

James Thomas O'Donnell
Pharm.D., M.S., F.C.P., A.B.C.P., F.A.C.N., R.P.H.

Pharmaconsultant Inc.

Barrington
IL, US

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Challenges

Total Challenges: 36

Kovach vs. Midwest

913 N.E.2d 193; CCH Prod. Liab. Rep. P18,298

No. 49S04-0902-CV-88

State Supreme Court

Indiana

09/8/2009

Challenge Analysis:

The Court did not need to consider O'Donnell's testimony to resolve this case, thus the court did not need to determine if his testimony was properly admitted; the court also noted that its conclusion was supported by O'Donnell's testimony.

Retained by:

Plaintiff

Nature of Case:

Products Liability

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology,
Toxicology

Van Hattem vs. Kmart Corp.

308 Ill. App. 3d 121 ; 719 N.E.2d 212; 241 Ill.
Dec. 351

1-98-2423

State Appellate Court

Illinois

Hon. Thomas E. Hoffman

09/30/1999

Challenge Analysis:

Testimony relied upon at trial.

Retained by:

Plaintiff

Nature of Case:

Wrongful Death

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology,
Toxicology

Bakhtari v. Estate of Dumas

No. 05-09-00200-CV

State Courts of Appeals

Texas

Hon. Elizabeth Lang-Miers

06/29/2010

Challenge Analysis:

Testimony not ruled upon; affirmed.

Retained by:

Defense

Nature of Case:

Health Care

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

Sylvia Davis vs. Duran
Case No. 08-C-6314
Federal District Court
Illinois Northern
Hon. Jeffrey Cole
05/11/2011

Challenge Analysis:
Motion to exclude denied.
Retained by:
Defense
Nature of Case:
Constitutional Law
Specialty:
Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

Ruiz-Troche vs. Pepsi Cola of Puerto Rico
Bottling Co.

161 F.3d 77 ; 50 Fed. R. Evid. Serv. (Callaghan)
984

98-1163

Federal First Circuit

U.S. Court of Appeals

Hon. Bruce Marshall Selya

12/1/1998

Challenge Analysis:

Testimony admitted.

Retained by:

Unreported

Nature of Case:

Wrongful Death

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

Newton vs. Roche Labs., Inc.

00-782

Federal District Court

Texas Western

Hon. Andrew W. Austin

12/5/2002

Challenge Analysis:

Testimony inadmissible.

Retained by:

Plaintiff

Nature of Case:

Products Liability

Specialty:

Nutrition/Dietetics,Pharmacy,Pharmacology,Toxicology

B. DR. JAMES O'DONNELL'S TESTIMONY
Plaintiffs have presented Dr. James O'Donnell as their expert to testify regarding general causation, i.e., that Accutane is pharmacologically capable of causing schizophrenia. Defendants attack both Dr. O'Donnell's qualifications and the reliability of his opinions.

The Court finds that O'Donnell does not possess the qualifications to render a causation opinion in this case. Although he holds himself out as a "doctor" and a pharmacologist, he has never earned an M.D., a Ph.D., or any degree in pharmacology. n1 See Plaintiff's Combined Response to Defendants' Motions to Exclude, Tab B, O'Donnell Dep., pp. 16-21 (hereafter referred to as "O'Donnell Dep."). In fact, his only claim to the title of "doctor" is based upon the completion of a one-year "Pharm.D." n2 program in 1971. Id. at 16.

O'Donnell admits that he took just one course related to pharmacology during his year-long Pharm.D. program. n3 Id. at 20. Although he is listed as an Assistant Professor of Pharmacology at the Rush Medical College, he offers only a single class there as an unpaid, volunteer

lecturer, spending roughly a half-day a week in connection with the job. Id. at 15. The class is entitled "New Drug Development and Regulation," and can hardly be described as primarily scientific or pharmacological in nature. Id.

