

Genetic intervention is on the near horizon for the treatment of substance abuse. Genetic intervention involves a reprogramming of a person's own genetic instructions so that that person will no longer have the physical craving for the drug of choice. Unlike pharmacologic intervention, genetic intervention will change the genetic identity of the person, albeit slightly. The legal issue is whether one has a fundamental right to this medical procedure. A fundamental right is one that the government cannot deny without a compelling interest. The case law indicates that the right of medical necessity applies when the person's affliction is serious, there are no reasonable or effective alternatives, the person did not intentionally cause the condition, and the treatment is effective for the long term. Unlike the medical marijuana phenomenon, genetic intervention is per se anti-drug, unrelated to illegal, recreational drug use, and on its face has a medical use. Legal doctrines to date though not directly on point are conceptually compatible with the existence of a fundamental right of medical necessity for genetic intervention.

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## The Lena Scenario <sup>2</sup>

The following scenario is completely fictitious but entirely plausible. Lena is a fourteen year old. She first experimented with marijuana, and this has led her to heroin. Ken, a sixteen year old, is already addicted to heroin and has drawn Lena into his circle of drug buddies. Lena is quite taken with Ken. He is, in her eyes, good looking, exciting, and older. Plus, real drugs seem to be a lot more fun than marijuana.

Lena's parents are clueless. They went through their teen years in another era and either do not recognize the signs that Lena is a user or are in denial or most likely both ignorant and in denial at the same time. However, as Lena is transformed from a fun kid to a little package of hate, the parents begin to wake up into their nightmare. When they finally discover enough evidence that Lena is using heroin that their denial is shattered, they frantically seek advice. They learn that in today's America, they cannot force their little Lena to stay in a rehabilitation program until she commits a crime, something that to their knowledge she has not yet done. One counselor encourages them to allow Lena to be arrested in possession of heroin so that then she can be forced into taxpayer-financed rehab through the American criminal justice system. Lena's mother, a juvenile court master, realizes that the primeval American criminal justice system - for juveniles and adults alike - would more likely harden Lena into a life on drugs rather than help her get off drugs.

Another counselor informs the parents of rehabilitation programs in Mexico where Lena could be made to stay "until she graduates"<sup>3</sup>. The drawback here is that the medical insurance industry has pretty much dosed the door on effective rehab by the 30 day rule<sup>4</sup>. Rehab requires an extended period of time, i.e., substantially more than thirty days for most illegal drugs, to have any chance of success<sup>5</sup>. Consequently, the 30 day rule appears to be a blatant deception perpetrated by the insurance company on the policyholder. Anyway, Lena's parents are afraid to go the Mexican route because they cannot overcome their fears and prejudices about Mexican lawlessness, some adverse press coverage of Baja rehab facilities, and the dangers of just being American in Mexico.

Then the parents are put into contact with a physician who is associated with one of the country's leading medical research institutions. The physician informs the parents of what she calls "medical intervention". She explains that the grip which heroin has on Lena is maintained because the sensations when using heroin are so "good". It's so "good" that Lena wants more, more often. The physician explains that the physical craving for more heroin is caused by some neurochemical processes set into motion by the heroin, and she explains that certain genetic "markers" are central to the heroin-caused sensation of feeling so good. The physician explains that these "markers" can be reprogrammed so that Lena will not get the same sensations, indeed will get no real sensations at all, and will, therefore, be no more drawn to heroin than to flour or corn meal. In short, the parents are presented with an option to deal with the

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<sup>2</sup> This scenario is completely fictitious, and any similarities to real persons is completely accidental.

<sup>3</sup> Indeed, there is a thriving drug rehab industry in Mexican Baja where Americans go to get the help they are prohibited from getting in their own country. An Internet search of the terms "drug rehabilitation Baja" reveals an industry which has been highly criticized and under regulated but one with a number of rehabilitation successes.

<sup>4</sup> This rule limits drug rehabilitation to 30 days. Every experienced drug rehab counselor and physician who has gone on record on the issue asserts firmly that 30 days is completely inadequate for practically every rehabilitation.

<sup>5</sup> For example, it takes about a year for the neurological pathways damaged by cocaine to reconstruct themselves. (Hamer 1999, 139).

physiological aspect of heroin addiction, (though certainly not with the psychological aspects which underlie so much addiction)<sup>6</sup>.

Lena is only fourteen. With some finesse, the parents can make the decision for Lena to undergo this medical intervention at the genetic level. There is no claim that it cures addiction. The claim is that it diminishes the *physical* dimension of addiction to the point that the psychological aspects can be dealt with more successfully and more aggressively.

### The Patient's Interest

The patient - in our scenario, Lena - has a number of conflicting interests at issue. First, the patient has a right to at least some level of personal autonomy. No child is completely at the medical mercy of anyone else, parents included. For example, a parent, absent medical necessity, can hardly order a child's kidney be taken out, but a parent can order wisdom teeth to be extracted even though there is no immediate medical necessity. Likewise, a parent can make a decision for the child and against the child's wishes that the child receive speech therapy.

To which is the genetic intervention for substance abuse more similar - a kidney operation, wisdom tooth extractions, or speech therapy? Table One lists four major "rights" inquiries which attach to involuntary medical procedures. Three of the rights inquiries attach to any medical treatment being considered for a minor who has not given informed consent to the treatment. First, we ask whether the treatment intrudes on the minor's personal autonomy. Most but arguably not all medical treatments against one's will violate one's right to personal autonomy.

**Table One**  
Four Rights Inquiries Implicated by  
Involuntary Medical Treatment for a Minor

Inquiry	Leading Judicial Case
Does the treatment intrude on the minor's personal autonomy?	No Case
Does the treatment violate the minor's right to be free from physical intrusion?	<i>Winston v. Lee</i> 470 U.S. 753 (1985)
Does the treatment violate the minor's right to be free of conduct which shocks the conscience?	<i>Rochin v. California</i> 342 U.S. 165 (1952)

<sup>6</sup> Genetic intervention is quite different from pharmacologic intervention. Genetic intervention will involve the use of a contained virus to introduce into the human body instructions which will "permanently" change the behavior of a targeted genetic receptor or marker. Pharmacology involves the use of a substance to alter the behavior of the person's physiology in some temporary way. Genetic intervention slightly changes the person's genetic configuration and, thus, arguably changes who that person is. Thus, there is a personal identity issue here. Prescribed medicines do not change who the person is, only how the person's biology operates during the effective duration of the medicine.

