

4-1-2018

Banned from the IV League: Advocating the Extension of the Choice of Evils Defense to Protect Blood Manufactures from Liability for Taking Donations from Individuals at "High-risk" of Transmitting Human Immunodeficiency Virus (HIV) During Times of Extreme Emergency

Andrew J. Mertzenich

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Banned from the IV League: Advocating the extension of the choice of evils defense to protect blood manufactures from liability for taking donations from individuals at “high-risk” of transmitting Human Immunodeficiency Virus (HIV) during times of extreme emergency.

ANDREW J. MERTZENICH¹

“The work goes on, the cause endures, the hope still lives, and the dream shall never die.” (Senator Edward M. Kennedy, 1932–2009)

A-positive to O-negative, men who have sex with men face an uphill battle when attempting to give the greatest gift of all, life itself. Current FDA Regulation places a twelve-month deferral on MSM from their last sexual encounter. Many previous articles seek to attack the constitutionality of this ban; others seek to recommend reducing the ban; still others advocate no change. This article differs from these, however, by assuming the constitutionality of the ban and, instead, advocating protection for blood manufacturers who, under certain narrow but extreme circumstances, are justified in taking donations from high-risk donors.

INTRODUCTION	398
I. GENERAL HISTORY AND OVERVIEW OF HIV/AIDS AND BLOOD REGULATION	399

1. J.D. Candidate 2018, Northern Illinois University College of Law. The Author would like to express sincere and profound gratitude to the following people: Professor Robert Jones for help in evaluating and writing on this topic; to Professors Jeanna Hunter, Sandra Kupelian, and Meredith Stange for their helpful training; to all the faculty and staff of the NIU College of Law for their continued support of the Law Review; and, of course, my parents Nancy A. Mertzzenich, M.B.A. and Edmond F. Mertzzenich, D.P.M. for their love and support in both life and scholarship. A final thanks to my cat, Jeffrey, for keeping my laptop warm, even when I wasn't using it.

This Comment is dedicated to all those who died from HIV/AIDS, discovered and researched its treatment, advocated to end societal stigma, and to those who continue to fight for a permanent cure.

A.	General History of the HIV/AIDS epidemic in the United States	399
B.	Historical FDA and Blood Manufacturer Regulations ...	400
C.	Current FDA Regulations regarding Deferral of Donors of Whole Blood Collection and Transfusion	401
i.	Licensing in General.....	402
ii.	Inspections.....	403
iii.	Donor Eligibility.....	403
iv.	Testing of Whole Blood.....	405
v.	Suitability of Donation.....	405
vi.	Donor Deferral, Donor Notification, and Record Keeping	406
D.	Current FDA Recommendations regarding deferral of donors who are at higher risk for HIV	407
II.	CONSEQUENCES TO BLOOD MANUFACTURERS WHO DO NOT FOLLOW FDA REGULATIONS.....	408
A.	Negligence on the part of the Blood Center.....	408
B.	Revocation of a Biologics License by the FDA	413
III.	CURRENT STANDING OF HIV “WINDOW PERIOD” INFECTION, TESTING METHODS, AND TREATMENT.....	414
A.	Window Period Infection.....	414
B.	HIV Treatment & Life Expectancy	416
C.	A Narrowed Focus on HIV Testing Methods	417
IV.	OVERVIEW OF THE COMMON-LAW DEFENSE OF “NECESSITY”	418
A.	General Information.....	418
B.	Elements.....	419
V.	DISCUSSION ON NECESSITY AND BLOOD MANUFACTURERS.....	420
A.	When would a manufacturer need to raise a necessity defense?.....	420
B.	Discussion on Arguments allowing the defense.....	421
i.	Facing the choice of evils and choosing the lesser of them	421
ii.	The Blood Manufacturer Acted to Prevent Imminent Harm	422
iii.	The Blood Manufacturer reasonably anticipated a direct causal relationship between their conduct and the imminent harm averted	423
iv.	The Blood Manufacturer had no legal alternatives to violating the law.	424
VI.	HYPOTHETICAL CASE STUDIES.....	424
A.	A Terrorist Attack.....	425
i.	Facts.....	425
ii.	Analysis.....	426
B.	The Nightclub Shooting.....	427

i.	Facts.....	427
ii.	Analysis.....	428
C.	The Hurricane.....	430
i.	Facts.....	430
ii.	Analysis.....	431
VII.	CONCLUSION.....	432
A.	A Synthesized Rule for Blood Manufacturers wishing to proffer the defense.	432
B.	Recommendations to Blood Manufacturers Asserting the Defense.....	432
i.	Mandatory quick HIV testing for high-risk donors	433
ii.	Labeling the blood in on a first-in, first-out system.....	433
iii.	Seeking an exception from the FDA.....	433
iv.	Destruction or isolation of remaining inventory upon conclusion of the emergency	434
C.	How would Blood Manufacturers be protected?.....	434
D.	A Benefit to All.....	435

INTRODUCTION

In December of 2015, the Food and Drug Administration (hereinafter “FDA”) issued revised recommendations to the blood manufacturing industry, which provide guidance to blood manufacturers to reduce the risk of passing HIV by blood donation and transfusion.² These recommendations lift the lifetime deferral previously bestowed upon men who have sex with men (hereinafter “MSM”), and replaced it with a one-year deferral from last sexual contact.³ Previous legal writings that discuss blood donation will often deliberate, to some extent, the constitutionality of indefinite or partial deferral of donors who are men who have sex with men (hereinafter “MSM”).⁴ For the purposes of this Comment, the constitutionality of these deferrals is assumed.

2. U.S. DEP’T OF HEALTH & HUMAN SERVS. FOOD & DRUG ADMIN., REVISED RECOMMENDATIONS FOR REDUCING THE RISK OF HUMAN IMMUNODEFICIENCY VIRUS TRANSMISSION BY BLOOD AND BLOOD PRODUCTS: GUIDANCE FOR INDUSTRY (2015) [hereinafter REVISED GUIDANCE].

3. *Id.* at 14 (The revised recommendations urge blood manufacturers to “defer for 12 months from the most recent sexual contact, a man who has had sex with another man during the past 12 months”).

4. See, e.g., Vianca Diaz, *A Time for Change: Why the MSM Lifetime Deferral Policy Should Be Amended*, 13 U. MD. L. J. RACE, RELIGION, GENDER & CLASS 134, 146-52 (2013); Christopher McAdam & Logan Parker, *An Antiquated Perspective: Lifetime Ban for*

Using this information, this Comment advocates that the Common-Law affirmative defense of *Necessity* should extend to blood manufacturers (or blood banks) that, when observing standards—which are different from those recommended by the FDA but are proven safe and effective—collect blood for transfusion and manufacture of blood products during a state of prolonged and severe emergency. This Comment also gives a brief overview of the affirmative defense of *Necessity* and some of the questions regarding the defense as applied to federal administrative law.⁵ On that note, for purposes of this Comment, it is also assumed that the defense of *Necessity* is an available defense for violations of federal administrative law.

In this context, Part I provides a brief historical overview of regulations affecting HIV and blood donations. The next Part looks at the consequences that blood manufacturers may face for negligent conduct or violation of FDA regulations. Part III takes an in-depth look at the current medical situation facing HIV and HIV testing. The following Part gives a broad overview of the defense of *Necessity*. Part V discusses the implications of the information given in previous Parts, and Part VI will apply this information and analysis to hypothetical fact patterns. Finally, Part VII gives a summary and conclusion.

I. GENERAL HISTORY AND OVERVIEW OF HIV/AIDS AND BLOOD REGULATION

A. *General History of the HIV/AIDS epidemic in the United States*

Acquired Immune Deficiency Syndrome (AIDS) was first identified in the gay communities of the east coast in 1981.⁶ However, it was not until 1987 that the United States government finally acknowledged the scope of the AIDS epidemic.⁷ What caused this sudden change of heart on the part of an administration that had, until then, denied

MSM Blood Donations No Longer Global Norm, 16 DEPAUL J. HEALTH CARE L. 21, 52-59 (2014).

5. See *infra* Part 0.

6. VICTORIA A. HARDEN, AIDS AT 30: A HISTORY 20 (Potomac Books, 1st ed. 2012).

7. See RANDY SHILTS, AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC 589-90 (St. Martin's Press, 20th Anniversary ed. 2007).

funding, research, and compassion for those stricken with the disease?⁸ The metaphorical straw that broke the camel's back and made AIDS a priority for anyone outside of the affected community occurred when the disease took the life of someone the world "actually" cared about, that of Rock Hudson.⁹ Prior to the announcement, the tragedies of the AIDS Epidemic crossed racial and social barriers, and caused families and the community—even attending doctors and nurses—to abandon their gay sons for fear of stigma, disease, or public ridicule.¹⁰ The cries of the victims and the tragedy of the epidemic were finally heard by Congress and the administration; and President Ronald Reagan, in May of 1987, finally addressed the nation on the AIDS epidemic.¹¹ Nonetheless, by the time President Reagan gave his first speech acknowledging the disease, over 30,000 Americans were diagnosed with the disease and nearly 20,000 had died.¹²

B. Historical FDA and Blood Manufacturer Regulations

In 1983, because the cause of AIDS was unknown¹³ and the epidemic had grown to monumental proportions, the Centers for Disease Control, National Institutes of Health, and the FDA called for donor disqualification of *high-risk* groups and urged members of these

8. *Id.* at 35 (In its efforts to curb government "[as] the problem" of American society, the Reagan Administration sought to quickly downsize the executive agencies of the United States, including the National Institutes of Health, the Centers for Disease Control, and other health agencies).

9. *Id.* at xxi ("[S]uddenly . . . when a movie star was diagnosed with the disease and the newspapers couldn't stop talking about it, the AIDS epidemic became palpable and the threat loomed everywhere."); *Id.* at 582 (The AIDS epidemic had "embarrassed" people, government, and communities. By announcing that a celebrity had the disease, the process of allowing the nation to face the epidemic, rather than to hide from it, could begin). *See also* HARDEN, *supra* note 6 at 167.

10. David Koon, *Keeping the Flame*, OUT, June-July 2016, at 63.

11. SHILTS, *supra* note 7, at 589-90 ("Reagan announced he would accede to the Senate's wishes and appoint a . . . commission to advise [the president] on the epidemic. . .").

