Sterilization Regulation: Government Efforts to Guarantee Informed Consent

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COMMENTS

STERILIZATION REGULATION: GOVERNMENT EFFORTS TO GUARANTEE INFORMED CONSENT

INTRODUCTION

As the legal and medical right to an elective sterilization developed and more women and men chose sterilization as a method of family planning, increased attention focused on the actual voluntariness of such sterilizations. At the center of this controversy is the doctrine of informed consent and the recent federal and state legislative efforts to codify it.

The outcry over sterilizations had its origins in statistical studies which seemed to indicate that some of the "voluntary" sterilizations being performed and funded by government programs were in fact coerced by physicians, particularly those

1. Elective sterilization can be:
   Nontherapeutic: Primary purpose of the procedure is to render an otherwise fertile person permanently incapable of producing offspring.
   Therapeutic: An elective procedure performed for prevention of a future pregnancy which would be life-threatening to the mother because of existing illness or injury.


2. AM. J. OBSTETRICS & GYNECOLOGY 1076 (1972). At one major teaching hospital, The Women's Hospital of the Los Angeles County Medical Center, the following increase in the number of sterilization procedures occurred in the two-year interval between July 1968 and July 1970:

   Elective Hysterectomy 742% increase
   Elective Tubal Ligation 470% increase
   Tubal Ligation after Delivery 151% increase

From 1970 to 1973 the total number of vasectomies performed in this country rose from 200,000 per year to almost 1 million per year.

   Added to an estimated 1 million female sterilizations a year, a total of 2 million people in this country are undergoing surgical sterilization each year. Westhoff & Jones, Contraception and Sterilization in the United States, 1965-1975, 9 FAMILY PLANNING PERSPECTIVES 153, 155 (July/Aug. 1977). Sterilization is now the single most popular method of birth control for couples married ten years or more. Among couples who have had all the children they want, sterilization clearly dominates the field.

3. The doctrine that a doctor must impart some quantum of medical information relevant to a proposed treatment which is sufficient to enable a patient to make an intelligent choice as to whether to undergo such treatment. D. HARNEY, MEDICAL MALPRACTICE 58 (1973).

4. Title XIX of the Social Security Act provides for federal matching of funds for reimbursements for sterilizations. 42 U.S.C. § 1396a(a)(13) (1970); id. § 1396d(a)(4)(C) (Supp. V 1975). Those provisions require State Medicaid plans to provide family planning services and supplies furnished to individuals of childbearing age who are eligible under the State plan and who desire such services and supplies. The Medicaid Bureau has not defined family planning services by regulation; however, the
performed on minority women. These statistics pointed to a tension between competing governmental policies; that of making sterilizations freely available as a legitimate means of family planning, and that of assuring that sterilizations were performed with knowing and intelligent consent. Women's groups, minority groups and medical groups have been actively involved in the process of trying to strike a balance between the two policies. In the midst of an intensive lobbying effort and skirmishes in the courtroom, officials in the federal Department of Health, Education and Welfare and the California State Department of Health have promulgated regulations which emphasize attempting to guarantee informed consent above all else.

This comment will describe the existing federal regulations, the newly created California regulations, and the proposed new federal regulations on human sterilization in the context of the legal doctrine on which the regulations depend—that of informed consent. It will examine the arguments of various legal and political groups regarding the impact of these regulations on other related legal and medical rights of women. In particular an inquiry will be made as to whether,

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6. The California Coalition for the Medical Rights of Women was formed in August, 1974 for the purpose of making local and state public health agencies, private practitioners, and the pharmaceutical and medical industries accountable to women health consumers and health workers. The organization, claiming an umbrella membership of 2000 members, including the Comicion Femenil Mexicana, and Buena Vista Women's Services and represented by the Women's Litigation Unit of the San Francisco Neighborhood Legal Assistance Foundation, 1095 Market, San Francisco 94103, and Equal Rights Advocates, 1535 Mission, San Francisco, was instrumental in getting the new state regulations promulgated. The coalition first urged the state to issue comprehensive guidelines to insure informed consent. It then filed an administrative petition under Government Code section 11426 followed by negotiations with the Dept. of Health and the California Medical Association. Amicus Brief for Intervenors, Exhibit F, California Medical Ass'n v. Lackner, No. 268099 (Cal. Super. Ct., filed July 18, 1977) [on file with Public Advocates Inc., San Francisco, Cal.].


first, the guarantee of informed consent to a non-therapeutic sterilization will have an adverse effect on the unimpeded exercise of a woman's right to obtain a sterilization under the constitutional right of privacy,¹¹ and secondly, whether this guarantee of informed consent will jeopardize medical safety by creating a greater medical risk to women in a substantial number of situations.¹² Finally, this comment will examine the effects of the California regulations on civil tort law in the context of a medical malpractice action based on lack of informed consent to a sterilization procedure.

**The Heart of the Controversy**

*The Right to Elective Sterilization*

In California, there is a legal right to an elective sterilization after the informed consent of the patient has been obtained.¹³ While there is no statute affirmatively declaring it, the right has been firmly established by *Jessin v. County of Shasta*,¹⁴ and an overlay of “fundamental right” decisions by the United States Supreme Court.¹⁵

Prior to *Jessin*, in the absence of affirmative law declaring elective sterilization legal or illegal, physicians were often reluctant to perform such operations.¹⁶ Although now legal, hospitals or physicians are not compelled to perform sterilizations. In fact there can still be difficulty in persuading a doctor to do

¹¹. The meaning of the constitutionally based right to privacy was explained in *Griswold v. Connecticut*, 381 U.S. 479 (1965), where the Court invalidated a Connecticut anticontraceptive statute. Justice Douglas traced the origin and development of the privacy doctrine through constitutional text and court decisions. The Court ruled that the Constitution protects certain private areas of activity against state interference.

¹². The focus of this comment is on elective sterilization of women, although the regulations apply equally to sterilizations of men and other procedures which happen to result in sterilization.