Do prohibitions by the government of the treatment violate the minor's right to medical necessity?

*U.S. v. Oakland Cannabis Buyers' Cooperative*  
532 U.S. 483 (2001)

Second, we ask whether the treatment violates the minor's right to be free of a physical intrusion into one's body. There are, of course, degrees of intrusion, and the courts have allowed intrusion against one's will, for example, for the drawing of a blood sample, *Schmerber v. California*, 384 U.S. 757 (1966) but not for the surgical removal of a bullet which could be evidence of a crime, *Winston v. Lee*, 470 U.S. 753 (1985).

A third question implicated by treating a minor against his or her will is whether the treatment procedure would "shock the conscience". The formulation is intrinsically subjective but recognizes that certain procedures are so out of keeping with our notions of decency that the government cannot force them on anyone because they shock the conscience. This approach is expressed most clearly in *Rochin v. California*, 342 U.S. 165 (1952).

A fourth inquiry, somewhat different from the first three, is whether a law prohibiting a procedure which is needed by the minor in a circumstance where another procedure cannot reasonably accomplish the same medical result violates the minor's right to medical necessity. The philosophical foundation here is that one has a natural right to successful medical treatment and (a) unless there is an equally successful medical alternative and (b) so long as the treatment does not endanger another person, the government may not prohibit that treatment. Thus, we allow narcotics to be used to treat a cancer victim's pain. Indeed, the degree to which a society recognizes the right to medical necessity is arguably an accurate gauge of the society's devotion to individual rights.

Table Two gives an admittedly subjective rendition of various medical treatments in terms of the four rights inquiries. Category one of Table Two includes medical procedures which either do not infringe on the minor's right or infringe only minimally. Thus, if the minor has a speech impediment, few would maintain that the minor, forced to undertake speech therapy, had his or her personal autonomy violated. There is no physical intrusion, and practically no one would say that speech therapy shocks the conscience. However, if the government were to prohibit speech therapy or corrective glasses, as a training regime for coping with dyslexia, the right to medical necessity as that concept has been developed by American courts would clearly be violated.<sup>7</sup>

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<sup>7</sup>The concept of medical necessity is discussed more fully below.

Table Two  
A Comparison of Various Medical Procedures

	If Done Against Will, Does It Intrude on Personal Autonomy?	If Done Against Will, Does It Violate Freedom from Physical Intrusion?	If Done Against Will, Does It Shock the Conscience?	Would Prohibition Violate the Right of Medical Necessity?
<b>Category I</b>				
Speech Therapy	Minimally	No	No	Yes
Aggression Mgt. Therapy	Minimally	No	No	Yes
Coping Skills for Dyslexia	Minimally	No	No	Yes
<b>Category II</b>				
Glasses, Vision Correction	Moderately	No	No	Yes
Psychoanalysis	Moderately	No	No	Yes
Treatment for Wheat Allergy	Moderately	No	No	Yes

Prescribing of anti-depressants	Moderately	No	No	Yes
<b>Category III</b>				
Preventive Wisdom Teeth Removal	Yes	Yes	No	No
Corrective Surgery for Toe Alignment	Yes	Yes	No	No
<b>Category IV</b>				
Kidney Removal	Yes	Yes	No	Yes
Tonsils Removed	Yes	Yes	No	Yes
Anthrax Inoculation	Yes	Yes	No	Yes
Insulin for Diabetics	Yes	Yes	No	Yes
Abortion to Save Mother's Life	Yes	Yes	No	Yes
Smallpox Inoculation	Yes	Yes	No	Yes
Use of Marijuana for Pain Management	Yes	Yes	No	Yes

DR. RUPNATHJI (DR. RUPAK NATH)

Genetic Intervention for Parkinson's Disease	Yes	Yes	No	Yes
Genetic Intervention for Substance Abuse	Yes	Yes	No	Yes
<b>Category V</b>				
Unnecessary Stomach-Pumping	Yes	Yes	Yes	No
Preventive Mastectomy	Yes	Yes	Yes	No
Unnecessary Cosmetic Surgery	Yes	Yes	Yes	No

Category two includes those treatments which intrude on personal autonomy more than category one treatments, but the intrusions in category two are only moderate. Thus, for example, if a minor has depression and an anti-depressant is properly prescribed by a psychiatrist, there is an invasion of the minor's personal autonomy if the minor is forced to take the medication involuntarily. However, such an intrusion onto the minor's personal autonomy, though more than minimal, is nonetheless acceptable because with rare exceptions (1) the alternative is less acceptable and (2) the intrusion does not shock the conscience. One can always create a scenario wherein involuntary administration of an anti-depressant *does* shock the conscience - - - e.g., when the particular anti-depressant is contra-indicated, when it is not prescribed by a competent, psychiatrist, etc. - - - and it is the resulting "shocks the conscience" aspect which makes the intrusion on personal autonomy unacceptable.

Category three includes procedures which, though intrusive, seem to fall short of shocking the conscience. Thus, removing a child's wisdom teeth where no physical problems have occurred would not shock the conscience but would arguably violate one's right to be free of physical intrusion. It is not the fact of physical intrusion but rather the nature of the specific intrusion which determines whether the conscience is shocked.

Category four includes among other medical procedures genetic intervention for substance abuse. Along with the other examples in the fourth category, this is one where there is an intrusion on the minor's personal autonomy, and there is also a physical, bodily intrusion. Thus, for example, if anthrax were to be widely used as a terrorist weapon and government policy were to allow, but not require, anthrax inoculations, even given the apparent side effects of that serum and the unknowns surrounding it, few would maintain that within the prevailing circumstance of a domestic terrorist threat the inoculation of an unwilling thirteen year old shocks the conscience or is an unacceptable invasion of personal autonomy. Because it does not shock the conscience, it is an acceptable intrusion on personal autonomy. Practically any medical treatment violates one's personal autonomy, even it only minimally. What determines whether the violation is acceptable is whether, given the circumstances, the violation is contrary to our notions of decency, propriety, and civilized conduct as those notions have been developed over the years. If the violation is contrary to those notions, then it is not acceptable. It shocks the conscience.

