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AB 159: Can it Really Hurt "to Try"?

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Code Section Affected
Health and Safety Code § 111548 (amended).
AB 159 (Calderon); vetoed.

TABLE OF CONTENTS

I. INTRODUCTION

The modern Right to Try movement can be traced back to Abigail Burroughs and the barriers she faced attempting to obtain an experimental drug in 2001.[1] After Abigail exhausted all available conventional cancer treatments, her oncologist advised that she seek treatment using Erbitux,[2] a then-experimental drug that specifically treated her type of cancer.[3]

Her family initiated a significant media campaign and pressured drug manufacturers, as well as Congress, to give Abigail access to Erbitux.[4] Despite meeting all of the requirements for access to an investigational drug under the FDA's Compassionate Use Exception Doctrine, the FDA denied Abigail's request.[5] Abigail passed away on June 9, 2001 without ever having the opportunity to take Erbitux.[6]

Abigail's father, Frank Burroughs, founded the Abigail Alliance for Better Access to Developmental Drugs in response to the difficulty his daughter faced when seeking access to investigative products.[7] Right to Try supporters have shifted their efforts away from federal courts and directed them toward state legislatures.[8] There are a growing number of states that have passed Right to Try laws to give patients some hope in treating their terminal illnesses, but with AB 159's veto, California does not join their ranks.[9]

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1. Sam Adriance, *Fighting for the "Right to Try" Unapproved Drugs: Law As Persuasion*, 124 YALE L.J. FORUM 148, 150 (Dec. 4, 2014).

2. Letter from Dr. Karen D. Weiss, Dir. of the Office of Drug Evaluation VI, U.S. Food and Drug Admin., to Dr. Lily Lee, ImClone Systems, Inc. (Feb. 12, 2004) (on file with *The University of the Pacific Law Review*) (granting FDA approval to ImClone Systems, Inc.'s drug Erbitux).

3. Frank Burroughs, *Our Story*, ABIGAIL ALLIANCE, http://www.abigail-alliance.org/story.php (last visited July 14, 2015) (on file with *The University of the Pacific Law Review*); *see also* Press Release, Abigail Alliance, Abigail Alliance Supports ACCESS Act (Nov. 10, 2005) (on file with *The University of the Pacific Law Review*) (explaining that Abigail was diagnosed with head and neck cancer).

4. *See* Adriance, *supra* note 1, at 150 (stating that the Right to Try movement can be traced back to Abigail Burroughs).

5. Peter Hart, *Abigail Alliance Case Discussed: Balancing Study Drugs, Safety*, UNIV. OF PITT.: UNIV. TIMES (Feb. 19, 2009), http://www.utimes.pitt.edu/?p=8605 (on file with *The University of the Pacific Law Review*). The criteria that must be met to permit use of any non-FDA approved drug includes: 1) no comparable treatment alternative exists, 2) the drug is currently in clinical trials, and 3) the manufacturer of the investigational drug is seeking formal FDA approval. *Id.* In addition "the FDA is allowed to deny a compassionate-use request if the scientific evidence does not provide a reasonable basis to conclude that the drug may be effective for its intended use or if it would add an unreasonable and significant risk of illness." *Id.*

6. *See* Adriance, *supra* note 1, at 150.

7. Burroughs, *supra* note 3 (describing the backstory of Abigail Alliance).

8. Adriance, *supra* note 1, at 151.

9. *"Right to Try" Legislation Passes Senate Unanimously*, STONE SENTINEL (June 12, 2015), http://district28.cssrc.us/content/stone-sentinel-june-2015#1 (on file with *The University of the Pacific Law Review*).

II. LEGAL BACKGROUND

In California, the use of investigational drugs, biological products, and devices are subject to certain standards set forth by both federal and state law.[10] The applicable federal law is the Food, Drug, and Cosmetic Act (FDCA), while the controlling state laws include the Sherman Food, Drug, and Cosmetic Law (Sherman Law) and the Protection of Human Subjects in Medical Experimentation Act (Protection Act).[11]

A. Federal Law

In 1906, President Theodore Roosevelt signed the first federal drug law in United States history: the Pure Food Drugs Act.[12] The Act prohibited misbranded and adulterated foods, drinks, and drugs in interstate commerce.[13] The convergence of three political forces catapulted the food and drug regulation into Congress' purview.[14] First, female activists organized a decades-long fight to place pressure on Congress to meet the public demands to regulate food and drug production.[15] Secondly, thanks to journalistic pieces like Upton Sinclair's *The Jungle* and Samuel Collins Adams' articles in *Collier's* magazine, concerns regarding "widespread adulteration of ethical drugs as well as . . . food" pressured Congress.[16] Lastly, Harvey Washington Wiley and the Bureau of Chemistry fostered a "multifaceted coalition behind food and drug regulation" that helped garner support in Congress for food and drug regulation in the form of the Pure Food and Drugs Act.[17] The Department

10. *See generally* SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT, COMMITTEE ANALYSIS OF AB 159, at 2–3 (June 19, 2015) [hereinafter Senate BPED] (describing the applicable laws in California regarding investigational products). "Investigational drugs, biological products, and devices" may also be referred to as "experimental product(s)" or "investigational product(s)" throughout this article.

11. *See generally* CAL. HEALTH & SAFETY CODE §§ 109875–110040 (West 2015) (containing the entire code section for the Sherman Food, Drug, and Cosmetic Law); s*ee also id*. at 2 (describing the applicable laws in California regarding investigational products).

12. *See generally* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG. (Jan.–Feb. 2006), http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/CentennialEditionofFDAConsumer/ucm093787.htm (on file with *The University of the Pacific Law Review*) (describing the history of federal drug law in the U.S.).

13. *Id.*

14. Daniel P. Carpenter, *Pure Food and Drug Act (1906)*, ENCYCLOPEDIA.COM (2004), http://www.encyclopedia.com/topic/Food_and_Drug_Act_of_1906.aspx (on file with *The University of the Pacific Law Review*) (describing the history of the Act).

15. *Id.*

16. *See generally id*. (describing the history of the Act). *The Jungle* by Upton Sinclair exposed the unsanitary practices in the Chicago meat-packing industry. *Id.* Samuel Collins Adams' article in *Collier's* magazine discussed patent medicines and advertising fraud. *Id.*

17. *Id.*

of Agriculture's Bureau of Chemistry enforced this Act, which subsequently became the Food and Drug Administration (FDA) in 1930.[18]

1. The Federal Food, Drug, and Cosmetic Act of 1938

On June 25, 1938, President Franklin Delano Roosevelt signed the Federal Food, Drug, and Cosmetic Act (FDCA), which required manufacturers to prove the safety of a drug prior to marketing it to the public.[19] Before marketing, the FDCA required drug manufacturers to submit a drug's safety data to the FDA for evaluation.[20] The FDCA mandated that all drug studies utilize "adequate tests by all methods reasonably applicable to show whether or not the drug is safe."[21]

In 1961, an Australian obstetrician discovered that a widely prescribed drug, thalidomide, was associated with severe birth defects and sometimes death.[22] In Germany, a newspaper reported that 161 babies suffered severe birth defects from their mother's use of thalidomide.[23] Thanks to the processes set forth by the FDCA and FDA inspector Dr. Frances Kelsey,[24] the manufacturer of thalidomide, Merrell,[25] never marketed thalidomide in the

18. *See generally* Meadows, *supra* note 12 (describing the history of federal drug law in the U.S.).

