FDA
DOCKETS MANAGEMENT
BRANCH (HFA-305)
DOCKET NO. 98-N-1265

RE: MOU
DEFINITION OBJECTION TO
"INORDINATE AMOUNT"

5-21-99

7202 '99 MAY 25 A10:52

IN RESPONSE TO THE FDA PHARMACEUTICAL SPECIALTY SERVICES & OUT-OF-STATE PRESCRIPTIONS - INORDINATE AMOUNTS THE LIMITS PROPOSED BY THE FDA ARE LUDICROUS & A DOUBLE STANDARD THAT FAVORS BIG GREEDY DRUG COMPANIES WHO ALREADY OWN & SUPPLY PHARMACIES THAT DISPENSE PRESCRIPTIO OUT-OF-STATE IN HIGH VOLUME. ALL EMPLOYER HEALTH PLANS, HMO COMMERCIAL, & SENIOR HEALTH INSURANCE PLANS ARE OUT-OF-STATE MAILORDER - WHAT GIVES HERE ???

IN ADDITION TO OUT-OF-STATE DISPENSING OF DRUGS - THE PATIENT HAS NO CHOICE IN THE FORMULARY. THE DRUG LIST IS LIMITED TO THE CONTRACT BETWEEN INSURANCE COMPANIE & DRUG DISTRIBUTERS. SPECIALTY REQUIREMENTS ARE NOT AVAILABLE EVEN IF THE PATIENT PAYS OUT-OF-POCKET. THE PATIENT MUST SEEK SPECIALTY PHARMACEUTICAL SERVICES TO MEET THEIR UNIQUE NEEDS, OR SUFFER THE COST OF GENERALIZED TREATMENT, RESULTING IN SIDE AFFECTS & DEBILITATING HEALTH. THE NUMBER OF SPECIALTY PRESCRIPTIO ARE MINISCULE COMPARED TO THE DRUG COMPANIES VOLUME OF BUSINESS. APPARENTLY, THOSE PATIENTS WHO HAVE A CHEMISTRY THAT DOESN'T TOLERATE THE CONCEPT OF "ONE SIZE FITS ALL" CAN SUFFER - OR DIE. WELL, THAT IS NOT A VIABLE OPTION IN HEALTH, OR POLITICS -

DOCTORS HAVE HAD TO RELY ON SPECIALTY PHARMACIES FO CUSTOM ASSISTANCE FOR YEARS. THESE PHARMACIES ARE RARE & UNIQUE. THEY REQUIRE HIGHLY SPECIALIZED PROFESSIONALS THAT MUST DEVELOP TESTS, COMPOUNDING TECHNIQUES (INCLUDING ADVANCED LAB SCIENCES) &

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ONGOING SYSTEMS OF COMMUNICATION WITH DOCTOR & PATIENT. NO DRUG COMPANY OR PHARMACY CAN PROVIDE THIS ESSENTIAL SERVICE.

I HAVE EXPERIENCED 17 YEARS OF DISCOMFORT TRYING TO TOLERATE PATENT COMMERCIAL DRUGS FOR HORMONE IMBALANCE. THIS PROBLEM IS NOW UNDER CONTROL WITH SUPERIOR CHEMISTRY TESTING & CUSTOMIZED FORMULA TO MY UNIQUE CHEMISTRY. NO SIDE AFFECTS, NO ADDITIONAL COSTS FOR SPECIALISTS - NO SHOCKING SURPRISES WHEN FILLING PRESCRIPTIONS. (UNFORTUNATELY NO COMMERCIAL DRUG ADDRESSES THE TOTAL REQUIREMEN TO STABILIZE THE CHEMISTRY FOR DIFFICULT HRT PATIENTS. EVEN THE STANDARD BLOOD SCREEN IS MIS-LEADING - RESULTING WITH TOO MUCH, OR TOO LITTLE, MEDICATION.)

