

Title: Seifromax

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Description: A clinician-researcher who is participating in a multi-site study of an anti-depressant for adolescents refuses to prescribe the drug off-label to patients whose parents do not consent to enroll them in the clinical trial. One parent complains to the IRB.

Headings: Identifying and Managing Conflicts of Interest; Dual roles of researchers; Financial conflicts of interest

Case Type: Decision making

Seifromax

Dr. Bentham is participating in a multi-site study of a recently approved anti-depressant, Seifromax. Seifromax has been proven to effectively reduce the symptoms of clinical depression in adults with far fewer side effects than its competitors. The current study is aimed to test effectiveness and safety among people aged 10-17. Like many medications in the US, the drug was originally only tested for safety and efficacy using participants 18 years old and older, but it is frequently prescribed to younger patients "off label." Nevertheless, the manufacturer believes it will be easier to get insurance companies to pay the higher cost of prescribing Seifromax if the FDA approves it for this population.

The manufacturer of Seifromax pays Dr. Bentham \$5,000 for every patient he enrolls in the study. This not only covers the expenses Dr. Bentham incurs by using the services of clinical coordinators, but also helps to underwrite the general operating expenses of his psychiatric practice. This fee is quite common in his field of research, and serves as an incentive to physicians to enroll patients. Pharmaceutical companies are eager to see their products to market quickly, because the costs of research and development are astronomical (approximately \$500 million per drug approved).

Dr. Bentham has had little trouble enrolling patients for the trial because many parents have heard of Seifromax and they like the idea that their child may receive this drug at no cost. In enrolling these patients, Dr. Bentham has assured patients that they will receive some effective treatment (either Seifromax or the current "gold standard") but he has extolled the "very, very promising" results with Seifromax so far. However, in the past month several patients told Dr. Bentham they did not want to enroll in the study. They would prefer to pay for Seifromax and simply have it prescribed off-label. Dr. Bentham insists that the drug is still experimental and he refuses to make it available to his patients outside of the clinical trial. Consistent with this, his informed consent form does not mention the possibility of receiving Seifromax off label as an alternative to participation in the study. One parent was very upset by Dr. Bentham's refusal to prescribe Seifromax off label and complained to the IRB, using the number listed on the information sheet he provided to all prospective participants.

As an IRB member, after reviewing the facts of this case, would you require any changes in Dr. Bentham's protocol?