19. *Id.*

20. Suzanne White Junod, *FDA and Clinical Drug Trials; A Short History*, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm (last visited June 22, 2015) (on file with *The University of the Pacific Law Review*) ("A new provision in the act—requiring drug sponsors to submit safety data to FDA officials for evaluation prior to marketing—appeared with relatively little discussion following on the heels of the Elixir Sulfanilamide disaster."); *see also Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm176522.htm (last visited July 7, 2015) (on file with *The University of the Pacific Law Review*) (explaining that the FDA requires drug manufacturers to submit safety data that typically includes, but not is not limited to, the following: chemistry, manufacturing, and control; samples, methods validation package, and labeling; nonclinical pharmacokinetics and bioavailability; microbiology; clinical data; safety update report; statistical; case report tabulations; case report forms; patent information; and patent certification).

21. White Junod, *supra* note 20 ("[T]he law did require that drugs be studied by 'adequate tests by all methods reasonably applicable to show whether or not the drug is safe.'").

22. *Id.* (describing the 1961 thalidomide tragedy); *see also* Bara Fintel et al., *The Thalidomide Tragedy: Lessons for Drug Safety and Regulation*, HELIX MAG. (July 28, 2009), https://helix.northwestern.edu/article/thalidomide-tragedy-lessons-drug-safety-and-regulation (on file with *The University of the Pacific Law Review*) (describing the thalidomide tragedy).

23. Fintel et al., *supra* note 22. A total of 161 German babies were adversely affected by thalidomide, which caused the drug to be banned in Germany, as well as most other countries in which it was previously sold.

24. *Id.* ("Kelsey felt the application for thalidomide contained incomplete and insufficient data on its safety and effectiveness. Among her concerns was the lack of data indicating whether the drug could cross the placenta.").

25. Frances Oldham Kelsey, *Autobiographical Reflections*, FDA, http://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/OralHistories/SelectedOralHistoryTranscripts/UCM406132.pdf (last

U.S.[26] The European disaster and Dr. Kelsey's refusal to approve thalidomide bolstered the importance of the FDCA and helped lead to significant amendments to the FDCA in the form of the Kefauver-Harris Drug Amendments of 1962 (Kefauver-Harris Amendments).[27]

2. Kefauver-Harris Drug Amendments of 1962

The Kefauver-Harris Amendments introduced procedures that improved the control over investigational drugs in the U.S.[28] They required drug manufacturers to provide support that their drugs were both safe and effective prior to marketing.[29]

In addition to satisfying the FDCA requirements, manufacturers must also provide substantial evidence of the product's effectiveness for its intended use before advertising it.[30] The FDCA requires manufacturers to provide "substantial evidence" of the product's effectiveness based on "'adequate and well-controlled studies, i.e. clinical trials."[31]

Clinical trials involve human volunteers who receive specific interventions as prescribed by a research plan or protocol designed by the investigating body.[32] Conducting clinical trials allows investigators "to determine the safety and efficacy of the intervention by measuring certain

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visited Aug. 6, 2015) (on file with *The University of the Pacific Law Review*). Dr. Kelsey described the application review process for thalidomide that was submitted by the drug company Merrell for the German firm that created thalidomide. *Id.*

26. *See* White Junod, *supra* note 20 ("Because of the concerns of FDA drug reviewer Dr. Frances Kelsey, the drug was never approved for sale in the U.S.").

27. *Id.*

28. *Id.* ("The Kefauver-Harris Drug Amendments and the 1963 investigational drug regulations themselves introduced many new procedures that strengthened control over investigational new drugs in the United States.").

29. Fintel et al., *supra* note 22 ("By passing the Kefauver-Harris Drug Amendments Act in 1962, legislators tightened restrictions surrounding the surveillance and approval process for drugs to be sold in the U.S., requiring that manufacturers prove they are both safe and effective before they are marketed. Now, drug approval can take between eight and twelve years, involving animal testing and tightly regulated human clinical trials.").

30. *See generally* Meadows, *supra* note 12 (providing background regarding the trigger that created the Kefauver-Harris Drug Amendments).

31. *See* White Junod, *supra* note 20 (noting this was a revolutionary requirement).

32. *See Learn About Clinical Studies*, U.S. NAT'L INST. OF HEALTH, https://clinicaltrials.gov/ct2/about-studies/learn (last visited July 7, 2015) (on file with *The University of the Pacific Law Review*) (explaining that interventions may include drugs or devices; procedures; or changes to a patient's behavior and defining "clinical trial").

outcomes in the participants."[33] These tested interventions include, but are not limited to, new drugs, devices, and innovative therapies.[34]

Most prominently, the amendments required the FDA to approve the marketing application before the manufacturer could market the drug.[35] Furthermore, the Kefauver-Harris Amendments allowed the Secretary of the U.S. Department of Health and Human Services (HHS) to institute rules of investigation[36] for new drugs and devices and to require manufacturers to obtain informed consent from human subjects.[37]

3. Access to New Investigational Products Outside of Clinical Trials

If a patient is unable to access an investigational product through a clinical trial, he or she may do so under the FDA's expanded access program.[38] In the 1960s, the FDA began to offer patients access to investigational products through the expanded access—also known as compassionate use—program so long as they met specific criteria.[39] By 1987,

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33. *Id*.

34. *Clinical Trials: How They Work; Why Participate*, COLUMBIA UNIV. MED. CTR., http://columbiasurgery.org/clinical-trials/clinical-trials-how-they-work-why-participate (last visited July 10, 2015) [hereinafter *Clinical Trials*] (on file with *The University of the Pacific Law Review*).

35. *See* Meadows, *supra* note 12 (describing the 1962 amendments that mandated the requirement of approval by the FDA of the marketing application of a drug prior to being marketed the public).

36. *Kefauver-Harris Amendments Revolutionized Drug Development*, U.S. FOOD AND DRUG ADMIN. (Oct. 10, 2012), http://www.fda.gov/ForConsumers/ConsumerUpdates/ ucm322856.htm (on file with *The University of the Pacific Law Review*). The 1962 amendments gave the Secretary authority to require manufacturers to prove the effectiveness of drugs pre-marketing and post-marketing the drug, required qualified experts to conduct adequate and well-controlled studies to show the evidence of effectiveness, and that the human subjects gave their informed consent. *Id.*

37. *See* Meadows, *supra* note 12 (providing the Secretary of the HHS the ability to establish rules of investigation of new drugs which includes the requirement to obtain the informed consent of human subjects).

38. *Expanded Access (Compassionate Use)*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm20080392.htm#Investigational_Medical_Devices (last visited July 10, 2015) (on file with *The University of the Pacific Law Review*).

39. Rebecca Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1636 (June 2015) (discussing the history of the expanded use program). Under expanded access, a patient must meet the following criteria to be eligible:

> [1)] the person's physician determines that there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the person's disease or condition, and that the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition; [2)] FDA determines that there is sufficient evidence of the safety and effectiveness of the investigational product to support its use in the particular circumstance; [3)] FDA determines that providing the investigational product will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and [4)] the sponsor (generally the company developing the investigational product for commercial use) or the clinical investigator submits a clinical protocol (a document that describes the treatment plan for the patient) that is consistent with

the compassionate use program expanded to include terminally ill patients who met certain criteria.[40] Specifically, it required that these patients were unable to enroll in clinical trials, had no reasonable treatment alternatives, and had their physician submit an application to the FDA requesting treatment utilizing investigational products.[41]

A drug sponsor or treating physician must submit an application to the FDA explaining the patient's terminal illness and why the use of the investigational product is justified.[42] In addition, the expanded use program requires a patient's informed consent, as well as an Institutional Review Board (IRB) approval.[43] Upon approval by the FDA, the FDA will issue a treatment protocol or an Investigational New Drug (IND).[44] Generally, the FDA only allows access to an investigational product during Phase III clinical trials, or after they are complete.[45]

The FDA may grant an emergency IND absent a written application as long as the physician agrees to submit an expanded access application within fifteen business days of the FDA's initial authorization.[46] The use of an investigational product absent IRB approval is proper if the physician notifies the IRB of the emergency expanded use within five business days of treatment.[47]

The FDA does not require the manufacturer of the investigational product to grant expanded access.[48] Manufacturers may turn down a request for a number of reasons, like if it is unwilling.[49] For instance, the manufacturer may deny an expanded access request if it is unwilling to release an investigational product that has not completed all phases of a clinical trial.[50] When a

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FDA's statute and applicable regulations for INDs or investigational device exemption applications (IDEs), describing the use of the investigational product.

