Health and Safety

Chapter 683: Extending Whistleblower Protections to Members of the Medical Staff of Health Facilities

Regina Cabral Jones

Code Section Affected

AB 632 (Salas); 2007 STAT. Ch. 683.

I. INTRODUCTION

In June of 2002, Father John Corapi, a Catholic priest, was told by the chief cardiologist at Redding Medical Center (RMC), Dr. Moon, “that he had a fatal heart condition” and that he needed coronary artery bypass surgery. But when another cardiologist looked at his heart, he informed Father Corapi that there was not anything to bypass. His heart was perfectly normal. Stunned, the priest tried to contact the administrators at RMC, which was then owned by Tenet Healthcare. Despite reports from seven other cardiac specialists who agreed that Corapi’s heart was normal, the administrators refused to take action against Dr. Moon. Finally, Father Corapi turned to the Federal Bureau of Investigation (FBI).

On October 30, 2002, FBI agents raided RMC. It turned out that Father Corapi was, indeed, not alone. According to the FBI warrant affidavit, “many known and unknown patients [had] been victims of a scheme to cause patients to undergo unnecessary invasive coronary procedures.” The FBI obtained thousands of files, including the medical records “of at least 167 patients who died after surgery ordered by [Dr.] Moon”—surgeries and deaths that may have been unnecessary. The four doctors responsible eventually settled with the


2. Id.

3. Id.

4. Id.

5. Id.

6. Id.


8. Id.

9. Id.

10. 60 Minutes: Unhealthy Diagnosis, supra note 1.
victims for over $32 million in exchange for avoiding criminal liability.\textsuperscript{11} In addition, Tenet Healthcare paid a staggering $395 million to settle 750 other lawsuits connected to RMC.\textsuperscript{12}

Although the saga at RMC ended with some measure of relief for the victims,\textsuperscript{13} one cannot help but wonder what went wrong. How could anyone get away with performing so many medically unnecessary procedures at a respected hospital? Although many factors contributed to the corruption at Tenet,\textsuperscript{14} it became evident after the scandal broke that the medical staff felt that they could not speak out against the unethical surgeons without fear of retribution.\textsuperscript{15} According to the affidavit filed by the FBI in the raid of RMC, some physicians at RMC were concerned about the unnecessary surgeries, but Dr. Moon and the other doctors in charge of the cardiac program generated so much revenue for the hospital that they were “extremely powerful.”\textsuperscript{16} In a qui tam action filed by Dr. Patrick Campbell against RMC contemporaneously with Father Corapi’s lawsuit, Dr. Campbell stated in a declaration that he “knew that such complaints about Dr. Moon would undoubtedly find their way back to him and lead to retribution against me.”\textsuperscript{17}

Concrete, substantiated evidence of retaliation against physicians can be difficult to find.\textsuperscript{18} This could be due to a few reasons: retaliation or threats could

\begin{thebibliography}{18}
\bibitem{11}Press Release, McGregor W. Scott, U.S. Attorney, Doctors Accused of Performing Unnecessary Heart Surgeries at Redding Medical Center Agree to Pay Millions to Settle Fraud Allegations and Accept Restrictions on Their Medical Practice (Nov. 15, 2005), http://mathiasconsulting.com/cases/2005/11/CA/redding (on file with the \textit{McGeorge Law Review}).
\bibitem{13}Id.
\bibitem{14}See generally Letter from Senator Charles Grassley, Chairman, U.S. Senate Comm. on Fin., to Trevor Fetter, Acting Chief Executive Officer & President, Tenet Healthcare Corp. (Sept. 5, 2003) (on file with the \textit{McGeorge Law Review}) (citing the holdover of prior corrupt leadership, conflicts of interest, failure to acknowledge wrongdoing, and dozens of investigations showing that Tenet has been and continues to be a corrupt “morally bankrupt” organization).
\bibitem{15}See \textit{60 Minutes: Unhealthy Diagnosis}, supra note 1 (reporting on medical staff fearfully telling patients that their surgery was potentially unneeded).
\bibitem{16}Abelson, supra note 7.
\bibitem{17}Brief of Appellee United States of America at 9, United States \textit{ex rel.} Campbell v. Redding Med. Ctr., 421 F.3d 817 (9th Cir. 2005) (No. 03-17082). Dr. Campbell’s declaration is available online at http://allianceforpatientsafety.org/campbell/campdecl.pdf, although it is an unsigned version. Ironically, the government lashed out at Dr. Campbell for continuing to refer patients to Dr. Moon and neglecting to come forward, even though Dr. Campbell’s declaration stated that he only did so when they were already “being treated for existing cardiac problems and insisted on seeing Moon.” Maline Hazle, ‘Whistle-blower’ Accuses Feds, RECORD SEARCHLIGHT (Redding, Cal.), Oct. 10, 2003, http://web.redding.com/specials/doctorsui/stories/Whistle-bloweraccusesfeds.shtml (on file with the \textit{McGeorge Law Review}) (“Rather than a ‘true whistle-blower’ with ‘the determination and courage to expose the defendants’ fraud,’ Campbell’s ‘conduct suggests greater interest in personal gain than public welfare . . . .’” (quoting Assistant U.S. Attorney Michael J. Hirst)).
\bibitem{18}See \textit{SENATE JUDICIARY COMMITTEE, BACKGROUND INFORMATION REQUEST FORM}, at 2 (June 16, 2007) (on file with the \textit{McGeorge Law Review}) (noting in response to the question, “Please summarize any studies, reports, statistics or other evidence showing that the problem exists and that the bill will address the problem,” the answer, “There are no reports highlighting this specific issue,” was given); see also Letter from
be verbal and, therefore, go unsubstantiated; or retaliation could remain unreported for fear of further retribution. The evidence that does exist, however, is troubling. At RMC, the California Medical Association (CMA) says, Tenet “silenced” the physicians who tried to speak out about the surgeries. The doctors were told that if they went public, the hospital would “destroy” their practice. Some of the doctors tried to encourage other medical staff members to expose the problem by pointing to existing statutory protections to show that they could blow the whistle without fear. However, the other doctors did not feel that the statute provided adequate protection and never came forward. The atmosphere was such that after another patient of Dr. Moon’s was admitted with what was supposedly a badly clogged artery, a nurse and a doctor both secretly came into the patient’s room and implored him to leave because he did not need the surgery.

The combination of fear of retribution from fellow physicians and upper management, along with murky statutory language and questionable protection in the law, laid the foundation for Chapter 683. This bill’s purpose is to clarify California law so that physicians will feel comfortable speaking out about quality of care issues without the fear that their livelihoods will be compromised.

II. LEGAL BACKGROUND

A. Federal Law

Congress enacted the whistleblower provision of the Sarbanes-Oxley Act (SOX) specifically to protect persons reporting instances of fraud that could


19. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 6 (June 12, 2007).
21. Id.
22. Id.
23. 60 Minutes: Unhealthy Diagnosis, supra note 1.

24. See SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4 (June 12, 2007) (“[E]xisting law does not fully protect physicians and other health professionals from retaliation if they make a complaint or grievance about a health facility.”).

25. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4-5 (July 12, 2007).

26. 18 U.S.C.A. § 1513(c) (West Supp. 2007). The section reads:

Whoever knowingly, with the intent to retaliate, takes any action harmful to any person, including
damage investors. Although SOX primarily applies to publicly traded companies, the whistleblower provision applies to all companies, public or private.

The California Legislature seemed to contemplate the application of SOX to physician whistleblowers in its committee analysis of Chapter 683, but it did not discuss SOX in detail. It remains to be seen whether California courts will enforce the new whistleblower provision against health facilities engaging in retaliatory action against their employees. One California court confronted with an alleged retaliation action brought by hospital employees against their employer has held that section 1107 of SOX “simply cannot be read to reach the reporting of ethnic remarks to a local hospital’s governance board.”

B. California Law

Current law protects patients, employees, and “any other person” from discrimination or retaliation by a health facility for “present[ing] a grievance or complaint, or . . . initiat[ing] or cooperat[ing] in any investigation or proceeding of any governmental entity, relating to the care, services, or conditions of that facility.” If a health facility engages in discriminatory treatment, the law creates a rebuttable presumption that the facility took the action in retaliation for the patient or employee making the complaint. A willful violation of the statute

interference with the lawful employment or livelihood of any person, for providing to a law enforcement officer any truthful information relating to the commission or possible commission of any Federal offense, shall be fined under this title or imprisoned not more than 10 years, or both.

Id. SOX also allows a private cause of action under the civil Racketeer Influenced and Corrupt Organizations (RICO) statute. See § 1961(1)(b) (West 2000 & Supp. 2007) (defining “racketeering” as including those activities under section 1513(e)).


28. Id.

29. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 3 (June 12, 2007).

30. Lechner & Sisco, supra note 27, at 86 (citing MacArthur v. San Juan County, 416 F. Supp. 2d 1098, 1134 n.40 (D. Utah 2005)).


32. “[D]iscriminatory treatment of an employee [includes] discharge, demotion, suspension, any other unfavorable changes in the terms or conditions of employment, or the threat of any of these actions.” Id. § 1278.5(d).

33. Id. § 1278.5(c).
constitutes a misdemeanor and up to a $20,000 fine, and a health facility could be subjected to a civil penalty of up to $25,000. This section does not apply to inmates or long-term care facilities.

Because the language of the statute prior to Chapter 683 only applied to “patients,” “employees,” and “any other person,” physicians had to argue that they fell under the ambiguous label of “any other person” in order to show that they had suffered discriminatory treatment. Since California bans the corporate practice of medicine, doctors usually cannot be directly employed by a health facility.

III. CHAPTER 683

Chapter 683 extends existing whistleblower protections to medical staff members of hospitals and other healthcare facilities, including physicians and surgeons. Specifically, the statute broadens the rebuttable presumption existing in section 1278.5 to medical staff members and expands the scope of “discriminatory treatment” to encompass “any unfavorable changes in, or breach of, the terms or conditions of a contract, employment, or privileges of the employee, member of the medical staff, or any other health care worker of the health care facility, or the threat of any of these actions.” A medical staff member can be reinstated, receive reimbursement for any resulting lost income, and collect legal costs associated with pursuing his or her case.

Chapter 683 also expands the list of persons and entities whose retaliatory actions against medical staff members can give rise to liability under the statute. The definition of a “health facility” now includes, but is not limited to, “the facility’s administrative personnel, employees, boards, and committees of the

34. Id. § 1278.5(f).
35. Id. § 1278.5(b)(2).
36. Id. § 1278.5(h), (i). Long-term care facilities are already covered by CAL. HEALTH & SAFETY CODE § 1432 (West 2000 & Supp. 2007).
37. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4 (June 12, 2007).
38. CAL. BUS. & PROF. CODE § 2400 (West 2003) (“Corporations and other artificial legal entities shall have no professional rights, privileges, or powers.”).
39. Instead, they are given privileges to practice at a hospital and have a relationship with a hospital that is established by the self-governing medical staff, including medical staff bylaws, the peer review process, and other governance measures as set forth in the CAL. BUS. & PROF. CODE §§ 2282-2282.5 (West 2003 & Supp. 2007).
40. CAL. HEALTH & SAFETY CODE § 1278.5(b)(1) (amended by Chapter 683). Again, this section does not apply to long-term care facilities. Id. § 1278.5(k) (amended by Chapter 683).
41. Id. § 1278.5(d)(1) (amended by Chapter 683).
42. Id. § 1278.5(d)(2) (amended by Chapter 683) (emphasis added).
43. Id. § 1278.5(g) (amended by Chapter 683).
44. Id. § 1278.5(b)(2), (i) (amended by Chapter 683).
board, and medical staff."45 Further, a parent company, like the health care facility it owns, is precluded from engaging in retaliatory behavior.46

Despite these expansions, Chapter 683 also provides some protection for hospitals.47 When a medical staff member with a peer review hearing pending files an action against a health facility, Chapter 683 allows a facility’s medical staff to petition the court for an injunction from complying with any evidentiary demands imposed by the action where the demands would impede the peer review process or put patient health and safety in danger.48 In that case, Chapter 683 requires the court to conduct an in camera review of the evidence that is sought and to grant the injunction if it determines that discovery will impede the peer review hearing.49

IV. ANALYSIS OF CHAPTER 683

A. Explicit Protection for Members of the Medical Staff of Health Facilities

According to Chapter 683’s sponsor, the CMA, Chapter 683 was introduced in response to CMA members reporting retaliation by health facilities against those physicians and other medical staff members who reported concerns.50 In addition to the methods previously discussed, the CMA identified other modes of retaliation that could be used by a hospital: “removing a physician from a referral list, forcing a doctor out of a hospital-owned complex, or underwriting the salary or practice expense of a competing physician.”51 Chapter 683’s amended definition of “discriminatory treatment” does not explicitly address these more subtle forms of retaliation, although it provides the statutory framework for enabling physicians to pursue redress for this discrimination.52

45. Id. § 1278.5(i) (amended by Chapter 683).
46. Id. § 1278.5(b)(2) (amended by Chapter 683).
47. Id. § 1278.5(h) (amended by Chapter 683).
48. Id. (amended by Chapter 683).
49. Id. (amended by Chapter 683).
50. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4-5 (July 12, 2007).
51. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 5 (June 12, 2007).
52. See CAL. HEALTH & SAFETY CODE § 1278.5(d)(2) (amended by Chapter 632) (leaving it unclear whether “discharge, demotion, suspension, or any unfavorable changes in, or breach of, the terms or conditions of a contract, employment, or privileges of the employee, member of the medical staff, or any other health care worker of the health care facility, or the threat of any of these actions” could be interpreted as encompassing these other forms of retaliation); SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 9 (July 12, 2007) (“It would seem that none of these remedies would give adequate redress to a physician who suffered any of the retaliatory acts named above.”).
Reports of retaliation are not limited to the egregious example of RMC.\textsuperscript{53} Recently, a major hospital corporation in Southern California filed a defamation lawsuit against a medical staff doctor that criticized the hospital’s financial performance and questioned its impact on patient care.\textsuperscript{54} According to the CMA, during the lawsuit, the hospital allegedly “threatened to retaliate against the medical staff [there and at other] hospitals if they participated in the investigation.”\textsuperscript{55} In its opening brief, the hospital corporation argued that the statute (as it existed before Chapter 683) did not apply to physicians, and in its argument did not acknowledge the language “and other health care workers” in the statute.\textsuperscript{56} This argument was not pursued on the appellate level, but if it had been successful, it would have created an unfavorable precedent for physicians. Although health facility employees were protected under the prior law, the physicians, not being employed by the facility, could not utilize the whistleblower provision to bring an action against the facility.\textsuperscript{57} By adding explicit protection for physicians and other medical staff members in the statute, Chapter 683 greatly reduced the prior ambiguity in the statute.\textsuperscript{58}

\textsuperscript{53} See Integrated Healthcare Holdings, Inc. v. Fitzgibbons, 140 Cal. App. 4th 515, 44 Cal. Rptr. 3d 517 (4th Dist. 2006) (granting physician’s special motion to strike a lawsuit filed against him by hospital holding company for defamation and breach of contract, inter alia. The physician brought the motion under the anti-SLAPP (Strategic Lawsuit Against Public Participation) statute in the CAL. CIV. PROC. CODE § 425.16 (West 2004 & Supp. 2008)). The statute reads, in pertinent part

\begin{quote}
A cause of action against a person arising from any act of that person in furtherance of the person’s right of petition or free speech under the United States or California Constitution in connection with a public issue shall be subject to a special motion to strike, unless the court determines that the plaintiff has established that there is a probability that the plaintiff will prevail on the claim.
\end{quote}

CAL. CIV. PROC. CODE § 425.16(b)(1).

\textsuperscript{54} Integrated Healthcare Holdings, Inc., 140 Cal. App. 4th at 520-21, 44 Cal. Rptr. 3d at 521-22.

\textsuperscript{55} SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 6 (June 12, 2007).

