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COMPLETE TRANSCRIPT OF BHC JOURNAL'S INTERVIEW ON ADOLESCENT DEPRESSION WITH SCOTT SEGAL, M.D., PRESIDENT OF THE SEGAL INSTITUTE FOR CLINICAL RESEARCH

By Dennis Miller

BHC Journal: This is Dennis Miller of the BHC Journal. Today, we're talking with Dr. Scott Segal, President, Director of Operations and Co-Founder of The Segal Institute for Clinical Research in North Miami, Florida. He's also the Founder of Compass Health Systems, the largest provider of mental health services in south Florida. He has conducted over 220 phase I-IV clinical trials in outpatient, inpatient and nursing home facilities. The Segal Institute is now engaged in clinical trials to determine whether a drug recently approved for treating major depression in adults may also be effective for treating the disorder in adolescents. Dr. Segal thank you for joining us today.

Scott Segal, M.D.: You're welcome.

BHC Journal: Tell us a little bit about this study you're conducting.

SS: The study is based on medication that's been available — or, that is, the type of medicine has been available — for more than 50 years as one of our most effective agents for depression. However, in the past, the types of medicines that we used for this were fraught with a lot of side effects and difficulties in prescribing it. This is a new form of delivering the medicine without having to deal with some of the side effects that precluded people from using it. Anywhere from 8 to 25 percent of adolescents suffer from depression at some point during their teen years, and the very wide spread of those numbers gives you some idea how little the phenomenon has been researched and documented.

BHC Journal: What are some of the challenges involved in treating adolescent depression?

SS: Adolescent depression can look different than adult depression. So sometimes it is more difficult to determine if a child or an adolescent is depressed. In an adult, it's usually pretty obvious to everybody because they are withdrawn, sad and many times, crying. Whereas children and adolescents can be more irritable; their grades may be dropping; they may be hanging around different types of children that are not the best influences, etc. So it's a little more challenging trying to determine if the adolescent is in fact depressed.

BHC Journal: What percentage of teens are affected by clinical depression?

SS: That number is usually underreported. And, again, it really depends a lot on the actual age, so you have reports anywhere from 8 to 25 percent. It's all over the board, but they have found that an alarming number of adolescents — I believe it's over 50 percent — have actually thought of suicide sometime during their adolescence.

BHC Journal: What are some of the risks involved with treating adolescents with antidepressants?

SS: One of the biggest risks is actually just not having the adolescent be compliant. They often don't come in for treatment, and are not usually compliant with their medication. So it's a challenge to try to get them to take the medicines in the first place. The other issue you have is that sometimes, because they're depressed, they may take an overdose of the medications. And oftentimes, at that age range, they do tend to share the medications and get high off the medication, which can be quite dangerous.

BHC Journal: What is the thinking as to why some antidepressant medications seem to have different effects on adolescents than they do on adults?

SS: I'm not sure they necessarily do. The different medicines have side effects both in adults and adolescents. There hasn't been a lot of study of these medications in the adolescent and child population, so we sort of "guesstimate" whether they will work or not. The other problem is that when you do these studies, there is a tremendous placebo effect during studies with any population.

Certainly, that happens often with adolescents as well. So it becomes difficult to determine whether the medicines are in fact working or not. Now in clinical practice, people are able to see that they work very well, but it's actually harder to show in research.

BHC Journal: When I referred to antidepressant medications having different effects on teens than adults, I was thinking of some of the FDA warnings that have come out with regards to possible suicide risks specifically with adolescents. Can you speak to that a bit?

SS: Yes, this is something that a lot of psychiatrists and child psychiatrists were confused about.

We have heard anecdotal reports of suicidal adolescents and teenagers. In fact, you are right — there is a warning that the FDA came out with — but many psychiatrists have not actually seen it in practice. Upon reviewing many reports and journals, they have found that there appears to be a subset of adolescents — and probably adults, too, but it is more studied in adolescents — that actually do become suicidal being on antidepressant medication. It appears that it is genetically determined. We're just starting to understand the genes and how they affect depression. I think in the future,

we'll be able to determine ahead of time, which patients are going to have this side effect.

So, that's an exciting development but, needless to say, it's concerning to parents. Once this warning was put in place, the prescriptions for antidepressants in adolescents dropped pretty perceptively. We discovered that we were under-treating adolescent depression based on these warnings. So, we're now doing our best to make sure we treat these adolescents appropriately.

A lot of the newer recommendations call for these adolescents to be brought back more frequently, because typically in psychiatry, you see somebody once and you see them again in about a month. Now they are recommending that if you put an adolescent on the antidepressant, you see them in a week and then again two weeks later, so you keep a much closer eye on them. We find that in practice this is not always feasible because of the patient's lifestyle and schedule, as well as the physician's availability. Again, that is one of the reasons that makes our study safer. That's also one of the benefits of being in the study. The visits are much more frequent and the monitoring is more frequent as well.

BHC Journal: What are some of the other challenges involved with conducting clinical trials on an adolescent population?

SS: Well, the general perception of a lot of parents and patients in general in any study is being treated, as I say, like a guinea pig. That's generally one of the areas that you'll run into — that people are frightened of that, that they'll be a guinea pig. But, in fact, these medicines, when they are studied at this level and in particular in this study, have already been through several preliminary studies, and the safety has already been determined. So the concern really shouldn't be as great as it is. Another concern is being on a placebo and not being on the "real medication." This is something that concerns a lot of doctors and especially those who are not familiar with doing research. And it can be quite concerning. However, once you get involved with research and you're used to doing these placebo trials, you realize that within a study it's very difficult to tell who's on the medication and who's on the placebo. It's generally very safe and people generally do very well.

BHC Journal: How long is this study anticipated to go on for?

SS: It really depends upon the whole enrollment in the country but generally, most studies will last about a year.

BHC Journal: Is this one just getting started now?

SS: This one has been started for a little while now, but it still has a ways to go.

BHC Journal: Can you talk about anything you have learned so far?

SS: Specifically within the study, no. However, this type of medicine has been used, as I said, for a long time. This medicine is actually available on the market right now, but it's typically been used more for adults more. But we have used it in adolescents and children in the past and it seems to give a robust response.