

# Player Summaries

## C.J. Craig— The Plaintiff

CJ is a 45-year-old school teacher (biology) who suffered from skin problems. She is married and is the mother of 14-year-old son. In addition to her teaching job, she worked part-time as a hostess in a local restaurant to make ends meet.

In 1991 she began seeing a local dermatologist, Dr. Marcus Welby, for treatment of psoriasis. Dr. Welby began treating her with methotrexate (MTX) in 1991. In 1992 she began suffering from psoriatic arthritis (PS) and her MTX dosage was increased. From 1991 – May 2000 her PS was fairly well managed with the MTX. She continued to see Dr. Welby periodically for management of her condition.

In April 2000 she saw Dr. Welby for a regular appointment and he suggested to her that she would be a good candidate for a study of a new drug that he was conducting in his office. CJ had never been in a study before and didn't know much about it, but she thought it would be a good idea because Dr. Welby suggested it. She understood that he "wanted to put her on a better drug." Besides, she was beginning to have some nausea from time to time which she associated with the MTX use. Based upon what Dr. Welby told her, she knew that she might not get the drug right away, but that eventually she would get the new drug in the study. He told her that she would have to stop taking the MTX and gave her a stop date of May 3, 2000.

On June 13, 2000 she returned for a visit and was given a copy of the consent form to take home by Nurse Barton. (She had also received one by mail earlier). She read over it, but didn't consult with anyone else. She began having more psoriasis

plaques soon after discontinuing the MTX. She began to get concerned about coming off the MTX, but had confidence in Dr. Welby's care and knew that she would be monitored.

On July 11, 2000 she returned to the office for a screening visit and met with Nurse Barton again. Nurse Barton didn't review the informed consent document with her, but did ask if she had any questions. Her only question was about whether being in the study would cost her anything and whether her insurance company would pay for most of it. Nurse Barton referred her to the section of the informed consent which said that "you and/or your health plan/ insurance company will need to pay for some or all of the costs" of this study and which directed her to contact her insurance company.

She signed the consent form in the office that day. She didn't understand a lot about the study, but didn't really know what questions to ask, either.

And she trusted Dr. Welby to do what was best for her.

On July 14, 2000 she got her first injection on the study. Over the next few weeks she began to feel worse and her psoriasis increased significantly. She strongly suspected that she was getting placebo instead of the drug. She kept going back to the doctor's office for her weekly injections (usually administered by Nurse Barton) but Nurse Barton couldn't tell her for sure which one she was getting.

On October 10, 2000 she had finished her first 12 weeks of injections and when she went to the doctor she knew that she was supposed to start getting the drug (she

assumed by now that she had been on placebo). Her knees were hurting and she was using a cream for the psoriasis (which did not provide much relief) and so she was hoping that she would have a significant improvement with the next part of the study.

Her psoriasis improved slightly, but she still had big patches of red raw skin on forearms and thighs. Her arthritis got worse. Joint pain increased in her knees. She was unable to go to her restaurant job many nights because of her joint pain. In November she was fired from the hostess job due to her absences (and she thinks, in part, because of her unsightly skin condition). She also began to miss more days at her teaching job because some days she was bedridden with arthritis.

On her December office visit, CJ was miserable and despondent because of her pain, her skin condition and her inability to work. Nurse Barton suggested to her that she withdraw from the study. CJ quickly agreed (she had been hoping that Dr. Welby would offer her this choice a long time ago). She knew that the consent form said that she could withdraw, but she didn't want to offend Dr. Welby or hurt his research. She did see Dr. Welby that day and asked him to restart her on the MTX. He said that he would, beginning in January, but asked her to return before that for final lab tests.

