as corrected by D.C.

Vermont State General Assembly

Judiciary Committee

Monday, May 12, 1997

S. 103: An Act Relating to Involuntary Medication of Mental Health Patients

Testimony of Dr. David Cohen, University of Montreal

Q: (Representative Costello, Chair) David, can you tell us a little bit about your educational background?

A: Yes. I am a Doctor of Social Work, not a physician. I am a professor at the University of Montreal since 1989. I have been studying for the last 15 years or so psychotropic drugs, psychiatric drugs -- as a clinician, as a researcher -- mostly the last 10 years as a researcher, and mostly I have focused on neuroleptic drugs, antipsychotic drugs... [E]ssentially, I am a researcher and have published a number of papers and book chapters and have [given] conferences on social aspects of antipsychotic drugs and quality of life on antipsychotic drugs, and I have just completed a large review of the effectiveness of the antipsychotic drugs: meta-analyses where I look at studies after studies and the issues related to that.

Q: Do you have a curriculum vitae, Dr. Cohen?

A: Yes I do.

Q: Could you fax that down to us this morning?

A: Yes I could.

Q: Does that CV include your publications?

A: Yes it does.

Q: [fax number given] How much of your time do you spend writing books and articles?

A: Most of my time.

Q: What else do you do?

A: Most of my time right now during the last couple of years I have just authored here in Quebec in French a handbook of psychotropic drugs. It came out in November of 1995. Sort of a 400 page handbook. It's a critical handbook. It's called "A Critical Handbook of Psychotropic Drugs." Since it's been out, I have been working on an English adaptation. But half my work is in French, half my papers are in French. I do extensive consultation in French with the French government.

Q: Do you have any experience, Dr. Cohen?

A: I have clinical experience as a social worker for about 10 years.

Q: We are dealing with a forced medication bill here in Vermont. Are you familiar with the particulars of our responsibilities?

A: I am not entirely familiar. I have received, but just very recently, a copy of what seems to be a draft of something called an "Act Related to Involuntary Medication of Mental Health Patients." I have just glanced at it, but I was asked to discuss [...] my area of expertise, [which] has to do with the questions of risks and benefits of medication and I can address several issues that I have done research [on]. I have just completed a large scale research of how dangerousness is evaluated by what we have here in Quebec. These are administrative tribunals that evaluate a committed individual, who is involuntarily committed. When [these individuals] ask to have their commitment reviewed, they pass in front of this administrative tribunal made up of two psychiatrists and a lawyer, and this tribunal, this committee, rules on their dangerousness and decides whether they will be detained or they will be let go. And so I have looked at the decisions of this tribunal for the past 20 years. I have just finished it so I have some knowledge of the kind of factors that go into the determination of dangerousness and its circumstances. So I look at a number of issues related [to] psychiatric services. But most of my expertise is related to medication.

Q Why don't you visit with us then about your knowledge or insight into these antipsychotic drugs and their risks and benefits.

A: Essentially, what I would like [to say], that may help your committee or not, relates to what I see as a very large over[estimation] of their benefits. Essentially, when you look at research of the last two decades, you will find that there is a difference in what is said about the drugs and what the research actually shows. What we hear about the drugs is they're really wonderful for agitated persons, the psychotic person, people in the throes of psychosis who are losing control, aggressive, wasting their money, and that early intervention with the drugs really does make a difference. Research does not show this to be accurate. There are a lot of problems with the neuroleptic or antipsychotic drugs on the market today, including the so-called "atypical neuroleptics" which have been introduced in the last 5 to 8 to 3 years and so forth. So essentially there is a large overevaluation. Several studies show up to two-thirds of people not responding, even in the very short term -- that is even in the two weeks during the acute crisis -- which is where the drugs have been known to really have their major impact, which is the immediate control of psycho-motor agitation. This kind of effect is not shown to be as fantastic as it is often claimed to be. So, in the short term we have some problems. On the longer term, that's where the real problems are coming up. In other words, all the long term studies, the consensus is simply that two-thirds of the people were relapsed. Whether on medication or whether out of medication -- whether not on medication -- people were relapsed. And so the question simply has to be: let's look at this -- what does this suggest, for early intervention or no intervention with the older drugs. With the newer drugs these questions get somehow sidetracked because we hear that the drugs are just fantastic.