Expanded Access (Compassionate Use), *supra* note 38.

40. Dresser, *supra* note 39 (discussing the history of the expanded use program).

41. *Id.*

42. 21 C.F.R. § 312.1 (West 2015).

43. *Id.* § 312.88.

44. *Id.*

45. *Clinical Trials*, *supra* note 34. Phase III clinical trials involve a large group of people, typically ranging from 1,000 to 3,000 participants, that help validate the effectiveness, monitor side effects compared to other commonly used treatments, and collect other information to improve the safety of a drug or treatment. *Id.*

46. U.S. FOOD AND DRUG ADMIN., INDIVIDUAL PATIENT EXPANDED ACCESS APPLICATIONS: FORM FDA 3926 GUIDANCE FOR INDUSTRY 1, 4 (Feb. 2015) (on file with *The University of the Pacific Law Review*).

47. *Id.*

48. *Expanded Access (Compassionate Use)*, *supra* note 38.

49. *Id.*

50. *Id.*

manufacturer does approve an expanded use request, an eligible patient may only be charged for "the direct costs of making [the] drug available."[51]

B. California Law

The California legislature passed the Sherman Law in 1995, allowing the California Department of Public Health (CDPH) to regulate the packaging, labeling, and advertising of drugs and devices.[52] The California legislature drafted the language of the Sherman Law to mirror that of the FDCA.[53] The Supreme Court of California held in *In re Farm Raised Salmon Cases* that the FDCA could not preempt the Sherman Law because Congress had envisioned that the states would establish their own requirements so long as they were identical to the FDCA.[54]

The Protection of Human Subjects in Medical Experimentation Act (Protection Act) also provides guidelines and protections for human subjects in clinical experimentations.[55] Additionally, California's Health and Safety Code provides procedures to properly conduct independent medical reviews as well as clinical trials involving human subjects.[56]

1. Sherman Food, Drug, and Cosmetic Law

Article 4 of the Sherman Law sets out parameters for the experimental use of drugs.[57] Before a manufacturer may give an experimental drug to an eligible patient, a committee reviews "the [experiment] as a whole, including the consent procedures required" by the CDPH for the protection of human rights.[58]

Additionally, the Sherman Law prohibits the sale, delivery, or giving away of a new drug or device unless: 1) the CDPH has previously approved

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51. U.S. FOOD AND DRUG ADMIN., CHARGING FOR INVESTIGATIONAL DRUGS UNDER AN IND – QS & AS (GUIDANCE FOR INDUSTRY) 1, 6, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM351264.pdf (on file with *The University of the Pacific Law Review*).

52. *See generally* Senate BPED, *supra* note 10, at 1–2 (describing the function of the Office for Human Research Protection).

53. *In re* Farm Raised Salmon Cases, 175 P.3d 1077, 1095 (Cal. 2008).

54. *Id*.

55. CAL. HEALTH & SAFETY CODE §§ 24170–24179.5 (West 2015).

56. *Id.* §§ 1370.4–1370.6.

57. *See generally* Senate BPED, *supra* note 10, at 1–2 (explaining the role and responsibilities of the Office for Human Research Protection).

58. HEALTH & SAFETY § 111540. Committees for the protection of human subjects may review and approve the experiment and the consent procedures so long as they operate under the authority of the federal Department of Health, Education, and Welfare. *Id.*

the new drug or device's applications, and it has not withdrawn, terminated, or suspended that approval; or, 2) the FDA has previously approved the device or drug's application, and likewise it has not withdrawn, terminated, or suspended its approval.[59]

2. California Health and Safety Codes §§ 24170-24179.5

In 1978, the California legislature enacted the Protection Act, which provides protections for human subjects involved in medical experimentation.[60] These protections include a bill of rights; informed consent procedures and documentation; and specified disclosures which include the right of a subject to give or withdraw consent freely and without duress.[61] A court of law will enforce these protections and charge penalties to anyone who violates these protections.[62]

3. California Health and Safety Codes § 1370.4 and § 1370.6

Under California Health and Safety Code (HSC) § 1370.4, every health plan shall provide an external, independent review process to examine the plan's coverage decisions.[63] More specifically, the HSC requires coverage for experimental or investigational therapies for individual enrollees who have a life-threatening or seriously debilitating condition.[64]

Under HSC § 1370.6, every health plan must provide health coverage for all routine patient care costs related to the treatment of an enrollee diagnosed with cancer and who has been accepted in a FDA-approved cancer clinical trial in phases I through IV.[65] Clinical trials are broken up into a total of four phases, with each phase serving a different function.[66] Phase I clinical trials allow researchers to try out a new drug or treatment with a small cohort of

59. *Id.* § 111550.

60. *Id.* § 24170; s*ee also* Senate BPED, *supra* note 10, at 2–3 (describing the applicable California law).

61. HEALTH & SAFETY §§ 24170–24179.5; *see generally* Senate BPED, *supra* note 10, at 1–2 (explaining the types of protections provided by the Protection Act).

62. *See* Senate BPED, *supra* note 10, at 2, ¶ 7 (describing penalties to be imposed by a court that finds a violation).

63. HEALTH & SAFETY § 1370.4.

64. *Id.* Additional requirements required by the California Health and Safety Code include a certification by the physician of the terminal condition; the physician's recommendation of the usage of an investigational product or treatment; the patient's denial of coverage for the investigational product; and the drug, device, or treatment would ordinarily be covered except the plan's determination that is investigational. *Id.*

65. *Id.* § 1370.6.

66. *Clinical Trials*, *supra* note 34.

human subjects to determine its safety, its safe dosage range, and identify any side effects.[67] Phase II continues testing the drug or treatment's effectiveness and safety on a larger group of human subjects.[68] Phase III expands the trial to a vastly larger group, continues monitoring the drug or treatment's effectiveness, compares the drugs or treatment to other common treatments, and collects data to improve the drug or treatment's safety.[69] Lastly, Phase IV involves post-marketing studies to evaluate the drug's risks, benefits, and optimal use.[70] Additionally, the enrollee's treating physician must first conclude that there may be a meaningful benefit before the enrollee may participate in the clinical trial.[71]

C. Federal Judiciary's Interpretation of the Right to Try

In 2003, in an effort to expand the availability of investigational drugs, the Abigail Alliance for Better Access to Developmental Drugs (Alliance) proposed a new regulation to the FDA that would "make investigational drugs available for purchase at the earliest stages of testing."[72] The FDA Associate Commissioner denied the Alliance's proposal.[73] As a result, the Alliance filed a lawsuit against the FDA.[74]

In Alliance's lawsuit against the FDA, it claimed that terminally ill patients had a constitutional due process right to access non-FDA approved drugs.[75] The District Court subsequently dismissed Alliance's complaint for

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67. *Id.* Phase I generally involves twenty to eighty human subjects. *Id.*

68. *Id.* Phase II generally involves 100–300 human subjects. *Id.*

69. *Id.*

70. *Id.*

71. CAL. HEALTH & SAFETY CODE § 1370.6 (West 2015).

72. *See generally* Abigail Alliance for Better Access to Developmental Drugs v. McClellan, 03-1601 (RMU), 2004 WL 3777340, at *1 (D.D.C. Aug. 30, 2004) (showing the first legal battle between Alliance and the FDA regarding access to experimental drugs).