¹⁶. Fear of legal consequences, whether real or imagined, probably resulted in restrictive regulations regarding voluntary sterilizations. For example, 1) the age-parity formula restricting sterilizations to older women or to young women with many children. Age times number of children had to equal 120; 2) approval by hospital sterilization committees fearful of liability for such things as mayhem; 3) approval by spouse. (Clearly no longer allowed under *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52 (1976)). Comment, *A Woman's Right To Voluntary Sterilization*, 22 BUFFALO L. REV. 291, 296-98 (1972).
a sterilization in certain situations. However, if the doctor practices in a clinic or hospital which does permit elective sterilizations, (s)he may not refuse to perform the operation for non-medical reasons.

Informed Consent

At the heart of both this right to elective sterilization and of the controversy surrounding the sterilization regulations is the question of the consent of the patient. Defining competent consent to ensure that an elective sterilization is really voluntary poses a problem. It is in response to that problem that the already developing doctrine of informed consent continues to be interpreted and debated. Informed consent is one of the most frequently encountered expressions in medical malpractice literature; however, it has been troublesome for the courts to ascertain its true essence.

The basic tenet of informed consent is that a physician who proposes a medical procedure has an obligation to explain the procedure to the patient and disclose the dangers incident to the procedure so the patient can make an intelligent and informed choice whether to consent. The California Supreme Court described the physician's duty in Cobbs v. Grant, where it held that: "as an integral part of the physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each." This general statement of the physician's duty does not provide any hard and fast rules concerning the quantum of medical information which must be supplied when discussing a proposed procedure. That quantum required could range

17. Id. A physician is reluctant to perform a sterilization on a young woman or man in the fear that they will have later regrets.
19. D. Harney, Medical Malpractice 58 (1973); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) (the scope of the physician's communication is to be measured by the patient's need); Wilkinson v. Vesey, 11 R.I. 606, 295 A.2d 676 (1972) (physician must disclose all the known material risks peculiar to the proposed procedure); Fogel v. Genesee Hospital, 41 App. Div. 2d 17, 344 N.Y.S.2d 552 (1973) (must be a reasonable disclosure of the known dangers incident to the proposed treatment).
21. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).
22. Id. at 243, 502 P.2d at 10, 104 Cal. Rptr. at 514.
from an amount determined by professional judgment to complete disclosure of any and all facts and dangers however remote.

_Cobbs_ rejected both extremes and emerged as a variation of the medical community standard which requires disclosure of all information normally disclosed by physicians in a similar field of practice in the same or similar community.

For a complex procedure, _Cobbs_ requires, at a minimum, the disclosure of the potential for death or serious harm and an explanation in lay terms of the complications that might occur. Beyond this, a doctor must also reveal to the patient such additional information as a skilled practitioner of good standing would provide under similar circumstances. The reasonableness of the disclosure is measured both by the patient's need and by the community standard.

Use of the community standard has both procedural and evidentiary effects. Under _Cobbs_, if the plaintiff proves less than the minimum disclosure for a complicated procedure, expert testimony is not needed. But when the minimum disclosure is made, the plaintiff must produce expert testimony on whether the community standard has been met. The standard might require such additional information as the risks involved in alternative methods of treatment or in a decision to forego...

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24. The doctrine of informed consent was developed to get around this notion. However, the therapeutic privilege is retained in most jurisdictions, providing that a physician need not disclose those things which would upset the patient to the point of foregoing necessary treatment. _Canterbury v. Spence_ rejects this privilege as inconsistent with the principle that the patient should make the choice. The therapeutic privilege is viewed as a paternalistic notion that the physician may remain silent simply because divulgence may prompt the patient to forego therapy the physician feels the patient really needs. _Canterbury v. Spence_, 464 F.2d 772, 789 (D.C. Cir. 1972).

25. _Canterbury v. Spence_ comes closest to this but tempers by saying "all risks potentially affecting the decision must be unmasked." 464 F.2d at 787.

26. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

1) Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected. 8 Cal. 3d at 242, 502 P.2d at 9, 104 Cal. Rptr. at 513.

2) The patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. And, there is no physician's duty to discuss the relatively minor risks inherent in the common procedures when it is common knowledge that such risks inherent in the procedure are of very low incidence. 8 Cal. 3d at 244, 502 P.2d at 11, 104 Cal. Rptr. at 515.


28. 8 Cal. 3d at 244, 502 P.2d at 11, 104 Cal. Rptr. at 515.

29. _Id._ at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515.

30. _Id._

any treatment, and the likelihood of success. The materiality of the information to the decision "is a nonmedical judgment reserved to the patient alone" and likewise would be within the province of lay knowledge (the jury) in a trial.

In addition to establishing the community standard, Cobbs specifically enumerated the defenses available to the physician. The doctor need not disclose risks when the patient asks not to be informed or when the doctor can demonstrate that disclosure would so seriously have upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment. The second ground is commonly referred to as the therapeutic privilege.

With respect to elective sterilization, the rule announced in Cobbs would require a physician to explain other possible methods of birth control, the relative dangers of each, and the specific nature and result and possible complications of the sterilization operation. For a treatment not designed to produce sterilization but which could result in sterilization, the physician must disclose that possible result and explain alternatives, if any. If a physician fails to disclose those things, the plaintiff must prove a causal relationship between lack of disclosure and the injury. The test is objective: what would a prudent person in the patient's position have decided if adequately informed of all significant perils. This objective test has great significance to the sterilization issue because many complaints arise from an alleged failure to inform the patient of the irreversible nature of the operation. These complaints, when coupled with various statistical studies, became the impetus behind the passage of federal and state regulations governing elective sterilizations.

**History of the Regulations**

In 1973 and 1974 statistics began to show a great increase in the number of people, men and women, seeking sterilization as a means of birth control. Private studies conducted in var-

32. 8 Cal. 3d at 243, 502 P.2d at 10, 104 Cal. Rptr. at 514.
33. Id. at 246, 502 P.2d at 12, 104 Cal. Rptr. at 516. Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 154 Cal. App. 2d 560, 317 P.2d 170 (1957), was the first modern case to articulate what have become the standard defenses in an informed consent case.
34. 8 Cal. 3d at 245, 502 P.2d at 11-12, 104 Cal. Rptr. at 515-16.
ious large urban training hospitals showed that the percentage of women, particularly ethnic and racial minority women, sterilized under federal programs had increased dramatically. The suspicion drawn from those statistics led to further study, interviewing, and investigation, resulting in charges that doctors either neglected to explain the operation and its permanence properly, or performed sterilizations without securing the woman's permission.