Moreover, he has no expertise in what causes psychosis, including schizophrenia, or in any field of science relevant to plaintiffs' claims (such as psychiatry, psychology, dermatology, neurology, biology, biochemistry, or epidemiology). Id. at 24-27. Not only does O'Donnell lack appropriate pharmacological training relevant to the issues in this case, he concedes that he has not performed even basic "bench or clinical research" on Vitamin A or Accutane. n4 Id. at 42-43. He has conducted no serious scientific research independent of this litigation. See *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir.), cert. denied, 516 U.S. 869, 133 L. Ed. 2d 126, 116 S. Ct. 189 (1995) ("One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.").

Instead, O'Donnell's opinion in this case is based solely on an incomplete review of existing literature (mainly limited to anecdotal case reports), certain FDA documents, and a small subset of the spontaneous adverse event reports produced in an earlier litigation. n5 See O'Donnell Dep. at 66-67, 103-04. As one Court of Appeals has put it, an individual's "review of literature" in an area outside his field does "not make him any more qualified to testify as an expert ... than a lay person who read the same articles." *United States v. Paul*, 175 F.3d 906, 912 (11th Cir. 1999).

In summary, O'Donnell has no relevant expertise regarding Accutane, Vitamin A, schizophrenia, or psychosis outside of that which he has gleaned from a scant literature review for the purpose of consulting and testifying in this case. He possesses no special knowledge, skill, experience, training, or education that would

qualify him to render an expert opinion on general causation in this case.

In fact, in describing O'Donnell's experience relevant to his opinions here, Plaintiff's counsel stated: He has been a pharmacist for twenty-eight years, and he's also been a -- he holds himself out as a pharmacologist. He's done a number of -- he has done research in pharmacology. n6

He does not hold a Ph.D. in that, but he holds himself out as that ... Transcript of October 15, 2002 Daubert Hearing, at 155 (Clerk's Doc. No. 76) (emphasis added) (hereafter "Hearing Tr."). Removing the doublespeak, what Plaintiffs' counsel is saying here is that O'Donnell is not a pharmacologist at all, but has somehow managed to "hold himself out" as one.

In fact, rather than fitting the mold of a pharmacologist who is scientific in his approach, he much more closely fits the profile of an "expert for hire" whose opinions are more likely to be biased. n7 As Daubert explains, the Court has a "gatekeeping" responsibility that requires it to prevent such individuals from giving unqualified scientific opinions to juries.

Here, the Court cannot in good conscience present James O'Donnell to a jury as an expert in the effects of Accutane on the human body. Quite frankly, the Court finds Plaintiff's attempts to present O'Donnell as an expert pharmacologist to be an extremely bold stretch.

Although the Court's decision that O'Donnell is not qualified to render an opinion on general causation in this case is enough to grant the motion to exclude his testimony, the Court will also briefly discuss the reliability of O'Donnell's testimony.

O'Donnell's first contention is that Accutane is "an analog of Vitamin A" and, therefore, it will "share many of the side-effects experienced with Vitamin A." See Defendants' Motion to Exclude Expert Testimony, O'Donnell Rep., Ex. 12 at 4 (hereafter referred to as "O'Donnell Rep."). In his report, O'Donnell lists the "typical" side effects he believes result from ingesting too

much Vitamin A, including "acute schizophrenia or remitting psychosis." Id. at 4-5.

For this opinion to be admissible, O'Donnell must have a reliable scientific basis to support not only (1) a causal relationship between Vitamin A and psychiatric side-effects, but also (2) his assertion that Accutane will also produce these side-effects. He has shown neither.

The only support O'Donnell cites for his opinion that ingestion of large doses of Vitamin A causes "acute schizophrenia and remitting psychosis" comes in the form of isolated anecdotal case reports, including an Arctic explorer's journal from the mid-nineteenth century. He admittedly relies on no epidemiological or clinical studies. See O'Donnell Dep. at 66. In the October 15, 2002 Daubert hearing, Defendants' testifying expert, Dr. Lorraine Gudas, n8 found O'Donnell's research to be "shockingly unscientific" because, in manufacturing his report, he ignored "hundreds of [sic] n9 thousands of peer-reviewed articles" that demonstrate "no link between Vitamin A and schizophrenia." See Hearing Tr. at 25-26.