\textsuperscript{56} CAL. HEALTH & SAFETY CODE § 1278.5(a) (West 2000); SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4 (June 12, 2007) (“The author states that some attorneys have interpreted this to deny protections to physicians and other members of the medical staff because they are not employees or patients of the health facility.”); Michelin Interview, supra note 20; see Letter from Mark T. Kawa, Attorney, Tenet Counsel, to Kevin J. Mirech, Attorney (Feb. 15, 2002), http://www.allianceforpatientsafety.org/kawaletter.pdf (on file with the McGeorge Law Review) (arguing that Health and Safety Code section 1278.5 did not apply to physicians, and Business and Professions Code section 2056 was similarly irrelevant to the defendant’s situation). Indeed, the bill’s opponents explicitly argue that the statute currently excludes physicians from its purview. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 6 (June 12, 2007). CHA points out that the original section 1278.5 was not enacted with the intent to protect physicians, but only to protect employees (including nurses) and patients. \textit{Id.} The Hospital Corporation of America makes the same argument in its opposition letter to Senator Kuehl. Letter from Terry M. McGann, Senior Legislative Advocate, & Alice D. Toler, Legislative Advocate, Hospital Corp. of Am., to Senator Sheila Kuehl, Cal. State Senate (June 8, 2007) (on file with the McGeorge Law Review). The California Nurses Association sponsored the original bill that became section 2056 in 1999, and the legislative history never expressly mentioned physicians or surgeons being included in the protection afforded by the bill. See ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF SB 97, at 1-2 (June 22, 1999) (indicating the bill was intended to protect hospital employees and patients).

\textsuperscript{57} SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 4-5 (June 12, 2007).

\textsuperscript{58} \textit{Id.} at 4.
B. Application of Other Provisions of California Law

Opponents of Chapter 683 argued that California Business and Professions Code section 2056 and other state and federal laws protecting physicians for reporting “fraud, overbilling, and violations of Stark and anti-kickback statutes” sufficiently protect physicians from retaliation. Section 2056 states that physicians and surgeons shall not be discriminated against for advocating for medically appropriate care for their patients. Although the statute primarily addresses the problem of managed care organizations, such as HMOs, interfering with physicians’ communications with their patients, California courts have applied the law to any situation in which a physician advocates for their patient.

However, the plain language of the statute still expressly applies only to a doctor who “advocate[s] for medically appropriate health care for his or her patients.” Therefore, the scope of the statute excludes physicians and surgeons who report a problem not related to their own patients. In addition, section 2056 applies only to physicians and surgeons, excluding the many other professional medical staff members.

---

59. The bill’s registered opposition consists primarily of the California Hospital Association (CHA), as well as the United Hospital Association, Hospital Corporation of America (HCA), Adventist Health, and Loma Linda University Medical Center. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 13 (July 12, 2007).


61. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 632, at 6-7 (June 12, 2007).


63. See Khajavi v. Feather River Anesthesia Med. Group, 84 Cal. App. 4th 32, 100 Cal. Rptr. 2d 627 (3d Dist. 2000) (holding that the trial court’s determination that the statute did not apply because the dispute did not involve a third party payer was erroneous). “[T]he plain language of the statute demonstrates that it protects physicians and surgeons from termination or penalty ‘for advocating for medically appropriate health care,’ without limitation.” Id. at 38, 100 Cal. Rptr. 2d at 632 (citation omitted). “Indeed, the ‘person’ who makes the decision to terminate or penalize a physician . . . extends beyond a third-party payor.” Id. at 48, 100 Cal. Rptr. 2d at 638.

64. CAL. BUS. & PROF. CODE § 2056(b) (emphasis added).

65. See id. (excluding protection for doctors who advocate for patients other than their own).

66. See id. (protecting only "physician[s] and surgeon[s]”).
The Hospital Association (CHA) proposed amending section 2056, but the Legislature amended the Health and Safety Code instead.

C. Potential “Chilling Effect” of Statute on Hospital Peer Review

The CHA’s primary concern was the “chilling effect” that the rebuttable presumption may have on the peer review process. The CHA defines “[p]eer review [as] the process by which the self-governing Medical Staff, not hospital administrators, evaluates physicians and surgeons with respect to patient care they provide in a hospital.” The peer review process is an integral part of the way California health facilities deliver quality healthcare because physicians are considered the best persons to adjudge each other’s conduct and consequences on patient care and safety. The CHA pointed out that various provisions in California law, such as immunity from monetary liability and protection from discovery, exist to encourage participation in the peer review process and to be free from fear of retribution for doing so. The CHA argues that Chapter 683 would make any peer review action a “retaliatory action,” thereby criminalizing the very process intended to protect physicians’ and hospitals’ interests. Chapter 683’s sponsor countered that Chapter 683 only creates a rebuttable presumption, which means that the facility would only have to show actual evidence of wrongdoing, which they would presumably have anyway. However, the CHA pointed out that the “hospital would be required to produce evidence of why the peer review action is being contemplated or conducted even before that evidence has been fully developed and presented in a Medical Staff fair hearing.”

Although it is not clear whether a peer review action would constitute “discriminatory treatment” for purposes of the statute, the Legislature eventually included amendments to the bill that addressed opponents’ concerns regarding the evidentiary burden on medical staff members. As described

---

68. van der Griff Letter, supra note 18.
70. Id.
71. Id.; see also CAL. BUS. & PROF. CODE §§ 809-809.7 (West 2003 & Supp. 2007) (explaining the peer review process).
72. van der Griff Letter, supra note 18.
73. Id. (citing CAL. CIV. CODE §§ 43.7, 43.8, 43.97 (West 2007 & Supp. 2008); CAL. EVID. CODE §§ 1156, 1157 (West 1995 & Supp. 2008)).
74. Id.
75. Interview with Maria Garcia, Staff Member, Cal. State Assembly, in Sacramento, Cal. (June 20, 2007) (notes on file with the McGeorge Law Review).
76. van der Griff Letter, supra note 18.
77. Chapter 683 includes under the term “discriminatory treatment” “the threat of [changes in privileges],” which could be interpreted as including peer review, depending on the circumstances of each case. CAL. HEALTH & SAFETY CODE § 1278.5(d)(2) (amended by Chapter 683).
78. See id. § 1278.5(h) (amended by Chapter 683) (providing some protection for the peer review
earlier, these amendments include a preliminary in camera hearing before a judge to determine what effect, if any, the action taken by the medical staff member would have on a pending peer review hearing. The amendments may not fully alleviate health facilities’ concerns that a disruptive physician may “stop a peer review action in its tracks” by immediately filing a complaint, rendering the peer review action a retaliatory action. Hopefully, this kind of conduct will be recognized in the in camera review and an injunction granted to allow a legitimate peer review action to continue unhindered.

V. CONCLUSION

Physicians should be able to come forward with quality of care concerns without wondering if their practice will be “destroyed.” Chapter 683 provides explicit protection to those medical staff members who, like those at RMC, were outraged by their colleagues’ actions but feared for their own livelihoods. In the ongoing struggle to mend the healthcare system, the hope is that Chapter 683 will bring to light quality of care concerns as expeditiously as possible, potentially saving the lives of patients, preserving doctors’ practices, and reducing the cost of delivering healthcare for health facilities.
The Revised Uniform Anatomical Gift Act: Bringing “California Donation Law up to Contemporary Medical, Legal, and Bioethical Practices”

Jacqueline Zee

Code Sections Affected
Health and Safety Code §§ 7150, 7150.10, 7150.15, 7150.20, 7150.25, 7150.30, 7150.35, 7150.40, 7150.45, 7150.50, 7150.55, 7150.60, 7150.65, 7150.70, 7150.75, 7150.80, 7150.85, 7150.90, 7151.10, 7151.15, 7151.20, 7151.25, 7151.30, 7151.35, 7151.40 (new), §§ 7150, 7150.1, 7150.2, 7150.5, 7151, 7151.5, 7152, 7152.5, 7152.7, 7153, 7153.2, 7153.5, 7154, 7154.5, 7155, 7155.5, 7155.7, 7156, 7156.5 (repealed); Vehicle Code §§ 12811, 13005 (amended).

AB 1689 (Lieber & Berryhill); 2007 STAT. Ch. 629.

I. INTRODUCTION

Humans began experimenting with organ and tissue replacement centuries ago, with Hindus using skin from foreheads to repair mutilated noses as far back as the sixth century, and Italians repairing lip, nose, and ear defects with forehead and forearm skin in the fourteenth century. The first human-to-human organ transplant was conducted in the United States in 1911, and such transplantations continued to improve throughout the twentieth century. Great strides occurred in the late 1970s with the invention of an immunosuppressive drug that “led to an explosion in the number of organ transplants in the 1980s and 1990s.” Xenotransplantation, the use of animal organs to replace human organs, developed in the late twentieth century simultaneously with the use of artificial organs.

Centuries of technological development have paid off: “As of the end of 2004, there were 153,245 persons living with a functioning organ transplant in the United States. . . . a 1.7-fold increase since 1996.” And in 2005 alone, there were 27,527 organ transplants in the United States. Unfortunately, at the same time technology was making it easier to transplant organs, the supply of organs

3. Id. at 920.
4. Id. at 920-21.
5. Id. at 921.
7. Id.
for transplantation got smaller. In 2005, approximately 62,294 people were awaiting kidneys, 17,168 were awaiting livers, and 6,248 were awaiting a heart, lung, or both. Our aging population accounts, in part, for the 96,983 people who were organ donation waiting list candidates as of July 19, 2007. Nearly 20,000 of those on the waiting list are Californians, representing twenty-one percent of the national total.

The shortage of organ donations is often attributed to problems with public understanding and confidence in the organ donation process. Media hype in the form of medical thrillers and prime time news stories on “organ donations run-amok” and instilled superstitions and distrust that ultimately leads to a potential donor’s unwillingness to donate. Fears that a potential donor’s intended wishes will not be followed or that they will not receive the best medical care in order that their viable organs might be procured for donation are cited as some of the reasons for not donating. And in light of an ever-mobile society, it makes matters worse that states cannot seem to agree on a uniform process for organ and tissue donation, so potential donors who have executed the appropriate donation documents in one state may find themselves having to start over again if they move to another state. The Uniform Anatomical Gift Act was enacted to address these fears and concerns, and provide a solution for the increasing gap between the supply of and demand for anatomical donations.

8. See id. at 2 (noting that the number of wait-listed candidates for organ transplants rose fifteen percent between 1996 and 2005).
9. OPTN REPORT, supra note 6, at 2.
13. Id.
Perhaps much of the doubt about the ultimate wisdom of transplantation is rooted in the fear that using parts of one human being to save another can be subject to great abuse. . . . Possible premature pronouncements of death would appear to constitute the most feared abuse in the transplant field.
Id.
II. LEGAL BACKGROUND

A. Property Rights in Corpses and Living Tissues

The need for nationally uniform legislation governing anatomical donations can be traced back to common law property rights. Prior to 1968, jurisdictions resolved the question of the existence of rights in human corpses and living tissues without the benefit of any guidance, the result of which was inconsistency among the states. Though English common law did not recognize property rights in a corpse, American courts generally recognized a quasi-right in a decedent’s surviving relatives “for purposes of burial or other lawful disposition.” The refusal to grant an absolute property right in corpses is consistent with important differences recognized by the judiciary between human bodies and other property. Though humans seemingly possess their bodies and all of its parts in a very absolute way, they nevertheless lack the ability to do with them what they are permitted to do with other things they own, such as sell them for valuable consideration or have judgments levied against them.

This quasi-right, however, could be overruled by a “compelling state interest or statutory rights granted to either the coroner or the medical examiner,” and jurisdictions that considered the question have differed in the limitations they set on this quasi-right. For example, the Sixth Circuit, applying Ohio law, recognized in Brotherton v. Cleveland a widow’s quasi-right in her decedent husband’s corneas, which had allegedly been removed without consent for the purposes of donation. However, the Georgia Supreme Court in Georgia Lions Eye Bank, Inc. v. Lavant limited parents’ quasi-rights to their decedent child’s corneas to a right to burial of the remains only; this decision upheld the constitutionality of the statutory presumption of consent for removal of corneas for donation.

In the landmark case of Moore v. Regents of the University of California, the California Supreme Court refused to grant property rights to a leukemia patient.

---

17. See Alfred M. Sadler, Jr. & Blair L. Sadler, A Community of Givers, Not Takers, HASTINGS CTR. REP., Oct. 1984, at 6, 7 (“In 1967, there was considerable variation in the law relating to dead bodies. . . . Each law was different: some required that a donation be made as part of a will; others said nothing about next-of-kin; some required three witnesses; still others, none.”).
18. Id.
21. Id.
22. Siegel, supra note 2, at 927-28.
23. Id. at 928.
24. Brotherton v. Cleveland, 923 F.2d 477, 479-82 (6th Cir. 1991); see also Siegel, supra note 2, at 928 (discussing the Brotherton case).
25. Ga. Lions Eye Bank, Inc. v. Lavant, 335 S.E.2d. 127, 128-29 (Ga. 1985); see also Siegel, supra note 2, at 929 (discussing the Lavant case).
whose living tissues (blood, sperm, bone marrow, spleen, and skin) had been sold to a researcher without his consent and patented into a cell line worth billions of dollars.\textsuperscript{26} In its reasoning, the court held that California law did not recognize in Mr. Moore an ownership interest in his body because of public policy concerns over the fiscal impact that granting property rights in living tissue would have on biomedical research.\textsuperscript{27} In contrast, the Tennessee Supreme Court in \textit{Davis v. Davis} held that neither of the divorcing spouses had an absolute property right in their cryogenically preserved fertilized eggs, but both had an interest in their disposition.\textsuperscript{28}

### B. An Effort to Obtain Uniformity

The growing importance of organ and tissue transplantation paired with the growing mobility of Americans means it is now more important than ever to ensure that documents expressing wishes for the donation of anatomical gifts are portable from state to state, and uniform laws are the vehicle through which this need is most efficiently met.\textsuperscript{29} “Uniform laws are developed with the goal of consistency among state laws.”\textsuperscript{30} They help “reduce the confusion created by the differences among state laws,” reduce litigation, and reduce the need to execute duplicate documents whenever a person makes an interstate move, such as those appointing an agent of representation or providing directives on how one wishes to have his or her bodily remains handled.\textsuperscript{31} The demand for anatomical donations spurred significant legal developments to define “the rights involved in the organ donation process,” most notably, the National Organ Transplant Act of 1984 (NOTA) and the Uniform Anatomical Gift Act (UAGA).\textsuperscript{32}

The “NOTA halted any development of a commercialized organ donation system, forbidding the exchange of human organs for any type of valuable consideration,” and provided “logistical structure to organ donation and procurement.”\textsuperscript{33} The NOTA created “a nationwide Organ Procurement and Transplantation Network as well as regional Organ Procurement Organizations” to

\textsuperscript{26} Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 125-48, 793 P.2d 479, 480-97 (1990); see also Siegel, supra note 2, at 931 (discussing the Moore case).

\textsuperscript{27} Moore, 51 Cal. 3d at 142, 793 P.2d at 493-97; see also Siegel, supra note 2, at 931 (discussing the Moore case).

\textsuperscript{28} Davis v. Davis, 842 S.W.2d 588, 589-97 (Tenn. 1992); see also Siegel, supra note 2, at 931 (discussing the Davis case).

\textsuperscript{29} Cf. Kester, supra note 15, at 593 (discussing the need for a uniform bodily remains law that allows for the portability of executed documents from state to state).

\textsuperscript{30} Id. at 592.

\textsuperscript{31} Id. at 593.

\textsuperscript{32} Peterson, supra note 20, at 171, 173.