Category five is provided simply to give some comparative context and to identify that medical treatments can exist which so shock the conscience that regardless of the circumstances they are unacceptable violations of one's personal autonomy. For example, there are some reported incidents of parents opting for preventive mastectomies on their children when breast cancer has run in the family. Though not clinically indicated for the child, there might be family history indications, but, nevertheless, most would agree that such preventive mastectomies do shock the conscience.

Likewise, numerous unnecessary or experimental treatments might shock the conscience, though for very different reasons. The unnecessary treatment administered against a minor's will is simply a per se violation of the minor's right to personal autonomy. Therefore, unnecessary cosmetic surgery on a minor's face or body - - - which if it is against the minor's will would probably be for the parents' vanity - - - would so shock the conscience that it would be an unacceptable violation of the minor's personal autonomy.

An experimental procedure presents a different problem. Assuming that some treatment is necessary and that traditional treatments do not work, one might elect a procedure which holds promise but has unknown side effects and a somewhat unknown success rate. Here the calculus is not so much whether the procedure shocks the conscience because it is engaged in for non-therapeutic or per se unacceptable reasons. Instead the calculus is whether the potential benefits can reasonably be expected to outweigh the possible costs, given the context that there is no alternative treatment which holds a reasonable expectation of achieving the same results. The experimental treatment can reasonably be expected to achieve. The experimental procedure does not shock the conscience if the anticipated benefits clearly outweigh the anticipated costs.

#### **The Institutional Context for a Policy of Genetic Intervention for Substance Abuse**

For the medical treatments listed in Table Two or for other analogous treatments, authoritative policies have been made by the federal government, state governments, or the people directly through initiatives and referenda, or in some cases all of the above. For example, the federal government threatened to prosecute medical marijuana users in California because use of that substance violated federal criminal laws even though California had legalized the medical use of marijuana. In *Gonzales v. Raich*, 125 S.Ct. 2195 (2005), the U. S. Supreme Court ruled that the federal government prevails in this state-versus-federal controversy apparently because the majority was of the opinion that the Constitution gives the federal government the power to

regulate anything which even speculatively affects more states than one. The Court's expansive ruling was based purely on the commerce clause and did not mention the right of medical necessity nor was medical necessity even argued.

The plethora of various state policies and judicial opinions on medical marijuana stand in contrast to genetic intervention for substance abuse. On that topic there is no specific government policy at either the federal or state levels.

### The Congress

Congress is particularly ill-equipped to make policy on genetic intervention for substance abuse because the issue is so technical and because just about any conceivable policy has potential ideological triggers which probably preclude meaningful Congressional action in the first place. On the one hand, a policy restricting genetic intervention foregoes a major weapon in the so-called war on drugs and arguably violates the fundamental right to medical necessity. The pharmaceutical, medical, civil liberties, and "people" interests could probably block definitive Congressional action.<sup>8</sup> On the other hand, a policy endorsing genetic intervention would likely antagonize the religious fundamentalists who currently have such power over the national Republican party that a Congressional majority endorsing genetic intervention could probably not be assembled. "If God wanted those genetic markers turned off, he would never have turned them on" will echo through the chambers of Congress.<sup>9</sup>

Perhaps the best indication of the danger of Congress's making policy on this issue for the foreseeable future is that two large restraints on Congress are largely absent on the topic of genetic intervention. Missing are (1) a clear public opinion on genetic intervention<sup>10</sup> and (2) a clear signal regarding a policy on genetic intervention from the moneyed interests which are so critical to the financing of congressional elections campaigns.

Table Three gives a classification of Congress's making of "new" policy, that is, policy on a topic addressed either only minimally or not at all in the past. If the anticipated public reaction is substantial, the prediction is that Congress will most likely make policy in the direction of that anticipated reaction. If there is sure to be a substantial reaction, but the direction of that reaction cannot be predicted with confidence, the prediction is that Congress will not act at all.

Table Three  
Congress's Making Policy in a New Area  
Anticipated Public Opinion Reaction

	<u>Substantial Reaction</u>	<u>Minimal Reaction</u>

<sup>8</sup>The key word is "definitive". Congress can always pass a law designed not to establish a permanent policy but rather to take it off the hook and throw the issue back into the courts. Congress's handling of flag burning comes to mind.

<sup>9</sup>Recent research on a related topic indicates that the greater one's religious intensity, the greater the likelihood that that person will oppose human reproductive cloning. (Bainbridge, 2003).

<sup>10</sup>On the related issue of stem cell research, public opinion is highly fragmented with no clear majority sentiment on any policy option. See Genetics and Public Policy Center 2004. Also see Pew Research Center 2002.

Direction of Public Opinion	<u>Positive Public Opinion Reaction</u>	Quick Action Per Public Opinion Definitive Policy	Quick Action/Either Direction
	<u>Negative Public Opinion Reaction</u>	Quick Action Per Public Opinion Definitive Policy	Quick Action/Either Direction
	<u>Direction of Public Opinion Reaction Unknown</u>	No Definitive Policy	No Definitive Policy

Congress can act swiftly and, unleashed from public opinion, in any reasonable direction if the public reaction is anticipated to be inconsequential. Congress can withstand a slight negative public reaction. It takes more than that to affect a Congressperson's vote unless the particular Congressperson is cursed with one of those rare competitive seats in which case that Congressperson may well still be on the public leash.<sup>11</sup>

Genetic intervention policy seems today to fit best in the final cell of Table Three. Because a relatively small percentage of the population will be directly or immediately affected by any genetic intervention policy, public reaction for the foreseeable future will probably be inconsequential, at least initially. Whether the public will initially support or oppose a particular policy (this concerns the direction of public opinion) is unknown. However, the chances are outstanding that the religious right will make an endorsement of genetic intervention politically risky for a large number of Congresspersons and Senators. Consequently, we can expect Congress either to pass no laws at all on the issue or to pass equivocal or meaningless laws. This is the "punt and let the courts handle it" option.