In Dr. Gudas' opinion, O'Donnell's reliance on such arcane and isolated case reports (much of which was taken from a nineteenth century Arctic explorer's journal), coupled with his neglect of such a plethora of available scientific literature, rendered his report "well below" the "standards of scientific validity." Id. at 26. She testified that there is simply no scientific basis in the existing literature for O'Donnell's contention that large doses of Vitamin A are known to cause schizophrenia and psychosis. Id. at 24-25.

Even if O'Donnell were able to point to reliable evidence that Vitamin A taken in large doses could cause psychosis, he would also have to show that Accutane acts in the same way. He claims that because Vitamin A and Accutane are chemically similar, one can assume that they will have similar effects on the body, although he concedes that he nor anyone else has ever tested this assumption. See O'Donnell Dep. at 135-36.

Defendants point out that in Moore the Fifth Circuit rejected the plaintiff's expert's claims that because two chemicals were similar and one was known to cause Reactive Airways Dysfunction Syndrome (RADS), it could be assumed that the other would cause RADS as well. See Moore, 151 F.3d at 278. Here, important chemical differences exist between the two: Vitamin A is an alcohol, and Accutane is an acid. See O'Donnell Dep. at 126.

O'Donnell admitted further that the human body reacts to Accutane and Vitamin A in different ways. Id. at 124-26. Dr. Gudas testified at the hearing that Vitamin A is able to bond with acids, and is stored in the liver (as retinol palmitate), while Accutane cannot bond with acids, and as a result is excreted rapidly from the body. Hearing Tr. at 23.

Further, O'Donnell conceded that despite their chemical similarity, there are in fact pharmacological differences "as well as pharmacokinetic differences" between Accutane and Vitamin A. Id. at 126-27. Furthermore, Dr. Gudas also stated unequivocally that "psychosis is not a known side effect of Accutane." Id. at 26. As she explained, O'Donnell failed to even acknowledge many recent studies -- including double-blind, placebo-controlled studies n10 -- in which doses of Accutane were administered over long periods of time to cancer patients. Id. at 28.

None of these studies showed that there is "any biological plausibility" to O'Donnell's opinion that Accutane can cause psychosis or schizophrenia. Id. And with regard to O'Donnell's continued reliance on the journal of an Arctic explorer, Dr. Gudas told the Court: "I think that talking about explorer's journals from 1850 is not science. I am sorry, but we have done science for the last fifty years in this country that -- where patients have been given high doses of Vitamin A and psychosis and schizophrenia have not been reported, so I think it's completely irrelevant and unscientific to even be wasting time talking about this old polar bear stuff." Id. at 42.

The Court agrees. In conclusion, it is clear that instead of relying on acceptable scientific foundations, O'Donnell bases his opinion on isolated, anecdotal case reports, many of which were from a nineteenth century Arctic explorer's journal, and most of which dealt with depression and not schizophrenia. The Fifth Circuit and many other courts have soundly rejected case reports as an acceptable basis for causation. n11 Not only was the "research" he did so unreliable, O'Donnell plainly ignored a voluminous and directly relevant group of scientific studies on Vitamin A and Accutane which dramatically undermine his claim that either could be said to cause psychosis in general or schizophrenia in particular.

O'Donnell fails the Daubert reliability criteria in virtually every regard. There is no evidence that any of O'Donnell's theories have been tested; plaintiffs can produce no peer-reviewed, published, scientific articles concluding that Accutane causes psychosis or that Accutane and Vitamin A will have similar effects; there is certainly not general acceptance in the scientific community of O'Donnell's theories (as Dr. Gudas testified and O'Donnell conceded in deposition); n12 moreover, O'Donnell is a professional witness who has demonstrated little, if any, non-litigation basis for his opinion. In light of his lack of qualification and the unreliability of his testimony, the Court finds that Defendants' Motion to Exclude the Expert Testimony of James T. O'Donnell (Clerk's Doc. No. 54) should be GRANTED.