\textsuperscript{33} Id. at 173-74, 176; see also 42 U.S.C.A. § 274e (West 2000 & Supp. 2007) (prohibiting the transfer of human organs for valuable consideration).
maintain a computerized database of potential recipients and organ matching criteria, to

preserve[] quality and testing standards for donated organs[,] carr[y] out studies and projects to help improve organ donation rates, [and] establish agreements with local hospitals and health care entities to identify potential organ donors and to help educate medical professionals and other citizens about organ donation in order to acquire as many usable organs as possible.34

Its counterpart, the UAGA, was the product of the National Conference of Commissioners on Uniform State Laws (NCCUSL), comprised of “practicing lawyers, judges, legislators and legislative staff and law professors, who have been appointed by state governments.”35 The NCCUSL is “charged with creating model statutes, which states may adopt, with any appropriate variations to accommodate local circumstances,” the goal of which “is to provide national consistency on issues that are solely within the province of state regulation and which, if they were handled differently from state to state, would create difficulty.”36 The NCCUSL attempted to increase anatomical donations by providing “legal structure to the organ donation process” with the goal of “replacing a confusing mix of state statutes with a uniform process for obtaining consent.”37 Chief among the UAGA’s concerns is that the donor’s right to give or withhold consent to donate is respected, not only by medical organizations but also by the donor’s next of kin or appointed representative, while opportunities for organ procurement are maximized to meet the increasing demand.38 The security of knowing what will happen to one’s bodily remains upon death, whether it be anatomical donation, cremation, burial, or otherwise, is important to many people.39

C. The (Non)-Uniform Anatomical Gift Act

1. The 1968 UAGA

In 1968, the NCCUSL promulgated the UAGA, which “created the power, not yet recognized at common law, to donate organs, eyes and tissue, in an immediate

34. Peterson, supra note 20, at 174-75.
37. Peterson, supra note 20, at 176.
38. See id. at 176-78 (discussing the UAGA’s attempt “to increase the supply of transplantable organs” by “providing the legal framework for making and accepting anatomical gifts” and “encourage[ing] organ donation by giving hospitals an affirmative duty to obtain consent to organ donation”).
39. See generally Kester, supra note 15, at 573-90 (“For many people, knowing how and where one’s final remains will ultimately be disposed [or utilized] is important.”).
By 1973, every state in the nation had adopted the 1968 UAGA in a uniform and unchanged condition. The 1968 UAGA contained provisions addressing five basic areas of anatomical donations law: (1) who could make an organ donation, (2) who could receive such a donation, (3) how an organ donation could be made, (4) how it could be amended or revoked, and (5) how an organ donation document could be delivered. First, the UAGA provided that any individual of majority age and sound mind could gift all or any part of his body. If a potential donor is deceased or otherwise unable to make a gift, and there is an “absence of actual notice of contrary indications by the decedent,” a gift could be made by the decedent’s spouse, adult child, parent, adult sibling, guardian, or any other person authorized or under obligation to dispose of the decedent’s bodily remains, so long as the gift is not opposed by another individual listed.

Second, the UAGA allowed an anatomical gift to be made to any hospital, surgeon, physician, accredited medical or dental school, college, or university, or a bank or storage facility, for medical or dental education, research, or advancement of medical or dental science, therapy or transplantation. A gift could also be made “to any specified individual for therapy or transplantation needed by him.”

Third, the UAGA permitted an anatomical gift to be made by will, donor card, or by some other document signed by the donor and two present witnesses, or directed to be signed for the donor and two present witnesses. A potential donor may also make a gift by a telegraphic, recorded telephonic, or other recorded message.

Fourth, the UAGA provided that if an anatomical gift document had already been delivered to a donee, the potential donor could amend or revoke the gift by executing and delivering a signed statement to the donee, making an oral statement in the presence of two witnesses or an attending physician, or by a signed document on his person or in his effects. If the document had not yet

---

43. Id. § 2(b).
44. Id. § 3(1)-(3).
45. Id. § 3(4).
46. Id. § 4(a)-(b).
47. Id. § 4(e).
48. Id. § 6(a)(1)-(4).
been delivered to a donee, the potential donor could also amend or revoke a gift by destroying, canceling, or mutilating the document of gift.\(^{49}\)

Finally, the UAGA stated that if a “gift is made by the donor to a specified donee, the will, card, or other document, or an executed copy thereof, may be delivered to the donee to expedite the appropriate procedures immediately after death, but delivery is not necessary to the validity of the gift.”\(^{50}\) The gift document could also “be deposited in any hospital, bank or storage facility or registry office that accepts them for safekeeping or for facilitation of procedures after death.”\(^{51}\)

2. The 1987 Revisions to the UAGA

In 1987, in response to a dramatic increase in the demand for organ transplants due to the availability of new medical technologies and the resulting disparity between supply and demand, revisions to the UAGA were approved.\(^{52}\) Specifically, the revisions provided that (1) hospitals could make routine inquiries of incoming patients of their donation status in an effort to increase organ donations;\(^{53}\) (2) upon the donor’s death, the 1987 UAGA prohibits the attending physician from participating in the removal and transplantation of the anatomical donation;\(^{54}\) and (3) the sale or purchase of body parts was prohibited and hospitals were required to coordinate with each other and organ procurement organizations for the procurement and use of anatomical donations.\(^{55}\)

Only twenty-six states adopted the 1987 UAGA, including California in 1988,\(^{56}\) causing “significant non-uniformity between the states,”\(^{57}\) which worsened as the states themselves enacted revisions.\(^{58}\) The federal government has also developed organ procurement laws, which were recognized neither by the 1968 nor the 1987 UAGA.\(^{59}\)

---

49. Id. § 6(b).
50. Id. § 5.
51. Id.
54. UNIF. ANATOMICAL GIFT ACT § 8(b) (1987); see also Glazier, supra note 12, at 645-46 (providing an overview of the UAGA of 1987).
55. UNIF. ANATOMICAL GIFT ACT §§ 9-10 (1987); see also Glazier, supra note 12, at 646 (providing an overview of the UAGA of 1987).
56. 13 B.E. WITKIN, SUMMARY OF CALIFORNIA LAW, Personal Property § 6 (10th ed. 2005).
57. NCCUSL Press Release, supra note 52.
58. UAGA Summary, supra note 40.
59. Id.
3. The 2006 Revisions to the UAGA

Consistent with its goal of providing national consistency where state law may govern and in response to the explosion of biomedical research and “legal, sociological, technical, and medical changes” affecting organ donation, the NCCUSL promulgated the 2006 Revised UAGA to address the critical shortage of organ donations for transplantation, the lack of uniformity and harmony in state laws, the resulting impediment created to transplantation, and the need for “organs, eyes, and tissue for research and education” to improve transplant and therapy success rates. Chapter 629 represents California’s effort to put existing state anatomical donation law in harmony with the nationally promulgated standard.

III. CHAPTER 629

Chapter 629 repeals the 1987 version of the Uniform Anatomical Gift Act currently followed in California and replaces it with the 2006 Revised Uniform Anatomical Gift Act. First, Chapter 629 expands the list of individuals who may make an anatomical gift on behalf of a donor to include the donor’s agent, “provided that the power of attorney for health care or other record expressly permits the agent to make an anatomical gift[,]” the “[a]dult grandchildren of the decedent[,]” and any adults who have “exhibited special care and concern for the decedent during the decedent’s lifetime.” Chapter 629 also clarifies the order of priority for the classes of individuals who may make an anatomical gift. In case “there is more than one member of a class” entitled to make an anatomical gift, he or she can do so unless that member “knows of an objection by another member of the class.” When there is a known objection, Chapter 629 requires the authorization of “a majority of the members of the class who are reasonably available.”

60. Glazier, supra note 12, at 646.
62. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF AB 1689, at 1-2 (July 10, 2007).
63. CAL. HEALTH & SAFETY CODE §§ 7150.15(b), 7150.40(a)(1), (6), (8) (enacted by Chapter 629).
64. See id. § 7150.40(a) (enacted by Chapter 629). Priority is given in the following order: an agent of the decedent at the time of death, a spouse or domestic partner, adult children of the decedent, parents of the decedent, adult siblings of the decedent, adult grandchildren of the decedent, grandparents of the decedent, an adult who exhibited special care and concern for the decedent, guardians or conservators of the decedent, and any other person with the authority to dispose of the body (i.e. medical examiner or coroner). Id. § 7150.40(a)(1)-(10) (enacted by Chapter 629).
65. Id. § 7150.40(b) (enacted by Chapter 629).
66. Id. Reasonably available is defined as “able to be contacted by a procurement organization, without undue effort, and willing and able to act in a timely manner consistent with existing medical criteria necessary for the making of an anatomical gift.” Id. § 7150.10(a)(23) (enacted by Chapter 629).
Second, Chapter 629 restricts the receipt of anatomical donations made for research or education to “[a] hospital, accredited medical school, dental school, college, university, or organ procurement organization,” and provides that, except for directed gifts, organs intended for the purpose of therapy or transplantation shall pass “to the organ procurement organization as custodian of the organ.” 67

Third, Chapter 629 allows donors to make an anatomical gift “[d]irectly through the Donate Life California Organ and Tissue Donor Registry Internet Web site.” 68 Chapter 629 authorizes certain California organ procurement organizations to establish a non-profit organization to “be designated the California Organ and Tissue Donation Registrar.” 69 It also allows Californians renewing or applying for a new driver’s license or identification card with the Department of Motor Vehicles to register as a donor, with such registration notated on the driver’s license or identification card with a preprinted donor symbol. 70

Lastly, Chapter 629 provides that a gift may be made, amended, or revoked by a donor through a third party if the donor “is physically unable to sign a record” so long as the gift is “witnessed by at least two adults, at least one of whom is a disinterested 71 witness, who have signed at the request of the donor” or third party. 72 Chapter 629 also provides measures for handling a donor’s advance health care directive whose provisions conflict with the procedures necessary to ensure the viability of anatomical donations; namely, such conflicts are to be resolved by the attending physician and the prospective donor or a person authorized to make medical decisions on behalf of the donor. 73

IV. ANALYSIS

A. “A Community of Givers, Not Takers” 74

The decision to rely upon voluntary anatomical donations rather than a commercial or involuntary process reflects Americans’ belief that something as personal as anatomical donations must be protected from market forces and

67. Id. § 7150.50(a)(1), (b) (enacted by Chapter 629).
68. Id. § 7150.20(a)(2) (enacted by Chapter 629).
69. Id. § 7150.90(a) (enacted by Chapter 629).
70. CAL. VEH. CODE § 12811(b)(1) (amended by Chapter 629).
71. A disinterested witness is defined as anyone other than the donor’s “spouse, child, parent, sibling, grandchild, grandparent, or guardian of the individual who makes, amends, revokes, or refuses to make an anatomical gift” and includes any other “adult who exhibited special care and concern for the individual.” CAL. HEALTH & SAFETY CODE § 7150.10(5) (enacted by Chapter 629).
72. Id. §§ 7150.20(b)(1), 7150.25(a)(1)(C), (b)(1) (enacted by Chapter 629).
73. Id. § 7151.10(b) (enacted by Chapter 629).
74. Sadler, Jr. & Sadler, supra note 17, at 6.
Volunteerism is embedded in deeply held values concerning the inviolability of human life and bodies, and the “routine salvage” of body parts from the dead, dying, or living strikes a chord of alarm and horror. The term “anatomical gift” reflects, by design, the notion of a gift—a consensual giving of renewed health and life from one human to another—which “meets the measure of authentic community among men.” Long has society recognized that man has a right to complete certainty that “his doctor does not become his executioner” and that no one can violate the sanctity of his life by claiming a right to his body or any of its parts. A uniform law ensures the “rights of individuals and families are clear and simplified mechanisms of consent are in place” so that “public support for transplantation continues to exist [and] the principles of giving rather than taking are maintained.”

Until such time as both the technological and ethical issues of engineered human organs are resolved, people with defective organs will continue to rely on voluntary anatomical donations. Theoretically, a supply system based on volunteerism has the potential to meet the growing demand. Almost any person is a potential donor, with absolute exclusions limited to, for example, persons

---

75. See generally id. at 6-8.

In Los Angeles, headlines in the Los Angeles Times revealed that a technician in the County Coroner’s Office was accused of removing pituitary glands from cadavers during autopsy without having obtained consent. In Hennepin County, Minnesota, the coroner’s authority to remove human parts for other purposes was also questioned. This information surfaced in emotionally charged newspaper articles that sharply criticized a Federal government agency’s role in supporting the taking of human cadaver material without consent. This unauthorized taking, even for humanitarian purposes, was described with alarm and even horror and threatened to undermine if not destroy the enterprise.

Id.

76. See id. at 8.

The patient must be absolutely sure that his doctor does not become his executioner . . . . His right to this certainty is absolute, and so is his right to his own body with all its organs. Absolute respect for these rights violates no one else’s rights, for no one has a right to another’s body.

Id. (quotations omitted).

77. Id. (quotations omitted).

78. Id. (quotations omitted).

79. Id. at 9.

80. See Siegel, supra note 2, at 926-27.

Several companies and laboratories are transforming tissue engineering into a successful industry. Geron, a facility in Menlo Park, California, believes a market will develop within ten to fifteen years for transplantation of engineered organs. Within the next few years, the growth of the tissue engineering industry will reach the importance of present genetic technology. The ethical issues involved with fetal tissue sources pose a barrier to commercialization. Some scientists think that this can be overcome if adult cells are used or if parents consent for their children’s cells to be taken at birth for possible future use.

Id. (footnotes omitted).

who are HIV positive or have active cancer. 82 Existing technology allows for kidneys, hearts, lungs, livers, pancreata, and the intestines to be transplanted. 83 In addition, “[c]orneas, the middle ear, skin, heart valves, bone, veins, cartilage, tendons, and ligaments can be stored in tissue banks and used to restore sight, cover burns, repair hearts, replace veins, and mend damaged connective tissue and cartilage in recipients.” 84

Potential donors may donate in multiple ways. 85 Some anatomical donations, such as blood, blood platelets, bone marrow, a single kidney, part of the liver, one lung, part of the pancreas, or part of the intestine, may be made by living persons whose bodies either generate replacements or can function without them. 86 But “[m]ost of the organs used in transplants come from people who have suffered brain death,” defined as the “total cessation of brain function, including brain stem function[.,] . . . [where] the brain no longer functions in any manner and will never function again.” 87 Finally, donors can make arrangements in advance to donate their entire bodies to medical science. 88

B. Increased Opportunities and Protections

Implicit in Chapter 629 is the idea that what is standing between the potentially ample volunteer supply of organs and tissues and the ever increasing donee demand is a more efficient nationwide donation process. 89 However, underlying the objective of increased efficiency is an expansion of the provisions to ensure compliance with a potential donor’s wishes so that people will feel more confident in making a decision to donate. 90 The 2006 UAGA addressed this continuing concern by broadening the means through which a donor may plan for donations to be made, increasing the number of parties who may authorize a donation, and increasing protections to ensure a donation is made in accordance

82. Id.
84. Id.
85. See OrganDonor.Gov, Types of Donations, http://www.organdonor.gov/donation/typesofdonation.htm (last visited Sept. 21, 2007) (on file with the McGeorge Law Review) (discussing the various methods in which a donation may be made, from solid organ or tissue donation by living donors, to donation after brain death or cardiac death, to whole body donation).
86. Id.
87. Id.
88. Id.
89. ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF AB 1689, at 3 (Apr. 17, 2007).
with the donor’s wishes.\textsuperscript{91} For example, the increased availability of Internet registries and motor vehicle donor designations provide the potential donor with greater opportunity to plan their anatomical donations according to their wishes.\textsuperscript{92} Further, provisions requiring the participation and consent of at least two witnesses, one of whom is disinterested, in cases where a potential donor is terminally ill or injured provide added assurance that a potential donor’s wishes will not be overridden or ignored.\textsuperscript{93}

The 2006 UAGA also recognizes the need to improve communication and cooperation between organ and tissue procurement organizations so that anatomical donations are put to their most effective use.\textsuperscript{94} Because of the unusually time-sensitive nature of an anatomical donation, increased cooperation among the organizations involved will provide a greater level of peace of mind to the potential donor that his donation will not be legally or administratively delayed by an inefficient donation system, but will be utilized in a medically timely manner to save a life or otherwise improve the health of another person.\textsuperscript{95}

\textit{C. The Need for Uniformity}

Though California adopted the 1987 revision to the UAGA, it joined only twenty-five other states.\textsuperscript{96} What started out as a truly uniform law, promulgated in 1968 by the NCCUSL and uniformly adopted by every state by 1973, has become non-uniform over the past thirty-four years, with some states following...
the 1968 UAGA, some following the 1987 UAGA, and many states making subsequent changes that further increased the non-uniformity. The unique, time-sensitive nature of the organ and tissue donation process, paired with the shortage of potentially life-saving donors, makes it vital that the surrounding legal framework operates to facilitate rather than impede the donation process if our system of voluntary donations is to live up to its potential.