Various abuses were reported, including allegations that sterilization, preferably hysterectomies, were performed to provide young surgical residents with training and that doctors "sold" women on sterilization and even threatened them with withholding medical services or future denial of welfare benefits. One study of doctors' attitudes presumably exhibited their readiness to persuade minority and poor women to be sterilized because they all had too many children anyway, most of which would end up as a drain on the welfare rolls. As the number of reported abuses increased, medical rights groups called for some restrictions on sterilization "abuse."

In 1973 a lawsuit involving federally funded family planning programs focused national attention on the problem of coerced sterilization of mental incompetents, minors and welfare recipients. The case, Relf v. Weinberger, involved three mentally retarded sisters who had been coerced into sterilization. The court's decision took note of the "uncontroverted evidence" that indefinite numbers of poor people have been improperly coerced into accepting a sterilization operation under the threat that various federally supported welfare benefits would be withdrawn unless they submit to irreversible sterilization.

38. A tubal ligation is the cutting or tying of the fallopian tubes. A hysterectomy is the surgical removal of the entire uterus.
42. See note 4 supra.
44. Id. at 1199.
45. Id. This "uncontroverted evidence" was supplied by the doctors who had
Although initial regulations on sterilization restrictions had been promulgated by the Secretary of Health, Education and Welfare (HEW),44 the effective date of those regulations was delayed pending the Relf litigation.47 On March 15, 1974, the district court in Relf entered its judgment declaring that the regulations did not go far enough in implementing the congressional command that sterilization be voluntary and not coerced48 and ordering their revision. The only specific guideline imposed by the court was the requirement that the consent document prominently display the guarantee that no federal benefits can be withdrawn because of a failure to accept sterilization.49

Pursuant to Relf, interim federal regulations were in effect by April, 1974.50 More stringent than the court had ordered, the interim regulations defined informed consent in detail,51 provided for an auditor-witness,52 required a consent document prominently displaying the guarantee of no withholding of federal benefits,53 and provided that no federally funded non-therapeutic sterilization could be performed sooner than seventy-two hours following the giving of informed consent.54 These interim regulations remain in effect today following the appeal of Relf.55 In order to continue receiving federal funds for its Medi-Cal patients, California followed with similar regulations for federally funded non-therapeutic sterilizations.56

In the aftermath of Relf, citizens groups, using both the judicial and legislative processes, pressured for even stronger

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reported the abuses mentioned above: B. Rosenfeld, S. Wolfe & R. McGarrah, supra note 36, at 3-9. Dr. Rosenfeld filed an affidavit in the Relf case.

47. 42 C.F.R. § 50.201-.204 (1977); 45 C.F.R. § 205.35 (1977).
49. Id., at 1203.
50. 42 C.F.R. § 50.201-.204 (1977); 45 C.F.R. § 205.35 (1977). A moratorium ordered by the court in Relf on sterilization of people under twenty-one or who are legally incapable of consenting was continued and the regulations applied only to persons legally capable of consenting to a sterilization.
55. The case was mooted on appeal and dismissed. Both sides were satisfied with the interim regulations and the plans for issuing new regulations via the rulemaking process. Relf v. Weinberger, 565 F.2d 722 (D.C. Cir. 1977).
56. 45 C.F.R. § 205.35(3) (1978). A state plan under the Social Security Act must also comply with the federal requirements with respect to sterilization procedures and the state agency shall report to the Secretary of HEW every year the number of sterilizations performed according to the informed consent procedure.
STERILIZATION REGULATION

regulations. In California, legal pressure took the form of a lawsuit against the U.S.C.-L.A. County Medical Center, alleging that many low income Chicano women, confined, under sedation and/or in labor, were coerced into tubal ligations. On the legislative side, women's health and legal groups organized and helped in the drafting of State Department of Health regulations that would apply to all elective sterilizations performed in acute care hospitals, not just those funded with public funds. After public hearings, redrafting, and negotiating, such regulations were added, effective December 1, 1977.

The very day the California regulations went into effect, the federal government issued proposed rules changing the federal regulations in four major ways. The proposed rules require an interpreter if the consent form is not in the primary language of the patient; a thirty day waiting period between the date of the consent and the date of the sterilization; a minimum age of twenty-one to participate in the consent process, and elimination of federal financial assistance for hysterectomies performed solely for the purpose of rendering an individual permanently incapable of reproducing. Hearings for public comment on these proposed rules were held until March 13, 1978.

Because the federal sterilization regulations are closely mirrored by state regulations and the proposed federal changes are still awaiting release, the focus here will be on the basic provisions of the California regulations.

57. No. 75-2057 (C.D. Cal., filed June 18, 1975).
58. Id.; see also pleadings on file at Public Advocates Inc., 1536 Mission St., San Francisco, Cal. 94103. There is dispute over why the federal regulations then in effect did not cover the situation. One side argues the regulations were not complied with. McGarrah, Sterilization Without Consent: Teaching Hospital Violations of HEW Regulations (Jan. 21, 1975) (on file at Santa Clara L. Rev.). The other side claims that the federal regulations were not distributed to hospitals by Lackner, head of the California State Dept. of Health. There is also acknowledgement by the Circuit Court in Relf that HEW was unable to adequately supervise the procurement of consent, raising questions as to HEW's enforcement of the interim regulations and its capacity to enforce revised regulations.
59. CAL. ADMIN. CODE tit. 22, § 70037.1 (1977). These sections apply to general acute care hospitals. Any sterilization performed in an acute care hospital is subject to the regulations.
60. 21 C.M.A. NEWS, No. 51 (Nov. 18, 1977).
63. Id.
THE BASIC REGULATORY PROVISIONS

The State of California has two basic sets of sterilization regulations: one covering Medi-Cal patients and one covering health facilities, applicable to all sterilizations performed therein. 64