When Congress is unleashed from a well-formed public opinion but under the potential leash of powerful interests, Congress can be expected to act with great hesitation. The leash for Congress serves both as a guide and as a restraint, and in these circumstances (unformed public opinions and potential opposition from moneyed interests), Congress treads ever so unboldly. Without something analogous to the boogeyman of human cloning, genetic intervention will be difficult to oppose because it promises to be therapeutic. Moreover, it seems likely that genetic intervention will not stoke the fires of religious groups' murderous wrath as easily as reproductive cloning or stem cell research.

### The Courts

Like so many other issues, ranging from all kinds of privacy issues to all kinds of personal autonomy issues, the issue of genetic intervention for substance abuse will most likely play out in

<sup>11</sup>A Congressperson's policy position is also affected by that Congressperson's role perceptions concerning the degree to which constituency opinions control and dictate his or her votes and policy positions. See Schwartz 1988 and Bianco 1994.

the courts.<sup>12</sup> When properly presented to a court of competent jurisdiction as a justiciable issue, the issue will likely involve due process, privacy, and personal autonomy. Of the dozens of legal doctrines which govern those areas, few seem suitable or directly applicable to the issue of genetic intervention. Only three seem to me to be on point - - - the "shocks the conscience" doctrine articulated most eloquently in *Rochin v. California*, 342 U.S.165 (1952), the "physical intrusion" doctrine of *Winston v. Lee*, 470 U.S.753 (1985), and the fundamental right of medical necessity which several state courts have recognized but which the U.S. Supreme Court has never discussed as such. Though the Supreme Court has discussed the criminal defense of medical necessity, that is not the same thing as the fundamental right of medical necessity.

### Would Denial of Genetic Intervention "Shock the Conscience?"

"This is conduct that shocks the conscience". *Rochin v. California*, 342 U.S.165, 172 (1952). Thus wrote Justice Frankfurter in explaining why the police could not pump a suspect's stomach against his will in order to retrieve evidence which he had swallowed. Conduct which shocks the conscience is conduct which "offends those canons of decency and fairness which express the notions of justice of English-speaking peoples...." 342 U.S., 169. Though the context of *Rochin* is on the surface criminal procedure, Frankfurter makes clear that the issue is human rights, not just criminal procedure and that we have certain rights which though not precisely listed anywhere are nevertheless rights for which we retain protection from government intrusion: "In dealing not with the machinery of government but with human rights, the absence of formal exactitude, or want of fixity of meaning, is not an unusual or even regrettable attribute of constitutional provisions." 342 U.S., 169. The due process clause of the fourteenth amendment, therefore, contains certain substantive rights beyond those rights explicitly mentioned in the Constitution which government must observe. See generally *Bowers v. Hardwick*, 478 U.S. 186, 191, 106 S. Ct. 2841, 2844, 92 L.Ed.2d 140 (1986); *Hewitt v. Helms*, 459 U.S. 460, 466, 103 S.Ct. 864, 868-69, 74 L.Ed.2d 675 (1982); *Moore v. City of East Cleveland*, 431 U.S. 494, 503, 97 S.Ct.1932, 1937-38, 52 L.Ed.2d 531 (1977).

The "shocks the conscience" doctrine is controversial because of its inherent subjectivity. It is a per se contradiction of the idea that principles control the outcomes of judicial cases. Though some judges and many academics might reject, even ridicule, the doctrine, the doctrine is alive and well in the courts. Since 2000, my own electronic search reveals that it has been cited in 2178 cases and is used as a controlling concept in many of those cases! Obviously, the doctrine flourishes in the jungle of judicial output. Though some read the "shocks the conscience" doctrine as license for judicial activism (and it may well be) and others decry its unavoidable subjectivity, the doctrine has spread to areas of law other than police misconduct. For example, the doctrine is now routinely a part of the analysis in assessing whether damage awards are excessive (See for example *Carter v. Cox Cable, New Orleans*, 806 So.2d 24 (2001); *Layne v. Wal-Mart Stores, Inc.*, 24 Fed. Appx. 364, 2001 WL 1480736 (6<sup>th</sup> Cir. 2001) (not selected for publication in the Federal Reporter) and whether criminal sentences are proportional to the crime committed (See for example *Humetrix, Inc. v. Gemplus S.C.A.*, 268 F.3d 910 (9<sup>th</sup> Cir. 2001);

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<sup>12</sup>The issue is presented here by the Lena scenario involving a minor child for whom the parents elect genetic intervention. That issue could rather easily get before a court through a relative or public interest group petitioning the court to appoint an attorney for the child. If the issue does not arise within a research context, involving, for example, some regulation preventing genetic intervention research, it seems reasonable that the minor child context is the likely route to judicial action. If an adult were the patient, assuming that the adult were competent and wanted genetic intervention, it is difficult to see how a court would get beyond the standing issue. For that reason I am writing this discussion in terms of a minor patient.

*Miskovsky v. State*, 31 P.3d 1054 (2001); *Perryman v. State*, 990 P.2d 900 (1999). The doctrine has also been applied in a number of situations where a specific legal principle may not control but a general notion of what is fair, decent, and civilized, nonetheless, is arguably implicated, such as involving the alleged use of excessive force by the police, *Ferrante v. Peters*, 2005 WL 1432740 (6th Cir.(Ohio)), 2005 Fed. App. 0521N (Not selected for publication in the Federal Reporter), a principal pushing a student, *Gottlieb ex rel. Calabria v. Laurel Highlands School Dist.*, 272 F.3d 168 (3<sup>rd</sup> Cir. 2001), government intimidation of agency employees into unsafe work performance, *Eddy v. Virgin Island Water and Power Auth.*, 256 F.3d 204 (3<sup>rd</sup> Cir. 2001), the terms of an arbitration agreement, *Ferguson v. Countrywide Credit Industries, Inc.*, 2001 WL 867103, 86 Fair Empl. Prac. Cas 354 (C.D. Cal. 2001), and the propriety of a tax sale on a taxpayer's property, *Kabakjian v. U.S.*, 92 F. Supp. 2d435 (E.D.Pa. 2000).

