

The prospect of recovering compensation for psychiatric drug withdrawal harm through litigation because of missing or misleading information

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ABSTRACT: This article explores the prospects of people who were not told about the risk of withdrawal effects of psychiatric drugs obtaining compensation for the harm through litigation. The analysis is based on United States law and some of the principles may be relevant in other countries and some also may not.

KEY WORDS: Legal, Damages, Iatrogenesis, Drug Companies

To make a case for compensation (“damages”), for failure to inform about the risks of psychiatric drug withdrawal the following questions have to be answered in the affirmative:

1. Was there a duty to inform?
2. Who might have such a duty?
3. Was the duty breached (violated)?
4. Did the breach cause harm?

There are also practical issues, such as can one obtain a good lawyer to pursue the case, and the impediments created by the powerful doctor lobby through what is called Tort¹ Reform.

¹ “Tort” is the legal term for a claim against another person for harm that person caused.

Duty to inform

Prescribers

It is fairly universally accepted that prescribers, such as psychiatrists and other medical doctors have an obligation to obtain “informed consent” before treatment is administered. A prominent legal case articulating this is *Cobbs v. Grant*:

[A] person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment [and] ... the patient’s consent to treatment, to be effective, must be an informed consent².

More on “in sound mind,” later. With respect to what informed consent means, different US states have different standards. In some states, what a prescriber is obligated to inform a patient is determined by whether it is the custom of physicians practicing in the community to make the particular disclosure to the patient (“Standard of Care”). In other states the question is what the patient would have decided if they had been provided with the information (“Subjective Standard”). In others, the question is what would a “reasonable” or “prudent” patient have decided (“Objective Standard”).³

Each of these approaches has its supporters and detractors, although the Standard of Care standard has generally fallen out of favor as exemplified by *Cobbs*, one of the first to reject it:

[T]he patient’s right of self-decision is the measure of the physician’s duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice. The scope of the physician’s communications to the patient, then, must be measured by the patient’s need, and that need is whatever information is material to the decision.⁴

The Objective standard, has recently been articulated by the Iowa Supreme Court in the following way and in some states the standard has been adopted by statute:⁵

Generally, to succeed on a claim of informed consent, the plaintiff must establish four elements:

1. The existence of a material risk [or information] unknown to the patient;

2 502 P.2d 1 (Cal. 1972).

3 See *Hondroulis v. Schuhmacher*, 553 So.2d 398, n11 (La 1988).

4 502 P.2d at 11.

5 See, e.g., Revised Code of Washington, RCWA 7.70.050.

2. A failure to disclose that risk [or information] on the part of the physician;
3. Disclosure of the risk [or information] would have led a reasonable patient in plaintiff's position to reject the medical procedure or choose a different course of treatment;
4. Injury.⁶

There are exceptions to the duty to disclose such as an emergency situation where an unconscious accident victim needs immediate care. This exception would not apply to warning about the withdrawal effects of psychiatric drugs. One that could be seized as a defence against establishing a violation of the duty to warn about the withdrawal effects of psychiatric drugs, however, is if the patient is "so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient."⁷ This is the type of exception psychiatrists regularly abuse.

The primary objection to the Subjective Standard is the difficulty of determining what the patient would have decided, especially because once the harm has occurred the patient will tend to believe they would not have consented if they had been told about the risk.⁸

The main objection to the Objective Standard isn't what a reasonable patient would have decided, but what that specific patient would have decided.⁹ This criticism is clearly correct. The Objective Standard has been adopted because of the difficulty in determining after the fact what a person would have decided when the undisclosed risk has actually occurred. However, logically, if a reasonable person would have rejected the drug if provided the information this means no reasonable person would ever choose the treatment if adequately informed. This in turn means the drug should never be offered, at least for the particular use for which it was prescribed. In the case of more than very short term use of benzodiazepines (benzos), or any use of Selective Serotonin Reuptake Inhibitors (SSRIs) I think this is true. For the SSRIs this is based not only on the withdrawal effects, but also on their other adverse effects, such as permanent sexual dysfunction and their propensity to lead people to become manic, commit suicide, or commit violence, including homicide.

The lawsuits against prescribers for failure to obtain informed consent are sometimes considered malpractice claim, other times battery and other times simply a claim that the patient had not been provided informed consent.

6 *Andersen v. Khanna*, 913 N.W.2d 526 (Iowa 2018).

7 *Canterbury v. Spence*, 464 F.2d 772, 789 (DC. Cir. 1972).

8 *Cobbs*, 502 P.2d at 11.

9 *Arena v. Gingrich*, 748 P.2d 547, 549 (Or 1988).