White vs. Vrable

No official citation

98AP-1351

State Court of Appeals

Ohio

Hon.

09/30/1999

Challenge Analysis:

Paragraphs three, four and nine of affidavit testimony inadmissible.

Retained by:

Plaintiff

Nature of Case:

Tort Law (NEC)

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

Diliberti vs. Essex

190260

State Court of Appeals

Michigan

Hon.

09/15/1998

Challenge Analysis:

Testimony properly excluded; trial court did not err.

Retained by:

Plaintiff

Nature of Case:

Medical Malpractice

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

McClain vs. Metabolife Int'l, Inc.

401 F.3d 1233

03-12776

Federal Eleventh Circuit

U.S. Court of Appeals

Hon. C. Ashley Royal

03/2/2005

Challenge Analysis:

Testimony improperly admitted. Reversed and remanded.

Retained by:

Plaintiff

Nature of Case:

Products Liability

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

Devito vs. Smithkline Beecham Corp.

02-CV-0745 (NPM/DRH)

Federal District Court

New York Northern

Hon. Neal Peters McCurn

11/29/2004

Challenge Analysis:

Testimony inadmissible.

Retained by:

Plaintiff

Nature of Case:

Products Liability

Specialty:

Nutrition/Dietetics, Pharmacy, Pharmacology, Toxicology

1) Mr. John T. O'Donnell, a pharmacist with a Master's Degree in nutrition Glaxo argues that the court must preclude O'Donnell's testimony for two reasons. First, he is not qualified as an expert as to the issues upon which he is being asked to opine -- general and specific causation and the adequacy of the Paxil warnings.

Second, even if he does qualify as an expert, Glaxo contends that the court should preclude his opinions because they lack the requisite scientific foundation and are otherwise unreliable. Plaintiff responds that O'Donnell's "experience and credentials are impressive[.]" whether the issue is his qualifications to testify as an expert on causation or as an expert on warnings. Pl. Preclude Memo. at 4.

Plaintiff further responds that regardless of whether O'Donnell is opining on causation or warnings, any alleged "shortcomings" in that testimony go to "weight and credibility, and not [to] ... admissibility." Id. at 5 (citation omitted).

Plaintiff DeVito is offering O'Donnell's testimony on three separate issues, which require different areas of expertise. The court will examine O'Donnell's qualifications as to each.

This is not the first court to be confronted with the issue of whether Mr. O'Donnell is qualified to give an expert opinion here. In *Newton v. Roche Laboratories, Inc.*, 243 F. Supp. 2d 672 (W.D.Tex. 2002), the court found that he was not qualified to render an opinion on general causation. Id. at 679. There, the parents of a 16 year old girl claimed that Accutane, a

prescription acne medication manufactured by the defendant, caused or precipitated the onset of their daughter's schizophrenia.

In much the same way plaintiff DeVito is offering O'Donnell's testimony here, the plaintiffs in *Newton* offered O'Donnell as an expert "to testify regarding general causation, i.e., that Accutane is pharmacologically capable of causing schizophrenia." Id. at 677.

After outlining a number of ways in which O'Donnell's qualifications were lacking, the court expressly found that he was not qualified to render such an opinion. To support that conclusion, the *Newton* court relied upon O'Donnell's deposition testimony, which is substantially similar to his deposition testimony in this case.