Q: Doctor, we are mostly lay people here on the Committee. Could you spend just a minute and tell us how these drugs do operate on a person's mind and body?

A: That's a good question. First, what we know about the neuroleptic -- I call them "neuroleptics" -- that's what they are generally called in the literature right now. In fact they were termed "neuroleptics" because of their neurological effects. The main effect of any neuroleptic -- and I am including here drugs like Haldol, Thorazine, risperidone, olanzapine (Zyprexa) (the very latest one that has been introduced within a year, a couple of years, in Canada and the United States); These drugs will generally dampen a person's emotional reactions. This is what they will do: they will control and reduce any sort of spontaneous kind of agitation. They will do it on any person, and in fact, any animal that ingests the drug. The studies are pretty unanimous on that. That is, any sort of movement, any sort of aggression, any sort of agitation, in a number of cases it gets reduced. So whether you are looking at a cat, whether you are looking a horse, whether you are looking at a rhinoceros, it is responding to Thorazine. Whether you are looking at a diagnosed mental patient, whether you are looking at a manic person diagnosed with bipolar disorder, whether you are looking at a person diagnosed with paranoid schizophrenia, essentially the main effects are quick control of psycho-motor agitation. That is, the person who is claiming to be the Messiah and so forth will still claim to be the Messiah, but they will do it in a subdued manner, they won't be tugging at people's sleeves and saying "Look at me, I'm the Messiah." They will be much quieter about it. However all this happens while their consciousness is fairly intact. That is, their eyes are open, they are not asleep. That's the main immediate effect of neuroleptic drugs.

Q: That's the effect, but how is that effect achieved?

A: That's achieved, essentially what we understand today, is through blockade of dopamine receptors. Especially, what we understand today, most of the drugs on the market today work by blocking D-2 receptors. It is one [...] family of dopamine receptors. So by blocking the transmission of dopamine between nerve cells, psychomotor agitation is decreased. Now, that is one of the effects we can pinpoint to. Of course, the drugs, once they are inside the brain, influence a whole number of other neurotransmitter systems. Neurotransmitters [are] simply these chemical substances that conduct nerve impulses between cells. A lot of the communication between cells is by nerve impulses which are electrical impulses, and, so essentially the impulses fire a burst of neurotransmitters which jumps across a gap to enter into another cell. The neuroleptics block, they just block, the entrance of, among other chemicals, dopamine. So the dopamine does not circulate as it normally would. And by doing that, agitation and a lot of other behaviors get dampened. Now, what happens at the same time is you get abnormal movement. The very same biochemical activities which are believed to account for the desired effects of the neuroleptics are also invoked to account for their undesirable affects. Most of which are abnormal movements.

Q: Now, can you visit with us a little bit about what those abnormal movements are?

A: That is an area that I have spent alot of time looking at, clinically, and as a researcher, and as a reviewer of literature. Now, you have four main types of abnormal movements and mental states that accompany these abnormal movements.

The first and one of the most widespread, is called Parkinsonism, and that resembles and is considered almost identical to real Parkinson's disease. You've got reduced facial expression, you've got reduced arm swing, you've got muscular rigidity, you've got drooling, you've got shuffling gait -- the person sort of rubs their feet as they're walking -- and a general lack of facial expression. That's accompanied by depression. Now that is very, very, frequent -- that's probably 90% of people on neuroleptic drugs [...]. They will experience Parkinsonism to some degree or other. And that, in fact, is what in many ways accounts for the lessening of psychosis.