My experience and understanding is prescribers rarely warn about any negative effects of psychiatric drugs, let alone withdrawal effects.¹⁰ In states that have adopted the Objective or Subjective standard, they have breached the duty to warn, where the withdrawal effects would have caused a “reasonable patient,” or that particular patient, respectively, to reject the drug. In states where the duty to warn is based on the Standard of Care, even though the normal practice is not to warn I doubt many expert witnesses would testify the practice is not to warn. Cases against prescribers for failure to warn about the withdrawal effects of psychiatric drugs are legally sound, depending, of course, on the facts in each case.

Drug companies

Because drug companies are, to my mind, evil and have a lot of money, people want to sue them. The big impediment to successfully suing the drug companies is “The Learned Intermediary Doctrine” in which the drug companies are only obligated to inform the prescribers and normally have no liability to the patient if the prescriber has failed to warn. The prescriber is supposed to be knowledgeable about the drugs, including withdrawal effects, and use their expertise to make recommendations and provide all information material to a decision on whether to accept the drug or not. In other words, the prescriber is supposedly a “Learned Intermediary.”

The Learned Intermediary Doctrine was applied, in *Presto v. Sandoz Pharmaceuticals Corp.*, where the patient committed suicide after quitting Clozaril¹¹, holding “Ordinarily, in the case of prescription drugs, a warning as to possible danger in its use to the prescribing physician is sufficient.”¹² In that case, the following warning to the prescriber in the package insert was found sufficient:

[P]atients [should] be removed from the drug by gradually reducing the dosage over a one-or two-week period and stated, “[s]hould a patient’s medical condition require abrupt discontinuation..., the patient should be carefully observed for the recurrence of psychotic symptoms.”

The big cases against drug companies for failure to warn, such as the massive litigation over Zyprexa causing diabetes and other metabolic problems, are based upon the drug companies hiding damning information from the prescribers. In the Zyprexa

10 However, far too frequently the prescriber will fail to warn the patient, but the medical chart will erroneously state the patient was informed.

11 Note by the editors: Neuroleptic; active ingredient clozapine; marketed in countries with English as first or second language as Cloment, Clonia, Clopin, Clopine, Closin, Clozalux, Clozapin, Clozapine, Clozarem, Clozaril, Clozatab, Denzapine, FazaClo, Leponex, Leudex, Merbaril, Versacloz, Zaponex.

12 487 S.E.2d 70, 73 (Ga. 1997).

case, Eli Lilly actively hid and denied that Zyprexa caused diabetes and other metabolic problems. In such circumstances, the Learned Intermediary Doctrine is inapplicable because the drug company had violated its duty to inform the prescribers. In the case of Zyprexa, this author was instrumental in making public the information about Zyprexa causing diabetes and other metabolic problems and Lilly was forced to add a warning about it on the approved FDA label.¹³ While this was good in terms of informing the prescribers and the public, it cut off Lilly's liability to patients going forward for failure to inform about diabetes and other metabolic problems.

The drug "labels" that inform prescribers about psychiatric drugs tend to warn about withdrawal symptoms. For example, the Food and Drug Administration (FDA) label for Prozac (fluoxetine¹⁴) includes the following:

During marketing of PROZAC, SNRIs, and SSRIs, there have been spontaneous reports of adverse reactions occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these reactions are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with PROZAC.

It is perhaps noteworthy that this warning covers the whole category of SNRI (Serotonin-Norepinephrine Reuptake Inhibitor) and SSRI (Selective Serotonin Reuptake Inhibitor) drugs. In other words, the prescribers have been warned by the drug manufacturer about the withdrawal effects for these whole classes of so-called anti-depressants.

Similarly, the FDA label for Ativan (lorazepam¹⁵), one of the benzodiazepines includes the following about its withdrawal effects:

Physical and psychological dependence

The use of benzodiazepines, including lorazepam, may lead to physical and psychological dependence...

In general, benzodiazepines should be prescribed for short periods only (e.g., 2 to 4 weeks).

Extension of the treatment period should not take place without reevaluation of the need for

13 See The Zyprexa Papers, by Jim Gottstein, Jim Gottstein, Anchorage, Alaska 2020.

14 Note by the editors: Antidepressant; marketed as Adef, Afeksin, Affex, Barazac, Cozac, Dawnex, Deprexin, Flonital, Fludac, Fluohexal, Fluox, Fluoxetine, Fluoxone, Flutinol, Fluxil, Fluzac, Gerozac, Lorien, Lovan, Magrilan, Movox, Nuzak, Olena, Oxactin, Plazeron, PMS-Fluox, Proctin, Prohexal, Prolax, Prozac, Prozamel, Prozep, Ranflocs, Rezak, Salipax, Sarafem, Trizac, Zactin.