For example, O'Donnell testified in *Newton*, as he did here, that "he has never earned an M.D., a Ph.D., or any degree in pharmacology." Id. at 677; see also O'Donnell Dep'n at 24-25 and 53. Yet, he "still holds himself out as a 'doctor' and a pharmacologist[.]" Id. As in *Newton*, "O'Donnell ... [continues to] grant[] himself the title of 'doctor' in reliance upon his Pharm.D degree, [which] he conceded in his deposition that in the majority of pharmacy schools, that ... degree is 'an entry-level degree' that pharmacists must have to ... even practice pharmacy." Id. at 677 n. 2 (citation omitted); see also O'Donnell Dep'n at 24-25. In contrast, to obtain a degree in pharmacology usually three or four years of graduate school is required. O'Donnell Dep'n at 25-26. O'Donnell did get a graduate degree, but it was not in pharmacology. O'Donnell's formal education consists of a four year degree in pharmacy and a Master's Degree in clinical nutrition. Id. at 27.

In addition to questioning O'Donnell's background generally, the *Newton* court pointed out his "lack [of] appropriate pharmacological training relevant to the issues" therein, i.e. "Accutane, Vitamin A, schizophrenia, or psychosis[.]" Id. at 678.

The same may be said here. There is no factual basis upon which this court can find that

O'Donnell is an expert regarding SSRIs generally, not to mention Paxil or discontinuation of Paxil. Indeed, as his deposition testimony shows, O'Donnell's asserted expertise on these subjects is non-existent. See *id.* at 21, 24; 38-40; and 45. Given that SSRIs are a fairly recently developed class of drugs, understandably they were not the subject of O'Donnell's course work as an undergraduate, or when getting his Master's Degree in nutrition. *Id.* at 21 and 24.

Since that time, O'Donnell has done nothing to advance his own knowledge as to SSRIs generally or Paxil in particular. When directly asked if he had "done any clinical research whatsoever relating to antidepressants," O'Donnell replied that he had not. *Id.* at 38. He responded the same way when asked if he had "done any scientific research concerning Paxil or SSRI antidepressants[.]" *Id.* at 39.

Moreover, O'Donnell conceded that the first time he "reviewed ... scientific literature in connection with Paxil discontinuation symptoms[]" was for this case. *Id.* at 40-41. This is the sort of "litigation-drive expertise" which courts have eschewed.

To illustrate, the court in *Mancuso*, 967 F. Supp. at 1443, reasoned that it could not "help but conclude that [plaintiff's expert] was not in fact an expert ... when he was hired by the plaintiffs, but that he subsequently attempted, with dubious success, to qualify himself as such by selective review of the relevant literature." This appears to be an apt description of what Mr. O'Donnell attempted to do in the present case. The court stresses that it is no single factor which is dispositive of whether O'Donnell qualifies as an expert on the issue of general causation.

Rather, it is the cumulative effect of the foregoing which convinces the court that O'Donnell lacks the lack of relevant "knowledge, skill, experience, training or education" to testify as an expert on the issue of general causation vis-a-vis the discontinuation of Paxil. As he admitted, O'Donnell is not a pharmacologist. Therefore, he cannot, as he does in his "expert report," opine to a "reasonable

pharmacological certainty," that plaintiff is experiencing "withdrawal toxicity reactions from Paxil[.]" O'Donnell Rep.

Clearly, allowing a pharmacist/nutritionist such as O'Donnell to testify in that way would run afoul of the rule that an expert must stay "within the reasonable confines of his subject area[.]" *Kass*, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606, at *2475606, at *4 (internal quotation marks and citations omitted). Simply put, the court agrees with the court's comment in *Newton* that "plaintiff's attempts to present O'Donnell as an expert pharmacologist [is] ... an extremely bold stretch." *Newton*, 243 F. Supp. 2d at 679. n3 ii.

Reliability of Testimony

O'Donnell's lack of education, training and background as to Paxil becomes even more apparent when viewed in terms of the opinions which he has rendered in this case. That is so because a "court's evaluation of qualifications is not always entirely distinct from the court's evaluation of reliability." *Pearson v. Young*, 2002 U.S. Dist. LEXIS 26256, No. CIV-99-1559-F, 2002 WL 32026157, at * 3 (W.D.Okla. Jan. 17, 2002).