12. SHILTS, *supra* note 7, at 596.

13. The latent incubation period between initial infection and development of AIDS lasts between three and ten years. Christopher D. Pilcher, Joseph J. Eron, Jr., Shannon Galvin, Cynthia Gay & Myron S. Cohen, *Acute HIV Revisited: New Opportunities for Treatment and Prevention*, 113 J. CLINICAL INVESTIGATION 937 (2004). Prior to the development of blood testing methods that could quickly and reliably detect HIV infection, there was no way to spot a person who was HIV-positive until the individual developed symptoms of AIDS. *See generally supra* Part 0.

groups not to donate blood.¹⁴ From September of 1985 onward, blood manufacturers have deferred all MSM donors.¹⁵

The year 1992 saw the release of the, appropriately named, “1992 blood memo,” which expanded donor deferral to include commercial sex workers, individuals who inject illicit drugs, and individuals with other risk factors.¹⁶ The FDA periodically reviews donor deferral policy and changed these policies most recently in December of 2015.¹⁷

C. Current FDA Regulations regarding Deferral of Donors of Whole Blood Collection and Transfusion

Through regulation, the FDA has mandated and implemented a “multi-layered” protection system designed to protect the blood supply.¹⁸ These layers are: (1) donor screening, (2) blood testing, (3) donor deferral, (4) quarantine, (5) problem and deficiency investigation.¹⁹

Donor screening is when donors are informed of the potential risks of donations and answer questions that may have a bearing on the safety of blood taken from the individual donor.²⁰ Blood testing is when, after donation, each blood unit must undergo testing for communicable diseases, including HIV.²¹ In the quarantine layer, donated blood is separated from other blood until it tests negative for infectious agents.²² The final layer in the system is that blood centers must maintain good practice and notify the FDA when product deviations occur

14. HARDEN, *supra* note 6, at 86-88 (Blood manufacturers began to implement the deferrals, issuing voluntary disqualification forms noting that, at the time, “the medical community ha[d] noted the occurrence of a very serious disease known as . . . (AIDS),” until the cause of the disease could be ascertained, people in certain groups should not donate blood).

15. REVISED GUIDANCE, *supra* note 2, at 2 (This deferral constituted a lifetime ban, even if the potential donor had only a single sexual partner or MSM sexual experience after 1977).

16. REVISED GUIDANCE, *supra* note 2, at 2.

17. REVISED GUIDANCE, *supra* note 2, at 3.

18. *Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood*, U.S. FOOD & DRUG ADMIN. (June 11, 2015), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/BloodSafety/ucm095522.htm> [<https://perma.cc/KW3A-VWN5>].

19. *Id.*

20. *Id.*

21. *Id.* (While *requiring* testing for Hepatitis, HIV, Human T-Lymphotropic Virus, and Syphilis the FDA also *recommends* testing for West Nile Virus and Chagas disease).

22. *Id.*

in distributed products.²³ If any of the layers are breached, the blood collected during the deficiency is subject to mandatory recall.²⁴

i. Licensing in General

The FDA regulates licensing of facilities seeking to manufacture blood and blood products.²⁵ The process of obtaining a biologics license begins with an application on the part of the entity seeking to produce biologics.²⁶ The FDA makes a determination on whether to issue a biologics license based on several factors.²⁷ These include examining the product and ensuring that it complies with standards set forth by regulation;²⁸ inspecting the manufacturing process; seeking assurance of the continued safety, purity, and potency of the manufactured product, as well as the establishment(s) listed in the license application; and ensuring that the facility itself meets the standards established in applicable regulations.²⁹ Should the application be in good order and the inspections return satisfactory results, the FDA will then issue the biologics license.³⁰ The approval of a biologics license application and issuance of a biologics license constitute a determination that the establishment(s) and product meet applicable standards for continued safety, purity, and potency of the product.³¹ When approved, a biologics license is valid until suspended or revoked.³² However, if there is a determination that the establishment or product does not meet applicable standards, then the application for license will be denied.³³

23. *Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood*, U.S. FOOD & DRUG ADMIN. (June 11, 2015), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/BloodSafety/ucm095522.htm> [<https://perma.cc/KW3A-VWN5>].

24. *Id.*

25. FDA Biologics Licensing, 21 C.F.R. § 601.22 (2016).

26. Applications for Biologics Licenses; Procedures for Filing, 21 C.F.R. § 601.2 (2016).

27. Biologics Licenses; Issuance and Conditions, 21 C.F.R. § 601.20 (2016).

28. In the case of whole blood manufacturing, the relevant sections of the Code of Federal Regulations are 21 C.F.R. §§ 640.1–640.6 (2016).

29. The standards that establishments must comply with are found in 21 C.F.R. §§ 600.10–600.15 (2016).

30. Issuance and Denial of License, 21 C.F.R. § 601.4(a) (2016).

31. Applications for Biologics Licenses; Procedures for Filing, 21 C.F.R. § 601.2(d) (2016).

32. 21 C.F.R. § 601.4(a) (2016).

33. 21 C.F.R. § 601.4(b) (2016).

ii. *Inspections*

Following approval of the license application, an establishment and all affiliated locations must be inspected at least once every two years.³⁴ These inspections may be made at any time during normal business hours (unless otherwise directed), with or without notice.³⁵ During an inspection, an inspector³⁶ calls the active head of the establishment and states the objective of the visit.³⁷ The inspector then gathers information about the establishment, the manufacturing process, and the product.³⁸ They do this by interrogating personnel; examining the various manufacturing and storage facilities; investigating and observing procedures for testing, storing, dispensing, recording; and looking at other details of manufacture.³⁹ Throughout this process, the inspector will direct the attention of the manufacturer to any fault observed during the inspection.⁴⁰ The inspector also inspects and copies any records required to be kept by the manufacturer under 21 C.F.R. § 600.12.⁴¹

iii. *Donor Eligibility*

To be eligible to donate, a person must “be in good health and free from transfusion-transmitted infections as can be determined. . . .”⁴² A determination as to whether a donor is eligible to donate is made on the day of the donation and (with a few exceptions) before collection.⁴³ Therefore, the donor and the establishment must work together to ensure the safety of the blood supply;⁴⁴ this includes the establishment

34. Time of Inspection, 21 C.F.R. § 600.21 (2016).

35. *Id.*

36. *See* Inspectors, 21 C.F.R. § 600.20 (2016).

37. Duties of Inspectors, 21 C.F.R. § 600.22 (2016).

38. *See id.*

39. *Id.*

40. *Id.*

41. *Id.* Records that establishments are required to keep include detailed records (made concurrently with performance of each step of the manufacturing and distribution of products) identifying the person immediately responsible for the particular step in the process and dates of the various steps. Furthermore, the establishment must keep records of the sterilization of equipment and supplies as well as records of recall of biologic products. Records, 21 C.F.R. § 600.12. (2016).

42. General Donor Eligibility Requirements, 21 C.F.R. § 630.10 (2016).

43. *Id.* at (c).

44. *See id.*

providing educational materials—in a manner designed to be understood by the donor—concerning transfusion-related infections (*e.g.* HIV).⁴⁵

To determine if a donor is eligible to donate, an establishment must:

- (1) Consult the record of deferred donors prior to donation or prior to the release of the blood or blood component;⁴⁶
- (2) Assure that the interval since the donor's last donation is appropriate;
- (3) Assess the donor's medical history; and
- (4) Perform a physical assessment⁴⁷ of the donor.⁴⁸

To assess the donor's medical history, an establishment must conduct a medical history interview.⁴⁹ The interview seeks to identify factors demonstrating that the donor was or may have been exposed to transfusion-related infections.⁵⁰ These risks include institutionalization for seventy-two or more consecutive hours within the past year in a correctional institution or intimate contact with risk of a relevant transfusion-transmitted infection (including MSM activities) among others.⁵¹ The establishment must also ascertain if the donor shows signs of recent or current illness, is currently under certain medical treatment or taking certain medications, has traveled to or resided in a high-risk area, was pregnant at the time of or within six weeks prior to the donation, is under the influence of drugs and/or alcohol, or is the recipient of a transplant organ.⁵² Upon passing these examinations and interviews, a donor is considered eligible to donate;⁵³ if not, the establishment cannot collect blood or blood components from the donor.⁵⁴

45. *Id.* at (b).

46. The record should only be consulted after a donation is received but prior to releasing the blood or blood component if it is not feasible for the establishment to check the cumulative record of deferred donors because those records are not kept at the collection site. *Id.* at (d)(1).

47. The physical assessment of the donor entails determining several factors including: (1) body temperature, (2) blood pressure, (3) hemoglobin or hematocrit levels, and (4) weight of the donor. 21 C.F.R. § 630.10 at (f).

48. 21 C.F.R. § 630.10.

49. *Id.*

50. *Id.* at (e)(1).

51. *See id.* at (e)(1)(i)-(e)(1)(vi).

52. *Id.* at (2)(i)-(vii).

53. *See* 21 C.F.R. § 630.10(h).

54. *Id.*

In addition, if the interviewer determines that the donor has not provided reliable answers to medical history questions or states that the purpose of the donation is to obtain results for a relevant transfusion-transmitted infection, then the donor is ineligible to donate.⁵⁵

iv. *Testing of Whole Blood*

Generally, the FDA requires a laboratory test to determine blood group, Rh factors, and sterility of a specimen of blood taken from each donor.⁵⁶ The blood must also be visually inspected for any indication of contamination.⁵⁷ Specifically, the administration requires that establishments defer donors testing reactive for certain transfusion-related infections from future donations of human blood and blood components.⁵⁸ As such, the FDA has implemented certain testing requirements in order to protect the blood supply.⁵⁹ Each donation must be tested for evidence of infection for relevant transfusion-related infections⁶⁰ using one or more screening tests already approved by the FDA and administered in accordance with the producer's instructions.⁶¹ The relevant infections that establishments must test for include: HIV, Hepatitis B virus (hereinafter "HBV"), Hepatitis C virus (hereinafter "HCV"), Human T-lymphotropic virus (hereinafter "HTLV"), Syphilis, West Nile Virus, and Chagas disease.^{62,63}

v. *Suitability of Donation*

A donation is considered suitable when the donor is not currently deferred from donation, is in good health, and is free from risk factors

55. *See id.*

56. Testing the Blood, 21 C.F.R. § 640.5 (2018).

57. *Id.*

58. Donor Deferral, 21 C.F.R. § 610.41 (2018) Relevant infections required under this section are found in 21 C.F.R. § 610.40 (2018). Certain exceptions apply. *See, id.*

59. Test Requirements, 21 C.F.R. § 610.40 (2018).

60. *Id.* at (a)(1).

61. *Id.* at (b).

62. *Id.* at (a)(1)-(a)(2).

