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 of secondary hyperparathyroidism in a subject ~~having or at risk for developing secondary hyperparathyroidism~~ with established kidney failure 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 of secondary hyperparathyroidism in a subject ~~having or at risk for developing secondary hyperparathyroidism~~ with established kidney failure 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.