O'Donnell's opinion as to causation is that "DeVito is experiencing withdrawal toxicity reactions from Paxil, and indeed, each time he attempts to wean or lower the dosage, he again experiences such infinity [sic]." *Glanville Aff.*, exh. E thereto. O'Donnell states that when plaintiff's dosage of Paxil is lowered, he suffers from the following "withdrawal signs and symptoms[:] anxiety, jittery [sic], agitation, nausea, drowsiness, generalized discomfort and vertigo[.]" O'Donnell Report at 2.

"For this opinion to be admissible, O'Donnell must have a reliable scientific basis to support not only (1) a casual relationship between" Paxil and the enumerated side-effects, "but also (2) his assertion that [Paxil] will produce these side-effects." See *Newton*, 243 F. Supp. 2d at 679 (emphasis added).

O'Donnell's report and deposition testimony are void of a scientific basis to support either of those assertions. In terms of publications, O'Donnell testified that he was the editor of a non-peer reviewed book entitled "Drug Injury Liability, Analysis and Prevention." Id. at 98-99. That book contained a mere six sentences on SSRIs, including the two sentences on Paxil. Id. at 99. Given that minimal reference to SSRIs, it is not surprising that that book contains nothing about discontinuation symptoms. See id.

It further appears that he has performed absolutely no research regarding Paxil, much less its discontinuation. Id. at 38-39. What is more, O'Donnell has done no scientific or clinical research of any kind for almost two decades. The last time he did any such research was in he "early '80s as part of a pharmacology lab sabbatical," where he was looking at vitamins and critical care drugs used in Intensive Care Units. Id. at 36.

In light of the foregoing, to allow plaintiff to rely upon Mr. O'Donnell's opinions as to general causation clearly would violate Daubert's "requirement that the expert testify to scientific knowledge -- conclusions support by good grounds for each step in the analysis[.]" Amorgianos, 303 F.3d at 267 (citations and quotation marks omitted).

b. Specific Causation

It stands to reason that if Mr. O'Donnell lacks (which he does) the qualifications to testify as to general causation, he lacks the qualifications to testify as to specific causation. His opinion as to specific causation suffers from the same infirmities, detailed above, as to general causation.

Accordingly, the court finds that Mr. O'Donnell does not have the requisite qualifications to testify as to specific causation; and even if he did, his opinions in that regard are unreliable. c. Warnings Glaxo contends that because O'Donnell "lacks any pertinent qualifications[.]" Def. Memo. at 14, he should not be allowed to testify that in his opinion the "lack of ... a precaution and warning about withdrawal risk

and the need to taper [when discontinuing Paxil] renders the product defective due to an inadequate warning. See O'Donnell Report at 3.

Plaintiff did not directly respond to this argument. Included in the list of highlighted credentials in plaintiff's memorandum of law is that Mr. O'Donnell "is currently involved in the teaching of New Drug Development and Regulations[.] Pl. Opp'n Memo. at 2. However, plaintiff does not explain, or cite to any portion of O'Donnell's deposition explaining, how or why this position qualifies him to testify as an expert on warnings.

As with the other issues upon which plaintiff intends to offer O'Donnell's testimony, plaintiff baldly retorts that O'Donnell's "extensive experience qualifies as specialized knowledge gained through experience, training, or education[.]" Pl. Memo. at 4 (internal quotation marks and citations omitted).

And, once again, he relies upon the argument that Glaxo's reasons to preclude O'Donnell's testimony regarding warnings should be saved for trial, i.e. they should be used to attack O'Donnell's credibility and the weight which the jury might give to his opinions regarding Paxil warnings.

i Qualified

O'Donnell "claims to be an expert in drug labeling[.]" O'Donnell Dep'n at 90. Presumably he is including drug warnings within the province of this supposed expertise. In any event, to qualify as an expert it is not enough for a witness to simply declare that he is one. Federal Rule of Evidence 702 requires more.