63. This is the beginning of a slight divergence in mandatory testing requirements. *See* 21 C.F.R. § 610.40(a) (2018). Whereas the collection of whole blood requires testing for all the infections previously listed, *id.* at (a)(1)-(a)(2), the collection of source plasma (defined as "the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use [as opposed to for transfusion].") Source Plasma, 21 C.F.R. § 640.60 (2018). Source plasma does not require testing for HTLV, West Nile Virus, and Chagas disease. 21 C.F.R. § 610.40(2)(ii) (2018).

for relevant transfusion-transmitted infections.⁶⁴ Moreover, the procedures used to collect the blood must ensure that the donor's health will not be adversely affected.⁶⁵ A final requirement is that the blood be subjected to and pass required testing.⁶⁶

If a donation is considered not suitable, there are certain actions that a manufacturer must take.⁶⁷ The donation cannot be released for transfusion or be used in further manufacturing, and the donor must be deferred (if not already) and notified of the deferral.⁶⁸

vi. Donor Deferral, Donor Notification, and Record Keeping

Manufacturers are required to conduct medical history interviews of each donor, wherein the objective is to gather information as to whether the donor may have been exposed to transfusion-transmitted infections.⁶⁹ Among other information, the establishment looks for evidence and information of:

- (1) Behaviors associated with a relevant transfusion-transmitted infection;
- (2) Signs and symptoms of a relevant transfusion-transmitted infection; and
- (3) Intimate contact with risk for a relevant transfusion-transmitted infection.⁷⁰

It is the third point in this list that gives rise to the historical lifetime—now twelve month—deferral of sexually active gay men donating blood.⁷¹

In addition to deferring donors based upon questioning and physical examinations, manufacturers that collect blood must also defer donors who test reactive for evidence of certain infections (namely, HIV, HBV, and HCV) from future donations.⁷² Establishments must take

64. Donation Suitability Requirements, 21 C.F.R. § 630.30(a)(1)-(a)(5) (2018).

65. *Id.*

66. *Id.*

67. *Id.* at (b).

68. *Id.* Requirements for notification of deferred donors are found in 21 C.F.R. § 630.40. 21 C.F.R. § 630.40(b)(4) (2018).

69. General Donor Eligibility Requirements, 21 C.F.R. § 630.10(e) (2018).

70. *Id.* at (e)(1).

71. *See id.*

72. *See Donor Deferral*, 21 C.F.R. § 610.41 (2018) (The list of transfusion-related infections that establishments are required to defer are found at 21 C.F.R. § 610.40(a)).

reasonable efforts to notify donors of deferral status who, after a test for transfusion-transmitted diseases, are positive or who are deferred because the donor is deemed ineligible to donate based upon the eligibility criteria in 21 C.F.R. §§ 630.10 and 630.15.⁷³

Blood manufacturers are also required to keep records of deferred donors at all locations operating under a license.⁷⁴ The reason that these records are important is because if a donation tests positive for HIV, “within 3 calendar days after [a donation, . . . an establishment] must review all records required . . . to identify blood and blood components previously donated by [the] donor.”⁷⁵ After identifying any blood and blood component(s) given by the donor within the last twelve months, these products are then quarantined and the establishment must notify any recipients/consignees to quarantine any identified samples.⁷⁶

D. Current FDA Recommendations regarding deferral of donors who are at higher risk for HIV⁷⁷

The FDA published guidance for blood and blood product manufacturers in December of 2015.⁷⁸ This guidance mirrors many of the provisions and regulations set forth by the FDA regarding deferral of donors who may exhibit increased risk for HIV.⁷⁹

The administration continues to recommend an indefinite deferral for individuals who are commercial sex workers and current or potential non-prescription injection drug users.⁸⁰ However, the new recommendations extensively discuss the MSM lifetime deferral,⁸¹ and ultimately, recommend doing away with the lifetime deferral of MSM donors and reducing the deferral period to twelve months.⁸² The FDA

73. Requirements for Notifying Deferred Donors, 21 C.F.R. § 630.40 (2018).

74. Records, 21 C.F.R. § 606.160(e) (2018).

75. Human Immunodeficiency Virus (HIV) "Lookback" Requirements, 21 C.F.R. § 610.46 (2018).

76. *Id.*

77. REVISED GUIDANCE, *supra* note 2.

78. *Id.*

79. Compare REVISED GUIDANCE, *supra* note 2 with 21 C.F.R. § 610.41 (2018).

80. REVISED GUIDANCE, *supra* note 2 (“Recent data indicate that commercial sex work (CSW) and injection drug use (IDU) are behaviors that continue to place individuals both at a relatively high risk of HIV infection and at a relatively high risk of window period transmission of HIV and few data are available on the HIV risk in individuals who have discontinued CSW and IDU.”) (citations omitted).

81. *Id.* at 4-10.

82. *Id.* at 14.

recommended the change specifically regarding MSM for several reasons.⁸³ Notwithstanding, the final recommendations are that blood centers:

- (1) Defer indefinitely an individual who has ever had a positive test for HIV;⁸⁴
- (2) Defer indefinitely an individual who has ever exchanged sex for money or drugs;⁸⁵
- (3) Defer indefinitely an individual who has ever engaged in non-prescription injection drug use;⁸⁶
- (4) Defer for twelve months from the most recent sexual contact any individual who has a history of sex with a person who: has ever had a positive test for HIV, ever exchanged sex for money or drugs, or ever engaged in nonprescription injection drug use;⁸⁷ and
- (5) Defer for twelve months from the most recent sexual contact, a man who has had sex with another man during the past twelve months.⁸⁸

II. CONSEQUENCES TO BLOOD MANUFACTURERS WHO DO NOT FOLLOW FDA REGULATIONS

Blood centers potentially face several consequences if they depart from professional regulation and practice. These include the potential to be found liable for negligence if a plaintiff is harmed, revocation of the blood center's license to operate by the FDA, or both.

A. *Negligence on the part of the Blood Center*

In an ordinary negligence case, "[l]egal duty is defined in terms of a standard of care."⁸⁹ That is, the defendant has a duty to exercise

83. *Id.* at 4-7 (These reasons include, for example, the fact that the highest rate of new HIV infections occurs in the MSM community and there is a risk of window-period infection).

84. *Id.* at 14.

85. REVISED GUIDANCE, *supra* note 2, at 14.

86. *Id.*

87. *Id.*

88. *Id.* at 15.

89. *United Blood Servs. v. Quintana*, 827 P.2d 509, 519 (Colo. 1992).

some degree of care to ensure the plaintiff's safety.⁹⁰ Ordinarily, "an actor is required to conform his or her conduct to a standard of objective behavior measured by what a reasonable person of ordinary prudence would or would not do under the same or similar circumstances."⁹¹ However, for those practicing in a profession that involves specialized knowledge or skill, reasonable care requires the actor to behave in a manner consistent with the knowledge and ability possessed by members of the profession in good standing.⁹² Blood manufacturers, for legal purposes in many jurisdictions, are considered to be health-care professionals;⁹³ as such, they are subject to a professional standard of care.⁹⁴

The second point of analysis that the plaintiff must plead and prove is that the defendant breached the duty owed to a plaintiff in light of the defendant's unreasonably risky conduct.⁹⁵ In order to understand how this analysis works when dealing specifically with blood manufacturers, an analysis of applicable case law may be helpful.⁹⁶

90. DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, *THE LAW OF TORTS* § 124 (2d ed. 2016).

91. *Quintana*, 827 P.2d at 519 (citation omitted).

92. *See id.*

93. *See, e.g.,* Valdiviez v. United States, 884 F.2d 196 (5th Cir. 1989); *Zaccone v. Am. Red Cross*, 872 F. Supp. 457, 460 (N.D. Ohio 1994) (citing *McKee v. Miles Lab., Inc.*, 675 F. Supp. 1060 (E.D. Ky. 1987)), *aff'd* *McKee v. Cutter Lab., Inc.*, 866 F.2d 219 (6th Cir. 1989); *Smith v. Paslode Corp.*, 799 F. Supp. 960 (E.D. Mo. 1992); *Smythe v. Am. Red Cross et al.*, 797 F. Supp. 147 (N.D. N.Y. 1992); *Kozup v. Georgetown Univ.*, 663 F. Supp. 1048 (D.D.C. 1987), *aff'd in relevant part*, 851 F.2d 437 (D.C. Cir. 1988); *Osborn v. Irwin Mem'l Blood Bank*, 7 Cal. Rptr. 2d 101, 5 Cal. App. 4th 234 (Cal. Ct. App. 1992); *Doe v. Am. Red Cross Blood Servs.*, 377 S.E.2d 323, 297 S.C. 430 (1989), *answer to certified question*, 125 F.R.D. 637 (D.S.C. 1989).

94. *Advincula v. United Blood Servs.*, 678 N.E.2d 1009, 1026 (Ill. 1996) ("The application of a professional standard of care to the conduct of blood banking organizations in collecting blood comports with a majority of jurisdictions which have considered this issue, in a variety of contexts."); *see Zaccone*, 872 F. Supp. at 460 (finding that because the defendant (a blood manufacturer) utilized extensive medical expertise and personnel in providing its service of (1) collecting and processing of blood, which, in turn, was carried out by trained health care professionals, (2) testing blood through various laboratory processes, (3) separating the blood into components by trained medical professionals, and (4) conducting examinations of donors, the defendant was subject to professional standard of care); *see also Doe v. Am. Nat'l Red Cross*, 848 F. Supp. 1228, 1233 (S.D. W. Va. 1994) ("[The defendant] had the duty to exercise the degree of care commonly practiced by the ordinary skillful, careful, and prudent blood bank or equivalent personnel in the same or similar circumstances.").

95. DOBBS ET AL., *supra* note 90, at § 124.

96. It should be noted that the doctrine of *negligence per se* would not apply in these circumstances because, while the guidance for the industry is followed by many blood manufacturers in the industry, this guidance only gives suggestions and is not compulsory on blood manufacturers. REVISED GUIDANCE, *supra* note 2.