The second very common effect is exactly the opposite of that: It is called akathisia. And that is a psychomotor agitation. The person will rock back and forth, will be shifting from foot to foot. If they are sitting, they will be holding their hands or sitting on their hands; they will be fidgety; they will be pacing back and forth; they will report agitation sometimes originating in their abdomen; they will be moving and they will look agitated. That's called akathisia. That will affect in the studies up to three-quarters of the patients. Some of the latest neuroleptics, risperidone for example, are [...] noted for effects like that. Now that is very often seen as psychotic agitation. It's very difficult to distinguish a drug-induced effect from the original psychiatric disorder, for example. And very often akathisia calls for increasing doses and then sort of a vicious cycle continues. Now that is the second effect.

The third effect, the main effect, is called dystonia. Dystonias are essentially just strange, bizarre looking, sustained, muscular spasms. They affect mostly younger people, mostly men. They'll have spasms. It will affect mostly the neck muscles, the mouth, sometimes the extremities -- the arms and legs -- and they will look bizarre, and they are probably the most painful, physically, of the neuroleptic induced abnormal movements.

And then finally, you've got dyskinesia. Though dyskinesias are just uncoordinated twisting, rhythmical, involuntary, abnormal movements of mostly the mouth, the lips, the tongue, the jaw, sometimes the trunk, and so forth. Each of these effects, Parkinsonism, akathisia, dystonia, dyskinesia, can become tardive and irreversible. Meaning, they can emerge either early on during the initiation of the treatment: could be a few days, a few hours, a few weeks; or they can emerge later: a few months. Sometimes even after you cease the drug treatment, a dyskinesia can occur. And each one of those can become irreversible. It can progress, worsen, persist, and remain in spite of ceasing the medication. Each of the effects are very well documented. They have led to major dissatisfaction with neuroleptics and they are said to be less frequent with the newer neuroleptics, called frequently "atypical neuroleptics."

Q: (Rep. Wayne Kenyon) Dr. Cohen... You've done a great job of sketching the various types of neuroleptically induced responses. What I'm curious about, and I don't know if this is in your particular area of expertise, but in your total involvement of teaching, I'm guessing that you'd be aware of it; From the psychiatric standpoint, what do the psychiatrists present as the helpful aspects of the various neuroleptics?

A: From the psychiatric standpoint the most helpful aspects, what I hinted at at first, which is the relatively quick control of psychotic agitation, number one. Number two would be some success the drugs have in delaying the psychotic relapse. Meaning the re-occurrence of a psychotic episode, of loss of contact with reality, of delirium, etc. So, in other words, psychiatrically speaking, the advantages of the drugs are seen in the acute treatment, when you try to bring under control an active psychosis. And once the active psychosis is under control, or has simply subsided, then in the long term, prevention of other psychotic episodes. Now, these are essentially on what the reputation of neuroleptics today in psychiatry rests. But, I really hasten to add here, and it's very important, that the success of antipsychotics in delaying relapse is very modest. It is not very good, and for most people they have really heard that it's fantastic and there is really nothing like it. In fact, the research shows that -- and hang on to your hats here -- that even individual Freudian psychotherapy with schizophrenic patients is just as good. Now, it sounds funny, but it is just as good, and the research shows it, published in a reputable medical journal. So it is essentially, one person out of three who [are] on the drug [that] appears to have the relapse delayed because of the drug. For the other two out of three persons the drugs do not appear to play a role. So what you have is, because of this situation, because we can't tell who is going to benefit from the drugs, they are essentially given to everybody. And so everybody is exposed to the risks but will not necessarily benefit from the drugs. That is very important to say because it is not often stated that way, but that's clearly what the evidence shows.

Q: Let me ask you two follow-up questions, please. I had guessed from your presentation of the four types of abnormal movements induced by neuroleptic drugs that perhaps the purpose was to get the person calm enough from the psychiatrists' perspective so that they could deal with whatever methods they customarily deal with.

A: Right.

Q: And in the way you describe their view of control of agitation and delaying a relapse and to prevent at least as soon a recurrence of psychiatric symptoms, that suggested that that was what they're up to so that...