Types of Sterilizations

Both sets of regulations define the types of sterilizations. 65 For a sterilization other than an emergency, the following conditions must be met. First, the patient must be advised, prior to solicitation of the informed consent, that no benefits provided by public programs may be withdrawn or withheld by reason of a decision not to be sterilized; second, a minimum required waiting period of fourteen days must have passed since the signing of the Sterilization Consent Document. The patient may request a shorter period in writing but in no case less than seventy-two hours. Third, the patient’s informed consent must be obtained. In order to participate in the informed consent process a patient may not be in a physical condition or mental state in which judgment is significantly altered, whether due to medication, emotional state or impaired sensorium, or in labor, or less than twenty-four hours postpartum or post abortion. 66

Additionally, a patient may select or waive selection of an auditor-witness who, if selected, will be present during the informed consent process. The informed consent may be obtained by either a physician or the physician’s designee. The sterilization operation must be requested by the patient without fraud, duress, or undue influence. If the patient is not fluent in either English or Spanish, the Sterilization Consent Document must be verbally translated into a language in which the patient is fluent. 67

Explanation of Medical Procedure

Under the regulations the patient must be given an explanation of the proposed procedure and the anticipated result

65. Id. §§ 51163, 70037.1 ( Elective, Secondary and Emergency Sterilizations).
66. Id. §§ 51305.2, 70702.1.
67. Id. §§ 51305.3(e), 70707.3(e) (1977). This was changed from the original draft which provided that the patient supply the translator.
including but not limited to: 1) the surgical procedure to be used and how sterilization results therefrom; 2) the type of anesthesia to be used; 3) approximate length of hospital stay; 4) approximate length of time for recovery; 5) the effectiveness of the procedure in producing permanent and irreversible sterilization; 6) whether the procedure is new or experimental; 7) the financial cost to the patient; and 8) confirmed and/or suspected short and long term consequences, including but not limited to anticipated results of permanent and irreversible sterilization, common side effects and discomforts, significant health risks and complications. 68

**Age Requirement**

A person must be at least eighteen years of age to give informed consent to an elective sterilization whether therapeutic or non-therapeutic. 68 Additionally, the patient must be provided with the booklet, “Patients Information on Female Sterilization,” developed by the Department of Health and available in both English and Spanish. If the patient is not fluent in either language, the booklet must be read to her in a language in which the patient is fluent. 70

**Sanctions**

Sanctions for noncompliance under the Medi-Cal sections are nonpayment for the sterilization services and a referral to the Board of Medical Quality Assurance. 71 Hospitals are to verify the sterilizations performed in their facilities, reporting the numbers and types of sterilizations to the Department of Health quarterly. They are also required to report the name of any physician not complying to the Board of Medical Quality Assurance. 72 The sanction for noncompliance is the possibility of revocation or involuntary suspension of the hospital’s license. 73

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68. *Id.* §§ 51305.3(a)-(h), 70707.3(a)-(h). This section is the basic definition of informed consent to a sterilization.

69. *Id.* §§ 51305.5(1), 70707.5(1). This is an additional requirement for elective sterilization. The federal age requirement is 21. 42 Fed. Reg. 62,728 (1977). This prohibition against sterilization of minors was declared invalid by the trial court in California Medical Ass'n v. Lackner. California Medical Ass'n Executive's Memo No. 685 (May 1, 1978).

70. *Id.* §§ 51305.5(6), 70707.5(6).

71. *Id.* § 51305.7(a)-(b).

72. *Id.* §§ 70707.8, 70736.

73. *Id.* § 70707.8.
Despite the public pressure for increased regulation of sterilizations, a basic question still persists: Has the right to a sterilization been denied or abused often enough to warrant official regulation of the doctor/patient relationship by the state? The medical profession argues that the regulations are more than a set of safeguards designed to protect the medical rights of women, but rather form a giant wedge in the door of overall government regulation of the practice of medicine. Opponents of the regulations argue that they do more harm than good in the very area which they are aimed at aiding—women’s medical and legal rights. The National Organization for Women joins in the latter argument.

In the face of these two contentions, the regulations should be further scrutinized to see what impact they have on the right of the patient to seek an elective sterilization and, perhaps more importantly, on the medical well-being of the patient they are designed to protect.

**Effect of the Regulations on the Availability of Sterilization**

*The Constitutional Right*

The United States Supreme Court has ruled that the federal constitution reserves to the individual rights of reproductive choice. Emphasizing that legislation relating to human procreation “involves one of the basic civil rights of man,” the Supreme Court has invoked the Fourteenth Amendment and the privacy doctrine to invalidate state legislation which limited individual rights of choice in matters of human reproduction. Collectively, these decisions affirm the fundamental character of the right of individuals to choose whether they will...

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77. See note 11 supra.

or will not bear children.\textsuperscript{79}

The court’s affirmation of individual rights in this area necessarily reduces governmental authority to intermeddle.\textsuperscript{80} In \textit{Eisenstadt v. Baird},\textsuperscript{81} Justice Brennan speaking for the court succinctly framed this principle when he said: “If the right to privacy means anything it is the right of the individual, married or single, to be free from unwarranted governmental intrusion in matters so fundamentally affecting a person as the decision whether to bear or beget a child.”\textsuperscript{82}

\textit{Burdens on the Right}

There is no disagreement on the existence of a woman’s fundamental right to choose whether to bear children. The debate is over how the sterilization regulations affect that right—positively or adversely.

Proponents argue that the regulations serve a compelling state interest by insuring that the right to procreation is not taken away without informed consent. This view is based on the conclusion that scattered studies, reported abuses, and anecdotal evidence reflect wide-scale sterilization abuse by the medical profession. Or in more graphic terms, they reflect “genocide against the minority poor”\textsuperscript{83} in order to avoid the social costs of unwanted indigent children.

Despite these arguments, systematic data on sterilization abuse remains extremely difficult to collect. There is no mechanism whereby instances of abuse may be regularly and systematically identified.\textsuperscript{84} Additionally, there is also difficulty in defining “abuse” in this context. Because thousands are being sterilized does not necessarily prove that thousands are being coerced into sterilization. It is more likely that more and more women, including ethnic and racial minorities, desire sterilization because it is the best and easiest way for many to avoid more children. Individual case histories,\textsuperscript{85} no matter how com-

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79. See note 78 supra.
82. \textit{Id.} at 453.
pelling, may not accurately portray the actual consequences of alternative policy choices.