73. Letter from Peter J. Pitts, Assoc, Comm'r for External Relations, U.S. Food and Drug Admin., to Frank Burroughs, Pres., Abigail Alliance for Better Access to Developmental Drugs, (Apr. 25, 2003) (on file with *The University of the Pacific Law Review*) (rejecting the proposal and serving notice that the FDA was not receptive to the idea of allowing the commercial sale of investigative drugs in the early stages of testing).

74. *McClellan*, 2004 WL 3777340, at *6.

> The letter indicated that "several senior FDA officials have now carefully reviewed and considered [the plaintiff's] concept paper and numerous letters" and that officials had "concluded" that the proposal would "upset the appropriate balance [the FDA] is trying to maintain." [Citation.] By rejecting the proposal, the FDA served notice that it was not receptive to the idea of allowing the commercial sale of investigative drugs in the early stages of testing.

Id.

75. *See generally id.* (describing the first legal battle between the Alliance and the FDA regarding access to experimental drugs and the Alliance's argument that there is a fundamental right of access to

failure to state a claim because "[the Court] is bound by the law as it currently exists . . . [Alliance] do[es] not invoke a recognized constitutional right and the challenged FDA policy is rationally related to a legitimate state purpose."[76]

Alliance appealed, and the U.S. Court of Appeals vacated the District Court's holding in October 2005.[77] A divided Court of Appeals determined that "where there are no alternative government-approved treatment options . . . access to potentially life-saving investigational new drugs determined . . . to be sufficiently safe . . . warrants protection under the Due Process Clause."[78]

In 2007, an *en banc* review of the case by the Court of Appeal reversed the panel's decision, holding that terminally ill patients have no fundamental right to access investigational drugs under the Due Process Clause.[79] On January 14, 2008, Alliance filed a petition for certiorari with the Supreme Court, which was denied.[80] Therefore, the *en banc* review of the case by the Court of Appeal's decision stands as today's authority regarding access to investigational drugs.[81]

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experimental drugs by analogizing it to fundamental privacy rights that are recognized by the Supreme Court).

76. *Id.* at *12.

77. *Id.* at *6 (showing the first legal battle between the Alliance and the FDA regarding access to experimental drugs); *see* Abigail Alliance For Better Access to Developmental Drugs and Washington Leg. Found. v. Von Eschenbach, 445 F.3d 470, 486 (D.C. Cir. 2006) *on reh'g en banc sub nom.* Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695 (D.C. Cir. 2007).

> We conclude, upon applying the *Glucksberg* analysis and heeding the protected liberty interests articulated by the Supreme Court, that where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient's informed access to potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials warrants protection under the Due Process Clause. The prerogative asserted by the FDA—to prevent a terminally ill patient from using potentially life-saving medication to which those in Phase II clinical trials have access—thus impinges upon an individual liberty deeply rooted in our Nation's history and tradition of self-preservation.

Id.

78. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 701 (D.C. Cir. 2007).

79. *Id.*; *see also* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF AB 159, at 5–6 (Apr. 7, 2015), [hereinafter Assembly Health Analysis] (describing the holding and procedural history of the case).

80. Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach, 552 U.S. 1159 (2008).

81. *Abigail Alliance*, 495 F.3d 695 (D.C. Cir. 2007); *see also* Assembly Health Analysis, *supra* note 79, at 5–6 (explaining that with the denial of the Alliance's petition for certiorari, the Court of Appeals decision is the latest authority on the topic of the right to access investigational drugs).

D. Nationwide "Right to Try" Movement

In May 2014, Colorado became the first state to pass a Right to Try or "Dallas Buyers' Club" law, allowing terminally ill patients to access investigational products that have passed Phase I of a clinical trial.[82] Since May 2014, twenty-four states, including Arizona, Missouri, Louisiana, Oregon, Illinois, and Michigan, have passed similar laws giving eligible patients the right to try investigational products.[83]

Most, if not all, of the states have based their Right to Try legislation on the model legislation provided by the Goldwater Institute.[84] The Goldwater Institute is a nonprofit organization that developed the Right to Try model bill "to protect the fundamental right of people to try to save their own lives."[85] The model bill notably addresses several issues regarding a patient's use of investigative products.[86]

First, the Goldwater Institute's model bill would only permit eligible patients to access investigational products that have passed manufacturers' Phase I clinical trials.[87] Second, manufacturers would only provide investigational products to eligible patients who have no other available treatments.[88] Third, the manufacturing company has the discretion to decide whether to make the investigational product available to an eligible patient.[89] Fourth, a physician's diagnosis of a terminal disease and declaration that the investigational product is the patient's best alternative is required when

82. Patti Parson, *Colorado First State to Pass 'Right to Try,' or the 'Dallas Buyers' Club' Law*, PBS NEWSHOUR: THE RUNDOWN (May 19, 2014, 2:11 PM), http://www.pbs.org/newshour/ rundown/colorado-first-state-pass-right-try-dallas-buyers-club-law/ (on file with *The University of the Pacific Law Review*); *see also Dallas Buyers Club*, IMDB, http://www.imdb.com/title/tt0790636/synopsis?ref_=ttpl_pl_syn (last visited (July 13, 2015) (on file with *The University of the Pacific Law Review*) (describing a 2013 film that told the story of an AIDS patient who obtained non-FDA approved drugs from Mexico in order to treat his AIDS symptoms).

83. *See* Dresser, *supra* note 39, at 1640 (describing the states' progress in developing Right to Try legislation); s*ee also* Starlee Coleman, *Oregon Becomes 24th State to Allow Terminally Ill to Access Investigational Medications*, GOLDWATER INST., (Aug. 13, 2015) http://goldwaterinstitute.org/ en/work/topics/healthcare/right-to-try/medications/ (on file with *The University of the Pacific Law Review*) (describing the current movement of Right to Try legislation through the states).

84. *See* Parson, *supra* note 82 (explaining that the Goldwater Institute is a "conservative public policy advocacy and research group which has been trying to reduce the FDA's power"); *see also* Dresser, *supra* note 39, at 1640 (explaining the goal behind the Goldwater Institute's model Right to Try bill).

85. Dresser, *supra* note 39.

86. *See* Richard Cauchi, *"Right to Try" Experimental Prescription Drugs State Laws and Legislation for 2014 & 2015*, NAT'L CONF. OF STATE LEGIS. (Mar. 31, 2015) (describing the Right to Try model bill the Goldwater Institute developed).

87. *Id.*

88. *Id.*

89. *Id.*

submitting a patient's request for access to an investigational product.[90] Lastly, the model legislation requires that eligible patients provide a signed informed consent to reduce any legal liabilities of the manufacturers of an investigational product.[91]

III. AB 159

AB 159 would have provided "eligible patients" a last-ditch effort to treat their conditions by using an investigational drug, biological product, or device, also known as an investigational product.[92] AB 159 would have permitted an investigational products manufacturer to have complete discretion in deciding which eligible patients may use its product.[93] The bill would have permitted manufacturers to provide these products to an eligible patient absent any compensation, unless the manufacturer decides to charge the patient for the cost of the products.[94]

In an effort to prevent a complete bypass of the FDA's current processes to access investigational treatments, AB 159 would have provided an explicit criterion when defining an "eligible patient."[95] Specifically, the bill would have changed the definition of an "eligible patient" as one who either has been denied participation in the nearest clinical trial to their home or is unfit to participate in a clinical trial due to his or her current condition and stage of disease.[96] By including this criterion, AB 159 would have limited eligible patients to terminally ill persons who truly have no realistic routes to access

90. *Id.* at 2.

