

STATE OF NORTH CAROLINA
COUNTY OF BUNCOMBE

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT

CHRISTOPHER YAVELOW,)
Administrator of the Estate of)
LAURA YAVELOW)
Pro se)

PLAINTIFF)

v.)

[REDACTED], M.D.)

[REDACTED], M.D.)

[REDACTED], M.D.)

and)

[REDACTED], P.A.)

COMPLAINT

Wrongful Death

AMENDED July 21, 2016

(Jury trial requested)

Now COMES PLAINTIFF, Administrator of the Estate of his late wife
Laura Yavelow, complaining and alleging as follows:

PARTIES AND JURISDICTION

Laura Yavelow, hereinafter “Laura,” was a resident of Asheville in
Buncombe County, North Carolina, for 28 years. Laura’s husband, Chris
Yavelow, the Plaintiff in this action has been a resident of Asheville, in
Buncombe County, North Carolina for 7 years. The Defendants [REDACTED]
[REDACTED], hereinafter: the
“Doctors” practice at [REDACTED] in
Asheville, hereinafter: the “Clinic.” The Clinic has been in operation for at
least 20 years.

INTRODUCTION

1. Laura received weight-loss treatments periodically at the Clinic from 1994 until 2012. At the Clinic, Laura was given injections of Human Chorionic Gonadotropin (AKA Gonadotrophin), hereinafter: “HCG,” 10 months after the drug had been banned by the Food and Drug Administration, hereinafter: the FDA. And this was 9 months after the first study proved that the drug could transmit the prions that cause Creutzfeldt–Jakob disease, hereinafter: “CJD.” Laura died of CJD at 6:30 pm on July 14, 2014, which was 20 months after her final injection at Clinic.

BACKGROUND

2. Initially, the Doctors prescribed the now-outlawed “Fen-Phen” treatment. The Doctors at the Clinic prescribed the medications involved in the Fen-Phen scandal: Phentermine (30 mg) and Pondimin (20mg) AKA Fenfluramine daily from 1/9/1996 to 5/15/1996. The treatment affected Laura’s heart rhythms. Eventually, she was part of the nationwide class-action lawsuit that led to Fen-Phen being banned on September 15, 1997. SEE EXHIBIT 1

CAUSE OF ACTION

3. The Doctors at the Clinic next started Laura on a long-recognized to be completely ineffective treatment of injections of Human Chorionic Gonadotropin (HCG). HCG is a fertility drug made from female hormones extracted from pregnant women’s placenta or urine. SEE EXHIBIT 2

4. HCG was first suggested as a weight-loss treatment in 1954. Subsequently, Simeons’ results were not reproduced by other researchers and in 1976, in response to complaints, the FDA required Simeons and others to include the following disclaimer on all advertisements:

“These weight reduction treatments include the injection of HCG, a drug which has not been approved by the Food and Drug Administration as a safe and effective in the treatment of obesity or weight control. There is no substantial evidence that HCG increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or "normal" distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restrictive diets.”

— 1976 FDA-mandated disclaimer for HCG diet advertisements
In the Matter of Simeon Management Corp. (Fed. Trade Comm'n, 1976) 87 F.T.C. 1184; affirmed by *Simeon Management Corp. v. FTC* (9th Cir. 1978) 579 F.2d 1137, 49 ALR-Fed 1. SEE EXHIBIT 3

5. Then, in 1995, a meta analysis found that studies supporting HCG for weight loss were of poor methodological quality and concluded that “there is no scientific evidence that HCG is effective in the treatment of obesity; it does not bring about weight-loss or fat-redistribution, nor does it reduce hunger or induce a feeling of well-being.” (Lijesen GK, Theeuwes I, Assendelft WJ, Van Der Wal G (September 1995). “The effect of human chorionic gonadotropin (HCG) in the treatment of obesity by means of the Simeons therapy: a criteria-based meta-analysis.” *Br J Clin Pharmacol* 40 (3): 237–43. doi:10.1111/j.1365-2125.1995.tb05779.x. PMC 1365103. PMID 8527285) SEE EXHIBIT 4

6. According to the American Society of Bariatric Physicians (ASBP), no new clinical trials have been published since the definitive 1995 meta-analysis. There is no scientific evidence that HCG is effective in the treatment of obesity. The meta-analysis [referring to Lijesen, et al, above]

found insufficient evidence supporting the claims that HCG is effective in altering fat-distribution, hunger reduction, or in inducing a feeling of well-being. The authors stated "...the use of HCG should be regarded as an inappropriate therapy for weight reduction..." In the authors opinion, "Pharmacists and physicians should be alert on the use of HCG for Simeons therapy. The results of this meta-analysis support a firm standpoint against this improper indication. Restraints on physicians practicing this therapy can be based on our findings."