15 Note by the editors: Marketed as Almazine, Ativan, Larosh, Larpose, Lorans, Lorazepam, Lorivan, Temelor, Trapex, Tranqipam, Verlapam.

continued therapy. Continuous long-term use of product is not recommended. Withdrawal symptoms (e.g., rebound insomnia) can appear following cessation of recommended doses after as little as one week of therapy. Abrupt discontinuation of product should be avoided and a gradual dosage-tapering schedule followed after extended therapy.

Abrupt termination of treatment may be accompanied by withdrawal symptoms. Symptoms reported following discontinuation of benzodiazepines include headache, anxiety, tension, depression, insomnia, restlessness, confusion, irritability, sweating, rebound phenomena, dysphoria, dizziness, derealization, depersonalization, hyperacusis, numbness/tingling of extremities, hypersensitivity to light, noise, and physical contact/perceptual changes, involuntary movements, nausea, vomiting, diarrhea, loss of appetite, hallucinations/delirium, convulsions/seizures, tremor, abdominal cramps, myalgia, agitation, palpitations, tachycardia, panic attacks, vertigo, hyperreflexia, short-term memory loss, and hyperthermia. Convulsions/seizures may be more common in patients with pre-existing seizure disorders or who are taking other drugs that lower the convulsive threshold such as antidepressants.

It does not appear there is much in the way of withdrawal warnings for the neuroleptics, misbranded as “antipsychotics.” For example, the Seroquel (quetiapine¹⁶) FDA approved label only includes:

Acute withdrawal symptoms, such as insomnia, nausea, and vomiting have been described after abrupt cessation of atypical antipsychotic drugs, including SEROQUEL. ... The incidence of the individual adverse events (i.e., insomnia, nausea, headache, diarrhea, vomiting, dizziness and irritability) did not exceed 5.3% in any treatment group and usually resolved after 1 week post-discontinuation. Gradual withdrawal is advised.

Another difficulty arises if the drug at issue is generic. The generic drug maker is not allowed to change anything on the FDA approved label and therefore cannot be held liable for failure to inform. The original manufacture may not be liable because the patient did not take their drug. There was a case where the widow of a 57-year old lawyer who jumped in front of a train after six days on paroxetine¹⁷, the generic version of Paxil, sued GlaxoSmithKline (GSK), the original manufacturer, on the grounds it should have changed the label to reflect increased suicide risk, but lost because the FDA had refused to allow

16 Note by the editors: Marketed as Adequet, Alvoquel, Atrolak, Biquelle, Brancico, Conquet, Dopaquel, Geroquel, Ketipinor, Kizofrin, Mintreleq, Noletil, Notiabolfen, Pequit, Placidin, Psyquet, Psyquit, Quentiax, Quesery, Quetapel, Quetapil, Quetex, Quetiapin, Quetiapina, Quetiapine, Quetoser, Qusel, Serez, Seropia, Seroquel, Setinin, Sizonorm, Socalm, Sondate, Syquet, Tevaquel, Truvalin, Zaluron, Zimbiquet.

17 Note by the editors: Antidepressant; marketed as Arketis, Aropax, Brisdelle, Deparoc, Lenio, Loxamine, Onbixin, Oxedep, Paradise, Parax, Pari, Paronex, Parox, Paroxetine, Paxetin, Paxil, Paxtine, Pexeva, Sedarin, Seroxat, Serrapress, Texine, XET.

GSK to add the warning to the label¹⁸.

If the drug companies are withholding information on withdrawal effects that would be material to a decision on whether to take the drug or not from the FDA as well as prescribers then that would form a basis for a breach of a duty to warn. Otherwise, the drug companies are not viable targets for such lawsuits.

Compensation (Damages)

There are three types of damages; (1) economic damages, such as medical expenses and lost wages, (2) non-economic damages, such as pain and suffering or loss of enjoyment, and (3) punitive damages where the act was particularly unconscionable, such as where a surgeon intentionally left a sponge in a patient so they could charge for an additional surgery.

Proving economic damages, such as medical expenses and past lost wages, is pretty straightforward; receipts or checks and pay stubs. In contrast, proving non-economic damages, especially for pain and suffering and loss of enjoyment is more difficult. The courts have tended to hold the loss of future earnings needs to be proven with reasonable certainty and cannot be speculative. Where someone has been diagnosed with serious mental illness this can be a difficult standard because there is often the assumption the person is not employable. However, for the benzodiazepines and SSRIs most of the harmed people have not been diagnosed with serious mental illness - at least not before being prescribed psychiatric drugs. Overall, a psychiatric diagnosis is a hindrance to proving loss of future earnings. Normally, one would want an expert witness to testify about loss of future earnings and in some states it would be required.

Many states have enacted limits on how much one can receive for non-economic damages as so-called "Tort Reform" in response to grossly exaggerated claims by doctors' groups that juries are out of control and awards are often excessive. These limitations, or "caps" as they are known, tend to be in the \$250,000 to \$500,000 range.