All of these examples involve allegations of government's denial or violation of a particular right which is not explicitly set forth in the Bill of Rights but is an implicit substantive right protected by the due process clause of the fourteenth amendment. A denial of genetic intervention would in like manner implicate a right of medical necessity, and in spite of an unusual and awkward 2001 case by the Supreme Court,<sup>13</sup> medical necessity is exactly the type of issue which seems very likely to trigger a shocks the conscience inquiry.

#### Would Denial of Genetic Intervention Violate the Right of Medical Necessity?

If a defendant in a criminal case faces a choice of evils wherein obeying the law produces a greater harm than disobeying the law, then that defendant might be able to argue a general defense of "necessity". The defense of necessity has been part of the Anglo-American legal tradition since as far back as 1551.<sup>14</sup> The medical necessity defense is a special variant of the general necessity defense and is characterized by the following elements:

- ? The defendant did not intentionally bring about the medical condition which is being addressed by the medical action in question.
- ? An alternative treatment is not available to the defendant.
- ? The harm caused by engaging in the medical action is less than the harm caused by obeying a law or court order prohibiting the action.<sup>15</sup>

The medical necessity defense has been used in various jurisdictions in the United States, but unfortunately (or fortunately, depending on one's point of view!) many of the cases have involved claims that marijuana was a medical necessity such as to justify violation of various marijuana-related criminal laws. A few examples can illustrate medical necessity claims. The sixth Circuit assumed that the defense of medical necessity was a viable defense but in the circumstances of the case, the defense was not available. *U.S. v. Burton*, 894 F.2d 188 (1990). It seems that the defendant, claiming that he needed the marijuana to treat his glaucoma, must have had one bad case of glaucoma since he had enough marijuana to be charged with intent to distribute. A Florida court recognized the defense and reversed a conviction for using marijuana to treat nausea associated with AIDS, *Jenks v. Florida* 582 So.2d 676 (1991).

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<sup>13</sup>*U.S. v. Oakland Cannabis Buyers' Cooperative*, 121 S.Ct. 1711 (2001). See the discussion by Pongratz 2003.

<sup>14</sup>Wilton 1993.

<sup>15</sup>See, for example, *Florida Jurisprudence, Second Edition*, 2001.

<sup>16</sup> For a history of the defense related to the medical marijuana issue, see LeVay, A.J. 2000: 714-736.

Washington courts also have recognized the defense. In *State v. Pittman*, 943 P.2d 713 (1997), the defendant used marijuana to treat the pain associated with cancer. Though he did not successfully satisfy the elements of the defense, the court did not question the existence of the defense. However, in the year following that case, the Washington court held that the state legislature had put the defense out of bounds for possession of marijuana. Medical necessity is a common law defense and as such can be made unavailable by the legislature within a statutory scheme. The Washington state legislature had decided that marijuana had "no accepted medical use." *State v. Williams*, 93 Wash. App. 340, 347 (1998). Minnesota courts reached the same result. *State v. Corrigan*, 2001 WL 881394 (Minn. App.).

Two non-marijuana cases have also recognized the medical necessity defense. In Minnesota, the court observed that sterilization by vasectomy was prohibited in several states, but that the statutes of those states allowed for a medical necessity exception. *Christensen v. Thornby*, 255 N.W. 620 (1934). More recently, New York found that the distribution of hypodermic needles to prevent the spread of AIDS was a viable medical necessity defense to the criminal possession of a hypodermic instrument. *People v. Bordowitz*, 588 N.Y. S.2d 507 (1991). The point is that the medical necessity concept is well entrenched in American law.

In 2001, the U.S. Supreme Court issued its first opinion ever on the medical necessity defense in *U.S. v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). In 1996, California passed an initiative legalizing the possession and cultivation of marijuana for medical purposes. The Oakland Cooperative served as a marijuana dispensary for qualified patients. However, the U.S. Congress has classified marijuana as a Schedule I substance, meaning that Congress voted that marijuana has no accepted medical use, 21 U.S.C. § 841(a)(1), and cannot be possessed or distributed except as part of a government-approved research project § 823(f). Therefore, the federal government sought an injunction to close down the Cooperative's distribution program even though under California law the program was legal.

The majority opinion written by Justice Thomas contains far-reaching dicta and some sleight of hand which actually obscures a relatively narrow holding. The Court held only that since Congress had considered exceptions to the illegality of distributing Schedule I drugs and opted against a medical necessity exception, the Court did not have the power to unmake Congress's decision and create a medical necessity exception. Therefore, the Government's request for an injunction against the Cooperative was granted. This is simply an application of a recognized aspect of the defense of medical necessity, namely that the legislature can make a defense unavailable within a statutory framework.

Significantly, the Supreme Court did not address one rather narrow and one rather broad issue. The narrow issue is whether there is a medical necessity defense for possession. *Cooperative* concerned only distribution. As Justice Stevens noted in a concurring opinion, a court might reach a different result within a possession framework:

*Because necessity was raised in this case as a defense to distribution, the Court need not venture an opinion on whether the defense is available to anyone other than distributors. Most notable, whether the defense might be available to a seriously ill patient for whom there is no alternative means of avoiding starvation or extraordinary suffering is a difficult issue that is not presented here.*

*Stevens, conc., 532 U.S., 501.*

However, a *constitutional right* of medical necessity is more inclusive and far-reaching than a *statutory defense*, and the broader issue which the Court did not address is whether there is a

fundamental *constitutional right* of medical necessity. Congress has the power to withhold a defense from its statutory regime, but there may be a more fundamental *right* which Congress can regulate only if it has a compelling interest.

Generally, Congress may regulate controlled dangerous substances in any way which is rational and consequently may conclude that marijuana is a Schedule I drug and has no accepted medical use. Though that finding, especially given its absoluteness (*no* accepted medical use), may be wrong, the reasonableness approach used by the courts requires only that the finding be rational, that it make sense. Surely Congress's finding is plausible as demonstrated by the breadth of disagreement among medical and pharmaceutical experts.