One case that provides helpful guidance in determining the rule of law is *United Blood Services v. Quintana*,⁹⁷ which was heard before the Supreme Court of Colorado. In *Quintana*, United Blood Services (hereinafter “UBS”) received blood from a donor and processed it.⁹⁸ The plaintiff received a transfusion of the contaminated blood.⁹⁹ UBS later learned that the donor “pursued a ‘gay lifestyle’”¹⁰⁰ and was HIV positive.¹⁰¹ The screening procedures that UBS employed at the time of the donation included many of the multilayered protections adopted by the industry.¹⁰² However, the screening procedures utilized by UBS, at the time, did not include aggressive questions or physical examinations of donors.¹⁰³ Nor, at the time, did UBS test the donated blood using surrogate testing.¹⁰⁴ The Court noted in its judgement that that the type of test that the plaintiff promoted had been developed and was in use by many donation centers at the time of the contaminated donation.¹⁰⁵ Prior to trial, the defendant sought to introduce information that the blood manufacturing industry lagged behind in implementing proper safeguards to mitigate the risk of HIV transmission.¹⁰⁶

The court discussed, at length, the standards of the blood banking industry at the time of the contaminated donation and transfusion,¹⁰⁷ and found that the defendant was subject to a professional standard of care.¹⁰⁸ The court continued by stating that adherence to a professional standard of conduct does not provide conclusive proof of due care.¹⁰⁹ Therefore, the question remained with the jury as to whether the blood banking industry standards were adequate.¹¹⁰ The Court also noted

97. *United Blood Servs. v. Quintana*, 827 P.2d 509 (Colo. 1992).

98. *Id.* at 513.

99. *Id.* at 512.

100. *Id.* at 512.

101. *See id.*

102. *United Blood Servs. v. Quintana*, 827 P.2d 509, 516-17 (Colo. 1992) (testimony at trial stated that the defendant’s procedures met, and in some cases exceeded, the recommendations set forth by the FDA and other organizations).

103. *Id.* at 517.

104. *Id.* (noting that the type of test that the plaintiff promoted had been developed and was in use by many donation centers at the time of the contaminated donation).

105. *Id.*

106. *Id.* at 512-13.

107. *United Blood Servs. v. Quintana*, 827 P.2d 509, 513-17 (Colo. 1992).

108. *Id.* at 523-24 (explaining that “[a] practicing professional is generally entitled to be judged according to the tenets of the school of practice which the practitioner professes to follow.”).

109. *Id.*

110. *Id.* at 526.

that, at the time of the events leading to the litigation at bar, “scientific information on the etiology and epidemiology of AIDS was in the developmental stages.”¹¹¹ And, at that same time, the FDA neither mandated nor recommended the type of testing proffered by the Plaintiff.¹¹²

The court proceeded to affirm the ruling that a new trial was warranted due to the remaining question of fact, which, in the instance of this case, was whether the entire blood manufacturing industry lagged behind in its methods to prevent HIV transmission.¹¹³

Two years after *Quintana*, the paradigm shifted slightly. This was reflected in *Zaccone v. American Red Cross*.¹¹⁴ In 1982, a local university student donated blood at a mobile collection unit owned and operated by the Red Cross.¹¹⁵ Conforming to FDA recommendations and trade practice, the defendant blood center instructed the donor to review a pamphlet entitled, “What you Should Know about Giving Blood” and to sign a statement that he had read and understood the information therein.¹¹⁶ The donor was also asked to complete a questionnaire that included questions designed to identify signs and symptoms of AIDS; however, the questionnaire did not address sexual history.¹¹⁷ The donor then received a brief physical examination by a registered nurse.¹¹⁸ After donation, the blood was subjected to serologic testing as required by law and industry custom.¹¹⁹ At the time, no test had been developed that would detect HIV.¹²⁰ The donor was later confirmed to be HIV positive and, through a “lookback program,” the contaminated blood was later identified to have been transfused to the plaintiff.¹²¹ The Red Cross sent a letter to the hospital where the blood was transfused and encouraged recipients to be tested.¹²² The plaintiff received a blood test, and was informed by her physician that she had been infected with HIV.¹²³ She subsequently died as a result of

111. *Id.* at 524.

112. *United Blood Servs. v. Quintana*, 827 P.2d 509, 524 (Colo. 1992).

113. *Id.* at 527.

114. *Zaccone v. Am. Red Cross*, 872 F. Supp. 457 (N.D. Ohio 1994).

115. *Id.* at 458.

116. *Id.*

117. *Id.*

118. *Id.* at 459.

119. *Zaccone v. Am. Red Cross*, 872 F. Supp. 457, 459 (N.D. Ohio 1994).

120. *Id.* (noting that a subsequent donation took place after a test had been developed and the donor was deferred from future donation).

121. *Id.*

122. *Id.*

123. *Id.*

AIDS.¹²⁴ In 1993, the Red Cross filed a motion of summary judgement on this issue of negligence.¹²⁵ The plaintiff argued that the Red Cross should have employed blood tests and used more confrontational questions in its screening process that would have prevented the ultimate harm.¹²⁶ The Red Cross argued that, because it was subject to a professional standard of care, it could not be negligent if it met the generally recognized and accepted practices of blood bank professionals.¹²⁷ The trial court granted the motion.¹²⁸

The court's reasoning showed that because the Red Cross was subject to a professional standard of care, the court needed to discern what that standard of care entailed.¹²⁹ The court proceeded to discuss the "generally recognized and accepted practices" which showed that the Red Cross did not breach the duty of care.¹³⁰ In its analysis, the court noted that at the time the donation was taken, no government agency or "standard setting organization" recommended the specific blood test or confrontational questions that the plaintiff argued should have been performed.¹³¹ The court also recognized that a professional standard of care is not conclusive proof of due care.¹³² The court also found that the blood banking profession did not lag behind in adopting procedures and practices that were reasonable and within its duty to adopt.¹³³ Therefore, because the Red Cross conformed to professional standards that were adopted by virtually the entire profession, and the profession was found not to be lagging behind, the blood bank did not breach a duty of professional care.¹³⁴

124. *Zaccone v. Am. Red Cross*, 872 F. Supp. 457, 459 (N.D. Ohio 1994).

125. *Id.* at 458.

126. *Id.* at 460.

127. *Id.*

128. *Id.* at 462 (finding that no genuine issue of material fact existed and granting summary judgement).

129. *See Quintana*, 827 P.2d at 460.

130. *See id.* (reasoning that "[t]he blood banking profession is heavily regulated and therefore, the 'generally recognized and accepted practices' of the profession [were] discernible.").

131. *Id.*

132. *Zaccone*, 872 F. Supp. at 461 (citing *The T.J. Hooper*, 60 F.2d 737 (2d Cir. 1932) in concluding that "the standard of care adopted by a profession constitutes only a rebuttable presumption of due care.").

133. *Zaccone*, 872 F. Supp. at 462.

134. *Id.* (the court proceeded to grant summary judgement).

The synthesized rule from *Quintana*¹³⁵ to *Zaccone*,¹³⁶ consequently, is that if a transfusion of infected blood results in HIV infection to the recipient, as long as the individual blood center followed generally accepted industry standards *at the time of the collection*, and the standards set forth by the FDA and/or other standard setting organizations (e.g. American Association of Blood Banks) are not lagging behind what a reasonably prudent blood center would employ,¹³⁷ an individual blood center cannot be held liable for the collection and transfusion.¹³⁸

But what if a blood manufacturer discards professional standards and instead relies on its own safety standards?

B. Revocation of a Biologics License by the FDA

The importance of understanding licensing regulations including inspections, testing, and donor deferral,¹³⁹ is because the FDA will suspend or revoke an establishment's license if the establishment fails to conform to the standards necessary to maintain the safety, purity, and potency of the blood supply.¹⁴⁰ With enough violations, the FDA will contact the blood establishment¹⁴¹ and give notice that the FDA intends to revoke the establishment's license to manufacture blood and blood products.¹⁴² The FDA requires that there be an opportunity for a hearing before a revocation becomes effective.¹⁴³

If a license is revoked, several additional consequences may still befall an establishment that continues to manufacture blood and blood

135. *United Blood Servs. v. Quintana*, 827 P.2d 509, 519 (Colo. 1992).

136. *Zaccone v. Am. Red Cross*, 872 F. Supp. 457 (N.D. Ohio 1994).

137. *Id.* at 461 (finding that the practices employed by blood banks are, as a matter of law, adequate).

138. *Compare Zaccone*, 872 F. Supp. at 461, with *Quintana*, 827 P.2d at 526 (whereas *Quintana* stated that the blood banking profession *may* be lagging, and, therefore a jury should decide if there was a breach of duty, *Zaccone* states that, as a matter of precedent, the blood banking profession has employed adequate standards to meet the safety required for reasonable due care).

139. *See generally supra* Part 0. Sec. 0.

140. Revocation of License, 21 C.F.R. § 601.5(b)(1)(iv) (2018).

141. *See* Letter from Karen Midthun, M.D., Dir. of the Ctr. for Biologics Evaluation and Res., to Ms. Esther Hernandez, President of U.S. Blood Bank, Inc., (effective July 9, 2015), <https://cbsmiami.files.wordpress.com/2015/07/fda.pdf> [<https://perma.cc/VH4D-DH8X>].

142. Revocation of License, 21 C.F.R. § 601.5 (2018).

143. *Id.*

products and introduces those products into interstate commerce.¹⁴⁴ Doing so is a violation of the Public Health Service Act¹⁴⁵ as well as the Federal Food, Drug, and Cosmetic Act.¹⁴⁶

In violating the Public Health Service Act,¹⁴⁷ a person or entity may be subjected to a mandatory recall of the product,¹⁴⁸ fines, or imprisonment.¹⁴⁹ Moreover, depending on the circumstances, penalties may be imposed upon both individual persons and corporate entities.¹⁵⁰ Violations of the Federal Food, Drug, and Cosmetic Act¹⁵¹ may result in imprisonment of up to ten years, or up \$250,000 in fines.¹⁵²

III. CURRENT STANDING OF HIV “WINDOW PERIOD” INFECTION, TESTING METHODS, AND TREATMENT.

A. *Window Period Infection*

In its most recent revision of recommendations to the blood manufacturing industry, the FDA informed the industry that the window

144. See Letter, *supra* note 141, at 4.

145. 42 U.S.C.A. § 262(a) (West, Westlaw through Pub. L. No. 115-90 (also includes Pub. L. No. 115-92 to 115-117, 115-119 and 115-122. Title 26 current through 115-122)) (“No person shall introduce or deliver for introduction into interstate commerce any biological product unless . . . a biologics license . . . is in effect.”).

146. 21 U.S.C.A. § 331 (West, Westlaw through Pub. L. No. 115-90 (also includes Pub. L. No. 115-92 to 115-117, 115-119 and 115-122. Title 26 current through 115-122)). The Act prohibits the introduction or delivery of “adulterated” biologics. *Id.*

147. Regulation of biological products, 42 U.S.C.A. §262(a) (West, Westlaw through Pub. L. No. 115-90 (also includes Pub. L. No. 115-92 to 115-117, 115-119 and 115-122. Title 26 current through 115-122)).