91. *Id.* (describing the Right to Try model bill developed by the Goldwater Institute).

92. AB 159, 2015 Leg., 2015–2016 Sess. (Cal. 2015) (adding CAL. HEALTH & SAFETY CODE § 111548.1(b)). "Eligible patient" means: A person to who meets all the following conditions: (1) Has an immediately life-threatening disease or condition, (2) Has considered all other treatment options currently approved by the United States Food and Drug Administration, (3) Has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease or condition identified in paragraph (1) within one week of completion of the clinical trial application process, or, in the treating physician's medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease, (4) Has received a recommendation from his or her primary physician and a consulting physician for an investigational drug, biological product, or device, (5) Has given written informed consent for the use of the investigational drug, biological product, or device, or, if he or she lacks the capacity to consent, his or her legally authorized representative has given written informed consent on his or her behalf, (6) Has documentation from his or her primary physician and a consulting physician attesting that the patient has met the requirements of this subdivision; *see also* SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF AB 159, at 6 (Aug. 31, 2015), [hereinafter Senate Rules Analysis] (explaining the purpose of AB 159).

93. *Id.* at 2.

94. *Id.* at 4.

95. AB 159, 2015 Leg., 2015–2016 Sess. (Cal. 2015) (adding CAL. HEALTH & SAFETY CODE § 111548.1(b)(2)–(3)).

96. *Id.*

investigational drugs.[97] Additionally, California's Right to Try law would have addressed patient safety concerns regarding the risks of using an investigational product by removing its availability if the investigational product's clinical trial was closed due to "lack of efficacy or for toxicity."[98]

AB 159 would have added a means to proffer a health benefit plan to provide coverage for investigational products but does not require a health benefit plan or any state agency to provide coverage for the cost for any investigational products.[99] Additionally, AB 159 would have provided important legal protections for all parties involved in the recommendation, manufacturing, or administration of the investigational drug, biological product, or device to an eligible patient.[100]

Specifically, AB 159 would have prevented a state regulatory board from "revok[ing], fail[ing] to renew, or tak[ing] any other disciplinary action against a physician's license based solely on the physician's recommendation" regarding the use of an investigational product.[101] Secondly, AB 159 would have precluded any state agency from altering any recommendation made to the federal Centers for Medicare and Medicaid Services (CMS) regarding a health care provider's certification to participate in CMS because of the health care provider's recommendation to access an investigational product.[102] Thirdly, the law would have stated that it "does not create a private cause of action against a manufacturer" of investigational products or "against any person or entity involved in the care of an eligible patient resulting from the investigational products so long as they comply in good faith with the provisions of AB 159 and they exercise reasonable care."[103]

Lastly, this law would have required the physician's institutional review board to report certain data biannually to the CDPH, the Medical Board of

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97. *Id.*

98. *Id.* (adding CAL. HEALTH & SAFETY CODE § 111548.2(d)).

99. "'Health benefit plan' means any plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. 'Health benefit plan' includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345 of this code, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer." *Id.* (adding CAL. HEALTH & SAFETY CODE §111548.1(c); Section 111548.2(c)(2) states the following: This article does not require a health benefit plan to provide coverage for the cost of any investigational drug, biological product, or device, or the costs of services related to the use of an investigational drug, biological product, or device under this article. A health benefit plan may provide coverage for an investigational drug, biological product, or device made available pursuant to this section. *Id.* (adding CAL. HEALTH & SAFETY CODE § 111548.2(c)(2)).

100. *See* Senate Rules Analysis, *supra* note 92, at 5–6 (describing the various legal protections provided by AB 159).

101. AB 159, 2015 Leg., 2015–2016 Sess. (Cal. 2015) (adding CAL. HEALTH & SAFETY CODE § 111548.3(a)).

102. *Id.* § 111548.3(c).

103. *Id.* §§ 111548.3(d), 111548.5.

California (MBC), and the Osteopathic Medical Board of California (OMBC).[104] The entities would have received the following information from a manufacturer: 1) the number of requests made for the investigational product; 2) the status of the requests made; 3) the duration of the investigational treatment; 4) all costs paid by the eligible patient for each investigational product; 5) the success or failure of the investigational product in treating the eligible patient's terminal illness; and 6) any adverse effects from the investigational product.[105]

IV. ANALYSIS

Assembly Member Ian Calderon and his principal co-author Senator Jeff Stone believed the proposed law would have given terminally ill patients the ability to have a second chance at life through the use of non-FDA approved drugs.[106] Senator Stone stated, "medical decisions, especially those of terminal patients, should be made by doctors and patients, not bureaucrats, and this bill ensures that terminal patients have the right to make their own medical decisions."[107] However, critics of the bill indicated AB 159 was premature and would have thwarted the current FDA processes to ensure patient safety and protection.[108]

A. Basis and Benefits of AB 159

AB 159 was part of a nationwide legislative movement driven by fellow state legislatures to allow eligible patients the opportunity to seek out non-FDA approved investigational treatments that may possibly save their lives.[109]

Although Alliance may have created the initial spark, the Goldwater Institute has led the recent surge of Right to Try legislation.[110] Like AB 159, all states' Right to Try bills were mostly based off of the Goldwater Institute's

104. *Id.* at § 111548.3(b)(1)–(6).

105. *Id.*

106. Ian Calderon and Jeff Stone, *Gov. Brown Should Sign AB-159, The "Right to Try" Bill*, FOX AND HOUNDS DAILY (Sept. 25, 2015), http://www.foxandhoundsdaily.com/2015/09/gov-brown-should-sign-ab-159-the-right-to-try-bill/ (on file with *The University of the Pacific Law Review*).

107. SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT, COMMITTEE ANALYSIS OF SB 149 (Apr. 27, 2015), http://www.leginfo.ca.gov/pub/15-16/bill/sen/sb_0101-0150/sb_149_cfa_20150424_143236_sen_comm.html (on file with *The University of the Pacific Law Review*).

108. Jeremy B. White, *'Right to Try' Bills Would Let Dying Californians Use Experimental Drugs*, SACRAMENTO BEE (May 22, 2015), http://www.sacbee.com/news/politics-government/article21718809.html (on file with *The University of the Pacific Law Review*).

109. *Supra* Part II.D.