A: Our statements about what the drugs do and how helpful they are in conditions say like schizophrenia can only be derived from a body of research. You know, I have to say we all have anecdotal stories about how wonderful they were in a situation or how awful they were in a situation. But again, when you look at the body of research, you have to see that we investigated the role of neuroleptics in helping people vocationally, emotionally, socially, very little. That's a big, big gap in research. In fact, there is probably just a handful -- and I mean a handful, four, five

maybe -- studies that look at how neuroleptics are useful when you put in a lot of outcome criteria. That is, the major outcome criteria -- to figure out how useful are neuroleptics -- has been essentially one: relapse. That is, is there any increase of symptoms? Is the person back in hospital? That's been the major outcome criteria to study the effects of neuroleptics.

The other outcome criteria that we might reasonably expect are social functioning, quality of life, vocational achievements. When you broaden outcome to include these criteria and you try to figure out what role might neuroleptics play into that, you've really got just a handful of studies. Certainly not enough to conclude that neuroleptics are useful in that. What the evidence does show is long term use of neuroleptic depresses social functioning. That's very well established in the literature.

Q: As part of that same question, it occurred to me the possibility and I'd like your reaction. Has it occurred to you that it might be psycho-social factors on the part of the psychiatrists in assuming that they need to quiet the person down with the psychotropic drugs in order to deal with the underlying problem and that indeed if they were able to overcome what you might see as an imagined barrier if it weren't for the attitude, that perhaps they could deal with these same patients without the use of the psychotropic drug -- that is if they didn't have a negative reaction to the symptoms that were being presented.

A: If I understand your question correctly, you're implying ... Let me try to answer by making a comment about your question and see if I understood it correctly, is that all right?

Q: Yes. It's hard to express.

A: OK. Essentially, you're putting your finger on -- from what I understand -- on something very important which is the attitudes of the helpers. I believe -- and this is again my theory and this is not what I would consider a scientific opinion --

Q: Right.

A: -- is that the impact of the drugs is mostly on people around the patient. And that's at once on the immediate level and on the immediate interpersonal situation and also historically speaking. There is a study that came out in the November '94 issue of the American Journal of Psychiatry. It's called a "meta-analysis." That means that they took every single outcome study in schizophrenia of this century. From 1895 until 1992. Every single study followed people labeled schizophrenics and they looked at the impact of different treatments. Now, over the century it covered alot of different things. It covered water --dousing them with water; it covered fever -- giving them malaria; it covered the convulsive treatments -- the shock treatments, the insulin comas; it covered psychotherapy, and it covered neuroleptics from the 1950s onward. And so they compared the outcome and they came up with something like 384, 386 different studies. A lot of studies. And what they found is that the improvement rate from the last twenty studies of this century -- from 1986 to 1992, there were twenty outcome studies all using neuroleptic drugs -- and the

improvement rate was 36 per cent. Then they compared that with the studies from the first two decades of the century: 1895 until 1925. And they found that the improvement rate was 36 per cent. It was identical. The improvement rate way before the neuroleptics were even thought of, in the first two decades of the century, using the same diagnostic criteria because they controlled for the narrow diagnostic criteria, and the last decade of the century is the same improvement rate. Now, that is really an amazing finding when you think about it. This gives you a perspective of over a century. We have not necessarily come very far in the actual treatments we're applying. The drugs are not really working like we've said they're working. They are not working as well as they were 80 years ago. Now, what has changed in the meantime? Our attitudes have changed. The structures and the system has changed. The role of families have changed. The support given to psychiatric patients, financial support, all kinds of things have changed. But the treatments themselves -- they've changed technically -- but their impact is the same.

In a sense, I think that that helps; We need a bit of that background when we're looking, you know, this is the forest, we need a little bit of that background to look at the individual situation.

Q: That was exactly the area I meant.