THE SERVICES THAT SPECIALTY PHARMACIES PROVIDE TO ME & MY DOCTOR ARE NOT AVAILABLE FROM ANY COMMERCIAL PHARMACY (PHARMACEUTICAL MANUFACTURERS), OR MOST LOCAL PHARMACIES. THE PHARMACIES THAT CLAIM TO HAVE CUSTOMIZED-COMPOUNDING ARE NOT TRAINE FOR THE SPECIALTY REQUIRED. THE RESULTS ARE NON-STANDARD (NOT PRECISE) INACCURATE, & VERY EXPENSIVE (THE PHARMACIST DETERMINES THE PRICE.) THESE "HACKERS" CAN NOT ADVISE THE PATIENT, OR THE DOCTOR BECAUSE THEY DO NOT KNOW WHAT IS INVOLVED IN THE TOTAL PROCEDURE. I HAVE TRIED 3 PHARMACIES WITHIN A 30 MILE RADIUS - ALL WERE INACCURATE, INADEQUATE, EXPENSIVE & DIS-INTERESTED. THEY SCOFFED AT THE EFFICACY & COULD NOT PROVIDE PROPER MEASURING INSTRUCTIONS - SO MUCH FOR LOCAL ASSISTANCE !!

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IT IS INTERESTING TO NOTE THAT ALL FEMALE PHARMACISTS (& MANY MALES, TOO) ARE DELIGHTED THAT A SPECIALTY PHARMACY WITH WELL TRAINED PROFESSIONALS & LAB ASSOCIATES IS AVAILABLE. THEY RECOGNIZE THAT SUCH A SPECIALTY CANNOT BE HANDLED, OR EFFICATIOUS, IN THE TYPICAL COMMERCIAL OR LOCAL PHARMACIES.

MALE & FEMALE DOCTORS RELY ON DEDICATED RESEARCH SPECIALTIES TO ASSIST THEM WITH UNIQUE REQUIREMENTS WHEN PATIENTS DO NOT TOLERATE, OR RESPOND, TO COMMERCIAL DRUGS.

FOR THE FDA TO PUNISH DEDICATED SPECIALTY PHARMACIES TO LIMITATIONS WITHIN THEIR STATE IS GROSSLY UNJUST TO THEIR SOCIAL CONTRIBUTIONS & TO THOSE OF US WHO MUST RELY ON THEIR SKILLS FOR A CHANCE TO EXPERIENCE NORMAL HEALTH THAT CAN NOT BE ACHIEVED IN THE COMMERCIAL DRUG MARKET.
I CAN NOT RE-ARRANGE MY GENES, WHERE I WORK, & LIVE, TO SATISFY SOME POLITICAL AGENDA –

FOR 20 YEARS THE SPECIALTY PHARMACY RESEARCHERS TRIED TO INVOLVE THE DRUG MANUFACTURERS TO LOOK AT THE INADEQUACIES OF TREATING DEBILITATING ENDOCRINE ANOMALIES IN WOMEN WHO WERE MIS-DIAGNOSED & IMPROPERLY DRUGGED – OR JUST IGNORED AS MENTAL CASES – BIG PHARMACEUTICALS WERE NOT INTERESTED – WHERE WAS THE FDA THEN?

THERE IS NO DOUBTING THAT THE FDA DOES NOT SEE THE POTENTIAL PROBLEMS & THE DUAL STANDARD THEY CHOOSE TO IGNORE.

SPECIALTY PHARMACIES & SPECIALTY LABS REPRESENT THE CUTTING EDGE OF SCIENCE – THEY ARE FOCUSED ON A NEED. THEY ARE SORELY NEEDED & ARE NO THREAT TO DRUG GIANTS PROFITS. THEY DO NOT UNDERCUT COMMERCIAL OR LOCAL PHARMACIES. THEY HAVE "ONE GOAL" – TO ENHANCE THE HEALTH OF WOMEN WHO ARE STILL VICTIMIZED & MIS-DIAGNOSED WHEN THEIR CHEMISTRY DOES NOT RESPOND TO SYNTHETIC DRUGS.

ALSO, THEY MARCH TO SCIENCE NOT TO MANIPULATION ON WALL ST. – PERHAPS THAT'S THE RUB!

THE FDA IS OUT OF LINE & SHOULD FOCUS ON THE SAFETY OF DRUGS, & FOODS, AS IS THEIR CHARTER.

SINCERELY,

Jane Stone

cc
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