

STOHN BONJ PROCESS DEVELOPMENT





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Process

- ❖ Formation of Network
- ❖ Affiliation with PBRN
- ❖ Pilot Study
- ❖ STOHN member meeting
- ❖ Development

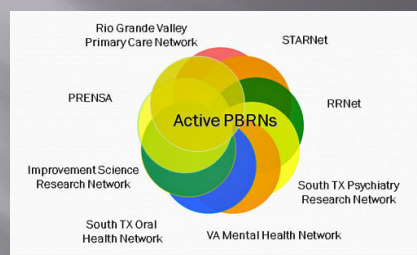
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network formation

- ❖ May 2008: Clinical Translational Science Award (CTSA)
- ❖ Included Funds for PBRN
- ❖ Dr. Michael Parchman & Holly Hayes co-direct PBRN resource center
- ❖ STARNet and RRNet
 - ❖ 25 years combined experience at PBRN
 - ❖ Serve as models for UTHSC PBRN

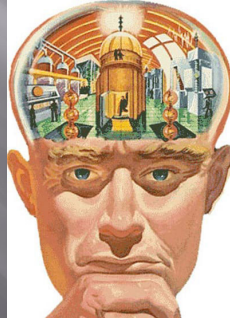
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Organization



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STOHN meeting



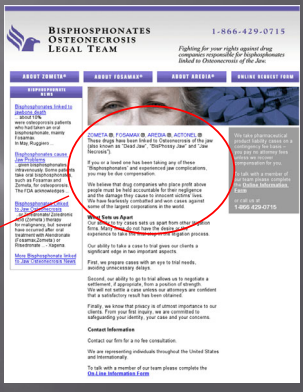
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- Fear
- Confusion
- Uncertainty
- Risk
- Panic
- Warning
- Litigation

ZOMETA **FOSAMAX** **AREZIA** **ACTONEL**
These drugs have been linked to Osteonecrosis of the jaw (also known as "Dead Jaw", "BisPhosJaw" and "Jaw Necrosis").

If you or a loved one has been taking any of these "Bisphosphonates" and experienced jaw complications, you may be due compensation.

We believe that drug companies who place profit above people must be held accountable for their negligence and the damage they cause to innocent victims' lives. We have fearlessly combatted and won cases against some of the largest corporations in the world.



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How much do we need to know?



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1st Generation – oral bisphosphonates



- Introduced in 1990's
- Improve bone quality in Pagets Disease
- Osteoporosis
 - Alternative to HRT in post menopause women
 - Prevent fractures of spine, wrist and hip
 - 2ndry to corticosteroid use, SLE, RA,
- Injectables introduced for pts with dosing difficulties, inability to sit upright for 60 mins or swallow tablets

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2nd and 3rd Generation – IV bisphosphonates



- Hypercalcemia of malignancy
- Prevent metastatic tumors in breast, lung and prostate cancer
- Prevent bone complications and pain in multiple myeloma and kidney disease
- Prevent post-operative fractures and weakness in kidney, liver and cardiac transplant patients

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Wonder Drug?

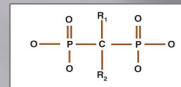


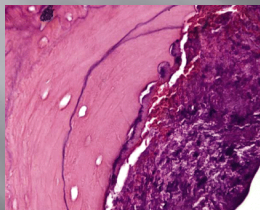
Figure 1. Basic Structure of Bisphosphonates



- 19th most prescribed drug group worldwide
- Synthetic analogues of pyrophosphates
- Not metabolized
- ½ absorbed dose is distributed to bone
- Increase bone density and thickness
- Prevent tumors from removing bone and spreading
 - Inhibit differentiation of bone marrow cells into osteoclasts
 - Inhibit Osteoclast activity
 - Reduction in bone turnover and resorption
 - Reduce local release of factors that stimulate tumor growth

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Side effects



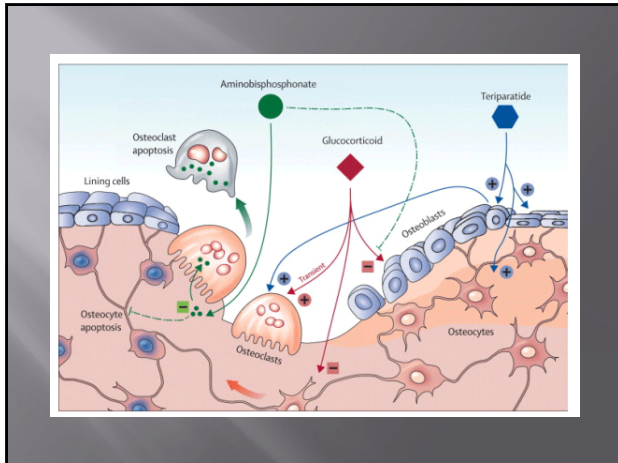
- Osteoclast function severely impaired
- Osteocytes not replaced
- Capillary network in bone not maintained
- Bone becomes too dense choking capillary network
- Avascular bone necrosis
- Osteonecrosis

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Incidence of BONJ in Maxilla and Mandible

- 3000 world cases
 - (191 million prescriptions)
- Mostly associated with intravenous (IV) bisphosphonates
 - Zometa (Zoledronic Acid)
 - Aredia (Pamidronate)
- Mostly following dental extractions or periodontal surgery
- Some spontaneously
 - Chronic infection
 - Trauma

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Facts

- IV Bisphosphonate = higher risk for BON
 - 50% of dose is bio available for bone matrix
- Oral bis-phosphonate = low risk for BON
 - 1% of dose is absorbed by GI Tract
- Time
 - Half life is 8-10 years

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Risk Assesment?

- Recent assessment test for necrosis potential
 - Arun Garg/Marx - Miami
 - C-Terminal Teloepptide (CTX) -- marker for serum bone turnover
 - scores - controversial

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Why a dental problem?

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What's Been Studied

- Only reported cases
- Worst cases in IV.....
- How many are related to "Oral" doses
- What's risk for "Oral" doses
 - Time dependant?
 - Dose dependant?
 - Drug dependant?
- Treatment

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STOHN BONJ Study

- "Oral" route most commonly seen in our practices.
- What are practitioners doing when encountered.
 - Basic Treatment
 - Referral??
- Baseline education level
 - Is literature doing it's job?
 - Altered treatment plans?

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BONJ Study development

- ❖ Formulated the question.
- ❖ Gathered current literature
- ❖ Formulated Hypothesis
- ❖ Developed study plan and parameters
 - ❖ Developed survey
 - ❖ Decided who to survey
- ❖ Gained IRB approval
- ❖ Survey
- ❖ Data Collection and Statistics

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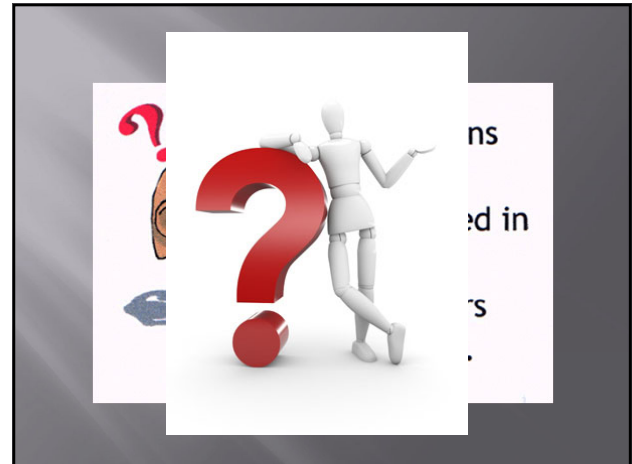
Dynamic Process



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