R.P.

Research Proposal

Due: One Class Period Late; 2/23/12

Comment [MD1]: This stuff needs to be aligned left, as per MLA.

Increase in Unexpected Side Effects from Medications

Have you ever noticed those annoying commercials that seem to interrupt your show every five minutes that begin with, “Was your baby born with this disease and did you take this medicine while you were pregnant? You may be entitled to a settlement!” or, “Has anyone in your family had a stroke and were taking this prescription within the year before?” These commercials that you so quickly dismiss highlight an important issue in the medical world. With each new prescription pumped through the pharmaceutical industry, are patients being truthfully informed about what their doctors are giving them? And do the doctors actually know how these medications could affect their clients? When medications are concocted, inspected, and mass-produced for consumption, they are first tested for their benefits as well as all possible side effects in all possible scenarios, or so the lab techs hope. When a cure is needed for people that were diagnosed with an illness yesterday, no one wants to hold their possible cure until tomorrow, but maybe an extended testing period could have indicated that the medicine could in fact cause the patient to suffer a worse ailment than they were cured of. Including seemingly mild cases of lost sexual performance, to more serious matters like cancer, birth defects, and heart failure, the issue at hand is the question of whether

Comment [MD2]: Avoid the second person.

Comment [MD3]:

Comment [MD4]:

Comment [MD5]: It’s good to set up your reader with questions you know you’re going to answer.

the medical industry has set appropriate, efficient trial testing periods for today's medicines.

Researchers, Irwig and Kolukula, reported on the unexpected side effects of Finasteride, a men's hair loss treatment, resulting in lasting sexual defects. They explain how, after a 28-month use of the product, the patients suffered various sexual hindrances. This "new onset of sexual side effects" for the more than 70, healthy observed men included: "94% developed low libido, 92% developed erectile dysfunction, 92% developed decreased arousal, and 69% developed problems with orgasm" (1747-1753). None of these post-Finasteride repercussions were warned against or observed prior to patients using the product for an extended period of time. This suggests that the clinical trial for this drug was not extensive enough to provide adequate information on potential patients' evidently probable side effects. Agreeing with this concept, but proposing another valid point of the importance for efficient testing, *Obesity, Fitness & Wellness Week*'s article on pregnant women using antidepressants says that "pregnant women may unknowingly take a medication that poses risk to their fetus; on the other hand, anxiety about the potential harmful effects to the fetus may discourage women from adhering to beneficial treatments" (1373). While it is important to know the risks for every prescription, it is equally important to know the beneficial aspects for which it may be necessary.

On the right track to knowing these risks and benefits for their medication in question, an issue of *The Breast,* discussing a new cancer treatment, stated, "[t]he goal of these new therapies is to improve the management of cancer with a specific targeting of the malignant cell and fewer side effects than traditional

Comment [MD6]: Nice job setting up the issue.

Comment [MD7]: 53 (only include the numbers that changed)

Comment [MD8]: Good transition

Comment [MD9]: Is style important here? Could you paraphrase?

chemotherapy," but what they ended with were horrible cases in which patients were lost due to heart failure (176-183). The results that these researchers found were similar to *Diabetes Care*'s article on antidepressant medication use as a possible cause for type 2 diabetes. The study demonstrated that the use of antidepressants was, in fact, associated with increased risk of diabetes. Their statistics stated that "participants with an exposure to ≥ 200[mg] defined daily doses of antidepressants… had [a]… higher [risk] for diabetes than those with antidepressant use <200[mg] defined daily doses" (2611-2616). Evidently, the clinical trials for these drugs were not all-telling and several patients lost their lives for trusting these forms of treatment to make them healthier.

The *New England Journal of Medicine* had an entirely different view on the effects of medications (taken during pregnancy) on the fetus. While it appears that anti-depressants taken during pregnancy could cause the baby to be born with defects, it could also just be that these rare illnesses may just be that: rare illnesses.

> "We found no appreciable or significantly increased risk of congenital heart defects overall in relation to the use of SSRIs overall…. The only significant association we found between either of these two defects and the use of SSRIs was an association between sertraline use and omphalocele, which was based on only three exposed subjects" (2675-2683).