A: Right, right. So we need -- in the individual situation, very often, it helps, the drugs will, I'll say in one case out of two in the immediate situation, it will calm the person down. No question about it. Now, whether that is useful in the long term, medium term, prognosis of the mental condition, whether that is really useful, that is an open question. My sense is that it's not really useful. That that dampening may be done by a benzodiazapine, maybe done by something like valium, maybe done by something like lithium. These are central nervous system depressants. Now, again, there are studies comparing opium powder, diazepam, valium, for example, with neuroleptics over four weeks and so forth. And, that dampening can be done with other drugs. It's that immediate control of symptoms. And in fact, today in the 1990s, no one just receives neuroleptics. It's almost unheard of. The studies show that in the late 1990s any patient that receives neuroleptics generally receives three other drugs. They very often will receive a benzodiazepine, a drug like clonazapam or something. These are drugs that are commonly called anxiolytic drugs. They'll very often receive -- up to 80% of them will also receive -- lithium, which is a powerful central nervous system depressant.

Q: Dr. Cohen, this is my final question. You may recall I said I had two questions. The second one, and you've touched on it in terms of practice but my question was on the underlying problem. You said that with schizophrenics they get as good results without the drugs and just using traditional Freudian methods -

A: Well, I wanted to highlight there are studies that show that. I believe that psycho-social interventions in structured settings get the same and slightly better results than the drugs.

Q: This is my question: Considering that there well may be a "chemical basis" for lack of a better term -- that it's a problem that hits people in their late teens or early twenties and continues on, sometimes, I guess they recover in their forties, and some never recover -- considering that it has fundamental causes; how can the traditional psychiatric approaches work without restoring chemical balance?

A: Mr. Kenyon, all I would have to say is that no specific, no biological dimension -- whether it be biochemical, neurological, structural, anatomical, electrophysiological -- no biological dimension specific to schizophrenia has yet been charted. You may have heard and seen and read a number of contrary affirmations. The fact is, we do not know the cause or the causes of schizophrenia. If we did know, if we had found them, it would be a Nobel Prize immediately and schizophrenia would be considered officially a neurological disease and would be in neurological textbooks. This has not happened yet.

Q: There is an assumption that there is a cause, right? There is an assumption that there is an underlying biological cause?

A: Most of that assumption comes from our investigations of the effect of the drugs. When we look at the drugs, we see what the drugs do. For example, we see that they block dopamine reception, so the main biochemical hypothesis of schizophrenia is called the "dopamine hypotheses." We say, "well, look we gave the drugs, the person is less agitated, and there is less dopamine transmission. So possibly why they were agitated is too much dopamine." That's called the dopamine hypothesis.

Q: I'm only asking can you perhaps go only so far with the traditional psychiatric approach?

A: There are studies of slightly less traditional, for example Soteria studies published in the American Journal of Psychiatry and others, the British Journal of Psychiatry 1992. What they've shown is -- it's not so traditional: It's structured, residential intervention without drugs or with very low doses of traditional drugs. It gives the same results or better. Certainly better results, socially speaking. This has been published, it is in the literature. We are talking about six months to eight months of structured residential treatment outside hospitals. Soteria Berne, for example, in Switzerland, which I visited in August of 1995, is a twelve room house. It's got -- it's run by a couple of physicians, it's got a couple of nurses, a couple of social workers, psychologists, and they have about a dozen patients.

Q: Dr. Cohen... Thank you. I think we got that answer.

Q: (Rep. William Lippert) Dr. Cohen, just to put this in the broader context of the current treatment at least with which I'm familiar in the United States, perhaps it may not be the same in Canada -- I don't know --

A: It's probably very similar.

Q: Are the conclusions that you are drawing are that the use of neuroleptics or phenothiazines are not appropriate or preferred treatment?

A: I am concluding that the research evidence does not allow us to tell that they're the most appropriate treatment. And I am also concluding that their effectiveness has been vastly -- and I mean vastly -- overestimated.