However, this so-called rational basis test does not apply when Congress is regulating fundamental rights. Instead of having just a rational reason, Congress must have a compelling reason before it can regulate fundamental rights. There is a very strong case to be made, as Justice Stevens implied in the portion from his opinion quoted above, that there may well exist a time when the law cannot mandate the withholding of a treatment.

When considering genetic intervention, it is probably more productive to think of medical necessity as a right rather than as a defense. As in *Rochin*, the stomach pumping case, we have certain rights which government simply cannot take away absent compelling reasons. In *Rochin*, it is the right to be free of government conduct which shocks the conscience, or to phrase it differently, the right to bodily integrity. For genetic intervention, the fundamental right involved is the right of medical necessity. Whether our law recognizes such a fundamental right has not yet been determined, but without digressing into a detailed discussion, one can construct a powerful argument that such a fundamental right does exist.

The Stevens quote from his concurring opinion in *Cooperative* contains two elements which make for the fundamental right of medical necessity:

- ? The patient's illness must be serious.
- ? There are no alternative means of avoiding extraordinary suffering.

To these, a third might be added:

- ? The patient must not have intentionally brought about the condition to be treated.<sup>17</sup>

Fundamental rights are not absolutes. With a compelling reason, government can proscribe and limit those rights. The following unknowns of genetic intervention might serve to limit genetic intervention when it first begins to be considered as an option in addressing drug abuse:

- ? The degree of intrusion into one's personal autonomy..
- ? The undesirability and unforeseeability of side effects.
- ? The effects on physiological and psychological factors other than the patient's desire for the targeted drug.
- ? The long term effectiveness of the treatment.

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<sup>17</sup>The third element is the one which will have spirited argument as applied to genetic intervention for substance abuse. If one defines the condition to be treated as receptors which are especially sensitive to opiate reinforcement, then the individual may have had no intent to bring about that condition. However, we do not know what creates differences in various individuals' receptor behavior. If one defines the condition being treated more broadly as "addiction," there is still doubt whether the individual *intentionally* created that condition, much less the underlying psychology which led to that condition. One surely may have intentionally made the choices which led to the condition, but that is not synonymous with intentionally bringing about the condition itself.

**Would Genetic Intervention Be So Physically Intrusive as To Compromise Bodily Integrity?**

In the context of criminal procedure the courts have placed limits on the government’s power to intrude into one’s body. Though genetic intervention is an entirely different context from criminal law, at least as presented in the Lena scenario above, the physical intrusion cases are instructive as to the courts’ probable willingness to allow an experimental procedure for an unwilling minor (and if for an unwilling minor, why not as a condition of probation for a recidivist drug offender?).

In *Winston v. Lee*, 470 U.S. 753 (1985), the U.S. Supreme Court held that the government cannot order the surgical removal of evidence from a nonconsenting suspect, but the holding was limited to the particular circumstances of that case.<sup>18</sup> The court noted that whether the government may intrude into the privacy of one’s body involves a weighing of a number of factors. These factors are listed in Table Four along with analogous application of those factors to the Lena scenario.

Table Four

Physical Intrusion Factors from *Winston v. Lee* and the Genetic Intervention Scenario

Factor To Be Considered	Surgical Removal of Bullet ( <i>Winston v. Lee</i> )	Genetic Intervention for Drug Abuse (Lena Scenario)
Is the end goal probably achievable?	Yes, there was notable cause to conduct the surgical search. (470 U.S., 763).	Yes, the genetic markers associated with the desire for opiates have been identified but their interactions are unknown.
Has a court had opportunity to review the medical and legal questions involved?	Yes, (470 U.S., 763).	No. The setting would be similar to <i>Winston v. Lee</i> in that someone with standing would seek a court order prohibiting the genetic intervention, and this would lead to an airing of the issues.
What is the threat to the subject’s health and safety?	“The medical risks of the operation, although apparently not extremely severe, are a subject of considerable dispute.” (470 U.S., 766). The dangers were a threat of infection from the incision, muscle damage, nerve damage, and damage to the pleural cavity because of the location of the bullet.	The dangers are unknown. The markers which are associated with heroin addiction could also be associated with other human behaviors and attitudes and those aspects of the individual’s behavior could be deleteriously affected. Reversibility of genetic intervention is an open question.

<sup>18</sup>*Winston v. Lee* does not issue a per se rule but instead instructs courts to deal with physical intrusion questions on a case by case basis. Consequently different courts and different facts can lead to various applications of *Winston v. Lee*. For example, in *Johnson v. Nagle*, 58 F.Supp. 2d 1303, 1377 (N.D.Ala. 1999), *Winston v. Lee* was distinguished and the involuntary removal of a bullet from fatty tissue in the defendant’s shoulder was found not to be a violation of the defendant’s rights.

<p>To what extent does the procedure intrude upon the subject's personal privacy and bodily integrity?</p>	<p>"... the intrusion on respondent's privacy interests can only be characterized as severe." (470 U.S., 766). The severity of the invasion of privacy results from the fact that it is physical and surgical. The Supreme Court, quoting from the Court of Appeals said that the government "proposes to take control of the respondent's body, to drug this citizen... with narcotics and barbiturates into a state of unconsciousness, and then to search beneath his skin for evidence of a crime." (470 U.S., 765).</p>	<p>The intrusion of genetic intervention is not so much an invasion of privacy as it is an invasion of one's personal identity. If a person has a great desire, even a debilitating desire for a drug of choice, who are we to change <i>who that person is</i> - that is, to slightly reconfigure that person into someone who no longer has the intense desire for the particular drug? This is a personal autonomy, personal identity issue more than a privacy issue.</p>
<p>How compelling is the need to use the procedure?</p>	<p>The state needed the bullet to prove which gun it was fired from, but that need was not compelling because the state had substantial other evidence which could prove the crime beyond a reasonable doubt. (470 U.S., 765).</p>	<p>Inside of the United States, Lena as a minor cannot be forced to stay in a drug rehabilitation program. If (1) expert testimony was that there was little hope for her to beat the addiction - or to stay alive - without some kind of procedure and (2) a court concluded that the personal and social costs of her addiction were substantial, then a court might well conclude that the need for the procedure, even given unknown side effects, outweighs the individual's right not to have the procedure.</p>

The core distinction of *Winston v. Lee* from a genetic intervention scenario are that (1) *Winston v. Lee* was surgically invasive, (2) involved some disagreement about known and not easily reversible risks, and (3) involved a result which could be achieved without the violation of the right to privacy. In contrast, the Lena scenario involves (1) more of an invasion of one's identity and autonomy than of one's physical body, (2) unknown risks, and (3) a result which may not be achievable without genetic intervention.