110. Adriance, *supra* note 1, at 150–51.

model legislation.[111] Advocates of Right to Try legislation characterize it as "a boon to personal liberty and a remedy of bureaucratic failure."[112] An example of this bureaucratic failure is the complexity and time-consuming commitment required to fill out the necessary paperwork to submit a formal request for expanded access.[113] A consequence of such an arduous and time-consuming process is that it often time prevents eligible patients from even having the option to acquire investigational treatment.[114] The Goldwater Institute's model Right to Try legislation bypasses these delays and provides a shortcut to treatment.[115]

If AB 159 had been chaptered, eligible patients who could not afford to wait for a drug to obtain FDA approval or lack the luxury of time to go through the motions of an expanded access request would have had the opportunity to request experimental treatment directly from the manufacturer of the drug.[116] Requests could have only been made for treatments that has passed Phase I of FDA clinical trials.[117]

AB 159 might have also "promote[d] federal policy reform through the FDA or Congress, or [may have] convince[d] federal courts to recognize a Right to Try under the Constitution."[118] Federalists believe that states are "laboratories of democracy," which are ideal platforms to launch federal reforms.[119] With the growing number of states enacting Right to Try laws, federal officials gain insight into how the public has reacted to Right to Try laws and how federal officials should respond.[120] Advocates claim there are two advantages that can occur by initiating a policy movement at the state level.[121] First, it grants access to medication to patients in need while simultaneously introducing a policy that the nationwide population is not yet

111. *Id.* Recent Right to Try bills used the Goldwater Institute's model bill for Right to Try. *Id.*

112. *Id.*

113. Alexander Gaffney, *From 100 Hours to 1: FDA Dramatically Simplifies its Compassionate Use Process*, REGULATORY AFFAIRS PROF'LS SOC'Y (Feb. 4, 2015), http://www.raps.org/Regulatory-Focus/News/2015/02/04/21243/From-100-Hours-to-1-FDA-Dramatically-Simplifies-its-Compassionate-Use-Process/ (on file with *The University of the Pacific Law Review*). The current FDA form requires twenty-six separate types of information and seven attachments. *Id.*

114. *Id.*

115. Cauchi, *supra* note 86 (describing the Right to Try model bill developed by the Goldwater Institute).

116. Senate BPED, *supra* note 10, at 7 (explaining the purpose behind AB 159).

117. *Id.*

118. Adriance, *supra* note 1, at 149 (describing a different function of Right to Try state laws and legislation).

119. *Id.* at 155–57 (describing the State Right to Try's function as a persuasive platform for nationwide reform).

120. *Id.*

121. *Id.*

ready to accept.[122] Second, it provides a way to generate national attention to the policy issue.[123] By drawing attention to the policy, AB 159 helped garner support and increased focus on the political figures backing the movement.[124] Despite the Governor's veto, massive support from legislators and the general public strengthened the credibility of the movement and ultimately helped increase the policy's legitimacy by shining light upon it.[125]

B. Concerns Regarding AB 159

Despite the national movement towards enacting Right to Try laws, opponents and critics[126] of AB 159 raised a series of issues regarding AB 159 that swayed Governor Brown to veto the bill.[127] Concerns ranged from a lack of adequate protections for patient safety, AB 159's prematurity in light of recent developments on the federal level in streamlining the FDA's current expanded access program process, a preemption issue between state law and the FDA's regulations, and uncertainties with how AB 159 will affect future drug research.[128] Governor Brown ultimately vetoed the bill on the grounds that the new streamlined process provided by the FDA should be given "a chance to work" before "authorizing an alternative state pathway."[129]

1. Patient Safety

Critics of AB 159 and other Right to Try laws share a common belief that "instead of adopting access rules that expose more terminally ill patients to harm and disappointment, 'the gate to access experimental treatments must be closed enough to prevent medical interventions that impose excessive

122. *Id.*

123. *Id.*

124. *Id.*

125. *Id.*

126. *Supra* Part II.D; *see also* Senate BPED, *supra* note 10, at 9–10. Opponents of AB 159 included the Association of Northern California Oncologists (ANCO), the California Medical Association (CMA), the California Nurses Association (CNA), and the Pharmaceutical Research and Manufacturers of America (PhRMA). *Id.*

127. *See generally* Senate BPED, *supra* note 10, at 9 (providing a summary of concerns from opponents of AB 159); *see also* Joan Koerber-Walker, *HCR 2005 – "Right to Try" Won't Benefit Patients*, ARIZ. BIOINDUSTRY ASSOC. (Mar. 24, 2014), http://www.azbio.org/hcr2005 (on file with *The University of the Pacific Law Review*) (arguing that the passage of a Right to Try law is ineffective in the face of preemption issues).

128. *Id.*

129. Press Release, Governor Edmund G. Brown Jr., Office of the Governor Veto Message for AB 159 (Oct. 11, 2015), https://www.gov.ca.gov/docs/AB_159_VetoMessage.pdf [hereinafter *Press Release, Veto Message*] (on file with *The University of the Pacific Law Review*).

harm.'"[130] Opponents state that laws like AB 159 undercut the FDA's authority to provide protective regulation in the best interest of pharmaceutical users and ultimately exposes them to unknown dangers due to the limited testing an investigational drug goes through in Phase I clinical trials.[131]

Medical professionals across the country have echoed concerns regarding Right to Try laws like AB 159 with respect to how these types of laws may ultimately cause more harm than good for eligible patients.[132] Dr. Paul Helft,[133] a professor of Medicine at Indiana University School of Medicine has stated:

> [One,] these are mostly coming out of the illusory thinking that meaningful benefit is likely . . . two, these come out of the sense there's nothing to lose, you're going to die anyway. But there are things that you could lose: You might die faster or might spend time getting sick from the side effects of the drug.[134]

The problem stems from the inability to properly inform patients about the risks and benefits of investigational drugs that have only have completed Phase I clinical trials or are still in the midst of completing Phase I.[135] Data regarding the risks and benefits of a drug during Phase I clinical trials is very minimal due to the small number of participants involved at this phase.[136] As such, the threat to patient's safety was a serious concern with AB 159.[137]

Furthermore, some terminally ill patients have a hopeless mentality, and critics of AB 159 feared that the legislation would have provided such patients a way around protections mandated by the FDA.[138] There is a risk that patients with serious illnesses may not fully understand or assess the risks and benefits while deciding whether to take an investigational product.[139] Due to their impaired mentality, concerned citizens have characterized terminally ill

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130. Dresser, *supra* note 39, at 1643.

131. Cauchi, *supra* note 86, at 2 (summarizing critics arguments against Right to Try bills and laws).

132. Shari Rudavsky, *Legislation Would Allow 'Right-to-Try' Trial Drugs*, USA TODAY (Feb. 3, 2015, 6:51 P.M.), http://www.usatoday.com/story/news/nation/2015/02/03/legislation-would-allow-right-to-try-experimental-drugs/22821457/ (on file with *The University of the Pacific Law Review*) (providing statements of supporters and opponents of Right to Try legislation).

133. *Id.* Dr. Helft also is an oncologist and director of the Charles Warren Fairbanks Center for Medical Ethics at IU Health. *Id.*

134. *Id.*

135. *See* Austin Winniford, *Expanding Access to Investigational Drugs for Treatment Use: A Policy Analysis and Legislative Proposal*, 19 HEALTH MATRIX 205, 224 (2009) (explaining the risks associated with providing investigational drugs that have only completed phase I clinical trials).

136. *Id.* at 225.

137. *Id.*

138. *See id.* (providing an explanation behind the problem with dealing with desperate patients and investigational drugs).

139. *Id.*

patients as "the most vulnerable research subject," and therefore, preventing these types of patients from utilizing the loophole around the FDA's regulatory protections that would have been created by AB 159 is necessary.[140] Patients readily see and pursue the slim chance that the drug will provide miraculous recovery, but fail to see the inverse of a truly painful reaction and hastened death from the drug.[141]

2. Was AB 159 Even Necessary?

Opponents of AB 159 proclaimed passing AB 159 would have been premature in light of recent developments at the federal level.[142] In February 2015, the FDA began streamlining patient access to investigational drugs in response to criticism that the process was complex and time-consuming.[143] Previously, the FDA reported that it took nearly 100 hours to fill out twenty-six information fields and seven attachments for the application.[144] The new format is shorter and less complex for physicians to fill out and will only take forty-five minutes to complete.[145] In addition, the FDA has redesigned its website to help patients and physicians have a more user-friendly access to instructions on how to fill out the new expanded access applications.[146]

Due to these recent advances in the expanded access arena, the problems AB 159 aimed to solve were moot.[147] By drastically reducing the amount of time required to fill out a request application, more patients will be able to obtain an answer from the FDA in a more time efficient fashion.[148] The FDA reports it may reply to the majority of expanded access requests, generally within days or hours after a request is submitted.[149] As a result of these recent developments by the FDA, if AB 159 had been chaptered, it may have been

140. *See id.* (explaining the risks associated with providing investigational drugs that have only completed Phase I clinical trials). "The most vulnerable research subject" is a term George Annas, a bioethicist and law professor, uses to characterize terminally ill patients. *Id.*

141. *Id.*

142. Senate BPED, *supra* note 10, at 9 (stating that the passage of AB 159 may be premature due to recent developments on the federal level); *see also* Gaffney, *supra* note 113.