As plaintiff acknowledged, a witness must satisfy the court that he has a certain amount of "knowledge, skill, experience, training or education[]" in the relevant field before he can be deemed an expert. See *Nora Beverages*, 164 F.3d at 746 (internal quotation marks and citation omitted).

Close examination of O'Donnell's deposition testimony reveals that he is lacking in each of

those areas when it comes to the subject of the adequacy of prescription drug warnings.

O'Donnell's claimed expertise admittedly is "through experience," not through formal education. O'Donnell Deposition at 90-92. His experience consists primarily of having attended continuing education ("CE") programs, where drug labeling was a topic. *Id.* Those CE programs were to satisfy his pharmaceutical and nutritionist CE requirements, however; and he was unable to elaborate on the substance of same. See *id.* Furthermore, O'Donnell has not consulted with any pharmaceutical company "concerning the labeling for any antidepressant[.]" *Id.* at 96.

O'Donnell agrees "that the FDA [Food and Drug Administration] is the highest authority on how drugs are labeled in this country[.]" but he has also never consulted with them "concerning the labeling for any antidepressant. *Id.* For that matter, O'Donnell has not worked for or consulted with the FDA in any capacity. See *Glanville Aff.* at 9, P 39. Thus, O'Donnell's experience in this area is extremely limited.

Moreover, O'Donnell made two especially damaging concessions which seriously undermine the suggestion that he is an expert as to the adequacy of prescription drug warnings. O'Donnell readily agreed "that in assessing the adequacy of a label for a prescription drug, the expert rendering the opinion generally should be familiar with the clinical trials data on the drug as it relates to the side effect concerning which he is opining[.]" *Id.* at 192.

Yet, O'Donnell frankly admitted that he had not reviewed any of the Paxil clinical trials data. See *id.* Similarly, O'Donnell conceded that "generally to reach a conclusion regarding the adequacy of a label for a prescription drug, the expert rendering the opinion should be familiar with at least a majority of the available medical literature on the drug as it relates to the side effect on which he is opining[.]" *Id.* at 193.

Despite the foregoing, O'Donnell went on to testify that he has "not read the specific

literature[]" relating to discontinuation symptoms of Paxil. *Id.* 193 and 45.

In fact, he has only read "abstracts" of articles. *Id.* at 46-47. Finally, Mr. O'Donnell has not lectured on, or written anything (peer reviewed or not) about, "Paxil discontinuation symptoms apart from [his] expert [sic] report in this case[.]" *Id.* at 45. As the foregoing clearly shows, Mr. O'Donnell does not "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field[.]" which here is the adequacy of prescription drug warnings and Paxil in particular. See *Kumho Tire*, 526 U.S. at 152, 119 S. Ct. at 1176.

Mr. O'Donnell may qualify as an expert in the fields of pharmacy or nutrition, but that is not the purpose for which his testimony is being offered here. Instead, his testimony is being offered on the adequacy of Paxil warnings. O'Donnell has never been drafter or been asked to draft a warning for any antidepressant, let alone for Paxil.

Likewise, he has not done any research or written any publications on prescription drug warnings. Thus, whether judged in terms of his education or experience, does not rise to the level of "expertise ... that the jury would expect from a bona fide warnings expert." See *Robertson v. Norton*, 148 F.3d 905, 907 (8th Cir. 1998) (internal quotation marks omitted).

In sum, O'Donnell is being called upon to testify regarding the adequacy of the Paxil warning, an issue which clearly is outside the "reasonable confines of his subject areas," which are pharmacy and nutrition. See *Kass*, 2004 U.S. Dist. LEXIS 22217, 2004 WL 2475606, at *4 (internal quotation marks and citations omitted).

