

What to Expect from CLINICAL TRIALS

When a person considers participating in a clinical trial, there are several things he or she should be aware of, in order to have realistic expectations and adequate knowledge of possible risks and benefits:

- What is the purpose of the trial? Is the intent to find a cure, or simply a treatment, or perhaps preventive measures or a diagnostic test? Don't sign up for a clinical trial unless your expectations are in line with the study's objective.
- Is an experimental clinical trial appropriate for you? Have you tried the standard treatments and failed to benefit from them? Are you willing to try a treatment for which little is known, rather than try a treatment that has risks and possible benefits that are well understood?
- What are the known risks and benefits of the experimental treatment? How many people have been in the experiment before you? Did they experience any harm?
- Is the experimental product only slightly different from other available treatments (e.g., a slightly revised version of an existing drug), or is it a completely new approach to treatment?
- Who is paying for the study? Is it supported by government funds or a commercial firm? Does your doctor have a commercial interest in the therapy (e.g., a patent, royalties, etc.)? Note: Some universities have "Conflict of Interest" committees who review these factors and decide whether a commercial conflict may

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Reconstructive Surgery Act of 2003

by Congressman Mike Ross (D-AR)

For the last two years, I have introduced the *Reconstructive Surgery Act*. This year the bill number is H.R. 1499. The initiative would require health insurance plans to cover medically necessary corrective reconstructive surgery for congenital defects, developmental abnormalities, infection, trauma or disease, with no age limit. Examples of conditions for which this bill would apply are cleft lips and palates, skull deformities, burns, unformed ears, and missing pectoral muscles that cause chest deformities.

I introduced this measure after my constituent, Wendelyn Osborne, contacted me with the problem of getting her insurance company to cover her medically necessary surgical procedure. As an infant, Ms. Osborne was diagnosed with a rare congenital bone disease, Craniometaphyseal Dysplasia (CMD), which was depicted in the 1985 movie *Mask* starring Cher. CMD involves an overgrowth of craniofacial bone that never deteriorates. At the time of her diagnosis, Ms. Osborne was the sixteenth CMD case in medical history. Doctors told her parents that she would not live past the age of ten. With many surgeries, starting at the age of six, she is now in her thirties. The severity of Ms. Osborne's craniofacial anomalies precludes adequate treatment through a single procedure and requires continuous surgical procedures for the rest of her life.

This issue is important because it is about doing what is right for Ms. Osborne and people like her, regardless of their age. These patients did not ask to be born with a congenital disease or experience a traumatic, disfiguring event. There are too many families and patients with stories about trying to convince their insurers that surgeries to construct an ear or repair a cleft palate are not cosmetic but are in fact medically necessary.

The National Organization for Rare Disorders, the Children's Craniofacial Association, the American Society of Plastic Surgeons, Easter Seals, the March of Dimes, and the National Foundation for Facial Reconstruction endorse the *Reconstructive Surgery Act of 2003 (H.R. 1499)*. Please visit the public legislative information site, <http://thomas.loc.gov>, and contact my healthcare legislative assistant, Sylvia C. Brown, for more information about the measure.

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