Diversity in anatomical gift laws among the states is an impediment to the procurement of organs for transplantation, and, as a result, one person on the organ donation waiting list loses his or her life every hour because of the failure to obtain a properly matched organ. Organ procurement and transplantation is a delicate, time-sensitive process. "[A] centralized computer network links all organ procurement organizations (OPOs) and transplant centers." When an organ becomes available, the computer generates a list of potential recipients who are ranked according to “blood type, tissue type, size of the organ, medical urgency of the patient, time on the waiting list, and distance between donor and recipient.” Once the organ is placed with a suitable and available recipient, surgical personnel for both the donor and the donee must be assembled. However, driving this process is the amount of time the donor may survive in conjunction with the amount of time an organ can be expected to remain viable for transplant. Hearts and lungs are viable for only six hours, while livers are viable for twenty-four hours. Some organs, such as kidneys and pancreata, need to be tested first to assess compatibility with the potential donee. In addition, the logistics of both the donor and donee families must be accommodated as much as possible. Because such “[l]ittle time is available to

97. KRAUSKOPF ET AL., supra note 41, § 14:1; NCCUSL REPORT, supra note 90.
98. See UNIF. ANATOMICAL GIFT ACT Scope of the 2006 Revised Act (2006) (revised 2008). Recent technological innovations have increased the types of organs that can be transplanted, the demand for organs, and the range of individuals who can donate or receive an organ, thereby increasing the number of organs available each year and the number of transplantations that occur each year. Nonetheless, the number of deaths for lack of available organs also has increased. While the Commissioners are under no illusion that any anatomical gifts act can fully satisfy the need for organs, any change that could increase the supply of organs and thus save lives is an improvement.

99. NCCUSL REPORT, supra note 90.
100. See generally id. (“The anatomical gift law of the states is no longer uniform, and diversity of law is an impediment to transplantation. Harmonious law through every state’s enactment of the 2006 UAGA will help save and improve lives.”).
102. Id.
103. Id.
104. See id. (discussing time constraints associated with organ transplants).
105. Id.
106. Id.
107. See id. (“The OPO coordinates the logistics between the organ donor’s family, the donor organs,
prepare, transport across state lines, and transplant life-saving organs,”¹⁰⁸ time spent assessing and complying with variations in state law only serves to delay and perhaps undermine the success of the donation.¹⁰⁹

In addition to accommodating the urgency inherent in the donation process, uniformity among the states serves other purposes.¹¹⁰ Uniform acts encourage efficiency by reducing the need for individual states to conduct their own research on current technologies, bioethical views, and relevant law in other states.¹¹¹ The Uniform Acts “facilitat[e] the development of a repository of judicial decisions that aid interpretation of statutory terms,” codifying law that is most consistent with the newest available technologies and most widely held bioethical views.¹¹² In addition, a uniform law reduces confusion, as well as the hardship imposed on citizens who travel or move around the country and are left to wonder if their current donation directives will be valid.¹¹³ The increasing mobility of Americans means it is more important now than ever before to ensure documents are portable across state lines and updates are not required in order to ensure compliance with a potential donor’s wishes.¹¹⁴

The NCCUSL “vowed to conduct an all out effort to get the [2006 UAGA] passed by all 50 [states] within the next two years.”¹¹⁵ Twenty states have already enacted the 2006 UAGA, including California through Chapter 629, and five additional states have introduced bills for legislative consideration.¹¹⁶ Chapter 629 incorporates the major revisions of the 2006 UAGA into California law with the goal of increasing the supply of anatomical donations to meet the increasing demand of Californians who are currently on waiting lists, while at the same time

---

¹⁰⁸ NCCUSL REPORT, supra note 90.
¹⁰⁹ Id.
¹¹⁰ See cf. Kester, supra note 15, at 591-93 (discussing, in the context of uniform bodily remains laws, the unnecessary confusion created by differences in state laws and the role uniformity would serve to minimize this confusion as well as “provide guidelines for interested lawmakers as to what their legislation should include” and “provide a means for those individuals who [have] certain beliefs or desires concerning the disposition of bodily remains to be sure that their wishes [will] be carried out”).
¹¹¹ See cf. id. (discussing, in the context of uniform bodily remains law, that a uniform law “would address novel methods of preservation, such as cryonics” and provide “a repository of judicial decisions that aid interpretation of statutory terms” in “emerging areas of the law” (quotations omitted)).
¹¹² Id. at 591-92 (quoting Larry E. Ribstein & Bruce H. Kobayashi, An Economic Analysis of Uniform State Laws, 25 J. LEGAL STUD. 131, 140 (1996)).
¹¹³ See cf. id. at 593 (discussing, in the context of uniform bodily remains laws, “substantial interstate implications,” including that an individual who executes a document in one state would not need to update the document upon moving to another state (quotations omitted)).
¹¹⁴ See cf. id. at 592 (discussing, in the context of uniform bodily remains laws, that “the differences in the laws from state to state create a hardship for people who frequently move or travel”).
¹¹⁵ UAGA Adoption Effort, supra note 96.
ensuring the utmost protection for the rights of Californian donors and their families.  

V. CONCLUSION

The 1968 UAGA remains one of the most widely accepted uniform acts in the history of the NCCUSL, with its success attributed in part to the Act’s twin aims of encouraging anatomical donations while protecting “the principles of informed consent and voluntary donation.” The system of anatomical donations in the United States has from the very beginning been based on “a community of givers rather than takers,” preferring voluntary donations to the “routine salvage” of organs. However, for this volunteer system to meet the growing demand for organ and tissue transplants that biomedical research has made possible, a potential donor must be informed of their options and feel confident that their wishes will be protected no matter which state they happen to call home at the time of their death. Additionally, our nationwide health care systems must function as well-oiled machines to ensure that procured organs are put to use where they are needed most and in a manner in which they will provide the highest chance of survival in the donee. Chapter 629 will put California at the forefront of contemporary donation law, protecting the wishes of its donor residents and ensuring a better chance of survival for potential donees.

117. See generally SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 1689 (June 20, 2007) (describing the effect of the non-uniformity of state law as being an impediment to organ and tissue transplantation and how AB 1689 (Chapter 629) addresses this concern).

118. Sadler, Jr. & Sadler, supra note 17, at 7.

119. Id. at 8.


Furthermore, the decision to be a donor is a highly personal decision of great generosity and deserves the highest respect from the law. Because current state anatomical gift laws are out of harmony with both federal procurement and allocation policies and do not fully respect the autonomy interests of donors, there is a need to harmonize state law with federal policy as well as to improve the manner in which anatomical gifts can be made and respected.

Id.

121. Id. (“Transplantation occurs across state boundaries and requires speed and efficiency if the organ is to be successfully transplanted into a recipient. There simply is no time for researching and conforming to variations of the laws among the states. Thus, uniformity of state law is highly desirable.”).

122. SENATE HEALTH COMMITTEE, COMMITTEE ANALYSIS OF AB 1689, at 7 (June 20, 2007).
The Missing Angels Act: Recognizing the Birth of Stillborn Babies

Colleen Snyder

Code Sections Affected


SB 850 (Maldonado & Correa); 2007 STAT. Ch. 661.

I. INTRODUCTION

Joanne Cacciatore gave birth to her daughter Cheyenne on her due date in July 1994.1 Sadly, however, Cheyenne’s tiny heart stopped beating only fifteen minutes prior to her delivery—she was stillborn.2 Joanne was living one of every parent’s worst nightmares, but the pain only grew when she called to order a birth certificate for her stillborn daughter.3 She had, after all, given birth to Cheyenne just as she had with her three previous children.4 The only difference was the horrible fifteen minutes that prevented Cheyenne from being born alive.5 A woman at the vital records office told Joanne that, because of those fifteen minutes, there would be no birth certificate.6 “You didn’t have a baby. You had a fetus and the fetus died,” the woman said.7

Joanne decided to channel her outrage and despair at this tragedy toward change.8 Keeping her daughter’s memory alive, she founded the Mothers In Sympathy and Support (MISS) Foundation, a support group for parents of stillborn babies.9 The MISS Foundation has since been advocating in state legislatures across the country for birth certificates for stillborn babies.10

---

2. See id. (“A stillbirth is a naturally occurring, intrauterine death that occurs after the 20th week of pregnancy all the way up to birth. The ‘stillborn infant’ is born without any attempt at respiration, including a beating umbilical cord.”).
3. See id. (detailing the remarks made by a person at the vital records office in Arizona).
4. See id. (describing how Cacciatore’s fourth pregnancy ended in stillbirth).
5. Id.
7. MISS FAQ, supra note 1; Jerome & Keating, supra note 6.
9. Id.
10. Id.
II. LEGAL BACKGROUND

A. Existing California Law

The State Registrar of Vital Statistics oversees the registration of all fetal deaths in California. It is the job of the local registrar to record “[e]ach fetal death in which the fetus has advanced to or beyond the twentieth week of uterogestation . . . within eight calendar days following the [death] and prior to any disposition of the fetus.” Because a stillborn baby never takes a breath outside of the womb, the medical field considers a still birth to be a fetal death for statistical purposes.

The parents are issued a certificate of fetal death containing “items relating to medical and health data” to be used for public health purposes. Before Chapter 661, this death certificate was the only official record parents of stillborn babies had of the life they lost. Although California law did not recognize the birth, it did mandate that parents of stillborn babies pay for the “final disposition” of their baby’s body—including funeral or cremation expenses.

B. Other States

Every state in the nation issues a fetal death certificate for stillborn babies and requires families to pay for the burial or cremation of the body. Some hospitals, in states that do not yet issue Certificates of Birth Resulting in Still Birth, offer families an unofficial certificate commemorating the still birth.

In 2001, Joanne Cacciatore’s home state of Arizona became the first state to pass the Missing Angels Act, allowing parents of stillborn babies to receive a Certificate of Birth Resulting in Still Birth. This certificate is available to all parents of stillborn babies—no matter how much time has passed since the death. Taking it a step further, the Arizona Legislature also passed a one-time

---

11. See Senate Judiciary Committee, Committee Analysis of SB 850, at 1 (Apr. 24, 2007) (“Fetal death is defined as a death prior to the complete expulsion or extraction from its mother of a product of conception (irrespective of the duration of the pregnancy).”) (quotations omitted).
12. Id. at 2.
16. MISS FAQ, supra note 1.
17. Id.; see also Cal. Health & Safety Code § 7100(a)(4) (West Supp. 2007) (providing that the surviving parent(s) have the duty and financial liability of disposing of the decedent’s remains).
19. Id.
20. MISS FAQ, supra note 1.
21. Id.
tax exemption for families of stillborn babies during the year of the still birth, to help balance the costs of preparing for and then burying a baby within nine months. As of October 2007, two other state legislatures, in Missouri and Indiana, were considering such a tax exemption.

Since 2001, nineteen other states have followed Arizona in passing the Missing Angels Act and now offer a Certificate of Birth Resulting in Still Birth to all parents of stillborn babies. Five other state legislatures were considering the bill during the current legislative session. Nine other states offer a similar document, a Certificate of Still Birth, which the sponsor of the Missing Angels Act, the MISS Foundation, would like to change to a Certificate of Birth Resulting in Still Birth. Although it may seem mere semantics, the MISS Foundation equates the word “stillbirth” with “death” and argues “all states should record births as births . . . whether live or still.”

III. Chapter 661

Chapter 661 gives parents of babies stillborn in California the right to obtain a Certificate of Still Birth from their local county registrar of births and deaths. The certificate must be on a form approved by the State Registrar of Vital Statistics and will include the following information: (1) the date of the stillbirth, (2) the county in which it occurred, (3) the name and gender of the baby, (4) the time and place of the stillbirth and the name of the hospital in which it occurred, if applicable, (5) the name, birth date, and state of birth of each parent, and (6) the file number of the fetal death certificate. Chapter 661 gives local county registrars permission to charge an “appropriate fee” for the issuance of the certificate, to be determined annually in accordance with state law but

23. MISS State Chart, supra note 22.
24. See id. (listing the states that currently have legislation allowing parents to get a Certificate of Birth Resulting in Still Birth: Arizona, Arkansas, Florida, Indiana, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, New Jersey, North Dakota, Rhode Island, South Carolina, South Dakota, Texas, Utah, Virginia, and Wisconsin).
27. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 850, at 5 (Apr. 24, 2007).
28. MISS State Chart, supra note 22.
29. CAL. HEALTH & SAFETY CODE § 103040.1(a) (enacted by Chapter 661).
30. Id. (enacted by Chapter 661).
31. Id. § 103040.1(d)(1)-(6) (enacted by Chapter 661).
never to exceed the actual cost of providing the certificate.\textsuperscript{32} For the 2007-2008 fiscal year, the fee is capped at twenty dollars.\textsuperscript{33} The certificate also must include a statement that reads, “This Certificate of Still Birth is not proof of a live birth.”\textsuperscript{34}

Chapter 661 carefully defines stillbirth as “the delivery of a fetus where there was a naturally occurring intrauterine fetal death after a gestational age of not less than 20 completed weeks.”\textsuperscript{35} The language of the new law makes it clear that it is not creating any new rights for the fetus nor is it altering any existing rights of women to “reproductive privacy.”\textsuperscript{36} In an apparent effort to increase legislative support for the new law, the authors even included specific language to “reaffirm these protections in accordance with [the law].”\textsuperscript{37}

Chapter 661 also changes the requirement in prior law that all fetal deaths beyond twenty weeks gestation be recorded with the local registrar of births and deaths within eight days of the death.\textsuperscript{38} Although that mandate still applies to naturally occurring fetal deaths, Chapter 661 exempts elective abortions performed in compliance with the Reproductive Privacy Act from the reporting requirement.\textsuperscript{39}

IV. Analysis

According to the Centers for Disease Control and Prevention (CDC), about 25,000 pregnancies end in stillbirth every year in the United States.\textsuperscript{40} By this estimate, stillbirth takes the life of ten times as many babies than Sudden Infant Death Syndrome (SIDS).\textsuperscript{41} The MISS Foundation estimates the number of stillbirths to be even higher, somewhere between 25,000 and 39,000 stillbirths each year.\textsuperscript{42} The Foundation believes the number of stillbirths is difficult to

\textsuperscript{32} Id. § 103040.1(f) (enacted by Chapter 661).
\textsuperscript{33} Id. (enacted by Chapter 661).
\textsuperscript{34} Id. § 103040.1(d)(8) (enacted by Chapter 661).
\textsuperscript{35} Id. § 103040.1(i) (enacted by Chapter 661).
\textsuperscript{36} Id. § 103040.1(j)-(k) (enacted by Chapter 661); see also SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 850, at 8-9 (Apr. 24, 2007) (describing concerns that SB 850 (Chapter 661) could have an unintended impact on a woman’s right to choose and proposing the wording later adopted in the law to protect against such consequences).
\textsuperscript{37} See CAL. HEALTH & SAFETY CODE § 103040.1(k) (enacted by Chapter 661) ("Through its courts, statutes, and under its Constitution, California law protects a woman’s right to reproductive privacy, and it is the intent of the Legislature to reaffirm these protections . . . .").
\textsuperscript{38} Id. § 102950 (amended by Chapter 661).
\textsuperscript{39} Id. § 102950(b) (amended by Chapter 661).
\textsuperscript{41} Id.
\textsuperscript{42} Cacciatore Letter, supra note 22.
estimate due to “lax handling of stillbirth records and varying state compliance” with the CDC’s effort to count stillbirths in the country.\footnote{MISS FAQ, supra note 1.}

The CDC agrees that the method currently used to record stillbirths is problematic, as each state submits its own numbers to the CDC’s National Center on Health Statistics.\footnote{CDC Stillbirths, supra note 40.} The problem with this system, according to the CDC, is that it often “underestimate[s] the true occurrence of stillbirth and . . . the information recorded on certificates is often incomplete.”\footnote{Id.} Adding to the mystery surrounding this all too common tragedy, almost half of all stillbirths occur with no known cause.\footnote{Id.} The CDC admits that “[a] better understanding of [the] causes [of stillbirth] is needed so that specific prevention and medical management strategies can be developed.”\footnote{Id.}

One of the biggest obstacles to determining the primary causes of stillbirth is variance in hospital protocols.\footnote{Id.} The CDC emphasizes the importance of performing an autopsy, examining the placenta, and, in some cases, doing genetic testing to determine the cause of death.\footnote{Id.} If a consistent protocol was developed nationwide for administering these tests, more causes might be identified and prevention strategies could be developed.\footnote{See id. (discussing the challenges of tracking causes of stillbirth and the main tests that should be performed for research purposes).}

The MISS Foundation believes that labeling stillborn babies as “fetal deaths” plays a part in the lack of awareness surrounding stillbirth.\footnote{Cacciatore Letter, supra note 22.} Because stillbirths are considered “fetal deaths,” they are not counted in infant mortality data in the United States.\footnote{Id.} The MISS Foundation argues that it makes no sense that a baby born at eighteen weeks gestation who takes one breath outside the womb is counted in infant mortality statistics and receives a birth certificate, while other babies, many of whom are full term when they die, are labeled “fetal deaths” and, before Chapter 661, could not receive birth certificates.\footnote{MISS FAQ, supra note 1.}

The refusal to issue a birth certificate was especially upsetting to parents of stillborn babies because most women still have to deliver their babies, despite the horrible reality that they will not be born alive.\footnote{MISS Foundation, Stillbirth: What Every Woman Needs to Know, http://www.missfoundation.org/miracles/stillbirth.pdf (last visited July 18, 2007) (on file with the McGeorge Law Review).} After delivery, California law requires parents of stillborn babies to take responsibility for burying or cremating
the remains. After labor, delivery, and planning for funeral arrangements, parents were shocked to learn the law did not allow for a birth certificate commemorating the life they lost. Chapter 661 corrects this perceived inconsistency for families of stillborn babies in California by allowing them to request a Certificate of Still Birth.