Even if the proponents' contentions support the need for some regulation, the regulations as they exist may be excessive. Arguably, they constitute an unwarranted interference with the exercise of a fundamental right since their burdensome provisions make sterilizations more difficult to obtain for all women, especially for those whose protection was the primary intent.

*General regulatory burdens.* The general thrust of the regulations is negative toward sterilization. The regulations require that each patient be given a booklet, developed by the Department of Health with no input from physicians, which describes the operations. While frank disclosure of the permanent results is necessary, the booklet makes the procedures sound overly threatening. Its “Don’t Be Sorry” approach comes over too heavy.86 A patient with the most positive attitude would be inhibited. While careful thought on the matter is good, being frightened is not. After all, the complications of pregnancy and childbirth can be much worse.87

The regulations put a burden on the patient and the doctor requiring both to place form over substance. Typically, a woman and her doctor discuss alternative post-delivery birth control methods late in the pregnancy. At that time, the woman indicates whether or not she chooses to be sterilized after delivery. The consent forms would be signed upon admission to the hospital without coercion or hard sell. Now, under the regulations, both patient and doctor will be concerned with missing a deadline and getting the forms executed early, perhaps with less thought on the substance of the decision.

By suggesting it is more dangerous than other surgery, the regulations similarly burden the choice involved in selecting one form of medical treatment. For example, these restrictive procedures will not be required for most male sterilizations since a vasectomy can and is usually performed in a doctor’s office whereas female sterilization is a hospital procedure.88

87. C. Tietz, J. Bongaarts & B. Schearer, Mortality Associated with the Control of Fertility, in 8 FAMILY PLANNING PERSPECTIVES 6 (Jan./Feb. 1976). A graph indicates that of all the methods of controlling fertility, no method, i.e., pregnancy, has the greatest number of deaths associated with it, in all ages except women 40-44 when oral contraceptives cause greater danger. Id. at 10.
88. Brief for Plaintiff at 59, California Medical Ass’n v. Lackner, No. 268099
Additionally, no similar procedure or mandatory delay is required for other permanent and irreversible surgery for which general informed consent has been considered sufficient.

In addition to the burdens the regulations place on women seeking sterilizations, the regulations may generally inhibit physicians, causing them to be less willing to perform the procedure. The deadlines and minimum waiting period, needless state defined recitation of "informed consent," the provision for a translator, and additional forms are viewed by many physicians as burdens on good medical care. In the face of these considerations private physicians may simply refuse to perform sterilizations. Having to search for willing doctors will make access to the right to sterilization more difficult for the patient.

Specific regulatory burdens. Specific provisions of the regulations may also pose problems for women seeking elective sterilizations. For example, the various waiting periods of seventy-two hours, fourteen days or thirty days could conceivably limit a woman's access to sterilization. Thus, if a pregnant woman wishing to be sterilized immediately after delivery delivers prematurely, before valid consent forms are executed, no sterilization could be performed. Similarly, a woman who had thought about sterilization and reaches a final decision at the time of labor would not be permitted a sterilization.

The regulations also state that the sterilization must be voluntarily requested by the patient. If a physician must wait for a request and the request comes too late, there can be no sterilization. Furthermore, consider the possibility of a woman who is unaware of the waiting period and wants to arrange sterilization surgery during a vacation period or another time period when she is off work. Even though she may have reached this decision after years of consideration, if the properly executed sterilization consent document is not filed in time to meet hospital surgery schedules, the result is no sterilization. This seemingly unwarranted denial of the right to an elective sterilization could be a frequent occurrence given the existence of regulatory provisions calling for a thirty-day waiting period and disallowing consent obtained during labor.89

The vagueness of the impaired judgment provision could also produce real dilemmas. For example, a woman, hysterical

at discovering an unwanted pregnancy, might desire an abortion and sterilization at the same time. However, she would likely be in an "altered emotional state"90 and thus not capable of rendering informed consent, again resulting in no sterilization. Similarly, a woman who desires sterilization upon delivery and executes the consent forms while in the hospital for pregnancy related problems (convulsions, bleeding) for which she is taking medication will get no sterilization and if such medication significantly alters her judgment and she cannot give an informed consent. No sterilization.

The statutory requirement of an auditor-witness, unless waived, poses additional problems. It forces a patient to take positive action in order to make fundamentally private decisions in private. As a result, the state requires a patient to affirmatively assert her right to privacy, a right it should have the burden of protecting.

The age minimums give rise to an equally wide variety of questions, such as problems surrounding discrepancy of treatment among patients, and unavailability of sterilization to a particular group. The Department of Health, Education and Welfare has adopted twenty-one as the age at which a person is capable of giving a voluntary consent to sterilization within the meaning of the family planning statutes. The department admits that any choice of age limit is imperfect,91 but since a line must be drawn somewhere, it opts for the higher limit and sets it by federal law.

Since the states have varying definitions of capacity to give informed consent (for example, California sets it at age eighteen), determination of capacity by resort to state law would produce the anomalous result of the federal government withholding funds for a sterilization of a twenty-year-old in one state while funding sterilization of younger people in others.92 It would be costly and impractical to mandate case-by-case inquiries into the maturity and judgment of prospective patients.

However, a single federal standard necessarily divides people into two groups: those over the minimum age for whom funds are made available and those below it, from whom funds are withheld. Despite the unequal treatment, the twenty-one-

year-old age limit is probably constitutional. Nevertheless, this age barrier will cause hardship and possibly the unavailability of sterilizations to a sizeable age group. There is no provision for sterilization below the minimum age under extraordinary circumstances. The person who wants and needs the sterilization can be as tragic a story as the person who gets one although not sure she wanted one. The discrepancy in minimum age under the federal regulations (twenty-one) and the California regulations (eighteen) will cause unequal treatment between those dependent on public funds and therefore subject to the federal limit, and those paying for their own sterilization, unless California decides to completely fund the sterilizations of eighteen to twenty-one year olds.

The more liberal California eighteen-year-old age requirement presents questions also. No exception is provided for minors who are married or have attained an emancipated status. However, several code sections recognize a right of those minors to consent to any medical treatment. Thus, the regulations seem to directly contradict existing state law.