The ASBP position statement (current version: December 2009) concluded:

1. The Simeons method for weight loss is not recommended.
2. The Simeons diet is not recommended.
3. The use of HCG for weight loss is not recommended.

—American Society of Bariatric Physicians' "Position Statement on Use of HCG in the Treatment of Obesity. SEE EXHIBIT 5

7. CJD is considered one of the worst ways to die. It combines symptoms mimicking those of Alzheimers, Paarkinsons, Huntingtons Disease, and other prion diseases in a very short period, usually lasting between one month and one year, with a mean age for a female becoming symptomatic with classic CJD being 63 years old. SEE EXHIBIT 6

8. CJD is known to be transmitted through the use of hormone-based medicines, such as Human Growth Hormone (HGH) and other hormones of pituitary- (including cadaveric pituitary) extraction that led to the banning of those products in the 1970s and 80s, including animal derived CGD in 1999 (SEE EXHIBIT 7c). There has always been speculation that human hormone based medicines including HCG might also transmit CJD. Pituitary-derived HCG (AKA HPG and p-HCG) had been banned in the USA in July of 1972 about two years before the first 4 such cases were confirmed in Australia. SEE EXHIBIT 7a and 7b

9. Finally, in March 2011, a study entitled, “Detection of prion protein in urine-derived injectable fertility products by a targeted proteomic approach.” revealed that CJD prions could be transmitted through urine-derived injectable fertility products. The study concluded “The risks of urine-derived fertility products could now outweigh their benefits, particularly considering the availability of recombinant products. “This study was made available online by the National Institute of Health immediately.” SEE EXHIBIT 8

10. National publicity ensued, starting the same day the study was release (March 23, 2011), and in August 2011 the findings of the study “Detection of prion protein in urine-derived injectable fertility products by a targeted proteomic approach” were reported in professional journals such as *Virology Journal* and others. SEE EXHIBIT 9a and 9b

11. Using HCG for weight-loss is illegal as of December 6, 2011. It is an “off-label” use of a dangerous drug that has been known to have no scientific basis for weight-loss. “Off-Label” means that it is an unapproved, unauthorized, potentially dangerous, and illegal use of the drug. SEE EXHIBIT 10

12. The FDA mailed major weight-loss clinics a warning letter informing them that the drug was now illegal and they should instantly stop using it and dispose of all supplies.

Sample letter here: SEE EXHIBIT 11

13. More than 8 months later, on August 17, Laura was seen by one of the Doctors who falsely diagnosed her as “Morbidly Obese” (diagnosis code 278.01). Laura had been a part-time model and had also appeared as a dancer in such films as *Dirty Dancing*, and she was always in very good shape. (As EXHIBIT 12: See photos at <http://Laura.yav.com> that show no evidence of Morbid Obesity). She was in no way “morbidly obese,” but such

a diagnosis would have served as the “hard sell” for the administration of another round of five HCG injections, once a week on the following dates:

8/17/2012

8/27/2012

9/05/2012

9/11/2012

9/18/2102

The receipts display the names of two of the Doctors, and also indicate that the injections were \$15.00 a piece. At the time of these injections, a safe, recombinant form of the drug was available. Ovidrel was released on 10/6/2003, but cost \$150 to \$172 per dose, whereas the human-derived illegal form of the drug cost less than \$20 and often closer to \$10.

SEE EXHIBIT 13

14. The price coupled with the medication name, “HCG,” reveals that the injection was of Human Chorionic Gonadotropin, more than 8 months after the drug was made illegal. Moreover, using HCG for weight-loss has always been an “off-label” use and declared illegal by the FDA. SEE EXHIBIT 14

15. Laura saved everything from the Clinic sessions organized in a folder. Among those items was NOT found an “Informed Consent for Human Chorionic Gonadotropin (HCG)” used by some other weight-loss clinics, a form that confirms that the patient understands that the FDA has declared, “HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or ‘normal’ distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.” SEE EXHIBIT 15

16. Moreover, none of the literature and pamphlets given to Laura mentioned the risk of contracting CJD from the injections. If the Doctors had once even mentioned CJD, Laura would have left the Clinic and never returned. Because of Laura's undergraduate studies in microbiology and her graduate studies in Epidemiology, she had, for decades, felt that CJD was the worst to die, and would not have willingly exposed herself to such a risk.

