

# DEVICE CONSUMER PROTECTORS: “WHO’S ON FIRST?”

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XAVIER HEALTH

- **MISBRANDING** is an ancient term for Labeling Problems
- **LABEL** is on your device or accompanies it physically
- **LABELING** about your device explains its use or benefits
- **INSTRUCTIONS FOR USE** tell how it must be used to be effective
- **ADVERTISING** is all other communication by you, the marketer

- LABEL
- LABELING – PACKAGE, OUTER BOX, LEAFLET, TRAINING VIDEO
- INSTRUCTIONS FOR USE – PACKAGE & TRAINING MATERIALS
- FOR PMA-APPROVED DEVICES, INITIAL ADVERTISING CLAIMS
- FOR 510(K) DEVICES, NO ADVERTISING NEED BE SHOWN
- NO GENERAL REQUIREMENT FOR ADS TO BE SENT TO FDA
- FDA LEAVES ADVERTISING ISSUES TO OTHERS, ESPECIALLY FTC

- FDA COULD SUPERVISE ADS FOR PRESCRIPTION DEVICES
- “PRESCRIPTION”: HOSPITAL & SURGICAL USE, OR IN DOCTOR’S OFFICE
- LABEL INCLUDES LEAFLET FOR MEDICAL USER
- PHYSICIAN APPROVAL OF DEVICE’S USE ON PATIENT
- SALES REP VISITS DOC OR HOSPITAL PURCHASING DEPT
- AVERAGE NORMAL PERSON CANNOT OBTAIN DEVICE
- NOT ALL PMAA’S ARE RX; NOT ALL RX ARE PMAA’S
- YOU COULD HAVE A “SUBSTANTIALLY EQUIVALENT” RX DEVICE

# MEDICAL DEVICE PROBLEMS & COMPLAINTS

- MOST MARKETED DEVICES WERE 510(K) OR EXEMPT TYPES
- NEW 21<sup>ST</sup> CENTURY CURES ACT DRIVES MORE INTO EXEMPT STATUS
- 21<sup>ST</sup> CURES ACT REMOVES MOST SOFTWARE FROM FDA OVERSIGHT
- FDA HAS COMPLAINT HANDLING SYSTEMS FOR DEVICE COMPLAINTS
- MEDWATCH IS KEY DATA BASE TO ALERT FDA OF PROBLEMS
- FD-3500 SUBMISSION RE PROBLEM DEVICES THAT CAUSED INJURY
- USUAL SOURCE OF TROUBLE: COMPETITOR'S ATTACK ON YOUR ADS



- 1976 AMENDMENTS LEFT ADVERTISING TO FTC, NOT FDA, WITH A LIMITED EXCEPTION FOR RESTRICTED DEVICES IN 502(r)
- SO FTC HANDLES THE “BOGUS BENEFIT” PROMOTERS
- ALSO PLAYING: POSTAL INSPECTION SERVICE, STATE ENFORCEMENT AGENCIES, U.S. CUSTOMS (CBP), PRIVATE SUITS(LANHAM ACT)
- FDA REVIEWERS COULD QUESTION ANY AD’S BENEFIT CLAIMS WHEN DEALING WITH SAME SPONSOR ON SUBSEQUENT PRODUCTS
- BUT FDA USUALLY LEAVES DEVICE ADS TO FTC EXPERTISE

# HOW DO CONSUMERS GET “SOLD” NON-RX DEVICE PRODUCTS NOW?



- **SOCIAL MEDIA**
- **CABLE TV**
- **MAINSTREAM NETWORK TV**
- **PRINT MEDIA**
- **IN-STORE, BILLBOARD, FREE T-SHIRTS, ETC.**

- **MEDCON IS PROUD TO PRESENT  
JON MILLER STEIGER, ESQ.,**
- **MIDWEST REGION,**
- **FEDERAL TRADE COMMISSION**