She went back in January and he started her back on the MTX. Her psoriasis gradually improved, but the joint pain continued. A few months later, she went to a rheumatologist to see if she could get another opinion on treatment for the knee and back pain. When she told him about the study she had been on, something he asked her made her wonder if Dr. Welby had been getting paid to do the study (and maybe that's

---

*...she trusted  
Dr. Welby to do  
what was best  
for her.*

---

## CJ Craig cont.

why he didn't take her out of the study sooner). She was already frustrated with Dr. Welby and this was the straw that broke the camels back for her – she began to get angry about why she had been allowed to deteriorate so badly on this study. In addition, she began receiving bills from Dr. Welby's office totaling approximately \$2,652 for visits and lab tests during the study. When she called the insurance company to find out why they weren't paying, she was told that when the insurance company learned (from someone in Dr. Welby's office) that the visits were a part of a research study, the insurance company refused to pay. Even though the consent form says that she or her insurance company might have to pay, she thinks that it isn't right for her to be billed for something that she was doing just to help out Dr. Welby.

So, she no longer goes to Dr. Welby for her medical care. She is in constant pain in her back and knees, which she now thinks may be permanent. She hasn't been able to keep a second job and can only barely maintain her teaching job. She walks with a cane, has no stamina and is constantly tired.

## Dr. Marcus Welby, MD— Defendant #1

Dr. Marcus Welby is a 59-year-old dermatologist who has been in private practice since 1977. Prior to being approached by Pharma, Inc. to serve as an investigator in this study of Rapido, he had never conducted clinical research in his office before.

Dr. Welby signed up for the study because he wanted to provide his patients with access to the latest

office, but not the primary incentive. Besides, if it was going to take more time (either for him or his staff), he should be adequately compensated for that time. (He enrolled a total of 10 patients in this study).

He vaguely recalls that a representative from Pharma came by his office to get the nurse, Ms. Barton, started on the protocol, but he only spent a few minutes meeting the Pharma representative. He was uninvolved in any of the IRB submission process.

He doesn't see any problem with the wash-out period at all since this involved a skin condition, not a life-threatening disease. Ms. Craig's long-term use of methotrexate may have led him to wean her off the drug, anyway, as a way of avoiding toxicities. He is sorry that Ms. Craig is doing poorly, but doesn't believe that this study or his conduct of the study is to blame for her worsened condition. She knew that this study had a placebo in it when she signed up and she's an educated woman who could understand what that meant.

---

*He did not particularly want to be bothered with more paperwork...that is what the nurse is for...*

---

investigational drugs. He did not particularly want to be bothered with more paperwork with the study (that is what the nurse is for). The payments for participating in the study were a noticeable boost in the bottom line for his

## Dr. Irby Chair — Defendant #2

Dr. Irby Chair is a retired cardiothoracic surgeon who is under contract with Southeastern IRB as chair of one of their Institutional Review Boards. Dr. Chair served as a board member from 1996-1999 and as chair from Jan 2000 – present. As chair, he is paid an annual salary of \$50,000 (which is not affected by whether or not the IRB approves or disapproves a study).

The Southeastern IRB is a free-standing, for-profit central IRB located in Atlanta and is not associated with a particular institution. Pharma Inc, the sponsor in this study, strongly encouraged all their

investigators to use Southeastern. The Southeastern IRB charges \$2,500 for initial review.

He has no knowledge of the particulars regarding Ms. Craig's complaint against Dr. Welby other than the fact the IRB reviewed the study (see the minutes from that meeting). The study was reviewed just like any other study. Once approved, the IRB must rely upon the investigator to conduct the study as indicated in the protocol – especially since the Southeastern IRB is located in Atlanta and Dr. Welby is located in Little Rock, Arkansas. There were no reported adverse events or other information to trigger involvement from the IRB after initial approval.

Dr. Chair thinks that the lawsuit against him is frivolous in as much as the IRB conducted an adequate review (just like any other IRB in any other study) and had no reason to believe that Dr. Welby's conduct of the study was below par. If the truth be told, however, he is slightly uneasy about the wash-out period because he wondered about that at the time of review. This study does not deal with a life-threatening disease, so he thought the wash-out period was ethically sound. He relied upon the investigator's ability to withdraw any subject who appeared to be having problems with the study.

## Nurse Clara Barton, RN

Clara is a 35 year old registered nurse. She began working for Dr. Welby straight out of nursing school and worked for him up until six months ago. At that time, she left his employ to work at a local hospital. Prior to this study with Pharma, Inc., she had never been involved in research.