143. Peter Lurie, *A Big Step to Help the Patients Most in Need*, FDAVOICE, *(*Feb. 4, 2015), http://blogs.fda.gov/fdavoice/index.php/2015/02/a-big-step-to-help-the-patients-most-in-need/ (on file with *The University of the Pacific Law Review*) (describing the new streamlined process for expanded access requests).

144. *Id.*

145. *See id.* (describing the benefits of the new streamlined process).

146. *See id.* (describing the new website for patients to use).

147. *See generally* Gaffney, *supra* note 113 (explaining the cause for streamlining the compassionate use process); *see also* ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF AB 159, at 5 (Apr. 21, 2015) (explaining the purpose behind AB 159).

148. Lurie, *supra* note 43 (describing the new streamline process for expanded access requests).

149. *Id.*

too late.[150] This criticism was the basis in Governor Brown's veto of the bill; he stated, "Before authorizing an alternative state pathway, we should give this federal expedited process a chance to work."[151]

Moreover, a drug manufacturer would not have had incentive to accept any patient requests for experimental treatment made under AB 159 because it may have interfered with its overall goal to gain FDA approval of an experimental drug.[152] The production of experimental drugs for use outside of clinical trials is expensive and burdensome.[153]

If AB 159 had gone into effect and a drug manufacturer had accepted patient requests, it would have jeopardized its chances for FDA approval of those experimental treatments due to potentially violating the FDCA.[154] The purpose of obtaining FDA approval for drugs is to allow the drug manufacturers to "recoup their investment and make a profit, because without FDA approval [drug manufacturers] can't sell the drug."[155]

Additionally, manufacturers may still have been at risk of violating the FDCA while acting under the authority of AB 159.[156] To best comply with FDA regulations and improve their chances of FDA approval, manufacturers would still have needed to seek a patient IND through the FDA's expanded use program.[157]

3. Preemption Issue

If AB 159 had been chaptered, its ability to survive a federal preemption challenge would have been doubtful.[158] Federal law already establishes the protocols and procedures that a person must take to access non-FDA approved

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150. *See generally* Senate BPED, *supra* note 10, at 9 (stating that the passage of AB 159 may be premature due to recent developments on the federal level).

151. *Press Release, Veto Message*, *supra* note 129.

152. Dresser, *supra* note 39, at 1646 (explaining why a drug manufacturer may elect not to accept a patient request under a Right to Try law).

153. *See id.* at 1646–47 (explaining why a drug manufacturer may elect not to accept a patient request under a Right to Try law).

154. *See id.* (explaining why a drug manufacturer may elect not to accept a patient request under a Right to Try law and that the FDA may cite a violation of the FDCA for any distribution of an unauthorized investigational drug).

155. David Gorski, *"Right to Try" Laws and* Dallas Buyers' Club: *Great Movie, Terrible for Patients and Terrible Policy*, SCIENCE-BASED MED. (Mar. 8, 2014), http://www.sciencebased medicine.org/right-to-try-laws-and-dallas-buyers-club-great-movie-terrible-public-policy/ (on file with *The University of the Pacific Law Review*) (providing an explanation of why Right to Try laws are terrible policy and bad for patients).

156. *Id.*

157. *Id.*

158. *See* Koerber-Walker, *supra* note 127 (arguing that the passage of a Right to Try law is ineffective in the face of preemption issues).

drugs.[159] AB 159 would have allowed an eligible patient to attempt to bypass the FDA's protocols and procedures, thus creating a contradiction between state law and federal law.[160]

The Supremacy Clause of the U.S. Constitution states that the "Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land."[161] In the past, the Supreme Court held against a finding of presumption for the preemptive authority of the FDA in regards to express and implied field preemption.[162] However, in recent years the Supreme Court has gradually moved to the opposite end of the spectrum and presumed FDA regulation preempts state law.[163]

The FDA's evident ability to regulate and monitor the pharmaceutical marketplace validates the Supreme Court's shift in supporting the FDA's preemptive authority as "the best way to ensure the optimal performance of the FDA."[164] Furthermore, several other federal courts have held that the FDA's "comprehensive regulatory regime governing manufacturing, approval, labeling, and distribution of drug products preempts state laws," and it would follow that the FDA would treat Right to Try laws like AB 159 the same.[165] Although no preemption challenges have been made against a state's Right to Try law, based on the latest decisions by the Supreme Court regarding the FDA's preemptive authority, AB 159 would not have survived a preemption challenge.[166]

Supporters of laws and bills like AB 159 say "they may [still] serve a valuable service in spotlighting the issue."[167] Frank Burroughs, founder of Alliance, agreed with this idea: "[A lawsuit] wouldn't be all bad news because it would further elevate this issue in the public arena and put pressure on

159. *See* Adriance, *supra* note 1 at 152–53 (explaining the difficulties of Right to Try laws in the face of federal preemption).

160. *Id.* at 153.

161. U.S. Const. art. VI. § 2 (describing that when state law and federal law conflict, federal law preempts state law due to the Supremacy Clause of the Constitution).

162. Jennifer A. Suprenant, *Should Preemption Apply in a Pharmaceutical Context? An Analysis of the Preemption Debate and What Regulatory Compliance Statutes Contribute to the Discussion*, 77 FORDHAM L. REV. 327, 329 (2008).

163. *Id.* at 329–30.

164. *Id.* at 342.

165. David Farber et al., *How State Right-To-Try Laws Create False Expectations*, HEALTHAFFAIRSBLOG (May 22, 2015), http://healthaffairs.org/blog/2015/05/22/how-state-right-to-try-laws-create-false-expectations/ (on file with *The University of the Pacific Law Review*).

166. *See* Koerber-Walker, *supra* note 127 (arguing that the passage of a Right to Try law is ineffective in the face of preemption issues).

167. *See* Michael Ollove, *Right-To-Try for the Terminally Ill*, USA TODAY (June 19, 2014), http://www.usatoday.com/story/news/nation/2014/06/19/stateline-fda-terminal-illness-drugs/10836705/ (on file with *The University of the Pacific Law Review*) (describing the potential benefit even if a Right to Try law failed to survive a court challenge).

Congress and the FDA to make this change."[168] Another lawsuit would generate additional momentum for the Right to Try movement, similar to that created by Mr. Burrough's case.[169] Therefore, even if a Right to Try bill does not survive a preemption challenge, the national attention may spark national reform.[170]

4. Hampering Future Drug Research

Right to Try laws, collectively, may hamper future drug research to the detriment of the general populace.[171] AB 159 could have negatively impacted the number of participants for FDA-sponsored clinical trials by allowing patients to bypass clinical trials and regulations enforced by the FDA and obtain the drug directly.[172] A recent article by Professor Tony Yang, a professor at George Mason's College of Health and Human Services, stated: "state laws could hinder future drug development because they threaten the research and approval process."[173]

Professor Yang and his colleagues concluded "it is unlikely that state Right to Try laws will result in improved access to experimental drugs and treatments."[174] Instead, Professor Yang explains that Right to Try laws, like AB 159, will threaten the structure of the research and approval process set forth by the FDA by providing an easier alternative path to experimental drugs; making the FDA's clinical trial process seem more onerous and complex compared to the state alternative.[175] He notes that unlike the compassionate use program, collected data is not required to be reported to the FDA under Right to Try laws.[176] In addition to reducing the number of clinical trial participants, Right to Try legislation may "hinder subsequent FDA

168. *Id.*

169. *Supra* Part II.C.