According to the MISS Foundation, this solution makes sense. The Foundation argues that some babies are born alive and, sadly, other babies are born still. They cite the World Health Organization’s use of separate definitions for “birth” and “live birth,” clearly distinguishing between the two. The fact that stillborn babies are not born alive, they argue, does not mean they are not born at all. Although the California Legislature did not word the Certificate of Still Birth exactly as the MISS Foundation would have hoped, it is a compromise that ideally will give parents of stillborn babies the validation they seek.

Chapter 661 does nothing, however, to change the way stillbirths are recorded in California. In fact, the Legislature was very careful not to expand the definition of a “stillbirth” to allow stillborn babies to be legally considered “infants” or counted in infant mortality statistics. By exempting abortions from the reporting requirement for fetal deaths, the Legislature ensured that stillbirths are in a class of their own—not to be considered with elective terminations or babies who are born alive, if even for an instant.

The Legislature seems to have considered carefully all aspects of Chapter 661 to ensure that recognizing the birth of a “fetus” will not impede abortion rights. Not only were the above precautions taken to isolate the definition of “stillbirth,” applying it to California Health and Safety Code section 103040.1

55. MISS FAQ, supra note 1; see also CAL. HEALTH & SAFETY CODE § 7100(a)(4) (West Supp. 2007) (providing that the surviving parent(s) have the duty and financial responsibility for disposing of the deceased’s remains).
56. MISS FAQ, supra note 1.
57. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 850, at 1-2 (Apr. 24, 2007).
58. MISS FAQ, supra note 1.
59. Id.
60. See WORLD HEALTH ORG., DEFINITIONS AND INDICATORS IN FAMILY PLANNING, MATERNAL & CHILD HEALTH, AND REPRODUCTIVE HEALTH 2 (2001), http://www.euro.who.int/document/e68459.pdf (on file with the McGeorge Law Review) (defining “birth” as “[t]he complete expulsion or extraction of a dead fetus of more than 500g or of a live fetus from its mother irrespective of the duration of pregnancy”).
61. MISS FAQ, supra note 1.
62. Id.
63. MISS State Chart, supra note 22 (explaining why the MISS Foundation wants the certificate to be called a “Certificate of Birth Resulting in Stillbirth”).
64. SENATE JUDICIARY COMMITTEE, COMMITTEE ANALYSIS OF SB 850, at 8 (Apr. 24, 2007).
65. CAL. HEALTH & SAFETY CODE § 103040.1(i), (j) (enacted by Chapter 661).
66. Id. § 102950 (amended by Chapter 661).
alone, but politicians took the new law one step further, adding language to reaffirm “a woman’s right to reproductive privacy.”

V. CONCLUSION

Although the Missing Angels Act was intended only to bring dignity and awareness to the births of stillborn babies in California, it was thrust into the middle of a heated abortion debate. Two groups of people, seemingly worlds apart—grieving parents of stillborn babies and abortion rights activists—were forced to work together to reach a compromise in word choice.

The result seems to be a success and should accomplish the main objective, giving parents of stillborn babies the solace they deserve, without treading on abortion rights. The MISS Foundation points to the tremendous impact similar legislation has had on parents of stillborn babies in other states. As one eighty-three year old woman described it, upon receiving her stillborn baby’s birth certificate fifty-six years after her loss, “I feel like I can finally die in peace.”

---

68. CAL. HEALTH & SAFETY CODE § 103040.1(i), (j) (enacted by Chapter 661).
69. Id. § 103040.1(k) (enacted by Chapter 661).
70. Lin, supra note 67.
71. Id.
72. See SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF SB 850, at 4-5 (Sept. 5, 2007) (describing the objective of comforting parents of stillborn babies while still safeguarding abortion rights).
73. MISS FAQ, supra note 1.
74. Id.
Toy Story: Timeout for Phthalates

James Bothwell

Code Sections Affected
AB 1108 (Ma); 2007 STAT. Ch. 672.

I. INTRODUCTION

Wondering just what her children’s toys were made of, Jackie Christensen, a mother of two small children, contacted McDonald’s about the miniature Barbie dolls in her daughter’s Happy Meals. After receiving little information from McDonald’s, the mother contacted Mattel, the company that manufactured the Barbie toy. A customer service representative related “that all Barbies are made of a plastic called polyvinyl chloride, or PVC.” Jackie knew that chemical plasticizers called “phthalates” were used to manufacture flexible PVC products and that phthalates have potentially adverse side-effects on people. Even more distressing, Jackie knew that “[p]hthalates are not chemically bound to PVC,” which gives them the potential to leak out into the surrounding environment. Since her infant son had a habit of chewing on toys, the surrounding environment happened to be her son’s mouth and digestive system.

According to the U.S. Centers for Disease Control and Prevention, “phthalates are industrial chemicals that can act as plasticizers, which, when added to plastic, impart flexibility and resilience.” Phthalates are used in consumer products such as vinyl flooring, adhesives, shampoo, soap, deodorant, fragrances, and nail polish. They are also widely employed in “inflatable recreational toys, blood-storage bags, intravenous medical tubing, and children’s toys.”

Human exposure to phthalates generally occurs through direct contact with products containing the chemical, and the main route of exposure to phthalates is through the mouth. Normally, phthalates metabolize quickly and only

2. Id.
3. Id.
4. Id.
5. Id.
6. Id.
8. Id.
9. Id.
10. Id.
accumulate in the body in cases of overwhelming high exposure to the chemical.\textsuperscript{11}

Some scientific reports, however, demonstrate that exposure to certain phthalates causes detrimental health effects, such as testicular injury, liver injury, and liver cancer.\textsuperscript{12} But these reports confirmed such side-effects primarily by testing rodents.\textsuperscript{13} While numerous studies researched the effects phthalates have on humans, research results have varied widely from one study to the next.\textsuperscript{14}

Due to the discrepancies between rodent and human studies, debate exists regarding whether exposure to phthalates indeed causes detrimental health effects in humans.\textsuperscript{15} Although many foreign countries already err on the side of caution by banning the use of phthalates in children’s toys, California recently became the first American jurisdiction to follow suit.\textsuperscript{16}

\textsuperscript{11} Id.
\textsuperscript{12} Id.
\textsuperscript{13} Id.
\textsuperscript{14} See infra Part IV.B.1-2.
\textsuperscript{15} See infra Part IV.B.D.
\textsuperscript{16} See CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672) (banning the use of phthalates in children’s toys and other child care items); Council Directive 2005/84/EC, 2005 O.J. (L 344) 40 (banning the presence of certain phthalates in children’s toys); SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007) (listing countries that ban the use of certain phthalates in children’s toys); Tom Chorneau, A Nationwide Toxic Toy Ban Likely to Follow State Lead, S.F. CHRON., Oct. 16, 2007, at A1 (“California became the first state in the nation to ban toys containing toxic plastic softeners . . . .”).

Bills similar to Chapter 672 have recently been proposed in a number of other jurisdictions. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007). In New York, Assembly Bill 6829 prohibits the manufacture, distribution, or sale of toys and childcare products intended for use by a child under three years of age containing phthalates or bisphenol-A. AB 6829, 2007 Leg., 2007-2008 Reg. Sess. (N.Y. 2007) (not enacted). Bisphenol-A is an “industrial chemical[] . . . used to make polycarbonate plastics” found in such products as “refillable beverage containers, protective linings in food cans, compact disks, [and] plastic dinnerware.” CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL REPORT ON HUMAN EXPOSURE TO ENVIRONMENTAL CHEMICALS: SPOTLIGHT ON BISPHENOL A AND 4-TERTIARY-OCTYLPHENOL 1 (2007), http://www.cdc.gov/exposurereport/pdf/factsheet_bisphenol.pdf (on file with the McGeorge Law Review). The first draft of Chapter 672 and the original San Francisco Ordinance banned bisphenol-A. AB 1108, 2007 Leg., 2007-2008 Sess. (Cal. 2007) (as introduced on Feb. 23, 2007, but not enacted); S.F., CAL., HEALTH CODE art. 34, § 34.1(c) (2006). However, both Chapter 672 and the San Francisco Ordinance were amended to remove bisphenol-A, due to inconclusive testing results and much opposition from manufacturers of consumer products. See 2007 Cal. Stat. ch. 672 (banning the use of the following phthalates: benzyl butyl, di-(2-ethylhexyl), dibutyl, diisononyl, diisodecyl, and di-n-octyl); S.F., CAL., HEALTH CODE art. 34, § 34.4(a)-(f) (2007) (same).

Assembly Bill 333, also introduced in New York, prohibits the sale of toys or other articles for use by children less than three years of age if such items contain phthalates. AB 333, 2007 Leg., 2007-2008 Reg. Sess. (N.Y. 2007) (not enacted). Moreover, New York City is considering an ordinance similar to the one adopted by San Francisco. Proposed Int. No. 0589-A, N.Y.C. (N.Y. 2007) (not enacted).

In Oregon, proposed Senate Bill 944 prohibits the sale of a toy or article intended for children less than five years of age if the toy contains “any measurable amount of phthalates.” SB 944, 2007 Leg., 2007 Reg. Sess. (Ore. 2007) (not enacted). Further, the Oregon Senate Joint Memorial Committee proposed sending a message to the U.S. President and Congress on behalf of the Oregon Legislature urging comprehensive testing of phthalates, especially considering their frequent presence in cosmetics and children’s toys. Senate Joint Memorial 8, 74th Leg., 2007 Reg. Sess. (Ore. 2007).
II. LEGAL BACKGROUND

A. Existing Federal Law

The Consumer Product Safety Act, passed by Congress in 1972, establishes and confers broad federal authority on the Consumer Product Safety Commission (CPSC). The CPSC “is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency’s jurisdiction.” The CPSC ensures the safety of consumer products that can injure children or “pose a fire, electrical, chemical, or mechanical hazard.”

The CPSC has authority under the Consumer Product Safety Act to promulgate binding labeling or performance standards to protect the public from risks posed by consumer products. Additionally, the CPSC is authorized to order appropriate corrective action for hazardous consumer products, such as product recalls or halting distribution.

B. Existing State Law

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, requires the Governor to annually revise and publish a list of chemicals that are scientifically proven to cause cancer, birth defects, or reproductive harm. Under Proposition 65, businesses cannot “knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning.” Such warning allows individuals “to make informed decisions about protecting themselves from exposure to [hazardous] chemicals.”

The Office of Environmental Health Hazard Assessment (OEHHA) is responsible for listing these chemicals and is the governor’s primary agency for

---

19. Id.
21. Id. § 2064(c)-(d) (West 1998).
22. CAL. HEALTH & SAFETY CODE § 25249.5 historical and statutory note (West 2006); id. § 25249.8(a) (West 2006).
23. Id. § 25249.6 (West 2006).
Proposition 65 provides four principal bases for listing chemicals that are known to cause cancer or reproductive toxicity.

First, a chemical can be listed if the state or federal government requires it to be labeled as causing cancer, birth defects, or other reproductive harm. Most of the chemicals listed on this basis are prescription drugs required by the U.S. Food and Drug Administration (FDA) to contain warning labels.

Second, a chemical can also be listed if either of two committees, the Carcinogen Identification Committee (CIC) or the Development and Reproductive Toxicant (DART) Identification Committee, after reviewing current scientific evidence, determines that the chemical causes cancer, birth defects, or other reproductive harm. The CIC and the DART are both part of the OEHHA’s Science Advisory Board.

The third basis for listing a chemical occurs when a body considered to be “authoritative” by the state’s qualified experts (the CIC or the DART Identification Committee) formally identifies the chemical as causing cancer, birth defects, or reproductive harm. “Authoritative bodies” include “the U.S. Environmental Protection Agency, U.S. Food and Drug Administration (U.S. FDA), National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer.”

Lastly, a chemical can be listed if it meets certain chemical criteria and is identified by the California Labor Code as causing cancer, birth defects, or other reproductive harm. This basis was originally the sole means of listing toxic chemicals following voter approval of Proposition 65.

There are currently five phthalates identified by Proposition 65. Di-(2-ethylhexyl) phthalate (DEHP) was listed as a carcinogen in 1988 and as a developmental and male reproductive toxin in 2003. The OEHHA, in 2005, placed the phthalates butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and
di-n-hexyl phthalates (DnHP) on the list of toxic chemicals that require warnings. More recently, the OEHHA determined that another phthalate, diisodecyl phthalate (DIDP), also met the criteria of Proposition 65 and added it to the list for causing adverse developmental reactions.

C. Existing Local Law

In July 2006, the City of San Francisco passed the Healthy Products, Healthy Children Ordinance. The Ordinance bans child feeding products, child care products, and toys likely to be placed in children’s mouths that contain specified phthalates in concentrations exceeding 0.1 percent. Research demonstrating that phthalates cause genital defects, sperm damage, reduced testosterone production, and premature deliveries in humans prompted the City to enact the Ordinance.

D. Foreign Nations

A number of foreign nations have banned the use of phthalates in products intended for use by children. In 2005, the European Parliament extended an earlier temporary ban on the use of phthalates in children’s toys. The directive permanently banned the phthalates DEHP, DBP, and BBP in all toys and childcare items and banned diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in toys capable of being placed in a child’s mouth. Similarly, fourteen other nations, including Argentina, Fiji, Mexico, and Japan, have banned the use of phthalates in toys and products intended for use by children.

III. CHAPTER 672

Chapter 672 prohibits, starting January 1, 2009, the manufacture, sale, or distribution of any toy or child care article that contains di-(2-ethylhexyl) phthalates (DnHP) on the list of toxic chemicals that require warnings. More recently, the OEHHA determined that another phthalate, diisodecyl phthalate (DIDP), also met the criteria of Proposition 65 and added it to the list for causing adverse developmental reactions.

C. Existing Local Law

In July 2006, the City of San Francisco passed the Healthy Products, Healthy Children Ordinance. The Ordinance bans child feeding products, child care products, and toys likely to be placed in children’s mouths that contain specified phthalates in concentrations exceeding 0.1 percent. Research demonstrating that phthalates cause genital defects, sperm damage, reduced testosterone production, and premature deliveries in humans prompted the City to enact the Ordinance.