Effect on Medical Well-Being

As the foregoing discussion illustrates, the basic regulatory provisions seriously inhibit the availability of elective steriliza-


The plaintiff, at 20, had been pregnant ten times. She had two children, aged 2 and 1, a third child dying within hours of birth. She had one miscarriage and six abortions.

After concluding the 21 year age barrier was constitutional, the judge made a plea to other agencies of government to hear the "poignant cry" for relief. Id. at 1063. "If [all] possibilities fail, it is reasonable to hope that somewhere in this State there is a doctor and a hospital and, if necessary, some private benefactor, willing to arrange for the medical procedure this plaintiff earnestly seeks." Id. at 1063.

95. This is unlikely due to recent Supreme Court decisions on funding of abortion which leave states in the position of choosing whether or not to fund Medicaid abortions. Maher v. Roe, 432 U.S. 464 (1977). See also San Francisco Chronicle, July 5, 1978, at 1 (California Legislature voted to dramatically restrict state-paid abortions similar to the federal standards).

96. CAL. CIV. CODE § 25.7 (West Supp. 1978) (minors on active military duty); id. § 25.6 (married minors); id. § 34.5 (prevention or treatment of pregnancy) (sterilization specifically excepted); id. § 34.6 (emancipated minor fifteen years or older living away from home). Apparently the court in California Medical Ass'n v. Lackner agreed. See note 69 supra.
tion by excessively burdening the patient's right to choose that
treatment. The regulations inhibit the availability of elective
sterilization in another fashion as well. They create a variety
of medical risks for the patient in operations, making it even
more unlikely that a woman will undergo the procedure.

Initially, the waiting period under the regulations will
cause greater medical risk to women in certain circumstances.
The waiting period will create situations requiring two hospi-
talizations and therefore two general anesthetics. This unnec-
essarily produces greater risk and greater cost to the patient.

For example, when it becomes clear at the time of a deliv-
ery by Caesarian section that another pregnancy would be life
threatening, a woman would be unable to give consent to a
tubal ligation at that point. This is something that cannot be
determined until delivery at which time the sterilization pres-
ents far less medical risk than later. To avoid this possibility,
doctors would have to get informed consent in advance from
every woman about to deliver a baby in case such a situation
should arise. This would produce ridiculous results for the ma-
jority of women who would experience undue concern about a
possible sterilization and about their doctor being an overzeal-
ous surgeon. 97

Similarly, a patient who wishes sterilization but delivers
her baby before the required consent forms are executed would
have to come back after fully recovering from one medically
risky situation to submit to another. Immediately after a nor-
mal delivery, a tubal ligation is technically easier for a physi-
cian to perform and far less risk is present to the patient than
the same operation at a later time. 98 From this standpoint,
three days, fourteen days, thirty days, or a year are irrelevant.
The risk is less at the time of delivery.

Finally, a woman with postpartem bleeding caused from
the trauma of delivering an oversized infant might eventually
require a hysterectomy to correct the situation. 99 In this situa-
tion, not an emergency, the consent for treatment producing
sterilization must be obtained seventy-two hours before the
treatment. While the patient bleeds, the physician must wait
out the three days, unduly endangering the patient.

97. Interview with Marvin Richards, M.D., Member, California Medical Asso-
ciation Committee on Evolving Trends in Society Affecting Life (March 1, 1978).
98. Id.
99. Id.; Brief for Plaintiff at 90, California Medical Ass'n v. Lackner, No. 268099
(Cal. Super. Ct., filed July 18, 1977) (declaration of Robert B. Domush, M.D.) [on
file at Santa Clara L. Rev.].
Proponents admit the problems with risking a second anesthetic for an elective sterilization but claim justification for that in the protection from duress. Both sides seem to agree that there is no way to safeguard both immediate freedom to be sterilized and freedom from duress while deciding on a sterilization.100

In addition to the attack on second anesthetics, the medical profession has criticized the soundness of applying the regulations in situations involving secondary sterilizations. In these situations, where the patient is not seeking a sterilization but such a risk is inherent in the surgical procedure, medical experts charge that the regulations in fact create greater risks for patients.

For example, a patient with a severe pelvic inflammatory disease such as a tubal abscess would call for treatment which may involve a risk of sterilization such as removal of one or both fallopian tubes.101 It is difficult if not impossible for the physician to tell if this condition is life threatening and thus could be classified as an emergency or if the procedure can safely be delayed for the three-day waiting period.

Alternatively, consider the following absurd result. . . . A woman with large hydrosalpingus (water in the fallopian tubes) caused by previous gonorrhea needs a hysterectomy. She is already sterile from the disease, but since the hysterectomy will technically cause sterility, there must be compliance with the consent process.102

Similarly, consider a woman with huge fibroids, a benign tumor of the uterus which displaces enough tissue to produce sterility, requiring a hysterectomy. The consent process grinds in the fact of sterility still further, making it sound as though the patient is choosing it when she is not.

Finally, suppose a woman is admitted to the hospital for a laparotomy (abdominal surgery) with a suspected ovarian mass. At the time of surgery, a malignant mass is discovered on the uterus and is immediately removed by the surgeon without a seventy-two hour waiting period. In similar situations Medi-Cal reviewers have concluded that no emergency existed and that the waiting period should have been observed.103

100. Letter from Katherine F. Carson, supra note 75.
101. Id.
102. Id.
103. Brief for Plaintiff at 66, California Medical Ass'n v. Lackner, No. 268099 (Cal. Super. Ct., filed July 18, 1977) (declaration of Truman Katz, Administrator, Cedars-Sinai Medical Center, Los Angeles, Cal.).
Statistics reflect that many people wish to be sterilized.\textsuperscript{104} When those who wish to be sterilized come up against the forms, the delays, and the legitimate hesitation of the medical profession, there is no question that a sterilization will be more difficult to obtain.

Given the tack the Court and Congress have taken recently, restricting rights to federally funded abortion, the right to obtain a sterilization should be as unimpeded as possible. These regulations, by complicating access to sterilization, make the right to sterilization fall victim to those who would limit all reproductive choice. In addition, it seems legitimately open to question whether the good produced from these regulations outweighs the invasion of privacy, the interference with the doctor-patient relationship, and the risk and sometimes absurd medical situations they will create.