170. *See* Adriance, *supra* note 1, at 156 (describing the State Right to Try's function as a persuasive platform for nationwide reform).

171. Rudavsky, *supra* note 132 (providing statements of supporters and opponents of Right to Try legislation).

172. *Id.*

173. Michele McDonald, *Mason Researcher: State 'Right to Try' Laws May Do More Harm than Good,* GEORGE MASON UNIV. NEWS (July 20, 2015), http://newsdesk.gmu.edu/2015/07/mason-researcher-state-right-to-try-laws-may-do-more-harm-than-good/ (on file with *The University of the Pacific Law Review*) (summarizing the conclusions of Professor Yang's article on Right to Try legislation).

174. Y. Tony Yang et al., *"Right-to-Try" Legislation: Progress or Peril?*, 33 J. OF CLINICAL ONCOLOGY 1, 2 (2015), *available at* http://jco.ascopubs.org/content/early/2015/07/14/JCO.2015.62. 8057. full.pdf+html (on file with *The University of the Pacific Law Review*).

175. *Id.*

176. *Id.*

approval" for those drug companies that grant access to eligible patients that seek experimental drugs outside of the FDA process.[177]

Drug companies would have likely found themselves at risk of requiring additional resources and money to cope with requests from eligible patients under AB 159 who seek experimental treatment "to conduct individualized trial programs or increased risks of higher rates of reports of adverse effects."[178] Higher rates of adverse events could have resulted from eligible patients who took drugs through AB 159, had it been enacted, compared to other clinical trial patients under the FDA.[179] Since the FDA requires drug companies to report all adverse events that occur during the preapproval phase, drug companies may fear that after accepting a patient's request, that obligations under AB 159 would have "reduce[d] the chance of approval [for that drug], [led] to additional label warnings, or create[d] negative publicity."[180]

These risks could have forced a delay in subsequent FDA approval of experimental treatments.[181] In consideration of these concerns, AB 159 would have imposed a significant barrier in the advancement of future drug research and development.[182]

C. Was AB 159 Still Worth It?

Despite the significant concerns that led to AB 159's downfall, this proposed law and others like it may "[leverage] a facet of American federalism: that state laws can be used to persuade federal actors."[183] The public spotlight on the experimental treatment access issue has already brought a much-needed renovation to the cumbersome and inefficient application and review process of the expanded access program.[184] Through persuasion and influence, federal actors may one day create a federally recognized legal Right to Try that both satisfies FDA safety standards and does not deter drug companies from participating.[185] By enacting laws like AB

177. *Id.*

178. *Id.*

179. Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 N. ENGL. J. MED 279, 281 (Jan. 15, 2015), *available at* http://www.nejm.org/doi/full/10.1056/NEJMhle1409465 (on file with *The University of the Pacific Law Review*).

180. *Id.*

181. Yang et al., *supra* note 174.

182. McDonald, *supra* note 173 (summarizing the conclusions of Professor Yang's article on Right-to-Try legislation).

183. S*upra* Part IV.B; Adriance, *supra* note 1, at 156.

184. *See* Lurie, *supra* note 143 (describing the new streamline process for expanded access requests).

185. *See generally* Adriance, *supra* note 1, at 149 (explaining the possibility of a future recognition of a legal Right to Try through the passage of state Right to Try laws).

159, states may shine light on the issue as well as apply pressure on the federal government and the FDA to make the necessary changes that will benefit all parties in the long-term.[186]

The ball is in the FDA's court to prove to the states and the public that the new streamlined process will remedy the access issues faced by many terminally ill patients.[187] Governor Brown made it clear in his veto message that "we should give this federal expedited process a chance to work."[188] As of early April 2016, it is too soon to tell whether the FDA's revamped process will deliver on its promises to help terminally ill patients access life-saving drugs.[189]

Calderon has already announced that he will "revive the proposal" for the next legislative session in a "challenge to the Governor's [October] veto."[190] Calderon went on to state that, "We were right on the issue. I think the governor was wrong."[191] 2016 proves to be a very important year for Governor Brown and proponents of Right to Try laws.[192] If the FDA falters in providing patients the expedited and streamlined access to experimental drugs, Californian patients and their families will have a strong platform to voice their dismay.[193] In response to a potential failure on the part of the FDA, Governor Brown will be pressured to sign a future Right to Try bill to appease legislators and their supporters.[194] On the other hand, if reports of successful stories by terminally ill patients spread and the new FDA process statistically shows that patients have better access to drugs, then the Right to Try movement may lose significant steam and its credibility may begin to fade.[195]

V. CONCLUSION

The lifespan of AB 159 may have been brief in the face of the Governor's veto, concerns over patient safety, efforts by the FDA to simplify the existing process to access experimental drugs, and low survivability of AB 159 in the face of a preemption challenge.[196] Yet, despite the veto and even if federal law

186. *See id.* (describing a different function of Right to Try state laws and legislation).

187. *Supra* Part II.B-C.

188. *Press Release, Veto Message*, *supra* note 129.

189. *Id.*

190. Melanie Mason, *Lawmaker to Retry 'Right-to-Try' Bill to Let Gravely Ill Access Experimental Drugs*, L.A. TIMES (Jan. 13, 2016), http://www.latimes.com/politics/la-pol-sac-experimental-drugs-bill-20160111-story.html (on file with *The University of the Pacific Law Review*).

191. *Id.*

192. *Supra* Part IV.C.

193. *Supra* Part II.D.

194. *Id.*

195. *Supra* Part IV.

196. *Supra* Part IV; *see also Press Release, Veto Message, supra* note 129.

had preempted AB 159, its presence, collectively with other states' Right to Try laws and bills, has placed the issue on the national stage for public consideration and for federal policymakers to address.[197] The emergence of stories like Abigail Burroughs' emphasizes the personal nature of the issues and strengthens the Right to Try movement.[198]

In light of the veto, the Goldwater institute believes the Governor's veto reasoning "actually bolsters the supporters' cause."[199] By deferring the issue to the FDA and stating that the new process should be given "a chance to work," the Governor's veto provides another example of bureaucratic failure and why a Right to Try law is necessary.[200] This "wait-and-see" approach by the Governor is a serious gamble of the lives of those terminally ill Californians that were looking forward to the enactment of AB 159.[201] If the FDA's new streamlined process proves to be a success then the Right to Try movement will lose some of its momentum and may even lose legislative support in California in the future.[202] If the gamble doesn't pay off and the FDA's streamlined process fails to meet the public's hopes and expectations, then Right to Try supporters, such as Calderon, will obtain a formidable platform to reinvigorate the Right to Try movement here in California to pressure the Governor into signing a Right to Try law for 2017.[203] In the future, AB 159 may be credited as a contributing factor in recognizing a Right to Try investigational drugs in California.[204]

197. *Id.*; Ollove, *supra* note 167.

198. Burroughs, *supra* note 3, s*ee also* Coleman, *supra* note 83.

199. Mason*, supra* note 190.

200. *Id.*; *supra* Part IV.

201. *Supra* Part IV.

202. *Id.*

203. *Id.*

204. *See id.* (explaining the possible future of a legal Right to Try experimental drugs).