D. Foreign Nations

A number of foreign nations have banned the use of phthalates in products intended for use by children. In 2005, the European Parliament extended an earlier temporary ban on the use of phthalates in children’s toys. The directive permanently banned the phthalates DEHP, DBP, and BBP in all toys and childcare items and banned diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in toys capable of being placed in a child’s mouth. Similarly, fourteen other nations, including Argentina, Fiji, Mexico, and Japan, have banned the use of phthalates in toys and products intended for use by children.

III. CHAPTER 672

Chapter 672 prohibits, starting January 1, 2009, the manufacture, sale, or distribution of any toy or child care article that contains di-(2-ethylhexyl) phthalates (DnHP) on the list of toxic chemicals that require warnings. More recently, the OEHHA determined that another phthalate, diisodecyl phthalate (DIDP), also met the criteria of Proposition 65 and added it to the list for causing adverse developmental reactions.

C. Existing Local Law

In July 2006, the City of San Francisco passed the Healthy Products, Healthy Children Ordinance. The Ordinance bans child feeding products, child care products, and toys likely to be placed in children’s mouths that contain specified phthalates in concentrations exceeding 0.1 percent. Research demonstrating that phthalates cause genital defects, sperm damage, reduced testosterone production, and premature deliveries in humans prompted the City to enact the Ordinance.

D. Foreign Nations

A number of foreign nations have banned the use of phthalates in products intended for use by children. In 2005, the European Parliament extended an earlier temporary ban on the use of phthalates in children’s toys. The directive permanently banned the phthalates DEHP, DBP, and BBP in all toys and childcare items and banned diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in toys capable of being placed in a child’s mouth. Similarly, fourteen other nations, including Argentina, Fiji, Mexico, and Japan, have banned the use of phthalates in toys and products intended for use by children.

III. CHAPTER 672

Chapter 672 prohibits, starting January 1, 2009, the manufacture, sale, or distribution of any toy or child care article that contains di-(2-ethylhexyl) phthalates (DnHP) on the list of toxic chemicals that require warnings. More recently, the OEHHA determined that another phthalate, diisodecyl phthalate (DIDP), also met the criteria of Proposition 65 and added it to the list for causing adverse developmental reactions.

C. Existing Local Law

In July 2006, the City of San Francisco passed the Healthy Products, Healthy Children Ordinance. The Ordinance bans child feeding products, child care products, and toys likely to be placed in children’s mouths that contain specified phthalates in concentrations exceeding 0.1 percent. Research demonstrating that phthalates cause genital defects, sperm damage, reduced testosterone production, and premature deliveries in humans prompted the City to enact the Ordinance.

D. Foreign Nations

A number of foreign nations have banned the use of phthalates in products intended for use by children. In 2005, the European Parliament extended an earlier temporary ban on the use of phthalates in children’s toys. The directive permanently banned the phthalates DEHP, DBP, and BBP in all toys and childcare items and banned diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in toys capable of being placed in a child’s mouth. Similarly, fourteen other nations, including Argentina, Fiji, Mexico, and Japan, have banned the use of phthalates in toys and products intended for use by children.
phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP) in concentrations exceeding 0.1 percent. 48 Chapter 672 further prohibits the manufacture, sale, or distribution of any toy or child care article intended for use by a child under three years of age if that product can be placed in the child’s mouth and contains diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP) in concentrations exceeding 0.1 percent.49

Chapter 672 mandates that when manufacturers replace phthalates in their products, they must use the least toxic alternative.50 Accordingly, manufacturers cannot replace phthalates with A, B, or C carcinogens as rated by the EPA, substances listed as known, likely, or suggestive of being carcinogens by the “List of Chemicals Evaluated for Carcinogenic Potential,” or substances known to the state to cause cancer as listed pursuant to Proposition 65.51 Manufacturers also cannot replace phthalates with reproductive toxicants that cause birth defects, reproductive harm, or developmental harm as identified by the EPA or listed pursuant to Proposition 65.52

IV. ANALYSIS

A. Chapter 672 and Proposition 65

Proposition 65 requires manufacturers to warn consumers about the presence of known hazardous chemicals contained in a product.53 Strictly speaking, manufacturers can, at their discretion, produce products with harmful chemicals so long as the consumer is warned about the presence of the chemicals.54 Realizing this shortcoming, the California Legislature enacted Chapter 672.55

Chapter 672 holds manufacturers to a higher standard and places a premium on children’s safety by completely prohibiting concentrations of certain phthalates beyond 0.1 percent in children’s toys.56

47. A “child care article” is defined as “all products designed or intended by the manufacturer to facilitate sleep, relaxation, or the feeding of children, or to help children with sucking or teething.” Id. § 108935(b) (enacted by Chapter 672).

48. Id. § 108937(a) (enacted by Chapter 672).

49. Id. § 108937(b) (enacted by Chapter 672).

50. Id. § 108939(a) (enacted by Chapter 672).

51. Id. § 108939(b) (enacted by Chapter 672).

52. Id. § 108939(c) (enacted by Chapter 672).

53. Id. § 20249.6 (West 2006).

54. Id.

55. See Telephone Interview with Assembly Member Fiona Ma, Cal. State Assembly, in Sacramento, Cal. (Dec. 21, 2007) [hereinafter Fiona Ma Interview] (on file with the McGeorge Law Review) (“[N]ot only is the routine of listing a chemical under Prop 65 very time-consuming, but we could not permit manufacturers to use measurable amounts of phthalates in their products, regardless of whether a warning label was attached, considering the harmful side-effects of the chemicals.”).

56. CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672).
B. Scientific Studies of the Effects of Phthalates on Humans

1. Studies that Support the Ban on Phthalates

Various scientific studies have demonstrated that phthalate levels in humans are not only higher than once believed but also that phthalates have wide-ranging, adverse health effects on the human body.57

In a 2000 study, the CDC found high levels of phthalates in all 289 adult Americans tested.58 A subsequent independent study concluded that children had even higher levels of phthalates (especially DBP, BBP, and DEHP) in their systems than the average adult in the CDC study.59 Another study conducted by the CDC in 2005 bolstered this conclusion by finding phthalates in virtually every person tested, with the highest levels among children, demonstrating the potential for adverse developmental effects on children and fetuses.60 Similar to the prior independent study, children had the highest concentrations of the specific phthalates DEHP, BBP, and DINP in the 2005 CDC study.61

A high level of phthalates in the human body is especially worrisome considering the assorted adverse health effects purportedly linked to the chemicals.52 For example, DEHP exposure has been linked to premature breast development in girls.63 A study of Puerto Rican girls concluded that girls suffering from premature breast development—girls with an average age of thirty-one months—had seven times as much DEHP in their system as the average infant girl.64 Moreover, another study found that exposure to DEHP may cause pre-term birth, as higher levels of phthalates in newborn children correlated with higher incidences of premature delivery.65

Phthalates have also been linked to sperm damage in men, as a study showed that men with higher phthalate levels, including DBP and DEHP, were more likely to experience low sperm count and impaired sperm quality.66 Unfor-

58. Blount et al., Levels of Urinary Phthalates, supra note 57.
60. Third National Report, supra note 7, at 254.
61. Id. at 260, 262, 265, 269, 273, 275.
62. See, e.g., Colón et al., Identification of Phthalate Esters, supra note 57 (finding high levels of DEHP in female toddlers exhibiting premature breast development).
63. Id. at 895, 899.
64. Id. at 896, 898.
65. Giuseppe Latini et al., In-Utero Exposure to Di-(2-ethylhexyl)phthalate and Duration of Human Pregnancy, 111 ENVTL. HEALTH PERSP. 1783, 1784 (2003).
66. Susan M. Duty et al., Phthalate Exposure and Human Semen Parameters, 14 EPIDEMIOLOGY 269,
tunately, evidence suggests the typical American man has two to three times the phthalate levels of those who experienced sperm damage in the experiment.67

Furthermore, a study of fetuses exposed to phthalates demonstrated two significant results.68 First, the study demonstrated a strong correlation between phthalates and changes in the anatomy and size of genitalia in male babies.69 Second, the study established that mothers with higher levels of phthalates in their urine who carried male fetuses were more likely to have babies with genital deformities.70

Additionally, Dr. Earl Gray of the U.S. EPA reported that DEHP, BBP, and DINP disrupt sexual development in male rats, resulting in undescended testicles and reduced testosterone production.71 Based upon similarities between previous rat and human studies, it is believed that the health effects present in rats also occur in humans.72

In 2000, the National Toxicology Program (NTP) of the U.S. Department of Health and Human Services reviewed extensive scientific literature on seven of the most controversial phthalates, six of which are identified by Chapter 672 (BBP, DBP, DnOP, DIDP, DINP, and DEHP).73 Although the NTP recommended that additional studies be conducted on the adverse effects of the phthalates, the NTP nonetheless reached a number of preliminary conclusions.74

274 (2003) [hereinafter Duty et al., Phthalate Exposure]. However, another study by the same research group found no significant correlation between deformed sperm or sperm DNA damage and exposure to DBP, BBP, and DEHP. Susan M. Duty et al., The Relationship Between Environmental Exposures to Phthalates and DNA Damage in Human Sperm Using the Neutral Comet Assay, 111 ENVTL. HEALTH PERSP. 1164, 1168 (2003) [hereinafter Duty et al., Relationship Between] (finding a correlation between exposure to diethyl phthalate (DEP) and deformed sperm and sperm DNA damage).

67. Duty et al., Phthalate Exposure, supra note 66. Another study by the same research group discovered that deformed sperm and sperm DNA damage are more likely to be found in men with elevated levels of diethyl phthalate (DEP). Duty et al., Relationship Between, supra note 66.

68. Shanna S. Swan et al., Decrease in Anogenital Distance Among Male Infants with Prenatal Phthalate Exposure, 113 ENVTL. HEALTH PERSP. 1056, 1061 (2005).

69. Id.

70. Id.


72. Id. at 363.

73. Meeting Notice, 65 Fed. Reg. 33,343, 33,344 (May 23, 2000); CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672).

With respect to BBP, an expert panel of the NTP stated that “oral exposure to BBP can cause reproductive toxicity in adult rats and developmental toxicity in rats and mice. These data are assumed to be relevant to humans.” The panel suggested that further studies were needed to establish the lowest doses of BBP that can alter the development of the male reproductive tract.

Similarly, the panel concluded that DBP can lead to developmental toxicity in both rats and mice, and that studies on DnOP evidencing toxicity results in rats and mice provide a “reasonable basis for assuming relevance of these data for judging potential hazard to humans.”

The NTP’s expert panel also concluded that oral exposure to DIDP should be extensively examined in children and pregnant women after toxicology results showed adverse effects on the developing skeletal system in rats following oral exposure to DIDP. The study ultimately found that small children and infants may be exposed to greater levels of DIDP because they “mouth toys and other objects that may contain DIDP which can migrate into saliva and be swallowed.” Likewise, the expert panel stated that while testing on DINP remains inconclusive, “[e]xposure of children to DINP through children’s products is a public concern” since children mouth toys that contain the potentially harmful phthalate.

In October 2005, a second expert panel of the NTP reaffirmed a 2000 finding by the first expert panel that DEHP poses a risk to human development and

75. The Center for the Evaluation of Risks to Human Reproduction (CERHR) impaneled a group of sixteen independent experts to review the evidence on phthalate exposure. Meeting Notice, 65 Fed. Reg. at 33,343-44. The NTP and the National Institute of Environmental Health Sciences (NIEHS) established the CERHR in order to “provide a strictly scientifically-based, uniform assessment of the evidence for reproductive and developmental toxicity of manmade or naturally occurring chemicals or chemical mixtures.” Meeting Notice, 63 Fed. Reg. 68,782, 68,782 (Dec. 14, 1998).

76. EXPERT PANEL REPORT ON BBP, supra note 74, at 31.

77. Id.


81. Id. at 31.

In the NTP’s second review of DEHP in the last five years, the second expert panel concluded that DEHP causes reproductive and developmental damage in animal studies, which the panel deemed relevant to humans, especially infants, children, and pregnant and nursing women. The panel concluded that further testing of children was “critical” because data suggests that infants and toddlers can be exposed to phthalates through the placenta while in utero, through breast milk (either directly or through phthalate-containing breast pumps), and by mouthing products containing phthalates.

2. Studies that Undermine the Ban on Phthalates

In 1998, the CPSC released the results of a comprehensive, five-year study of the health risks posed to children under three years of age by teethers, rattlers, and toys made from polyvinyl chloride (PVC) containing DINP.

The CPSC ultimately found that children were not at risk of liver or other organ toxicity from sucking on PVC toys that contain DINP. The CPSC stated that the amount that children might ingest from teethers, rattlers, and toys was not significant enough to cause organ toxicity.

Yet, the CPSC report stated that significant uncertainties remain with respect to DINP, such as the cancer risk of DINP exposure, and that additional scientific studies were necessary to determine the full effects of DINP. As a precaution, the CPSC requested that manufacturers remove phthalates from soft rattlers and teethers. Additionally, the CPSC requested that manufacturers “find a substitute
for phthalates in other products intended for children under [three] years old that are likely to be mouthed or chewed.\textsuperscript{91}

C. The Debate Over Chapter 672

Critics such as Louis W. Sullivan, former U.S. Secretary of Health and Human Services, contend that Chapter 672 “widely misses the mark on the most fundamental underpinning of all good public health policy—sound science.”\textsuperscript{92} Edward Manning of KP Public Affairs reiterated this sentiment, stating, “The bill seeks to substitute the judgment of objective science by government agencies with political considerations that are not well conceived. The bill bans chemicals not based on risk, but based on fear.”\textsuperscript{93} As evidence for their claims, critics point to the CPSC study, which concluded that plastic toys containing DINP were not harmful to children—a conclusion reinforced by the European Union’s European Chemicals Bureau, the CDC, and various other scientific bodies.\textsuperscript{94} The European Union’s European Chemicals Bureau also found that BBP and DBP do not pose adverse health effects in current consumer applications, such as toys and childcare articles, subsequent to the European Parliament’s legislative ban on the phthalates.\textsuperscript{95}

Further, critics assert that Chapter 672 is ambiguous and leaves much uncertainty for manufacturers.\textsuperscript{96} For example, Chapter 672 requires manufacturers to replace phthalates with the “least toxic alternative,” but no guidance is given as to what “least toxic alternative” means.\textsuperscript{97} In contrast, shortly after the European Parliament enacted its directive, the European Commission published a guidance document that provided examples and exceptions to the directive.\textsuperscript{98} The guidance document granted clarity to manufacturers by giving

\textsuperscript{91} Id.


\textsuperscript{93} Letter from Edward P. Manning, KP Pub. Affairs, to Assembly Member Fiona Ma, Cal. State Assembly (Mar. 23, 2007) (on file with the McGeorge Law Review).

\textsuperscript{94} Sullivan Letter, supra note 92.


\textsuperscript{96} Letter from Corinne Murat, Dir., Gov’t Affairs, Mattel, Inc., to Senator Alex Padilla, Cal. State Senate (July 13, 2007) [hereinafter Murat Letter] (on file with the McGeorge Law Review).

\textsuperscript{97} Cal. Health & Safety Code § 108939(a) (enacted by Chapter 672); Murat Letter, supra note 96.