The United States Supreme Court has held there has to be some proportionality to punitive damages awards to satisfy the requirement of Due Process of Law.¹⁹

Other issues

Contingent Fees

Most medical malpractice cases are taken by lawyers on a "contingent fee" basis which means the lawyer only gets paid out of the recovery, if any. The percentage seems to be 40% these days, up from the standard one third when I first became a lawyer. The lawyer will also front the expenses, such as expert witness fees, which can be considerable. There

18 *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803 (7th Cir. 2018).

19 *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (US 1996).

is a real benefit to this arrangement for the plaintiff, but the lawyers evaluate cases very carefully before agreeing to take them on. They try to determine the probability of success and the amount of any likely recovery to arrive at an expected value. Then, they look at how much work and other investment it is likely to take and if this calculation is not favorable they won't take it.

It is possible to pay a lawyer an hourly rate to take such cases, but I don't really recommend it because if the lawyers don't think it will be worth their investment, it is unlikely it will be worth yours.

Litigation is very unpleasant

Another thing to consider is that litigation is an extremely unpleasant process. The other side is entitled to "Discovery" which means requiring one to submit to out of court testimony, known as a deposition, and provide all documents that might be even remotely relevant or lead to relevant information. One's psychiatric history and other history will be examined very closely. It's like a rape victim being interrogated about their sex life and wasn't it their fault because of the clothes they were wearing.

Class actions

People tend to tell me they want to file a class action. I am not a fan in general. The individual class members tend to get relatively little while the lawyers make a huge amount of money. The defendant's liability to class members is cut off whether or not the class member participates in the recovery, usually a settlement. There are also certain requirements for class actions that will normally not be met for a claim of lack of informed consent regarding psychiatric drug withdrawal effects. In order to aggregate claims into a class action, the class members' claims have to be similar enough to be handled en masse. This is called "commonality." Class actions would tend to only be filed against the drug companies because they have "deep pockets" (lots of money to be obtained), but as is explored above, they are not likely to be liable unless actively hiding withdrawal effects from the prescribers.

Pre-suit requirements

As part of so-called Tort Reform, legislatures in many states have also enacted pre-lawsuit requirements such as having a doctor's letter opining that it is a legitimate malpractice case. However, at least one state court has ruled this medical malpractice rule does not apply to informed consent cases because "a claim of lack of informed consent is not a medical negligence claim."²⁰

20 *Shortell v. Cavanagh*, 15 A.3d1042, 1043 (Conn. 2011).

Whodunit

Another possible difficulty arises when there are multiple prescribers involved. Which prescriber caused the problem by not warning about the withdrawal effects when multiple prescribers failed to provide such a warning?

Sound mind

As mentioned above the right to informed consent only applies to people of “sound mind.”²¹ It is beyond the scope of this article to go into this issue in any depth, but a few words are in order. First, it seems likely that most informed consent claims over not being warned about the withdrawal effects of psychiatric drugs are likely to concern benzodiazepines and SSRIs, where many if not most of the people prescribed these would not have been diagnosed with a serious mental illness involving psychosis. Benzodiazepines and especially the SSRIs cause many people to become manic, a psychotic condition, but that shouldn’t apply to the initial prescription.

On the other hand, people who have been diagnosed with a serious mental illness involving psychosis would probably be faced with this as an issue. But informed consent has to be given by someone. If not it is a battery. Legally, a person has to be of “sound mind” for a prescriber to accept the person’s agreement to take the prescription. If, instead, a guardian has been appointed, the guardian would have a claim for lack of informed consent on behalf of their ward. A problem with this is the guardian is often in league with the prescriber.

Another scenario is where a judge orders someone to take psychiatric drugs because the patient is not of “sound mind,” i.e., not competent to decide whether to take the psych drug or not. In that situation, the prescriber makes their case to the judge and the lawyer appointed to represent the patient is charged with rebutting it. Unfortunately, the appointed lawyer normally doesn’t do much on behalf of their supposed client. The doctor is still supposed to provide sufficient information to provide informed consent, but who has the right to sue? I would say the patient still has the right to sue the prescriber for not providing material information to the judge. It is an added hurdle to a successful lawsuit, though.

Conclusions

Prescribers rarely provide any, let alone adequate, information on the withdrawal effects of psychiatric drugs, the most problematic ones of which are the benzodiazepines and SSRIs. This is a clear violation of the prescriber’s duty to provide all information that is material to a decision to take the drug and gives rise to a legal claim against the prescriber. Vindicating such claims in court is difficult.

21 *Canterbury, supra.*, 464 F.2d at 780; *Cobbs, supra.*, 502 P.2d at 9.