148. 42 U.S.C.A. §262(d) (West, Westlaw through Pub. L. No. 115-90(also includes Pub. L. No. 115-92 to 115-117, 115-119, and 115-122. Title 26 current through 115-122)).

149. *Id.* at (f).

150. See generally *United States v. Calise*, 217 F. Supp. 705, 707 (S.D.N.Y. 1962) (denying defendant’s motion to dismiss) (the defendant (and defendant corporation) were charged with several violations of the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. The two defendants were also charged with conspiracy to violate those acts. Calise, in a motion to dismiss, sought to exculpate his involvement. However, the court reasoned that “[t]he counts of the indictment each charge the defendant . . . with offenses in the relevant statutory wording. The fact that the offenses alleged concern blood products sold by the defendant [corporation], does not exculpate [the defendant] from criminal responsibility for the acts charged in the indictment”).

151. 21 U.S.C.A. § 331 (West, Westlaw through Pub. L. No. 115-90 (also includes Pub. L. No. 115-92to 115-117, 115-119 and 115-122. Title 26 current through 115-122)).

152. 21 U.S.C.A. § 333 (West, Westlaw through Pub. L. No. 115-90 (also includes Pub. L. No. 115-92to 115-117, 115-199, and 115-122. Title 26 current through 115-122)).

period¹⁵³ for HIV detectability is small, but still present and a high risk for persons associated with specific behaviors.¹⁵⁴ This window period varies based upon which testing method is used to detect HIV.¹⁵⁵ There are three types of HIV diagnostic tests available.¹⁵⁶ These include antibody tests, a combination of “fourth-generation tests,” and nucleic acid tests (hereinafter NAT).¹⁵⁷

Antibody tests look for indications of the presence of HIV antibodies, which are proteins exuded by the body to fight HIV, rather than detecting HIV itself.¹⁵⁸ Enzyme-linked immunoassay (hereinafter ELISA) is a testing method within this category.¹⁵⁹

Prior to the development of these tests, HIV was an undetectable virus with an incubation period lasting between three and ten years.¹⁶⁰ Conversely, all these aforementioned testing methods greatly reduced this expansive void of uncertainty. For example, ELISA tests shorten the window period to approximately twenty-two days,¹⁶¹ and NAT tests further condense the window period to just nine days.¹⁶² Nevertheless, there endures a risk of transmission,¹⁶³ though the risk is extremely low when these testing methods are employed.¹⁶⁴ The shortfall of all of these tests, however, is *recently acquired infection*.¹⁶⁵ So,

153. The period between initial infection with a communicable disease and the time at which the infectious agent becomes detectable. *See infra* note 155.

154. REVISED GUIDANCE, *supra* note 2, at 3-4 (namely, these activities include illicit drug use and commercial sex work).

155. *See* L.M. Kucirka et al., *Risk of Window Period HIV Infection in High Infectious Risk Donors: Systematic Review and Meta-Analysis*, 11 AM. J. TRANSPLANT 1176, 1176 (2011).

156. HIV TESTING, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Prevention/ucm117922.htm> [<https://perma.cc/Y2JZ-8SW>].

157. *Id.*

158. *Id.*

159. *See* Kucirka, *supra* note 155, at 1176.

160. Christopher D. Pilcher et al., *Acute HIV Revisited: New Opportunities for Treatment and Prevention*, 113 J. CLINICAL INVESTIGATION 933, 937 (2004).

161. *See* Kucirka, *supra* note 155, at 1176.

162. *Id.* at 1176.

163. *See id.* at 1180. In this meta-data analysis, it was found that—specifically for MSM—the use of ELISA testing resulted in 10.2 window period infections per 10,000 donors and NAT testing resulted in 4.2 window period infections per 10,000 donors. *Id.* at 1176. Compare this to donors who engage in high-risk sexual behavior, namely commercial sex workers. Respectively, the use of ELISA testing resulted in 0.7 window period infections per 10,000 donors, and NAT testing resulted in 0.3 window period infections per 10,000 donors. *Id.*

164. *Id.*

165. *Id.* at 1183.

depending on what test is administered to detect the virus, the window period can be as little as nine days or as much as twenty-two.¹⁶⁶

B. HIV Treatment & Life Expectancy

1996 saw one of the most effective treatments for HIV burst forth into the medical community; which was Anti-Retroviral Therapies (hereinafter ART).¹⁶⁷ By using a drug cocktail (the practice of using several different medications at the same time) HIV is so suppressed that it “bec[omes] undetectable in the blood of an infected person.”¹⁶⁸ Notwithstanding this treatment, studies settle that while the virus is suppressed, it never truly leaves the body.¹⁶⁹ Instead, it hides within various organs and tissues, awaiting for just one opportunity to begin its pillaging again.¹⁷⁰ Thus, while HIV infection is treatable, it is not curable.¹⁷¹ It is a chronic infection that a person must contend with for the remainder of their life.¹⁷²

This is not reason for an infected person to despair, however. Because of the treatment advances outlined, a diagnosis of HIV no longer automatically becomes a prognosis to AIDS and eventual death.¹⁷³ In fact, advances in HIV diagnosis and treatment have culminated to the effect that HIV-positive individuals maintain just a marginally lessened life expectancy compared to HIV-negative individuals.^{174,175}

166. Kucirka, *supra* note 155, at 1176.

167. The reason this development was so important is because previous treatments (such as azidothymidine or “AZT”) were less effective than ART because these treatments did not fully suppress the HIV virus and the virus continued to replicate and evolve. Hence, over time, it would develop resistance to the therapy. Harden, *supra* note 6, at 149-50.

168. Harden, *supra* note 6, at 150. It is important to note that undetectable does not mean gone; only that available tests will give a negative result.

169. *Id.* at 151.

170. *See id.*

171. *Id.*

172. *Id.*

173. *See generally* Kazuhisa Yoshimura, *Current Status of HIV/AIDS in the ART Era*, 23 J. INFECTION & CHEMOTHERAPY 12, 12 (2017).

174. *Id.*

175. It is important to note that, because a viable long-term treatment for HIV was not available until 1996, *See generally, e.g.*, Harden, *supra* note 6, at 149-50, the long-term effects of chronic, treated HIV infection are unknown. Only recently has the medical community had the opportunity to study these long-term effects and to fine-tune treatment to offer the longest possible term and quality of life. *See* Yoshimura, *supra* note 173, at 13-14.

C. A Narrowed Focus on HIV Testing Methods

As discussed earlier,¹⁷⁶ various testing methods are available to detect HIV, there remains one other factor to consider in promulgating an argument based on the employment of these tests, namely, the practicality of using such tests. Specifically, do these tests provide an accurate result in a reasonable period?¹⁷⁷ Luckily, the answer is, “yes.”¹⁷⁸

Advancements in antibody screening (immunoassay) testing technology have led to the development of rapid, in-home testing, which can provide results in thirty minutes or less.¹⁷⁹ While these tests have some margin of error,¹⁸⁰ it must be understood that no test can give perfect results every time it is used, and the FDA has determined that the benefits of a readily available over-the-counter test far outweigh the cons (a small number of potential false negatives and positives).¹⁸¹

176. See *supra* Part 0. Sec. 0.

177. Needless to say, if a test is accurate but takes an objectionably long time to receive results, it would be impractical to release such a test for ready-use, especially if the time to receive the test results is longer than the useful life of the collected blood.

178. See *infra* note 219.

179. *Testing*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 16, 2018), <https://www.cdc.gov/hiv/basics/testing.html>.

180. E.g., *Information Regarding the OraQuick In-Home HIV Test*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), <https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm311895.htm>.

[C]linical studies have shown that the . . . [t]est has an expected performance of approximately 92% for test sensitivity (i.e., the percentage of results that will be positive when HIV is present). This means that one false negative result would be expected out of every 12 test results in HIV infected individuals. The clinical studies also showed that the . . . Test has an expected performance of 99.98% for test specificity (i.e., the percentage of results that will be negative when HIV is not present). This means that one false positive result would be expected out of every 5,000 test results in uninfected individuals. *Id.*

181. See generally, e.g., *Information Regarding the OraQuick In-Home HIV Test*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2018), <https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm311895.htm>.

IV. OVERVIEW OF THE COMMON-LAW DEFENSE OF “NECESSITY”

A. *General Information*

Necessity (sometimes referred to as the “lesser evils” or “choice of evils” defense)¹⁸² is a justification defense recognized in approximately half of the jurisdictions in the United States.¹⁸³ Necessity is distinct from other common-law defenses (*e.g.* duress, entrapment, self-defense, insanity, etc.). What distinguishes necessity from other defenses is the “choice” element, which is central to plead and prove the defense.¹⁸⁴

Conduct constituting a [necessity] defense is justified if:

- (1) Any legally-protected interest is unjustifiably threatened . . . and
- (2) The actor engages in conduct constituting the offense,
 - (a) when and to the extent necessary to protect or further that interest,
 - (b) that avoids a harm or evil . . . greater than the harm or evil caused by the actor’s conduct.¹⁸⁵

This formula, while conceptually simple, has many intricacies. The first being the definition the relationship between a “legally-protected interest” and an “unjustifiable threat.”¹⁸⁶

Legally-protected interests are not restricted to interests that have the blessing of statute; instead, these interests are those that “the community is willing to recognize and are not specifically denied recognition by the legal system.”¹⁸⁷ The preservation of life, one of the most

182. PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES §124 (2016).

183. *Id.*

184. *See id.*

185. *Id.*

186. *See id.* at (b)(1).

187. PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES §124 (2016).

sacrosanct principles for many people, should inescapably be deemed a legally-protected interest.^{188,189}

Inextricably intermingled with a legally-protected interest (when raising a defense of necessity) is the concept of an unjustified threat to that interest.¹⁹⁰ In general, an actor may protect their interest “whenever the threat to [the interest] would produce a net societal harm.”¹⁹¹ The triggering threat need not be lawful.¹⁹² Moreover, the language of the defense’s elements are not meant to encompass only those threats made by persons; instead, “the language is meant to include all threats that are not justified,” including physical forces.¹⁹³

B. Elements

The Ninth Circuit provides a typical description of the elements of necessity.¹⁹⁴ To raise the defense, the proponent must have:

- (1) Been faced with a choice of evils and chose the lesser evil,
- (2) Acted to prevent imminent harm,
- (3) Reasonably anticipated a direct causal relationship between their conduct and the harm averted, and
- (4) Had no legal alternatives to violating the law.¹⁹⁵

188. In Judaism, the essential nature of human life is solidified in the obligation of *pikuach nefesh*, which compels practitioners to save a life in danger regardless of the law. In such circumstances, almost any command of the Torah (*mitzvah lo ta’aseh*) becomes inapplicable. *Jewish Concepts: Pikuach Nefesh*, JEWISH VIRTUAL LIBRARY, <http://www.jewishvirtuallibrary.org/pikuach- nefesh> (last visited May 5, 2018). In another realm, practitioners of medicine take on the duty of their profession by exercising caution when they face life and death. Through this duty, if they can “save a life, all thanks. But it may also be within [their] power to take a life; [and] this awesome responsibility must be faced with great humbleness and awareness of [their] own frailty.” Peter Tyson, *The Hippocratic Oath Today*, NOVA (Mar. 27, 2001), <http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html> (attributing the oath, revised in 1964, to Louis Lasagna, then Academic Dean of the School of Medicine at Tufts University and noting that the revised oath is used in many medical schools today).