She was directed by Dr. Welby, after he was approached by Pharma, Inc., to do whatever was required to get the study up and running. The Pharma training was done in her office by a representative they sent. It was quite confusing to her because she kept getting interrupted while he was trying to explain the necessary paperwork. After they spent nearly an hour getting more and more frustrated, he simply left her the forms and told her that if she had any questions she could call. She put them aside and thought if she had any questions she could ask Dr. Welby.

In April 2000, Dr. Welby told her that Ms. Craig would be joining the study and that she would be discontinuing her use of Methotrexate (MTX) on May 3, 2000. She did not verify that the subject met the inclusion/exclusion criteria set forth by the study. She assumed that Dr. Welby had done that when he presented the option to Ms. Craig. She sent out a copy of the informed consent on May 15, 2000 in preparation for Ms. Craig's June visit.

On June 13, 2000 she gave Ms. Craig a copy of the consent form to take home. On June 11, 2000 Ms. Craig returned to

the office for a screening visit and met with Clara again. Clara didn't review the informed consent document with her, but did ask if she had any questions. Her only question was about whether being in the study would cost her anything and whether her insurance company would pay for most of it. Clara referred her to the section of the informed consent which said that "...you and/or your health plan/insurance company will need to pay for some or all of the cost of this study..." and which directed her to contact her insurance company.

---

*She did not verify that the subject met the inclusion/exclusion criteria set forth by the study. She assumed that Dr. Welby had done that...*

---

Ms. Craig signed the consent form in the office that day and was randomized to the study. On July 14, 2000 Ms. Craig received her first injection.

Over the next weeks Clara administered the injections as the study protocol directed. She noticed that Ms. Craig was having more and more psoria-

sis plaques as time went on and suspected that she was on the placebo arm of the study. In July, Ms. Craig also started complaining of pain in her knees. Clara told Dr. Welby about it and he said it was fine. Clara hoped that when Ms. Craig started getting the drug in October that this would take care of her pain as well as her spreading plaques.

In August Ms. Craig said that her plaques were getting significantly worse. Clara thought that this was starting to be more serious, so instead of taking the PASI/BSA measurements herself, she asked Dr. Welby to start doing the measurements. She hoped that he would see the differences and possibly do something to help Ms. Craig. Ms. Craig started getting the active drug in October, but it did not seem to make any difference as she seemed to continue to get worse. She even told Clara that she was fired from her job in November.

In December Clara looked over Ms. Craig's chart to see when her next injection was due and noticed that even though Ms. Craig continued to complain that her plaques were worsening, Dr. Welby's measurements of the PASI/BSA always stayed the same. She was sure this was an oversight; she knew he was very busy, but she was very worried about Ms. Craig. After some careful thought, she decided to recommend to Ms. Craig that perhaps she should not continue with the study.

## Medical Terms Defined

**PASI** – Psoriasis Area and Severity Index.

Patients are evaluated using the Psoriasis Area and Severity Index (PASI). The PASI is a composite score that takes into consideration both the fraction of body surface area affected and the nature and severity of the psoriatic changes within the affected regions (erythema, infiltration/plaque thickness and desquamation).

**BSA** - Body Surface Area

**Psoriasis** is a chronic (long-lasting) skin disease characterized by scaling and inflammation. Scaling occurs when cells in the outer layer of skin reproduce faster than normal and pile up on the skin's surface. Psoriasis affects 2 to 2.6 percent of the United States population, or almost 5.8 to 7 million people. It occurs in all age groups and about equally in men and women. People with psoriasis may suffer discomfort, restricted motion of joints, and emotional distress. When psoriasis develops, patches of skin thicken, redden, and become covered with silvery

scales. These patches are sometimes referred to as plaques. They may itch or burn. The skin at joints may crack. Psoriasis most often occurs on the elbows, knees, scalp, lower back, face, palms, and soles of the feet. The disease also may affect the fingernails, toenails, and the soft tissues inside the mouth and genitalia. About 10 percent of people with psoriasis have joint inflammation that produces symptoms of arthritis. This condition is called **psoriatic arthritis**.

[www.medicinenet.com](http://www.medicinenet.com)