### The Personal Autonomy Issue

Requiring a minor child to undergo a genetic intervention indeed may involve an insurmountable constitutional barrier. First off, children do have constitutional rights of personal autonomy independent of their parents. *Whalen v. Roe*, 429 U.S. 589 (1977). Therefore, though the parents' choice may be for genetic intervention, their choice will likely be subject to a judicial hearing (unless the intervention were to be carried out in such a way that the judicial process was bypassed, and this would arguably be criminal if it were done on American soil). In another context, a 1995 U.S. district court had occasion to give a convincing listing of precedents on which an argument to prevent genetic intervention could be built:

In 1990, the Supreme Court unequivocally held that the "forcible injection of medication into a nonconsenting person's body represents a

substantial interference with that person's liberty." *Washington v. Harper*, 494 U.S.210, 229, 110 S.Ct. 1028, 1041, 108 L.Ed.2d 178 (1990). Still, other cases support the recognition of a general liberty interest in refusing medical treatment. *Riggins v. Nevada*, 504 U.S. 127, 112 S.Ct. 1810, 118 L.Ed.2d 479 (1992) (forced administration of antipsychotic medication during trial violated Fourteenth Amendment); *Youngberg v. Romeo*, 457 U.S. 307, 315, 102 S.Ct. 2452, 2457-58, 73 L.Ed.2d 28 (1991) (government has duty to protect involuntarily committed mental patients from physical assault); *Winston v. Lee*, 470 U.S. 753, 105 S.Ct. 1611, 84 L.Ed.2d 662 (1985) (surgical intrusion into attempted robbery suspect's chest to recover bullet without compelling need unreasonable under Fourth Amendment where surgery would place suspect at risk of adverse side effects); *Vitek v. Jones*, 445 U.S. 480, 494, 100 S.Ct. 1254, 1264, 63 L.Ed.2d 552 (1980) (transfer to mental hospital coupled with mandatory behavior modification treatment implicated liberty interests); *Parham v. J.R.*, 442 U.S. 584, 600, 99 S.Ct. 2493, 2503, 61 L.Ed.2d 101 (1979) (A child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment); *Whalen v. Roe*, 429 U.S. 589, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977) (Constitution protects personal autonomy "in making certain types of important decisions"); *Schmerber v. California*, 384 U.S. 757, 772, 86 S.Ct. 1826, 1836, 16 L.Ed.2d 908 (1966) ("The integrity of the individual person is a cherished value of our society"); *Rochin v. California*, 342 U.S. 165, 171, 72 S.Ct. 205, 209, 96 L.Ed. 183 (1952) (the forcible extraction of stomach contents shocks conscience and violates due process). See also *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 278, 110 S.Ct. 2841, 2851, 111 L.Ed.2d 224 (1990) (Fourteenth Amendment has been held to include medical decision-making, reflecting the "principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment.")

*In re Cincinnati Radiation Litigation*, 874 F.Supp. 796, 812 (S.D. Ohio 1995). Though these cases concern government's attempts to invade a person's bodily integrity, American tort law includes the same basic protections against other persons, including a minor's own parents. The individual is protected primarily by the operation of informed consent, without which the procedure is usually tortious.

Under the tort construct, absent an emergency or incompetency, the individual must voluntarily consent before medical treatment may be administered, and the physician is required to provide sufficient information so that the consent is informed. It is patently clear that the premise of the informed consent doctrine is the "concept, fundamental in American jurisprudence, that the individual may control what shall be done with his own body." *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C.Cir.1972), cert. denied, 409 U.S. 1064, 93 S.Ct. 460, 34 L.Ed.2d 518 (1972).

874 F.Supp., 817.

The right to bodily integrity is as close as the precedents get to a right of personal autonomy and the related right of personal identity. Since the right of personal autonomy is not an absolute, a balancing of the right of personal autonomy on one hand against the benefits obtained by doing the procedure on the other is metaphorically the approach taken by courts. *Winston v. Lee*, 470 U.S., 760.

### The Physiological Results from Genetic Intervention

At great risk of some oversimplification, drug abuse problems in full bloom addiction (as opposed to occasional use where a person's life is not adversely affected) have two main dimensions of disability, the physiological and the underlying psychological. Of course, there are all kinds of physiological aspects to drug addiction but one common to all drug addictions is the organic call in the brain for more of the "good feeling" associated with the drug of choice. Likewise, there are a myriad of psychological and psychiatric aspects of drug addiction, and they usually exist prior to the onset of the drug use (and are often causally related to the illegal drug use) though drug usage may modify them. Likewise, those underlying psychological aspects will influence certain of the drug-related choices such as which drug to use, how often to use it, what to mix it with, how to administer it, etc., but will apparently not affect the biochemistry of the addiction. Figure One illustrates the relationship between the physiological and the psychological dimensions of drug addiction. The point of this digression is to note that genetic intervention relates primarily to the physiological dimension and only incidentally to the psychological.