189. Emphasis should be added to the word, “should” in the preceding sentence because, as discussed below *infra* Part 0., strict adherence to regulation could result in the deaths of multitudes of innocent victims.

190. See PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES §124 at (b)(2) (2016).

191. *Id.*

192. *Id.*

193. *Id.*

194. Stephen S. Schwartz, Comment, *Is There a Common Law Necessity Defense in Federal Criminal Law*, 75 U. CHICAGO L. REV. 1259 (2008).

195. *United States v. Arellano-Rivera*, 244 F. 3d 1119, 1126 (9th Cir. 2001) (citing *United States v. Schoon*, 971 F.2d 193, 195 (9th Cir. 1992)).

For all of these elements (both federal and generally) there is also the undertone that the conduct of the proponent must “be necessary in both *time* and *degree*.”¹⁹⁶ As such, the defense will be allowed only if the action was necessary at the time of employment and no less drastic alternatives existed when the action was taken.¹⁹⁷

V. DISCUSSION ON NECESSITY AND BLOOD MANUFACTURERS

A. *When would a manufacturer need to raise a necessity defense?*

The need to raise the defense arises under two situations. One situation would be when a party was harmed by a contaminated blood transfusion and alleges negligence on the part of the blood manufacturer.¹⁹⁸ The second would be when the FDA, upon learning that a blood manufacturer has not followed applicable regulations, is seeking to suspend or revoke the manufacturer’s license.¹⁹⁹

There exists some question as to if the necessity defense extends to the violation of federal regulation.²⁰⁰ Moreover, even if the defense were available, courts have not definitively stated the limits on its applicability.²⁰¹ Some scholars premise that, when dealing with federal regulatory authority, the necessity defense cannot be recognized unless Congress has specifically enumerated the defense in applicable statute.²⁰²

196. PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES §124 at (c) (2016) (emphasis added).

197. *Id.*

198. *See supra* Part 0, Sec. 0.

199. *See supra* Part 0, Sec. 0.

200. *See generally* Stephen S. Schwartz, Comment, *Is There a Common Law Necessity Defense in Federal Criminal Law*, 75 U. CHICAGO L. REV. 1259 (2008).

201. *Id.* at 1266.

202. *See* Stephen S. Schwartz, Comment, *Is There a Common Law Necessity Defense in Federal Criminal Law*, 75 U. CHICAGO L. REV. 1259, 1266 (2008). *See also id.* at 1284. Schwartz cites (in footnote 146) the case of *The William Gray*, 29 F. Cases 1300 (C.C.D. N.Y. 1810). Schwartz argues that this case, which recognized the necessity defense as applicable to congressional statute, differs from crimes in a different context (the 19th century). As such, the circumstances have changed and the case applies to a different kind of crime. Stephen S. Schwartz, Comment, *Is There a Common Law Necessity Defense in Federal Criminal Law*, 75 U. CHICAGO L. REV. 1259, 1284 (2008). However, Schwartz fails to recognize the parallel. While it is true that the Legislative powers of the United States Federal System are vested in the Congress, U.S. CONST. art. I § 1, it has never been upheld that Congress is unable to delegate authority. *See* ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW 9 (3d

However, one fact remains true and consistent: where an applicable statute has clearly prohibited the defense of necessity (*e.g.* strict liability cases or where the legislature has expressly stated that necessity is unavailable), then the law is conclusive and the defense cannot be recognized.^{203,204} Many would agree, however, that “whether the common law necessity defense should be available should depend on the nature of the offense at issue.”²⁰⁵ While this Article mostly deals with state law tort actions, there may not be such a huge dichotomy when asserting this defense in the face of a potential revocation of a biologics license as opposed to exclusively in negligence cases.

B. Discussion on Arguments allowing the defense

i. Facing the choice of evils and choosing the lesser of them

The first question that must necessarily be probed when asserting a defense in either situation is, what are the evils being faced by the blood manufacturer? To work for blood manufacturers, the choice must be between the potential unintended spread of HIV throughout the blood supply, versus the suffering and death of persons unable to receive blood transfusions.

Recall that first, window period infections of HIV are statistically extremely low.²⁰⁶ Secondly, science allows not only the detection of

ed. 2014) (citing *Wayman v. Southard*, 23 U.S. 1, 43 (1825)). Since the duty to promulgate regulations has become a delegated power from Congress and the defense of necessity has never been abrogated under federal law, it only follows that the duty to explicitly deny a necessity defense also rests with those delegated powers. Moreover, even viewing necessity in the light of federal regulation, the purpose of the defense remains the same. That is where there is no legal alternative that the actor can take to mitigate the threat to a protected interest, then there is justification for their action and they should not be liable for it, especially when their action is not intended to inflict personal injury to another. *The William Gray* 29 F. Cases 1300, 1302 (C.C.D. N.Y. 1810). Furthermore, if the action is meant to benefit the public interest, then it gives further preponderance to the notion that the defense should be recognized under federal administrative regulation. See PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES § 124 (b)(3) (2016).

203. See PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES § 124(d)(3) (2016).

204. As argued *supra* note 202, it could be asserted that Congress has also delegated the right to decide whether or not the defense may be extended to federal agencies. As such, it would become the duty of the federal agency to explicitly state that the defense is unavailable.

205. Schwartz, *supra* note 200, at 1293.

206. See Kucirka, *supra* note 155, at 1176-80.

HIV in less than one year,²⁰⁷ but these detection methods are also reliable and timely.²⁰⁸ Finally, HIV does not pose as much of a public health threat as it once did as the disease (when treated) is now chronic rather than terminal.²⁰⁹

Advocates opposed to this view may state that taking blood from persons potentially infected with HIV could lead to an epidemic of the virus that, if left untreated or not treated in a timely manner, leads to one of the most gruesome deaths imaginable. However, these advocates either ignore or fail to realize just how far testing and treatment have come in the past two decades. Yes, HIV is not curable²¹⁰ and AIDS is a gruesome way to expire.²¹¹ However, HIV does not automatically lead to AIDS²¹² and even AIDS can be treated in early stages.²¹³ While it is true that taking blood from high-risk donors does increase the risk of HIV infection to others, the fact remains that given the choice between life with a treatable disease and death; most people would probably choose life. In addition, the fact that the chances of window period transmission are infinitesimally small²¹⁴ only strengthens the argument that there should not be a total blanket ban on high risk donors from giving blood in all circumstances.

ii. *The Blood Manufacturer Acted to Prevent Imminent Harm*

The definition of imminent harm may sometimes be equated to the definition of an emergency. Yet, several definitions exist as to what constitutes an emergency.²¹⁵ A common definition is “an unforeseen combination of circumstances or the resulting state that calls for immediate action”²¹⁶ *Black’s Law Dictionary* provides a more analytical definition for our purposes; viz., “1. A sudden and serious event or an

207. See *supra* Part 0, Sec. 0.

208. See *supra* Part 0, Sec. 0.

209. See *supra* Part 0, Sec. 0.

210. See *supra* Part 0, Sec. 0.

211. Koon, *supra* note 10.

212. See *supra* Part 0, Sec. 0.

213. Harden, *supra* note 6, at 155-57.

214. Kucirka, *supra* note 155, at 1176-80.

215. See generally *Emergency*, WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY (Philip Babcock Gove, Ph.D. et al. eds., 1993).

216. *Emergency*, WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY (Philip Babcock Gove, Ph.D. et al. eds., 1993).

unforeseen change in circumstances that calls for immediate action to avert, control, or remedy harm. 2. An urgent need for relief or help.”²¹⁷

Using these definitions, imminent harm could take many forms. If a particular area is unable to be accessed due to major disaster (*e.g.*, all bridges are knocked out for a prolonged period of major flooding or due to an earthquake, etc.), this may give rise to an imminent harm. In other circumstances, the imminent harm could be manmade (*e.g.*, or a killer smog or terrorist attack).

iii. The Blood Manufacturer reasonably anticipated a direct causal relationship between their conduct and the imminent harm averted

For the necessity defense to be proven, there must be a causal relationship between the actions of the blood manufacturer and the imminent harm averted. Basically, if the harm were to continue even though the defendant acted to mitigate it, then the causal relationship is lost.²¹⁸

The obvious weakness to this element is that blood collected will not be used immediately; to be transfused, blood must first be tested for various communicable diseases and, therefore, in the event of emergency, extending the defense unnecessarily makes the blood supply dangerous and does not directly affect the imminent harm. Because the donated blood may not help the actual victims (as the blood would only be disseminated to future recipients who are not associated with the threat under which the blood manufacturer is claiming justification), the blood donated does not help victims effected by the emergency. Therefore, the causal connection is lost.

First and foremost, “Rapid HIV tests [have made] it possible to provide results at the time that testing is done”²¹⁹ Because of this, blood collected in the event of an emergency could be used immediately or within a relatively short period.²²⁰

Secondly, while it is true that blood donated today may not be used today, the blood used during an emergency must somehow be

217. *Emergency*, BLACK’S LAW DICTIONARY (10th ed. 2014).

218. See PAUL H. ROBINSON ET AL., 2 CRIMINAL LAW DEFENSES § 124 (2017).

219. COMM. ON HIV SCREENING AND ACCESS TO CARE ET AL., HIV SCREENING AND ACCESS TO CARE: EXPLORING BARRIERS AND FACILITATORS TO EXPANDED HIV TESTING 22 (Nat’l Acad. Press, 2010).