Not only will the regulations adversely affect the exercise of the right to an elective sterilization, but, by defining informed consent in relation to the procedure, they will influence California civil tort law as well. Specifically, the regulations will play a key role in medical malpractice actions growing out of the sterilization procedure.

\textbf{The Impact of the Regulations on Civil Tort Law}

\textit{Battery Doctrine}

Informed consent is most often referred to in terms of an action in negligence. This has not always been the case.\textsuperscript{105} Lack of consent in a cause of action against medical personnel can be the basis of a battery action as well. Cobbs defined the difference:

Where a doctor obtains consent of the patient to perform one type of treatment and subsequently performs a substantially different treatment for which consent was not obtained, there is a clear case of battery. . . .

However, when an undisclosed potential complication results, the occurrence of which was not an integral part of the treatment procedure but merely a known risk, the courts are divided on the issue of whether this should be deemed to be battery or negligence. . . . [T]he trend appears to be towards categorizing failure to obtain informed consent as negligence.\textsuperscript{106}

\textsuperscript{104} See Westhoff & Jones, supra note 2.
\textsuperscript{106} 8 Cal. 3d at 239-40, 592 P.2d at 7-8, 104 Cal. Rptr. at 511-12.
The court stated that the battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. Given this definition, battery could be a logical cause of action in a case involving lack of consent to a sterilization operation, particularly in those cases of alleged pressure and duress. Under a battery theory, a doctor has no medical community standard defense (the plaintiff must merely prove a touching, absent consent); she may be held liable for punitive damages; and she may not be covered by malpractice insurance because it is an intentional tort.

Negligence Actions

Negligence per se. Under a negligence theory, a physician who fails to follow the regulations to the letter will be facing a possible presumption of negligence per se arising under Evidence Code section 669. Enacted in 1967 to codify existing case law, the statute provides for a rebuttable presumption of negligence from the violation of a statute, ordinance or regulation of a public entity if such violation was the proximate cause of a kind of injury which the statute was enacted to prevent to a person in a class which the statute was enacted to protect.

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107. Id. at 240, 502 P.2d at 8, 104 Cal. Rptr. at 512.
108. Id.
109. Id.
110. Id.; see also Comment, Informed Consent in Medical Malpractice, 55 Cal. L. Rev. 1396 (1967).
113. CAL. EVID. CODE § 669 (West Supp. 1978) provides:
   Failure to exercise due care
   (a) The failure of a person to exercise due care is presumed if:
      (1) He violated a statute, ordinance, or regulation of a public entity;
      (2) The violation proximately caused death or injury to person or property;
      (3) The death or injury resulted from an occurrence of the nature which the statute, ordinance, or regulation was designed to prevent; and
      (4) The person suffering the death or the injury to his person or property was one of the class of persons for whose protection the statute, ordinance, or regulation was adopted.
   (b) This presumption may be rebutted by proof that:
      (1) The person violating the statute, ordinance, or regulation did what might reasonably be expected of a person of ordinary prudence, acting under similar circumstances, who desired to comply with the law; or
Most of the cases interpreting section 669 involve determinations on the elements, that is, proximate cause, specific injury and protected class. In the sterilization situation those elements would be met. The sterilization regulations would constitute regulations of a public entity.\textsuperscript{114} Lack of disclosure of the sterilization itself or of a complication which subsequently occurred, would supply proximate cause for the "injury" which is lack of informed consent. Clearly, the patients of doctors performing sterilizations are the class for whose protection the regulations were adopted.\textsuperscript{115}

The presumption of negligence per se can be rebutted by proof that the physician acted in a manner that was reasonable and justifiable under the circumstances.\textsuperscript{116} At trial, since the ultimate question is whether the physician was negligent, rather than whether he or she violated the regulation, proof of justification or excuse would negate the existence of negligence instead of merely establishing an excuse for negligent conduct.\textsuperscript{117} Justification is normally a jury question.\textsuperscript{118}

Ability to justify a violation of the sterilization regulations would vary with the situation. It would seem justifiable for a physician to ignore the regulations when performing a hysterectomy on a postmenopausal woman or a prostate operation on an eighty-year-old man. Reiterating the effectiveness of the procedure in producing permanent sterilization and the anticipated results of permanent sterilization would be the classic case of adding insult to injury in the case where a woman needs a hysterectomy to cure a disease that has already made her sterile. A physician might choose to streamline informed consent in a case where a patient is believed to be sterile already

\textsuperscript{114} Most references are to cases involving safety regulations and orders of the Public Utility Commission, but all such regulations are in the Administrative Code, as are the sterilization regulations, and can certainly be viewed on the same level as safety regulations. \textit{See generally} Vallas v. City of Chula Vista, 56 Cal. App. 3d 382, 128 Cal. Rptr. 469 (1976); Levels v. Growers Ammonia Supply Co., 48 Cal. App. 3d 443, 121 Cal. Rptr. 779 (1975); Cade v. Mid-City Hospital Corp., 45 Cal. App. 3d 589, 119 Cal. Rptr. 571 (1975).

\textsuperscript{115} CAL. EVID. CODE § 669(a)(4) (West Supp. 1977).

\textsuperscript{116} Id. § 669(b)(1).

\textsuperscript{117} CAL. EVID. CODE § 669, Comment (West Supp. 1978).

(perhaps from heavy radiation therapy for Hodgkins disease). However, it is unknown how far a doctor could go in ignoring the regulations and still be safe from a malpractice action.

Negligence. The regulations have defined what constitutes informed consent to sterilization. That being the case, there is no room for professional judgment as to what a particular patient should or should not be told. In fact, the regulations were promulgated for the express purpose of removing such judgment from this one area. The regulations by their terms make no provision for a professional judgment except to the extent that the physician may expand on the already lengthy list of necessary disclosures. Therefore, the regulations leave very little room for a "prudent" physician to manipulate within them for the benefit of the patient or on behalf of a doctor-patient relationship.