Q: Can you tell me in the context of at least the practice as practiced by the Canadian psychiatric community and general psychiatric community --

A: The Canadian psychiatric community in this sense would be almost identical to the American psychiatric community. Essentially, for a person diagnosed with almost any kind of psychosis, whether the causes be known like organic types of psychosis, even dementia, very often the first line of prescription would be a neuroleptic drug. I would think that essentially 80 to 100 per cent of people with a diagnosis of schizophrenia would receive a neuroleptic drug, a course of neuroleptic drug. After two or three psychotic episodes or hospitalizations, they would be considered to be candidates for life long medication with these drugs. That is the way things are done today. And I just pointed out a number of caveats expressed by dozens and dozens of researchers that the drugs may not be sufficient for their main clinical purposes; that there are regular cycles of discontent with the drugs; and that the newer drugs that appear are marketed on the basis of their lower propensity to induce those negative effects. But it's certainly to early to tell for the couple of newer ones that are widely used today. Much too early to tell.

The control of behavior or agitation is always obtained at a price. There cannot be a drug that will calm a person down quickly and not have some kind of toxicity. As a concept it's impossible. It would be an illusion to think that you could obtain rapid, quick control of agitated behavior with no other effect.

Q: Dr. Cohen, have you reviewed studies where no treatment with neuroleptics has been offered at all?

A: Yes. There are a number of such studies and there are also a number of studies of the withdrawal of neuroleptics. There is a large analysis of 66 studies of neuroleptic withdrawal published in 1995 in the Archives of General Psychiatry which suggests that gradual withdrawal of neuroleptic drugs will produce the same relapse rate as continued medication. I don't know if I was clear, but, again, there are a number of studies that show that removing the drugs from patients on the drugs gradually will produce the same relapse as keeping them on the drugs. Removing the drugs equals keeping them on the drugs. This is in the literature, published, discussed, commented on by researchers.

Q: (Rep. Lippert) Thank you.

Q: (Rep. Costello) Thank you very much, Dr. Cohen.

Draft

Testimony of Dr. David Cohen (excerpt)
Vermont Legislature
House Judiciary Committee

Re: S. 103 (Community Forced Drugging Bill)
January 28, 1998

David Cohen: I had talked the last time I had spoken with you, testified on that basis, and my understanding is since that time your committee has heard some testimony about the new neuroleptics, the so-called atypical neuroleptics, am I under the right impression?

-- Yes

David Cohen: And my understanding is that the evidence that you've heard, or the opinions you've hard, is that we're dealing with a new class of drugs that do not present the dangers of the older neuroleptics, so that might give you a better feeling about going ahead with forced treatment with these drugs rather than the older, nastier drugs. And so I would just maybe like to make a couple of comments.

Rep. Little: Doctor, I think maybe a better way to characterize the testimony, that there are different and in many cases somewhat lesser consequences, but it wouldn't be fair to characterize the testimony as saying that there are none.

Rep. Lippert: Or undetermined --

David Cohen: So, I just wanted to wrap up that part of it -- suggest a lot that one should really separate the enthusiasm about the introduction of a new drug with what we really know about that drug. And I just want to suggest that throughout the last forty years or so of the psychopharmacological treatment of psychosis there have been a number of false hopes and immense enthusiasms generated by drugs that haven't really panned out, and that hasn't really been confirmed. And that is why we become very enthusiastic, in fact, when a new drug appears on the market. And I would just want to suggest that what we know about the atypical neuroleptics is very little. We have a number of confounding factors in the studies and in the system -- the mental health system around it -- that should urge anyone caution about having a law about forced treatment on evidence of the effectiveness of the new drugs.

Rep. Sinnot: I guess that raises one question with me, and that is -- when we first started discussing this bill, you know I'd wonder why, if there's medicine out there, why wouldn't somebody take it instead of sitting in a mental institution. And I think what I'm hearing is that there are risks--why wouldn't somebody take it -- that are not yet determined, and that somebody who is competent or at one time was competent could say, that's a risk I'm not willing to take at this time and therefore I would not want to be medicated. Would that be a rational, competent point-of-view--even if somebody might disagree with it -- for a decision for an individual to make for themselves?

David Cohen: If you're asking me the question, yes, I believe that would be a rational, competent decision, if only based on a perusal of the actual published evidence and leaving aside all issues of whatever distress the person would be in, that would be a competent decision for them to make. I would be happy to testify about the rational basis of such a preference. Absolutely.