220. See *id.*

replaced. If a natural disaster has reduced the blood supply to such a scarcity, and there is no ability to replenish the supply from outside sources, then a blood manufacturer would be justified in taking blood from high-risk donors—while following reasonable measures to protect the blood supply²²¹—in order to return the supply to an adequate level to manage concurrent or pending emergencies. The focus must be that the looming harm is not only the injury of harm to current recipients who may need blood, but also that the blood supply may not be able to cope with another disaster in the immediate future.²²²

iv. *The Blood Manufacturer had no legal alternatives to violating the law.*

As discussed previously,²²³ violation of regulation may still be treated almost as strict liability, wherein there are no defenses available to violation.²²⁴ However, the necessity defense is meant to justify violations of the law as a matter of policy.²²⁵ In a prolonged or isolated emergency, the only legal alternative is to deny donations and potentially cause the death of hundreds, if not thousands, of innocent victims for the sake of upholding regulatory bureaucracy.²²⁶

VI. HYPOTHETICAL CASE STUDIES

The definitions of an emergency outlined above,²²⁷ while generally accepted, do not adequately show how an emergency may affect a blood manufacturer to the extent of justifying taking of donations from high risk donors. Therefore, the following sections offer

221. See discussion *infra* Part 0, Sec. 0.

222. Opposing advocates might also attempt to argue that no previous emergency has ever strained the blood supply to such a degree as to justify ignoring the regulations (*i.e.*, allowing the defense). However, this is not a valid argument because it assumes that the past dictates the future. Just because an event *has* not happened doesn't mean it *could* not.

223. See *supra* Part 0, Sec. A.

224. See *supra* Part IV, Sec. A.

225. See *supra* Part 0, Sec. 0.

226. It would also be wise to note that this Comment does not advocate for forced or draft donation of high risk donors. Blood manufacturers should not drive about in stealth vehicles, find high risk donors, tie them down, stick a needle in their arm, and draw out humanity's precious bodily fluids. This Comment only advocates to open the door, albeit just a fraction, to allow "high-risk" donors a chance to give blood in times of emergency when it is necessary.

227. See *supra* Part 0, Sec. 0(0).

examples of where an emergency affecting the blood supply may exist and a blood manufacturer may be justified in taking donations from high-risk donors. These examples will also give a short exploration on if the defense would be upheld in a court of law based upon the scenarios.

*A. A Terrorist Attack*²²⁸

i. Facts

The day is calm and peaceful. The sunlight gleams off the newly washed siding of the monolithic structures therein retained. A speck in the distance grows larger as it approaches; its menacing shadow gliding on the waves of the ocean, as a hawk stalks its prey. It approaches the luminous tower of glass and steel, and only too late do those observing the heavens realize that their lives are about to change forever. The impact is immense and shaking as the plane impacts propelling smoke and flame into the metropolitan sky. One hour later, the building collapses.

The news reaches the local hospital. In anticipation, the nurses and doctors clear the emergency room and discharge anyone able. The expectation is for thousands of victims to enter in the coming hours. However, the blood bank can only handle a couple hundred. Therefore, the lead nurse calls the local blood manufacturer and states that there is an immediate need for blood that is not currently in the hospital's supply.

The blood manufacturer, acting on this information, checks its stores and sees that the blood supply is short due to a recent spike in accidents and surgeries. It cannot meet the demand. Neither can any of the other local blood manufacturers, as they are all anticipating the need to supply their local area hospitals. Moreover, all inbound and outbound flights are grounded at airports. With access into the city blocked and no flights inbound, there is no blood coming in.

The manufacturer, making an executive decision, solicits donors passing on the streets to give blood. An excited youth takes up the offer and takes part in the standard examination, which reveals information that they are a high-risk donor. The blood bank goes further than

228. This hypothetical is modeled upon the September 2001 terrorist attacks in New York City. Details are added and subtracted to highlight the legal issues. *See generally* NAT'L COMM. ON TERRORIST ATTACKS UPON THE U.S., THE 9/11 COMMISSION REPORT 285 (2004).

necessary by asking further combative questions and even gathers information from the donor's primary physician. The donor is deemed to not be at risk for passing HIV and the blood bank takes the donation because of the expected need and the fact that the donor had no other indicia of infection. However, this donor had, in fact, been infected a few days previous, but the virus is undetectable by any test available at the time of the donation.

The hospital, meanwhile, is standing ready, and waits with earnest. However, the bodies never come. The victims never arrive. There is a silence and stillness as the doctors and nurses realize that there are no injured; only dead.²²⁹

The blood enters the supply after being tested and is eventually transfused to a recipient. The recipient is infected with HIV. The recipient files a suit in state court and under state law against the blood manufacturer. Also, the FDA seeks to revoke the manufacturer's biologics license. Can the defendant raise the necessity defense, especially when the manufacturer disregarded industry standards?

ii. Analysis

The first question is if there was a choice of evils. This would pose problems for the manufacturer as the manufacturer faced a different situation than the one described in this Comment. That is, the evils they faced were to do nothing and see if the blood was needed versus taking the blood in anticipation of a huge spike in need. The anticipation factor coupled with the fact that the blood was not actually needed shows that the manufacturer did not face a choice of evils.

The element at issue in this case is whether the blood manufacturer acted to prevent imminent harm, as the blood manufacturer acted in anticipation of a potential imminent harm, rather than while facing the imminent harm itself. As stated previously, the defense must be timely in its use.²³⁰ Because the actions by the manufacturer were in anticipation—which can be read to mean that the manufacturer

229. See Danielle Ofri, *In Practice: A Bellevue Doctor Remembers 9/11*, L.A. TIMES, Sept. 5, 2011, <http://articles.latimes.com/2011/sep/05/health/la-he-911-doctor-remembers-20110905> [<https://perma.cc/8RZS-M2JF>] (“[i]n every disaster, there are three zones . . . [t]he center zone is death on impact. The middle zone is the gravely injured. The outer zone is minimal injury. Today . . . there was no middle zone.”).

230. ROBINSON ET AL., *supra* note 182, § 124.

engaged in pure speculation—of what the harm was, they did not act to prevent a defined imminent harm.

Therefore, the court would likely conclude that the defense cannot stand because these elements are lacking.²³¹

B. *The Nightclub Shooting*²³²

i. *Facts*

It's the hottest nightclub in the city, and the evening is even more lively than usual. Friends line up outside the door and around the block in anticipation of a grand night of fun and fancy. Just as things are heating up, a young man, not older than thirty, approaches the club carrying an assault rifle. As he approaches, a security guard tries to stop him, but fails. The man bypasses the guard, running full speed into the building. He finds his way towards the dancing crowd, all of whom don't know that the storm of bullets is about to befall them. He points his weapon toward the crowd and begins to flood it with the deadly spray. His aim is not for anyone in particular; it is only to shed as much blood as possible.

Through the panic, emergency responders navigate the confusing streets and corridors, altogether not knowing what they are about to face. Police ultimately dispose of the shooter, but it is too late to save the lives lost. Emergency medical technicians take those who might be saved to the local hospitals in the backs of ambulances and any other vehicles they can commandeer.

231. In regards to the negligence lawsuit, the court may analyze other tort concepts (*e.g.*, negligence per se). *See generally* 1 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, *PERSONAL INJURY ACTIONS, DEFENSES, AND DAMAGES* § 101.02 (Matthew Bender, Rev. Ed. 2017). However, if negligence per se were not applicable to the case (which is unlikely as regulation is an accepted part of the negligence per se analysis, *see id.*, then the jury would need to answer if the blood manufacturer breached the professional duty of care imposed. *See supra* Part 0, Sec. 0. On another point, depending on the jurisdiction, a violation “may be treated by the court as either negligence per se.” 1 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, *PERSONAL INJURY ACTIONS, DEFENSES, AND DAMAGES* § 101.02 (Matthew Bender, rev. ed. 2017). In this hypothetical, the jury concluded that the defendant blood manufacturer did not breach a duty of care because it behaved as a reasonable blood manufacturer would under the circumstances and violation of the regulation is only nonconclusive evidence of negligence in this jurisdiction.

232. This hypothetical is modeled upon the June 2016 shooting at the Pulse Nightclub in Orlando, Florida. Details are added and subtracted to highlight the legal issues analyzed. *See generally* Ralph Ellis et al., *Orlando Shooting: 49 Killed, Shooter Pledged ISIS Allegiance*, CNN, June 13, 2016, <http://www.cnn.com/2016/06/12/us/orlando-nightclub-shooting/index.html> [<https://perma.cc/NPF6-EZK7>].

Arriving at the hospital, the biggest need is for blood, as many of the victims bled at the scene and while being transported to the emergency room. In the process of providing care, the hospital exhausts its entire supply of blood and starts making calls to the local manufacturers to see what store is allowed. Calls go out to other hospitals and blood banks across the city seeking emergency assistance.

The blood manufacturer receives a call from the hospital asking for a replenishing supply. The manufacturer is ready, willing, and able to do so, and makes the arrangements to have the supply shipped within a couple of hours. However, in doing so, the blood manufacturer has exhausted their supply.

The manufacturer, making an executive decision, solicits donors passing on the streets to give blood. An excited youth of majority age takes up the offer and takes part in the standard examination, which reveals information that they are a high-risk donor. The blood bank goes further than necessary by asking further combative questions and even gathers information from the donor's primary physician. The donor is deemed to not be HIV positive and the blood bank takes the donation because of the expected need and the fact that the donor had no other indicia of infection. However, this donor had, in fact, been infected a few days previous, but the virus is undetectable by any test available at the time of the donation.

The blood enters the supply after being tested and is eventually transfused to a recipient. The recipient is infected with HIV. The recipient files a suit in state court and under state law against the blood manufacturer. Also, the FDA seeks to revoke the manufacturer's biologics license. Can the defendant raise the necessity defense, especially when the manufacturer disregarded industry standards?

ii. Analysis

The blood bank faced a choice of evils in this situation. This was to potentially spread HIV infection to the blood supply, or to allow people to die. This element is probably met as the blood bank chose the lesser of these two evils by attempting to preserve life.

The second element (acting to prevent imminent harm) could be satisfied. However, there is a chance it might fail. While the blood bank had exhausted its supply of blood, it could have taken measures

to renew the blood supply from other areas, including taking part in a disaster relief plan.²³³

This intermingles with the third element of reasonably anticipating a direct causal relationship between conduct and the harm averted. Because there was access into the city and transportation hubs (*e.g.* hospital helipads, emergency rooms, etc.), it would have been possible to get blood from places other than from high-risk donors. As such, there is no reasonable causal connection between the manufacturer's actions and the harm averted.