Since the government has definitely outlined the legal standard for informed consent to a sterilization, exact compliance with the regulations should absolve a physician of liability in negligence as a matter of law. Practically speaking, it would be difficult to prove that informed consent was lacking if the entire regulatory litany had been complied with unless the physician, taking such care to emphasize the sterilization, neglected some other complication which then befalls the patient.

In fact proponents argue protection of the doctor from malpractice suits as a benefit of the regulations. This is small comfort to physicians. The legal realities are presumptions of negligence per se for technical violations but no conclusive way to avoid liability by full compliance. Although compliance with the regulations is claimed as a complete defense to a law suit, there is no authority in California law for such a position. If


120. See B. Rosenfeld, S. Wolfe & R. McGarrah, supra note 36, at 33 (referred to as paternalism or racial and ethnic bias rather than professional judgment).

121. Explanation must include, but is not limited to, those things enumerated in CAL. ADMIN. CODE tit. 22, §§ 51305.3(f), 70707.3(f) (1977).

122. [See fact sheet on file at Public Advocates, Inc., San Francisco, Cal.]. The seemingly unavoidable progression from negligence to strict liability has also surfaced in the area of informed consent. One commentator advocates strict liability for informed consent based on a duty to warn theory. The article proposes that a hospital-employed Information Director read a form such as "Standard Appendectomy Form" and such procedure would act as a complete defense to a law suit based on informed consent. That comment is made without authority. Maldonado, Strict Liability and Informed Consent: "Don't Say I Didn't Tell You So!", 9 AKRON L. REV. 609, 610, 624-27 (1976).
there is any truism in California law, it is that negligence is a question of law for the jury. In cases involving safety regulations the courts have made it clear that compliance does not absolve the charge of negligence, only the charge of negligence per se.

The crucial question is what the executed consent form is worth if an action is brought against a physician based on lack of consent to a sterilization operation or any procedure resulting in sterilization. A signed consent form has rarely protected a physician. Such forms have often been repudiated by patients who claim they did not remember signing the form or that they did not understand the form or that the form was signed under duress because they were ill. One study has documented the fact that patients may not recall accurately a major portion of what they are told even though they have completely understood at the time and given a truly informed consent.

Even if physicians keep careful records, the written consent form signed by the patient will not defeat an action based on lack of informed consent. As one authority on medical malpractice has stated:

Because of the overly broad language used in a consent form, and because of the less than ideal circumstances under which the instrument is frequently signed, it is the author's opinion that written consent bears little relation to the true "free and informed consent" desired of the patient, and that the written consent merely should be considered as one item of evidence in the total physician-patient relationship on the issue of authority for treat-

126. Id.
127. MED. WORLD NEWS 26 (Nov. 4, 1976).
ment, with its importance being weighted by the trier of fact.\textsuperscript{129}

Because the sterilization consent forms under the regulations are not overly broad in their language and the consent process itself is safeguarded to prevent duress, a properly executed Sterilization Consent Document should operate as a rebuttable presumption that the physician obtained the informed consent of the patient.\textsuperscript{130}

In any event, by limiting the flexibility involved in the traditional informed consent procedure, the regulations make it difficult for a physician to predict what effect an attempt to deviate from the regulations will have. This measure of uncertainty with regards to potential tort liability may make physicians reluctant to perform elective sterilizations. In addition, the danger that liability will flow from a deviation reduces the likelihood that physicians will attempt to tailor their medical advice. This could conceivably result in a corresponding lowering of the quality of services a sterilization patient receives.

**CONCLUSION**

Arguments go both ways on how these regulations affect the fundamental right to decide whether or not to bear children. This author recognizes that just as that right should not be burdened, neither should it be denied. The woman who is sterilized without fully understanding what is happening is being deprived of her constitutional right. However, the woman who desires a sterilization faces undue burdens because of these regulations, and she too has a constitutional right burdened. Overall this will result in more difficulty in obtaining sterilizations, an increasingly favored method of family planning.

In attempting to define exactly what constitutes informed consent to a voluntary sterilization, the regulations have created potential situations of greater medical risk and tremendous bureaucratic hassle. While guaranteeing the protection of

\textsuperscript{129} Id. § 2.2(B).

\textsuperscript{130} CAL. ADMIN. CODE tit. 22 § 70707.7(a) (1977) provides that for the purposes of the hospital's compliance with the regulations, the signature of the patient, the physician, the physician's designee (if any) and the auditor-witness (if applicable) on the Sterilization Consent Document shall be sufficient evidence that the informed consent procedure has taken place. However, this says nothing about the compliance of the physician and the corresponding section involving Medi-Cal makes no mention of it either.
one legal right, that of informed consent, other medical and legal rights are being infringed upon.

The regulations are a burden on patients and doctors and a direct interference in the doctor-patient relationship. Nothing is left to professional judgment nor are allowances made for the infinite variations in human physiology and psychology. Although carefully developed, the regulations nevertheless are arbitrary and allow little discretion in doctor or patient. While we are long past the paternalistic era of doctors’ making our decisions for us, we have not reached the point, and hopefully never will, where a standardized form can capably handle the very personal dealings doctors have with patients. Medicine is not an exact science and cannot be reduced to a form which leaves no room for professional judgment. Patients are not well served by implying that an a) through f) standardized form tells them all they need to know.

Traditional informed consent requirements developed by California case law should adequately cover the sterilization situation as well as any other. Its parameters, while based on reasonable disclosure, allow variations for different situations; the regulations do not. The regulations potentially cover a myriad of diverse medical procedures in a number of different medical specialities and try to dictate in eight pages what physicians are supposed to say to their patients in all of those circumstances. In this regard, the rigid structure of the regulations flies in the face of common sense.

Perhaps the most unfortunate aspect of all is that poor women who claim to have been the victims of pressure from the medical profession to be sterilized will be the very ones subjected to the problems inherent in the regulations. Enmeshed more completely in the problems of day to day living, a poor woman has less time and energy to devote to logical, orderly, and sequential medical care. The burden of her existence makes her the most likely one to miss the deadlines imposed by the regulations. Having faced bureaucratic difficulties and failing to get sterilized, she may then face a later, undesired pregnancy which may not be terminated under legislation to deny government funds for abortions. This cannot be a desirable result.

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