\textsuperscript{98} European Comm’n, Guidance Document on the Interpretation of the Concept “Which Can be Placed in the Mouth” as Laid Down in the Annex to the 22nd Amendment of Council Directive 76/769/EEC,
examples of toys and childcare articles which can be “placed in the mouth.”\textsuperscript{99} At this time, there is no indication that the Legislature intends to draft a similar document in California.\textsuperscript{100}

Critics also allege that, with the exception of DINP, the phthalates named in Chapter 672 are not widely used in components of child care articles accessible to children.\textsuperscript{101} For example, the phthalate DEHP is commonly used as fire resistant wire insulation that prevents access to circuits in electronic components.\textsuperscript{102} Yet Chapter 672 bans the presence of DEHP in childcare articles and toys despite the fact that the phthalate is used to “enhance the safety of the product and protect children from hazards” and is generally inaccessible within toys and childcare articles.\textsuperscript{103}

Moreover, critics allege that if manufacturers must replace DINP in childcare products with an alternative chemical, it will result in more brittle plastics that could break\textsuperscript{104} and create serious choking hazards. By switching to less durable and untested alternate materials, critics believe that the California Legislature has needlessly abandoned scientifically-tested, safe, and durable plastics.\textsuperscript{105}

California Assembly Member Fiona Ma, author of Chapter 672, answers critics of the bill by stating that “the science is clearly in on phthalates; it has been proven in study after study that the six phthalates listed in Chapter 672 pose great risk to the human body.”\textsuperscript{106} Proponents of the measure point to both the independent and the NTP studies, which show that phthalates likely present serious health risks to children.\textsuperscript{107} Further, Assembly Member Ma pointed out that the number of CPSC employees has been cut in half, to approximately 400, since 1974, demonstrating a lack of priority for toy safety.\textsuperscript{108} Assembly Member Ma stated that the findings of the CPSC cannot be regarded as entirely reliable, considering the CPSC’s budget is not sufficient to support oversight of consumer products, and many in Washington are calling for a large-scale reform of the CPSC.\textsuperscript{109}

\textsuperscript{99} See id. (stating that an article can be placed in the mouth “[i]f an article or part of an article in one dimension is smaller than 5 [centimeters]”).
\textsuperscript{100} Murat Letter, supra note 96.
\textsuperscript{101} Id.
\textsuperscript{102} Id.
\textsuperscript{103} Id.
\textsuperscript{105} Murat Letter, supra note 96.
\textsuperscript{106} Fiona Ma Interview, supra note 55.
\textsuperscript{107} SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 2 (June 29, 2007).
\textsuperscript{108} Fiona Ma Interview, supra note 55.
\textsuperscript{109} Id.
D. Will Federal Law Have the Final Word?

In November of 2006, the Toy Industry Association, Ambassador Toys, the California Chamber of Commerce, and the American Chemistry Council brought suit challenging the San Francisco ordinance that banned phthalates. The suit maintained that the CPSC already reviewed the primary phthalate used in children’s toys, diisononyl phthalate (DINP), and concluded that the phthalate was safe for children. Thus, according to the plaintiffs, the City of San Francisco was precluded from banning DINP under the doctrine of preemption. The lawsuit is still pending, but the outcome is particularly relevant since Chapter 672 also bans DINP in concentrations exceeding 0.1 percent.

Preemption is “the principle (derived from the Supremacy Clause) that a federal law can supersede or supplant any inconsistent state law or regulation.” Both federal statutes and regulations developed by federal agencies pursuant to a valid delegation of authority from Congress can preempt state laws. According to Professor Tribe, however, “the fact that . . . Congress created a regulatory agency . . . is not by itself determinative of the preemption inquiry.” Critical to a preemption test is “[a]n analysis of the reasons why Congress created a particular regulatory agency, or of the policies pursued by that agency.”

The CPSC is a federal agency established and empowered by the Consumer Product Safety Act. Thus, any standards or regulations which it promulgates are considered federal law. The Consumer Product Safety Act was primarily enacted “to develop uniform safety standards for consumer products and to

---

110. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007).
111. Id.
112. Id. The lawsuit was also based on the allegation that the San Francisco ordinance directly conflicted “with the California Hazardous Substances Act, which grants the state, not local jurisdictions, the authority to regulate ‘hazardous substances’ in consumer products such as toys or other articles intended for use by children.” Press Release, Am. Chemistry Council, Lawsuit Asks Court to Overturn Flawed San Francisco Ban on Children’s Products 2 (Oct. 25, 2006) (on file with the McGeorge Law Review). However, this point was rendered moot upon enactment of Chapter 672, which prohibits the same phthalates identified in the San Francisco ordinance. Compare CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (enacted by Chapter 672), with S.F., CAL., HEALTH CODE art. 34, § 34.4 (2007) (both laws prohibit certain uses of the same six phthalates—DEHP, DBP, BBP, DINP, DIDP, and DnOP).
113. SENATE COMMITTEE ON ENVIRONMENTAL QUALITY, COMMITTEE ANALYSIS OF AB 1108, at 4 (June 29, 2007).
114. BLACK’S LAW DICTIONARY 1216 (8th ed. 2004).
116. Id. at 1212.
117. Id. at 1212-13.
119. TRIBE, supra note 115, at 1179 (“Regulations duly promulgated by a federal agency, pursuant to a valid congressional delegation, have the same preemptive effect.”).
minimize conflicting State and local regulations." Section 26(a) of the Consumer Product Safety Act states:

> Whenever a consumer product safety standard under this [Act] is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

Based solely upon section 26(a), Chapter 672 may be preempted by federal law, since Chapter 672 implements different safety standards for a consumer product: children’s toys. However, the CPSC does not have the authority to preempt a state or local law, and preemption can only be raised as a defense to enforcement of a state or local regulation where a concurrent federal regulation is in place. The final decision on any preemption issue thus lies with the courts, not with the CPSC.

Considering the current state of the CPSC, a court may be reluctant to strike down California’s foray into consumer product safety standards. Since July 2006, the CPSC has operated with only two of the three commissioners necessary for a quorum because President Bush and Congress have not been able to agree upon the next commissioner. Congress granted the CPSC a “temporary quorum” to operate in the interim, but that grant expires in February 2008. Unless the temporary quorum is extended, the CPSC can neither approve new regulations nor file suit against businesses that fail to recall hazardous products.

---

122. Compare DINP EXECUTIVE SUMMARY, supra note 86, at 4 (finding no DINP exposure health risks and, therefore, permitting manufacturers to use DINP in their products), with CAL. HEALTH & SAFETY CODE § 108937(a)-(b) (prohibiting manufacturers from using DINP in certain children’s products).
124. Id.
125. Id.
126. See Fiona Ma Interview, supra note 55 (“Since the CPSC refuses to act, the states must step in to fill the void. I cannot foresee the courts looking down upon necessary state action.”); Posting of Matt Madia to REG-WATCH Blog, Politicking Between Democrats and Nord Threatens CPSC, http://www.ombwatch.org/article/blogs/entry/4173/20 (Oct. 30, 2007) (on file with the McGeorge Law Review) (discussing the challenges facing CPSC).
127. Id.
128. Id.
Further, the U.S. Senate refused to pass a House of Representatives bill which would have drastically enlarged the budget of the CPSC and “reform[ed] the nation’s consumer product safety system.”\footnote{129} It thus seems highly unlikely that any major regulatory changes will affect children’s toys sold during 2008.\footnote{130} In addition, the CPSC has lost fifteen percent of its workforce since 2004 and, according to one of its commissioners, is in the midst of a dramatic “downsizing and dismantling,”\footnote{131} which gives the appearance that the CPSC is not meeting its congressional mandate. According to Ed Mierzwinski, the consumer program director for the U.S. PIRG, a federation of state Public Interest Research Groups, “[t]he Consumer Product Safety Commission is a little agency with a big job it simply cannot do.”\footnote{132}

The CPSC has also identified relatively few banned hazardous substances,\footnote{133} especially in comparison to California’s Proposition 65,\footnote{134} and its list of banned toys and articles intended for use by children is paltry.\footnote{135} Rather, the CPSC has generally delineated safety standards for a narrow selection of consumer products, such as matchbooks, bicycle helmets, and swimming pool slides.\footnote{136} Although Congress established the CPSC in order to provide nationwide uniformity for consumer product safety regulations, the actions and policies of the CPSC do not seem extensive enough to promote the best interests of the children of our country. Despite the preemption provision of the Consumer Product Safety Act, Assembly Member Fiona Ma believes that courts will refuse to enforce the provision to override Chapter 672 because “the CPSC has simply failed to act, not only with regard to phthalates, but a host of other hazardous chemicals as well. Since the CPSC refuses to act, the states must step in to fill the void. I cannot foresee the courts looking down upon necessary state action.”\footnote{137}

Due to the CPSC’s current state of flux and its lethargic identification of hazardous chemicals, it is unlikely that a court would find that Chapter 672 is preempted by the Consumer Product Safety Act.

\footnote{129} Id.
\footnote{130} Id.
\footnote{133} Products Requiring Special Labeling Under Section 3(b) of the Act, 16 C.F.R. § 1500.14 (2007); Banned Hazardous Substances, 16 C.F.R. § 1500.17 (2007).
\footnote{134} CHEMICALS, supra note 35.
\footnote{135} Banned Toys and Other Banned Articles Intended for Use by Children, 16 C.F.R. § 1500.18 (2007).
\footnote{137} Fiona Ma Interview, supra note 55.
V. Conclusion

Even after the enactment of Chapter 672, debate rages on regarding the health effects of phthalates.\textsuperscript{138} However, even with this debate, as many as ten other states are expected to introduce similar legislation within the coming months.\textsuperscript{139} Although Congress established the CPSA in order to create a uniform system of consumer product safety regulations, preemption of Chapter 672 could prove detrimental to children’s health.\textsuperscript{140} While Chapter 672 does not guarantee the safety of all children’s toys, it signals responsible action by the Legislature and sets an example for further regulation of children’s toys.\textsuperscript{141} If Chapter 672 survives federal preemption, it will give parents like Jackie Christensen some comfort to know that their children’s Happy Meal toys contain fewer potentially hazardous substances.

\begin{itemize}
  \item \textsuperscript{138} Compare Henry I. Miller, Stop Scaring Us: Feinstein’s Bill to Ban Some Chemicals in Toys Might Help Rats, But it’s Bad for People, L.A. TIMES, Dec. 18, 2007, at A27 (stating that the results of rodent studies should not be blindly analogized to humans, and that rigorous studies in the United States and Europe have shown that “human exposure to phthalates under ordinary circumstances is low and harmless”), with Al Meyerhoff, Dianne Feinstein & James T. Martin, There’s No Defense for Toxic Toys, L.A. TIMES, Dec. 23, 2007, at M2 (pointing out that “[a]nimal testing to predict risks posed to humans by toxic substances is a well-established principle that provides the basis for the nation’s fundamental cancer policy” and asserting that the dangers presented by phthalates are undeniable; each author answered Miller’s piece with their own section).
  \item \textsuperscript{139} Chorneau, supra note 16.
  \item \textsuperscript{140} 15 U.S.C.A. § 2051(b)(3) (West 1998).
  \item \textsuperscript{141} Chorneau, supra note 16; Shin, supra note 127.
\end{itemize}
Chapter 550: Relaxing Consent Requirements for HIV Testing

Colleen Snyder

Code Sections Affected
Health and Safety Code § 120990 (repealed and new), §§ 125090, 125107 (amended).
AB 682 (Berg, Garcia, & Huffman); 2007 STAT. Ch. 550.

I. INTRODUCTION

“According to the World Health Organization . . . , AIDS has killed more than 25 million people worldwide since [the early 1980s], making it one of the most destructive pandemics in history.”1 As of late 2003, an estimated 1.0 to 1.2 million people were living with HIV in the United States;2 of that number, approximately one quarter did not know that they were infected.3 Part of the reason for this lack of knowledge is that many of these people do not fit the stereotype of the AIDS patient—an increasing number are women and heterosexual men; many are minorities.4 The majority of these individuals probably do not realize that they are at risk for HIV.5 Because they do not appear to be at high risk for HIV, their doctors may not think a test is necessary.6

Under prior law in California, healthcare providers had to obtain each patient’s written informed consent before testing for HIV.7 In a busy practice, these requirements made testing every patient unrealistic.8 But an early diagnosis of HIV can add years to a person’s life, and no diagnosis can be made without testing.9 Sadly, an estimated forty percent of HIV cases are still not being diagnosed.10

---

1. ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF AB 682, at 3 (May 1, 2007).
3. Id.
4. See id. at 4 (describing the demographic shifts in persons affected by HIV and the diminished effectiveness of risk-based testing).
5. Id.
6. See AIDS Healthcare Found., AB 682-Routine Testing (Berg, Garcia, Huffman), http://www.aid shealth.org/index.php?option=com_content&task=view&id=143&Itemid=175#ab682 (last visited Dec. 18, 2007) [hereinafter Routine Testing] (on file with the McGeorge Law Review) (suggesting that healthcare providers may not have sufficient information about their patients to know whether a particular patient should be tested and that there is often inadequate time to assess each patient’s risk).
7. ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF AB 682, at 1 (May 1, 2007).
8. See Revised Recommendations, supra note 2, at 4 (“[P]roviders in busy health-care settings often lack the time necessary to conduct risk assessments and might perceive counseling requirements as a barrier to testing . . . .”).
9. See id. at 4 (explaining how “the introduction of highly active antiretroviral therapy (HAART)” in 1995 has improved survival rates and lengthened lives).
diagnosed until much too late—within one year of developing into full-blown AIDS. At such a late stage, patients cannot fully benefit from anti-retroviral therapy. By streamlining consent requirements for HIV testing, Chapter 550 aims to save Californians from these statistics.

II. LEGAL BACKGROUND

A. Prior California Law

Before the enactment of Chapter 550, California Health and Safety Code section 120990 required that healthcare providers obtain a patient’s written, informed consent before testing for HIV. The informed consent standard requires that a healthcare provider ensure that a patient has full knowledge of the risks involved with a medical procedure, such as HIV testing, before electing to be tested. The HIV test, however, was “recognized as different from other blood tests because of the potentially serious psychological risks” involved with a positive diagnosis.

Following this idea, informed consent for HIV testing took the form of pre-test counseling, where the provider informed the patient about the risks of HIV itself and possible treatments for the virus. The purpose of this counseling was to give patients both an idea of the serious repercussions of the test results should he or she test positive for HIV and an understanding about how to prevent transmission. The requirement that a patient’s consent be in writing ensured that no one would be diagnosed as HIV positive without an awareness of the difficulties that would follow.

Similarly, Health and Safety Code section 125107 required prenatal care providers to offer information regarding HIV and the risk of mother-to-child...
transmission to every pregnant patient.\textsuperscript{19} Prior to testing, the law required prenatal providers to specifically inform patients about

the routine nature of the test, the purpose of the testing, the risks and benefits of the test, the risk of perinatal transmission of HIV, that approved treatments are known to decrease the risk of perinatal transmission of HIV, and that the woman has a right to decline this testing.\textsuperscript{20}

Health and Safety Code section 125090 also required the patient’s consent to be in writing.\textsuperscript{21}

AIDS activist groups and many healthcare providers have come to view these strict pre-test requirements of written, informed consent as an unnecessary barrier to testing, diagnosing, and treating people with HIV.\textsuperscript{22} The Centers for Disease Control and Prevention (CDC) estimate that roughly 40,000 Californians are unaware that they are HIV positive.\textsuperscript{23} Not only are these people losing crucial treatment time, but they are “likely to have transmitted HIV unknowingly.”\textsuperscript{24}

\textbf{B. The Centers for Disease Control and Prevention Take Action}

In response to the alarming number of Americans who are unaware of their HIV status, the CDC recently revised its recommendations for routine HIV testing.\textsuperscript{25} The CDC agreed with supporters of Chapter 550 that “time constraints or discomfort with discussing their patients’ risk behaviors caused some providers to perceive requirements for prevention counseling and written informed consent as a barrier.”\textsuperscript{26} The new recommendations urge routine screening for “all patients aged [thirteen to sixty-four] years” using an “opt-out” model of testing.\textsuperscript{27} An “opt-out” model is where healthcare providers will inform patients that they will be tested unless they decline, and consent for the test will be incorporated into patients’ general consent to medical care.\textsuperscript{28} The CDC

---

\textsuperscript{19} \textit{CAL. HEALTH & SAFETY CODE} \textsection 125107(b) (West 2006).
\textsuperscript{20} \textit{Id.} \textsection 125090(d) (West 2006).
\textsuperscript{21} \textit{Id.}
\textsuperscript{22} See \textit{Routine Testing}, \textit{supra} note 6 (“To the extent that informed consent is comparable to pre-test counseling this bill recognizes it is the requirement for informed consent that is the greatest statutory barrier to routine screening.”).
\textsuperscript{23} Email from Joseph Terrill, Pub. Policy Coordinator, AIDS Healthcare Found., to Colleen Snyder, Author (May 22, 2007, 10:07 PST) [hereinafter Terrill Epmail] (on file with the McGeorge Law Review).
\textsuperscript{24} \textit{Revised Recommendations, supra} note 2, at 2.
\textsuperscript{25} \textit{Id.} (estimating that, at the end of 2003, out of roughly one million Americans living with HIV, one quarter were unaware of their HIV positive status).
\textsuperscript{26} \textit{Id.} at 3.
\textsuperscript{27} \textit{Id.} at 7.
\textsuperscript{28} \textit{Id.} at 7-8.
recommends that healthcare providers offer information about HIV and the significance of test results, and give patients the opportunity to decline testing.\textsuperscript{29}