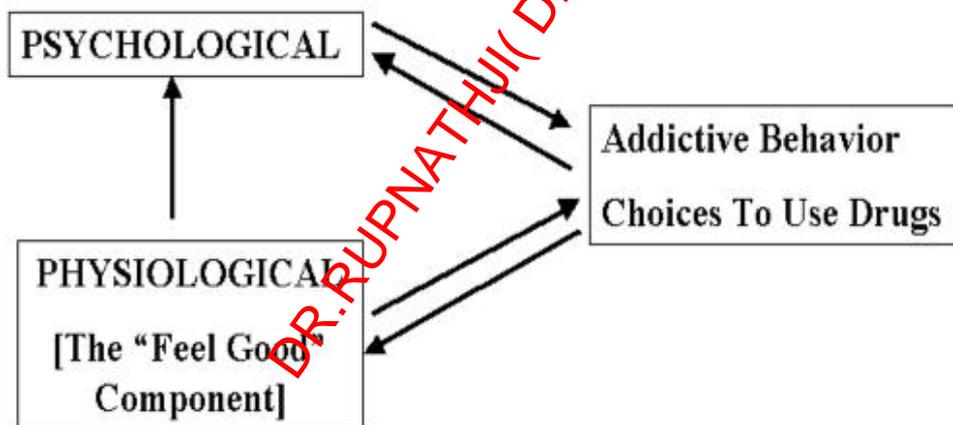


Figure One

### ADDICTIVE MODEL WITH SUBSTANCE ABUSE

Genetic intervention is a means of essentially eliminating the physiological variable from the addiction model so that the non-genetic therapy (for example, talk therapy) can focus more successfully on the underlying psychological variables. The neurophysiology of addiction - of the "feel good" aspect of certain drugs - is simply so strong that it often makes it impossible for the user to deal with the psychological issues which led to the addictive behavior in the first place.<sup>19</sup> Thus, genetic intervention does not cure addiction, but it makes a successful therapy more obtainable. It simplifies (but does not make simple!) the therapeutic challenge so that it resembles Figure Two rather than Figure One.

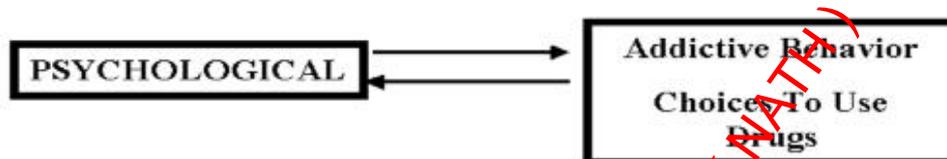


Figure Two

**ADDICTIVE MODEL WITHOUT SUBSTANCE ABUSE**

Specifically the neurophysiology of heroin addiction involves most prominently the  $\mu$  opioid receptor in the ventral tegmental area and in the nucleus accumbens.<sup>20</sup> Our knowledge of events at the receptor level is still limited, but apparently  $\delta$  and  $\kappa$ -receptors are also involved in the craving for heroin.<sup>21</sup> Our knowledge of the neurochemistry is similarly limited, but we do know that heroin triggers an increased release of dopamine in the nucleus accumbens.<sup>22</sup> These findings are from animal studies. Because of advances in human genetics, transferral to humans on the cellular and molecular levels have in other areas such as Alzheimer's disease been smooth enough that pending a few more years of study we can reasonably expect the findings from animal studies to apply closely to humans.<sup>23</sup>

<sup>19</sup>“Indeed, psychosocial interventions may be doomed to failure in many patients until medications are developed to effectively counter the powerful biological forces that drive a state of addiction.” (Nestler 2001, 8326).

<sup>20</sup>Koob et al. 1998, 468.

<sup>21</sup>Keiffer 1999, 537. We also suspect that the opioid receptors interact in some way. (Keiffer 1999, 540).

<sup>22</sup>Koob et al. 1998, 468.

<sup>23</sup>Nestler 2001, 8325.

We are not at the place today (2005) where genetic intervention is possible. But in 5 or 10 years we will be there,<sup>24</sup> and 5 or 10 years appears to be the outside time frame. With the acceleration of discoveries in this area and with certain advantageous peculiarities of substance abuse studies,<sup>25</sup> genetic intervention for substance abuse will in all likelihood be possible well before 2015.<sup>26</sup>

This discussion has looked at genetic intervention only within a scenario involving a minor child addict. In that scenario, the fundamental right of medical necessity appears to be the heart of the issue.<sup>27</sup> The shocks the conscience mentality and the physical intrusion cases also look quite relevant, but a court could give extended consideration to genetic intervention and actually avoid those two areas of doctrine.

Moreover, if the scenario changes, then the relevant legal doctrines might also change.<sup>28</sup> For example, assume that a minor addict for whom other treatment has not been successful does not get a genetic intervention because the parents are opposed to it. Later in life could that person sue the parents for tortious child neglect? Or another example, could a judge impose as a condition of probation genetic intervention if a defendant were willing? Probation conditions are generally constitutional so long as they are reasonably related to rehabilitation in drug abuse cases. Genetic intervention certainly seems to qualify.

As a medical treatment, genetic intervention will know few national boundaries. A national boundary will put genetic intervention out of reach only to those without the money or courage to seek it if Congress outlaws it or if the courts make it unobtainable. Because one will so easily be able to travel to another country for genetic intervention, I have not discussed the FDA's regulatory power in this area. It will be eminently bypassable. Those who want the treatment will simply get it from outside the United States. Given the grip the insurance industry has on American medical care and given the inadequacies of American legal treatment of minors in addictive situations, Americans have gone to other countries to save their kids. There is no reason to think that would not also apply to genetic intervention. Genetic intervention will be globally available.

In short, this genie is already peeping out of the topless bottle.

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<sup>24</sup>Nestler 2001, 8325.

<sup>25</sup>Nestler 2001, 8326.

<sup>26</sup>The 5 to 10 year time frame for genetic intervention is based on progress being made in the identification of various viral vectors for the introduction of engineered DNA fragments into targeted cells. See, for example, Peel 2004 and Smutzer 2000.

<sup>27</sup>The medical marijuana cases have probably done a disservice to the right of medical necessity because it is widely assumed that a large part of that movement is simply a push to legalize marijuana for recreational use, not just for restricted medical uses. Medical marijuana is seen as a more general "pro drug" movement. In contrast to the medical marijuana phenomenon, genetic intervention is clearly anti-drug and could even lead to the ruination of the illegal drug trade in America.

<sup>28</sup>Primary focus to date has been the threat of DNA and genetic data to personal privacy rather than on legal policy regulating the implementation of particular genetic methodologies. See, for example, Yesley 2000 and Rothstein 1999. As usual, political scientists are apparently unaware of the swirl of policy problems looming on the genetic horizon as evidenced by the dearth of social science publications on this topic, with the exception of the material appearing in *Politics and the Life Sciences*, published by the Association for Politics and the Life Sciences.

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