17. Even as early as May 2004, studies in the UK had indicated that there was a latency of 20 months between fertility treatments and the onset of symptoms. The final HCG injection from the Clinic occurred on 9/18/2012, and Laura's symptoms began in the middle of May, 2014, exactly 20 months after that final injections. SEE EXHIBIT 16 A & B

18. Laura suffered greatly during the illness. When the minor symptoms that started in mid-May became worrisome on June 17, 2014, Laura spent a full day at Parkridge hospital being tested (June 18, 2014). But CJD is difficult to detect and often misdiagnosed. The doctors at Parkridge found nothing wrong, and Laura, appeared normal for the next 2 days. At 4:30 pm on the June 20, 2014, Laura went to Mission Hospital for a spinal tap due to balance problems witnessed on June 14. She failed the "finger-to-nose" test, and the doctors at Mission wanted to observe her overnight. She did not leave Mission Hospital until July 10 when a CJD test (the 14-3-3 test) came back positive, and she was transferred to Solace Hospice. SEE EXHIBIT 17

19. Because the "14-3-3" test has a 26% false positive rate, the family awaited the results of another test, the "RT-QuIC" test, and the hospice allowed her to stay on her feeding tube until those results were in. That came back positive on the 14th of July, although the "RT-QUiC" test also has a small false positive rate. SEE EXHIBIT 17 (result on same page as 14-3-3)

20. By then, Laura's complete medical records had been sent to the office of Dr. Stanley Prusiner, who had received the 1996 Noble Prize in Medicine for discovering the link between CJD and prions, for him or one of his associates to provide a second opinion. His office returned their diagnosis of CJD on July 16th. SEE EXHIBIT 18

21. Laura died at 6:30 pm on July 16, 2014. SEE EXHIBIT 19

22. Laura and her husband Chris had sat next to each other from second grade straight through the end of high school. They lived less than 2 blocks apart. They re-met at a high school reunion, and once re-connected, the happy couple was practically never apart. They married a year later, and were almost never out of sight of each other. Her husband has not recovered from witnessing the gruesome way she died, so gruesome that then President Obama sent him a letter of condolences. SEE EXHIBIT 20

23. [REDACTED] continues to operate the same way and publicizes HCG Injections prominently on their website: SEE EXHIBIT 21

24. The only way to diagnose CJD with 100% certainty is a post-mortem brain autopsy. Laura's brain was autopsied by the National Prion Disease Pathology Surveillance Center that determined conclusively that she died of sCJD type MM1. Note that all cases of Iatrogenic CJD or iCJD (Iatrogenic means caused by healthcare professionals or products) are diagnosed as sCJD until the cause is determined, at which point, the diagnosis is changed to iCJD. SEE EXHIBIT 22

WHEREFORE, Plaintiff prays for the following relief:

1. \$25,000 in compensatory damages for Laura's expenses for care, treatment and hospitalization, and the funeral expenses of the decedent, and grave plot that had to be purchased.
2. \$250,000 in punitive damages for the egregiously reckless actions of the Bariatric Clinic of Asheville in prescribing a treatment that was illegal, as well as "off label," and long known and proven to be completely ineffective for weight-loss, and for not informing Laura of the risks in such treatment.
3. \$10,000,000 for Laura's pain and suffering and future net income and the society, companionship, comfort, guidance, kindly offices and advice of the decedent to the persons entitled to her husband, plus any other damages that the court deems applicable.

This, the _____ day of July 2016.

CHRIS YAVELow
Plaintiff
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NORTH CAROLINA
FILE NO. _____
BUNCOMBE COUNTY

CERTIFICATE OF SERVICE

I, Christopher Yavelow, Plaintiff pro se, certify that on the _____ day of _____, 20__ a copy of the preceding motion was served upon the opposing party by depositing a copy of same in the United States certified mail with prepaid, first-class postage, return receipt requested and addressed as follows:

_____, M.D.
_____, law, M.D.
_____, M.D.
_____, PA
Asheville, NC _____

This the _____ day of _____, 20__.

BY:

Your Signature

Your Name

Your Address