Therefore, because O'Donnell does not "possess the specialized knowledge required by Rule 702[.]" the court finds that he is not qualified as an expert on the issue of the adequacy of the Paxil warning. See *id.*

II. Reliability of Testimony?

Given the nature of the claims which plaintiff is alleging in this case, plainly there is a close relationship between excluding the causation opinion and excluding the warning opinions which are being offered by O'Donnell. *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062 (D. Kan. 2002), *aff'd* on other grounds, 356 F.3d 1326 (10th Cir. 2004), *cert. denied*, 125 S. Ct. 40, 160 L. Ed. 2d 201 (Oct. 4, 2004), provides a good example of how a decision to preclude causation "expert" testimony impacts upon a decision to also preclude warning testimony.

The plaintiff parents in *Miller* were suing the manufacturer of Zoloft, another SSRI, alleging that it caused their son to commit suicide. Similar to the present case, the plaintiffs in *Miller* asserted state law claims for strict liability for marketing defects and misrepresentations, and negligence for failure to test and warn. The court held that an "eminent" psychiatrist and neuropsychopharmacologist's proposed testimony regarding general causation, i.e. that Zoloft causes, suicide, did not satisfy the Daubert criteria for admissibility because, in short, "he lacked sufficient expertise on the issue of suicide." *Id.* at 1087 and 1088.

The *Miller* court, as is this court, was then confronted with the issue of whether that same doctor could qualify as an expert who would opine "that Zoloft labels do not adequately warn against the danger of SSRI-induced suicide." *Id.* at 1088. After finding that the doctor was not an expert on that issue, the court soundly reasoned, "if the jury will hear no evidence that [Paxil] causes [withdrawal symptoms/addictive], it cannot possibly conclude that [Paxil] labels do not adequately warn against the danger that [Paxil] causes [such condition.]" *Id.* at 1089. That reasoning applies with equal force here.

Even if O'Donnell qualifies as a prescription drug warning expert, because neither O'Donnell nor Dr. George (plaintiffs only proof as to causation) qualify to testify about causation, the former's warning testimony "would essentially be irrelevant to any larger issues in the case." See *id.*

Accordingly, there is no need to analyze whether O'Donnell's opinions, as to warnings pass muster under Daubert. In short, plaintiff DeVito has not sustained his burden of proving by a preponderance of the evidence that Mr. O'Donnell is qualified to render an opinion as to general causation, specific causation, or the adequacy of Paxil warnings.

Even if O'Donnell could somehow be deemed to have the requisite "specialized knowledge" to testify as to any or all of those issues, "courts do not have to credit opinion evidence connected to data 'only by the ipse dixit of the expert.'" *Prohaska*, 138 F. Supp. 2d at 438 (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997)). That is all O'Donnell has to rely upon; simply because he offers an opinion which he claims to be valid, plaintiff assumes it is so. This court will not, however.

For the reasons set forth above, the court grants in its entirety Glaxo's motion to preclude the testimony of Mr. O'Donnell; Dr. George; and Ms. Sweeney. O'Donnell's insistence on holding himself out as a pharmacologist, see O'Donnell Dep'n at 54, ignores at least one fundamental distinction between pharmacology and pharmacy - a distinction which is critical here. "Pharmacology can be fairly described as the study of the effect of drugs on living organisms. Pharmacy, on the other hand, is the profession of preparing and dispensing drugs." *Newton*, 243 F. Supp. 2d at 677, n.1.

It is self-evident that there is a vast difference in the education, experience and skill necessary to obtain degrees in these two different fields. Apparently O'Donnell recognizes this distinction because in *Newton* he "admitted ... that from approximately 1982 to 1985, he intentionally and falsely advertised that he possessed a doctorate in pharmacology in an attempt to attract more interest from lawyers for his consulting expert business." *Id.* at 677, n.3 (citation omitted). He made that same admission in this deposition herein. O'Donnell Dep'n at 28-31. O'Donnell did change this advertisement because, in his words, it was "incorrect." *Id.* at 29. This court cannot overlook what at best

appears to be a serious lapse in judgment,
however.