For pregnant women, the CDC also recommends an “opt-out” approach to testing in which prenatal care providers would routinely test pregnant patients as part of their prenatal care.\textsuperscript{30} However, prior to testing, prenatal care providers should offer patients “an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative test results.”\textsuperscript{31} If a pregnant woman is aware of her HIV status, timely medical interventions, such as anti-retroviral drugs, cesarean delivery, and avoidance of breastfeeding, can reduce the risk of mother-to-child transmission to less than two percent.\textsuperscript{32}

\section*{III. Chapter 550}

\subsection*{A. Routine HIV Testing in Most Healthcare Settings}

Less than a year after the publication of the CDC’s revised recommendations, the California Legislature enacted Chapter 550 to reform consent requirements for HIV testing.\textsuperscript{33} The new law eliminates the requirement that the patient’s consent be in writing.\textsuperscript{34} Under Chapter 550, a patient’s general consent to medical care fulfills the consent requirement for HIV testing.\textsuperscript{35} However, the patient maintains the crucial right to decline testing if he or she chooses.\textsuperscript{36}

Although Chapter 550 eliminates the requirement that a healthcare provider obtain informed consent before testing, providers must still give patients some information about HIV before performing the test.\textsuperscript{37} Specifically, Chapter 550 requires the provider to

\begin{itemize}
\item inform the patient that the test is planned, provide information about the test, inform the patient that there are numerous treatment options available for a patient who tests positive for HIV and that a person who
\end{itemize}

\begin{itemize}
\item 29. \textit{Id.}
\item 30. \textit{Id. at 8-9.}
\item 31. \textit{Id. at 9.}
\item 32. \textit{Id. at 4.}
\item 33. \textit{ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF AB 682, at 2 (May 1, 2007).}
\item 34. \textit{CAL. HEALTH & SAFETY CODE § 120990(a) (enacted by Chapter 550). Written consent is still required for “incompetent” persons, such as minors. \textit{Id. § 120990(c) (enacted by Chapter 550).}}
\item 35. \textit{See \textit{Id. § 120990(a) (enacted by Chapter 550) (detailing the information to be disclosed before performing a routine HIV test, and omitting any requirement of specific written consent); Routine Testing, \textit{supra} note 6 (discussing the CDC’s recommendation that Chapter 550 implemented of “[s]implifying testing procedures by not requiring pre-test counseling and a separate written consent for HIV testing incorporating consent into general consent for medical care”).}
\item 36. \textit{CAL. HEALTH & SAFETY CODE § 120990(a) (enacted by Chapter 550).}
\item 37. \textit{Id. (enacted by Chapter 550)}
\end{itemize}
tests negative for HIV should continue to be routinely tested, and advise the patient that he or she has the right to decline the test.\textsuperscript{38}

The Legislature designed Chapter 550 based on this simple consent model to maximize the number of people who are tested for HIV.\textsuperscript{39}

B. HIV Testing for Pregnant Women

Chapter 550 also changes the consent model to an “opt-out” model for routine HIV testing of pregnant women.\textsuperscript{40} This means that prenatal care providers will test every pregnant woman unless she declines testing, thereby eliminating the written consent requirement.\textsuperscript{41}

Because of the added concerns for the baby’s health and the risk of mother-to-child transmission of HIV, Chapter 550 maintains a different version of informed consent for testing pregnant women.\textsuperscript{42} In addition to the required pre-test information regarding “the routine nature of the test [and] the purpose of the testing,” prenatal care providers are also required to inform women of the risks and benefits of testing, the possibility of transmitting HIV during delivery, and existing treatments that could decrease that risk.\textsuperscript{43}

Like prior law, Chapter 550 requires healthcare providers to inform women of HIV test results and, if the tests reveal HIV, refer those women to a specialist in prenatal and post-partum care of HIV-positive women and babies.\textsuperscript{44} Chapter 550 also requires that all prenatal care providers\textsuperscript{45} offer HIV information and counseling about HIV transmission, risk reduction, and referral information when appropriate.\textsuperscript{46}

\begin{itemize}
\item \textsuperscript{38} Id. § 120990(a) (enacted by Chapter 550).
\item \textsuperscript{39} ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF AB 682, at 2-3 (May 1, 2007).
\item \textsuperscript{40} See CAL. HEALTH & SAFETY CODE § 125090(c) (amended by Chapter 550) (“[T]he physician . . . attending the woman . . . shall ensure that the woman is informed of the intent to perform a test for HIV infection . . . and that the woman has a right to decline this testing.”).
\item \textsuperscript{41} Id. (amended by Chapter 550)
\item \textsuperscript{42} See id. (explaining what information is required to be disclosed to pregnant women prior to an HIV test).
\item \textsuperscript{43} See id. (amended by Chapter 550)
\item \textsuperscript{44} Id. § 125090(c) (amended by Chapter 550).
\item \textsuperscript{45} Id. § 125107(a) (amended by Chapter 550) (“For purposes of this section, ‘prenatal care provider’ means a licensed health care professional providing prenatal care within his or her lawful scope of practice.”).
\item \textsuperscript{46} Id. § 125107(b) (amended by Chapter 550).
\end{itemize}
48. Id.
49. Id.
50. Id.
51. Id.
52. See CTRS. FOR DISEASE CONTROL & PREVENTION, REDUCING HIV TRANSMISSION FROM MOTHER-TO-CHILD: AN OPT-OUT APPROACH TO HIV SCREENING (2004), http://www.cdc.gov/HIV/topics/perinatal/resources/factsheets/opt-out.htm (on file with the McGeorge Law Review) (recommending the opt-out approach because it can increase testing, thereby reducing the risk of mother-to-infant transmission of the virus).
53. Id.
54. Id.
55. Revised Recommendations, supra note 2, at 5 (“[W]hen HIV is diagnosed early, appropriately timed interventions . . . can lead to improved health outcomes, including slower clinical progression and reduced mortality.”).
56. Id. at 4.
57. See Gary Marks, Nicole Crepaz & Robert S. Janssen, Estimating Sexual Transmission of HIV from Persons Aware and Unaware That They are Infected with the Virus in the USA, 20 AIDS 1447, 1449 (2006)
in the journal *AIDS* reported that high-risk sexual behaviors dropped by fifty-seven percent among individuals who were aware that they were HIV positive.\textsuperscript{58}

**B. How Much Information Do Patients Need?**

As recommended by the CDC, Chapter 550 only requires healthcare providers to give the general population limited information about HIV and allows patients the opportunity to opt-out before testing for the disease.\textsuperscript{59} This is a departure from the strict requirement of written, informed consent in the statute prior to Chapter 550.\textsuperscript{60} However, Chapter 550 still requires healthcare providers to give more information to pregnant women than the general population.\textsuperscript{61} Studies have shown that more pregnant women agree to be tested when they are educated about the high risk of mother-to-child transmission of HIV and the methods available to reduce that risk.\textsuperscript{62}

Because general consent to medical care replaces informed, written consent in most healthcare settings, providers will no longer have to inform patients about the “legal and social risks and benefits” of the HIV test.\textsuperscript{63} Supporters of Chapter 550, such as the AIDS Healthcare Foundation, believed this change “[makes] for good public health policy.”\textsuperscript{64} As Joseph Terrill, Public Policy Coordinator with the AIDS Healthcare Foundation, explained, “[i]nformed consent for an HIV test has been misapplied . . . . Except in very rare circumstances, [informed consent] is not used as a standard for tests, because there is no inherent [risk] to a test and the benefit is the knowledge that a test result brings.”\textsuperscript{65} Terrill argued that it “is not prudent to expect [healthcare providers] to be sufficiently knowledgeable about” the extensive “legal and social risks and benefits” of an HIV test.\textsuperscript{66}

Opponents of Chapter 550 disagreed: the “significant emotional and legal dimensions to an HIV diagnosis . . . make HIV infection different from many other diseases.”\textsuperscript{67} Requiring providers to obtain patients’ informed, written consent, opponents believed, ensures that patients are aware of these issues

\begin{itemize}
  \item \footnotesize{\textsuperscript{58} Id. at 1448.}
  \item \footnotesize{\textsuperscript{59} Cal. Health & Safety Code § 120990(a) (enacted by Chapter 550).}
  \item \footnotesize{\textsuperscript{60} Id. § 120990 (West 2006).}
  \item \footnotesize{\textsuperscript{61} Id. § 125090(c) (amended by Chapter 550).}
  \item \footnotesize{\textsuperscript{62} Letter from Bebe J. Anderson, HIV Project Dir., & Brian Chase, Staff Attorney, Lambda Legal, to Assembly Member Patty Berg, Cal. State Assembly (Apr. 4, 2007) [hereinafter Anderson Letter] (on file with the McGeorge Law Review).}
  \item \footnotesize{\textsuperscript{63} Terrill Email, supra note 23.}
  \item \footnotesize{\textsuperscript{64} Id.}
  \item \footnotesize{\textsuperscript{65} Id.}
  \item \footnotesize{\textsuperscript{66} Id.}
  \item \footnotesize{\textsuperscript{67} Anderson Letter, supra note 62.}
\end{itemize}
before deciding to be tested for HIV.\textsuperscript{68} Further, opponents argued that information about HIV, particularly information about prevention, is relevant for all patients, even those who test negative for the virus.\textsuperscript{69}

While the importance of this information is undisputed, the AIDS Healthcare Foundation argued that mandatory pre-test counseling lost its “desirability” after becoming the “greatest statutory barrier to routine [HIV testing].”\textsuperscript{70} Chapter 550 does not change post-test counseling requirements for those patients that do test positive for HIV, a group that arguably needs information about the virus the most.\textsuperscript{71}

C. More Testing, More Discrimination?

Opponents of Chapter 550 believed that the relaxed consent requirements keep patients ignorant of the discrimination that inevitably haunts people once they are diagnosed with HIV.\textsuperscript{72} The ACLU and Lambda Legal cite a 2005 study in which “[twenty-six percent] of adults with HIV believed they had experienced discrimination from a health care provider since being diagnosed with HIV.”\textsuperscript{73}

Moreover, this may be an underestimate.\textsuperscript{74} The Williams Institute, a “think tank” on sexual orientation and public policy at UCLA School of Law, found relatively high rates of discrimination against people with HIV in healthcare settings.\textsuperscript{75} Between 2003 and 2005, researchers noted that “[fifty-five percent] of obstetricians, [forty-six percent] of skilled nursing facilities, and [twenty-six percent] of plastic surgeons [in Los Angeles County] had a blanket policy of refusing services to all persons living with HIV . . . in violation of California’s anti-discrimination laws.”\textsuperscript{76} Further, according to U.S. Equal Employment Opportunity data, “[f]rom 2002 to 2006, HIV-related employment discrimination claims were filed at an average rate of about one per day.”\textsuperscript{77}

Opponents of Chapter 550 argued that healthcare providers should inform patients about the likelihood of encountering such discrimination before asking for consent.\textsuperscript{78} Opponents believed that each patient has the right to choose

\textsuperscript{68} Id.
\textsuperscript{69} PRE-TEST COUNSELING, supra note 16, at 3.
\textsuperscript{70} Routine Testing, supra note 6.
\textsuperscript{71} Id.
\textsuperscript{72} See Anderson Letter, supra note 62, at 2 (arguing that pre-test counseling informing patients about the social, emotional and legal consequences of an HIV diagnosis is necessary to ensure that patients understand the implications of HIV test results).
\textsuperscript{73} Id.
\textsuperscript{74} Cf. Letter from Brad Sears, Executive Dir., Williams Inst., to Assembly Health Committee, Cal. State Assembly (Apr. 2, 2007) (on file with the McGeorge Law Review) (noting a study finding relatively high rates of discrimination against people with HIV).
\textsuperscript{75} Id.
\textsuperscript{76} Id.
\textsuperscript{77} Id.
\textsuperscript{78} Anderson Letter, supra note 62.
whether to face these issues, should he or she be diagnosed with HIV.\textsuperscript{79} In its letter of opposition to Chapter 550, the ACLU emphasized that healthcare providers must respect “individuals’ right to privacy and autonomy” in the HIV testing process.\textsuperscript{80} The ACLU argued that eliminating the requirement of written, informed consent jeopardizes these rights.\textsuperscript{81} In support, the ACLU cited the results of one study in which sixteen percent of pregnant women in Arkansas, who had been tested for HIV under an opt-out model “did not [even] know that they had been tested.”\textsuperscript{82}

Supporters of Chapter 550 responded to these statistics by reiterating that under the new law HIV testing is still strictly voluntary and patient consent is still required.\textsuperscript{83} They also emphasized the protection that state and federal anti-discrimination laws afford people living with HIV.\textsuperscript{84} In an apparent effort to reach a compromise, Chapter 550 contains language to clarify the existing force of these protections, as a reminder that discrimination against HIV-positive individuals will not be tolerated.\textsuperscript{85}

\section*{V. Conclusion}

One thing that both proponents and opponents of the new law seem to agree on is the important role that education plays in the fight against HIV.\textsuperscript{86} Although the prior requirement of written, informed consent ensured that everyone tested for HIV was educated about the virus,\textsuperscript{87} supporters argued that this requirement was an obstacle to testing, diagnosis, and treatment of those who tested positive.\textsuperscript{88} Although the new law may increase HIV testing, opponents maintained that this should not be accomplished by sacrificing pre-test education.\textsuperscript{89} In an effort to balance these competing, but perhaps equally

\textsuperscript{79} See Letter from Francisco Lobaco, Legislative Dir., & Valerie Small Navarro, Senior Legislative Advocate, Am. Civil Liberties Union, to Assembly Member Patty Berg, Cal. State Assembly (Apr. 4, 2007) [hereinafter Lobaco Letter] (on file with the McGeorge Law Review) (arguing that patients should have sufficient information about HIV before consenting to testing).
\textsuperscript{80} Id.
\textsuperscript{81} Id.
\textsuperscript{82} Id.
\textsuperscript{83} Routine Testing, supra note 6.
\textsuperscript{84} Id.
\textsuperscript{85} CAL. HEALTH & SAFETY CODE § 120990(c) (enacted by Chapter 550) (requiring informed consent); id. § 120990(f) (enacted by Chapter 550) (prohibiting discrimination); id. § 125090(d) (amended by Chapter 550) (requiring informed consent); id. § 125107(d) (amended by Chapter 550) (prohibiting discrimination).
\textsuperscript{86} See Routine Testing, supra note 6 (“While prevention education is a desirable objective of pre-test counseling, it loses its desirability if it is actually a barrier to screening for HIV.”); see also Pre-Test Counseling, supra note 16, at 4-5 (explaining the important opportunity afforded by pre-test counseling to educate patients about HIV).
\textsuperscript{87} CAL. HEALTH & SAFETY CODE § 120990 (West 2006).
\textsuperscript{88} Routine Testing, supra note 6.
\textsuperscript{89} See Lobaco Letter, supra note 79 (“Expanded testing should be done with specific, informed consent and after patients are provided with information about HIV disease and HIV testing.”).
important interests, the Legislature enacted Chapter 550. It was the Legislature’s hope that the new law would result in earlier diagnoses of HIV—increasing treatment options and decreasing transmission rates—while still delivering a brief education to the public about the perils of this deadly virus.

90. See CAL. HEALTH & SAFETY CODE § 120990(f) (enacted by Chapter 550); id. §§ 125090(g), 125107(d) (amended by Chapter 550) (clarifying that discrimination against HIV infected individuals will not be tolerated).

91. See ASSEMBLY COMMITTEE ON APPROPRIATIONS, COMMITTEE ANALYSIS OF AB 682, at 2-3 (May 1, 2007) (linking the simple consent model to increased testing, with the goal of reducing the mortality rate and changing individual behavior that leads to transmission of the virus).