These findings further suggest the idea that the patients' children's ailments happen to occur not because of the anti-depressants prescribed to them but simply due to natural, genetic fault. Their test subject range was overly extensive and thorough to

Comment [MD10]: Good paragraph

Comment [MD11]: You need to end this phrase with a colon, so you should rephrase so you don't have to use one before the end.

Comment [MD12]: Block quotes don't need to be enclosed in quotes. Confusing, I know.

Comment [MD13]: The period goes before the citation with block quotes.

Comment [MD14]: Good explanation

the average experimenter, "including maternal age, maternal race or ethnic group…, first-trimester smoking, first-trimester alcohol consumption, history of a birth defect in a first-degree relative, prepregnant body-mass index, seizures, diabetes mellitus, hypertension, infertility, and first-trimester use of folic acid" (2675-2683). They did not find significant risks of increases in congenital heart defects which were originally associated with SSRIs or non-SSRI antidepressants. However, "a doubling of the risk of septal defects associated with sertraline use…, based on 13 exposed subjects, and a tripling of the risk of right ventricular outflow tract obstruction defects associated with paroxetine use…, based on 6 exposed subjects" was observed and reported, even though this would appear almost undeniably irrelevant when compared to the nearly 6,000 patients included in the study (2675-2683). As they mentioned in their thesis, "[d]espite the large size of [their] study overall, [they] had limited numbers to evaluate associations between rare outcomes and rare exposures" (2675-2683). Proving again that the small number of patients that did follow the anti-depressant association with birth defects may just be a genetic coincidence. This is an interesting thought, that, maybe, illnesses, which we originally blamed on medicine, are really to be blamed on poor genetic matches.

Comment [MD15]: Definitely don't need to quote this, yeah?

Comment [MD16]: Good distillation.

After researching and finding viable instances in which drugs were administered and caused horrific, unexpected side effects, and also studies that claim that their drug was falsely accused, I do believe that there are too many accusations and reports of unpredicted side effects for unknowing patients for the drug producers to ignore. Longer clinical trials certainly appears to be one acceptable solution for many of these cases, because if a drug is produced to be a

Comment [MD17]: Subject-verb agreement

long-term cure, it should certainly be tested long-term. I will certainly research more examples for this growing concern, and something definitely needs to change, for the patients' sake.

R,,

You did a number of things quite well here. While I think you should examine a number of these quotes to make sure style is the paramount concern, you did a great job explaining how each quote was important to your research. Your organization throughout the piece was quite strong; you used transitions well and kept us with you by signposting. Nice job.

Look back over my sentence-level critiques closely. As I said, the most pressing concern is your use of quotes. Don't feel like you have to include everything about a source in your description of it. A few of these quotes were lists of symptoms, reactions to medicine, etc. There might be times when listing all of them could be really effective, but you don't need to do that every time.

M. Grade: A- (92)

Works Cited

Irwig, Michael S., Kolukula, Swapna. " Persistent Sexual Side Effects of Finasteride for Male Pattern Hair Loss." *JOURNAL OF SEXUAL MEDICINE* Volume8.Issue6 (2011): 1747-1753. Print.

You don't need extra spaces between the citations, which should be double-spaced.

Kivimäki, Mika, Hamer, Mark, Batty, David, Geddes, John R., Tabak, Adam G., "Antidepressant Medication Use, Weight Gain, and Risk of Type 2 Diabetes: A population-based study." *Diabetes Care* Volume33.Issue12 (2010): 2611-6. Print.

Louik, Carol, Lin, Angela E., Werler, Martha M., Hernández-Díaz, Sonia, Mitchell, Allen A.. "First-Trimester Use of Selective Serotonin-Reuptake Inhibitors and the Risk of Birth Defects." *The New England Journal of Medicine* Volume356.Issue26 (2007): 2675-83. Print.

"Pregnancy; Researchers report widespread use of medications among pregnant women." *Obesity, Fitness & Wellness Week* 14 May 2011: 1373. Print.

Zambellia, Alberto, Portab. MGD, Eleuteric, Ermanno, De Giulid, Luciana, Catalanoe, Oronzo, Tondinif, Carlo, Riccardib, Alberto. "Predicting and preventing cardiotoxicity in the era of breast cancer targeted therapies. Novel molecular tools for clinical issues." *The Breast* Volume20.Issue2 (2011): 176-183. Print.