosage form.

3. The use of claim 1, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in a dose for administering about 20 ng/day to about 1 ug/day to the subject.

4. The use of claim 1, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in a dose for administering about 40 ng/day to about 600 ng/day to the subject.

5. The use of claim 1, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in a dose for administering about 600 ng/day to the subject.

6. The use of claim 1, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in a dose for administering about 400 ng/day to the subject.

7. The use of claim 1, wherein the subject is receiving hemodialysis treatment.

8. The use of claim 7, wherein the 2-methylene-19-nor-(20S)-1α,25-dihydroxyvitamin D_3 is formulated in a dosage form for administering about three times per week to the subject.

9. The use of claim 1, wherein the symptoms of secondary hyperparathyroidism are selected from the group consisting of increased levels of serum PTH, serum phosphorus and serum creatinine.