Rep. Sinnot: Thank you, that's basically what my question was. That's because I don't think we have to get into any depth at this point, but -- well, maybe we should. Maybe I just give you the range and let you run. I think you're onto the right track. About how -- let's say it was myself and let's say I wanted now, before anything happens, a durable power, advanced directive, and I'm not saying I feel like this so if the tape runs later on, but -- could I have that point of view to say, these drugs have a risk that I'm not sure of, and therefore at this time even it would help me in the short term I'm not willing to risk the long term dangers?

David Cohen: I think that is an extremely, an eminently rational type of decision. You know, preferences change based on long term and short term effects, and absolutely -- the fact is, the issue of why would a person make that decision with respect to certain drugs like the new neuroleptics -- I just want to address this specifically, when we are talking about neuroleptic drugs, the reason they're called neuroleptics or antipsychotics if you prefer is they really dramatically interfere with some pretty basic functions. Vital functions like movement, like thought, like decision making, etc. So a drug that has the power to stop certain insistent thoughts, or to immobilize the person, or to render them indifferent -- which is really what the drugs do and I'm not using rhetoric here, this is what they actually do. That's why we say the person's improved, their symptoms have decreased, because the drug is profoundly impacting on some vital functions. But for a drug to have that impact one has to raise the question, is the price the organism has to pay to have these functions interfered with.

Now with the older neuroleptics and a slew of other drugs, the price has been paid. You may have heard of tardive dyskinesia and the other movement disorders I had discussed in my previous testimony -- that's the price we've paid for the neuroleptics and it's a pretty heavy price, and it's the patients who've paid it. And to a lesser but unexamined extent it's the system that has to deal with these people -- who are not improved and who in fact are sometimes made much worse. Now that's the price we've paid with the older drugs.

The new drugs are sold on the basis that they have the same anti-psychotic efficacy -- they just as profoundly interfere with those functions. However, it's claimed they don't have the same price as the older drugs. The question is, what price do they have -- what price can we reasonably expect drugs to have, given that we know it interferes with these functions, vital functions. That's what we call behavioral toxicity. What impact will it have? And for tardive dyskinesia we waited twenty years to recognize what the impact really was and it's a major impact -- and it's led to a search for new drugs.

So again, it would be very rational for a person in the situation you've described to say now, I don't know what the risks could be. There could be risks and so I do not want to take this drug even though it might have a beneficial impact in the short term. I think that would be a rational decision.

Rep. Kenyon: Dr. Cohen, would your reaction be any different if the person was considered to be a danger to others, demonstrably so, so that a reasonable person would agree that this person at least at that juncture was dangerous to other people and the alternative apparently to using new neuroleptic drugs would be incarceration or some other restriction of movement, so that it would no longer be a danger to others -- would you think it appropriate that this individual in that kind of situation should make that kind of rational determination?

David Cohen: Well, I might think it appropriate but given certain circumstances, the first one would be that I would be very sure -- I would be very clear -- number one, what criteria are we using to say, this person is dangerous to themselves or others, let's say. Now that is often assumed that we have very valid explicit well-tested criteria for that —

Rep. Kenyon: Agreed, that's why my example said that any reasonable person would agree that in this particular instance that I'm proffering, that they would be dangerous.

David Cohen: Okay now, but the fact is that such determinations of dangerousness are not done by lay people, reasonable people. They're done by professionals, generally psychiatric professionals. That introduces a very large bias because of very systemic factors having to do with the role of psychiatrists in the mental health system. It may sound like an academic consideration -- the fact is reasonable people, as you call them, are rarely called on to make such evaluations, we give to certain professionals the mandate to carry out these evaluations but in fact the criteria are not necessarily reasonable criteria or not necessarily ever criteria that a reasonable person would say, "Well, that's the criteria I would use." So again, I would have to say, there's a problem there.

Rep. Kenyon: That's a very cogent argument. I agree.

Rep. Costello: Okay doctor, we're very grateful and we appreciate your insight.