Notwithstanding all of this, the main threat to the defendant's argument of necessity is the question of whether the blood manufacturer had any legal alternatives available other than to break the law. Here, the legal alternative would be to do nothing. Granted, a blood manufacturer is in the business of doing (that is, collecting blood to save lives); however, the blood supply would have taken care of itself.²³⁴ Therefore, while the manufacturer may have been responding to an imminent threat, its part in mitigating that threat was unnecessary and other legal means were available.²³⁵

As such, the essential element for the necessity defense, that no other legal options are available, would lead to the conclusion that there is no necessity defense available, and the blood manufacturer would be culpable.²³⁶

233. The American Association of Blood Banks (AABB) defines a "disaster" as something that:

- (1) Suddenly requires a much larger amount of blood than usual,
- (2) Temporarily restricts or prevents the local population from donating blood or restricts or prevents the use of the available inventory of blood products requiring immediate replacement or re-supply of the region's blood inventory from another region, or
- (3) Creates a sudden influx of donors requiring accelerated drawing of blood to meet an emergent need elsewhere

Disaster Response, AM. ASS'N OF BLOOD BANKS, <http://www.aabb.org/programs/disasterresponse/Pages/default.aspx> [<https://perma.cc/P5QL-ETKC>].

If any of the above criteria are met, standard setting organizations will implement a Disaster Inter-Organizational Task Force on Domestic Disasters and Acts of Terrorism. AM. ASS'N OF BLOOD BANKS, *DISASTER OPERATIONS HANDBOOK 7* (AABB 2008). The task force, after assessing the information, will put forth a plan to combat the disaster, which may include bringing blood in from other banks and manufacturers to fill the need. *Id.* at 43.

234. *Id.*

235. This includes implementing the Disaster Task Force. *Id.* at 7.

236. While this type of emergency may, if taken to a more extreme level, give rise to a necessity defense, the facts of this hypothetical preclude that determination.

C. *The Hurricane*²³⁷

i. *Facts*

Heavy winds and rain push upon the snakes of wires traversing the land. Unable to withstand the burden they give in, leaving the city in darkness. As the swirling mass of dark cloud and destruction descends upon the coast, the waters shove against the great barrier walls; as the people pray that the levees hold.

It happens in a fleeting second; the waters breach the ramparts. A short time later, the storm overflows the city. The sirens sound, calling the people to higher ground. Everything is drowning: the airports, the roads; even the hospitals are swept into the monsoon. For the lucky ones, they find refuge on rooftops. Others still wait in terror as the waters rise; imprisoned in tombs of rising tide and fear.

When the storm passes and the people emerge, they find the city devastated. However, the time to mourn is not at hand; there are dead to be buried and injured to be cared for. The storm has left only one hospital in operation, High Ground Memorial. Even here, there is no access. The helideck is swamped; the streets are sodden. There is no access. Yet, the thousands of injured keep coming: on floating doors, on canoes, on anything they can find.

Many of the wounded require blood, and the supply at the hospital is not enough. It is quickly exhausted and soon the inflowing patients are suffering and dying. News comes that a second storm is brewing and will make landfall soon. The hospital is facing a code black²³⁸ situation and more casualties are likely on the way.

The hospital, which is also a blood manufacturer, talks to the healthy of the waiting room and surrounding the building asking, "Who can give blood?" The pool is rather small as there are far more injured than not. Nevertheless, a battered but vigorous youth of majority age takes up the offer and takes part in the standard examination, which reveals information that they are a high-risk donor. The hospital

237. See generally Allison Plyer, *Facts for Features: Katrina Impact*, DATA CTR. (Aug. 26, 2016) <http://www.datacenterresearch.org/data-resources/katrina/facts-for-impact/> [<https://perma.cc/2AYH-L45W>] (modeling this hypothetical upon the response and aftermath of Hurricane Katrina throughout New Orleans in August of 2005. Details are added and subtracted to highlight the legal issues analyzed).

238. *Code Black*, FREE DICTIONARY BY FARLEX, <http://medical-dictionary.thefreedictionary.com/code+black> [<https://perma.cc/C7XZ-4YWT>] (understanding a code black is a code used in the medical profession with varying definitions depending on the institution).

goes further than necessary by asking additional combative questions and even gathers information from the donor's primary physician (who was a resident at the hospital). The donor is deemed to not be HIV positive by virtue of a quick oral test and, after the donation is taken, the blood is quickly tested in the laboratory. However, this donor had, in fact, been infected the week previous, but the virus is undetectable by any test available at the time of the donation.

The hospital transfuses the blood to the recipient on site after testing the blood in the hospital's lab. The recipient is infected with HIV. The recipient files a suit in state court and under state law against the blood manufacturer. Also, the FDA seeks to revoke the manufacturer's biologics license. Can the defendant raise the necessity defense, especially when the manufacturer disregarded industry standards?

ii. Analysis

These facts present a situation that will likely allow the court to deem that the defense of necessity is both available and applicable.

First, the hospital was faced with a choice of evils: take blood with the potential to pass HIV infection to the recipient, or allow patients to die.

Second, the hospital acted to prevent an imminent harm. In this case, the imminent harm was that people in the hospital were dying, and that further destruction was likely imminent. The other point furthering the necessity defense is that the hospital took the donation and used it as soon as possible while attempting to follow proper safety protocols. In fact, the hospital went above and beyond what it was expected to do to ensure safety, while acting posthaste to avert the harm of death.²³⁹

Third, the hospital reasonably anticipated a causal relationship between their conduct and the harm averted. Its actions of taking donations were meant to alleviate the specific harm it faced.

Fourth, the hospital did not have any legal alternatives to violating the law. The hospital faced absolutely no other alternative than that of taking a donation from a high-risk donor as the pool of donors was so constricted and the blood supply was so limited. Finally, unlike in our previous hypotheticals,²⁴⁰ the emergency response plan would not have worked because of the limited access to the area and the blood supply

239. *See supra* note 188.

240. *See supra* Part 0, Sec. 0(0).

could not be compensated for as there was no way to ship blood into the affected area.

All the elements being met, the court would likely allow the affirmative defense of necessity to stand, and the court would enter judgement for the defendant.

VII. CONCLUSION

A. A Synthesized Rule for Blood Manufacturers wishing to proffer the defense.

As demonstrated above,²⁴¹ there is an enormous hurdle that blood manufacturers must overcome to argue the defense's applicability. And, sadly, this hurdle is only met in the most devastating of tragedies. However, we still find that there is a small window that allows high-risk donors the chance to take part in times when selflessness is needed most. To invoke the necessity defense, the emergency must be imminent and prolonged enough so as to constrict the blood supply in a specific geographic area to such a degree that a blood bank or manufacturer must act to combat the emergency. In doing so, the blood manufacturer must take reasonable measures to ensure the safety of the blood supply.²⁴²

B. Recommendations to Blood Manufacturers Asserting the Defense.

If an emergency were to occur, the following recommendations are made to protect blood manufacturers faced with the emergencies as the examples describe above.²⁴³

241. See *supra* Part 0.

242. On a side note, the defense of necessity would most likely not be allowed to extend to donors who fit other categories but also face long or definite deferrals. For example, the defense would most likely not extend to manufacturers taking donations from potential carriers of Variant Creutzfeldt-Jakob disease ("vCJD") (colloquially known as "Mad Cow Disease"). While the jury is still out as to whether vCJD can be passed via blood transfusion, there remains evidence that the potential exists. Furthermore, there is no known cure or treatment for vCJD. It is sad conclusion is madness and death for the patient. As such, the "choice of evils" is not to save a life, but to potentially continue the spread of an incurable disease.

243. See *supra* Part 0, Sec. 0.

i. Mandatory quick HIV testing for high-risk donors

First and foremost, because of the availability of quick HIV tests,²⁴⁴ if the patient examination reveals that the individual is a high-risk donor,²⁴⁵ then the donor should be subjected to a mandatory, quick HIV test. However, each donation should be made on a case-by-case basis, with weight given to the various circumstances of the emergency and how the manufacturer conducted itself in taking the donation.

ii. Labeling the blood in on a first-in, first-out system

Secondly, per FDA regulations on labeling,²⁴⁶ the blood taken from a high-risk donor should be labeled as such. Recommended language should be, “High-Risk, use only for emergency started [xx/xx/xxxx]. To be destroyed if not used.”²⁴⁷

Within this, any donations taken from high-risk donors should be used *last*. Therefore, during an emergency, blood manufacturers should adopt a “first-in, first-out” inventory system,²⁴⁸ so that the current supply of low-risk donations should be completely exhausted prior to transfusing or releasing high-risk donations. Furthermore, whenever low-risk donations enter the supply during an emergency, these donations should be used on a quasi “last-in, first-out” system.²⁴⁹ That is, as low-risk donations enter the supply, the low-risk donations should be used as soon as possible (first-in, first-out) and before going back to using high-risk donations.

iii. Seeking an exception from the FDA

In cases of emergency, the blood manufacturer should immediately contact the FDA to seek an exception to regular practice.²⁵⁰ Because the FDA may respond immediately to an oral request,²⁵¹ this is

244. See *supra* Part 0, Sec. 0.

245. See *supra* Part 0, Sec. 0 (0).

246. See 21 C.F.R. § 606.120 (2016); see also 21 C.F.R. § 606.121 (2016).

247. See *infra* Part 0, Sec. 0 (0).

248. See generally CARL S. WARREN, JAMES M. REEVE & JONATHAN DUCHAC, FINANCIAL AND MANAGERIAL ACCOUNTING 274-79 (Rob Dewey et al. eds., 11th ed. 2012) (while this source deals with the cost accounting of business inventories, it provides a helpful illustration of how each system works from a practical standpoint).

249. *Id.*

250. See 21 C.F.R. § 640.120 (2016). The manufacturer should state that they are “respond[ing] to a public health need.” *Id.*

251. *Id.*

most advisable for manufacturers to seek protection for actions outside of the norm (*i.e.*, taking blood from high-risk donors).

Taking this action and receiving a response stating that the exception is allowed gives the blood manufacturer the chance to seek a regulatory opinion as well as to act in reliance of that opinion.

iv. Destruction or isolation of remaining inventory upon conclusion of the emergency

High-risk donations should never be released to blood banks unaffected by the emergency or into the general blood supply. Upon the conclusion of the emergency,²⁵² any remaining inventory that is labeled “high-risk” should be immediately dispatched for destruction or isolated to be given to research facilities.

C. How would Blood Manufacturers be protected?

In asserting the defense of necessity, blood manufacturers would be protected from FDA action seeking to suspend or revoke a manufacturer’s license.²⁵³

In addition, the defense of necessity also implies that the duty of care in a negligence case²⁵⁴ remains the same as before (that of a reasonably prudent blood manufacturer);²⁵⁵ however, the question of

252. It should be noted that the definition of *emergency* herein implied may extend beyond the physical events constituting the need to take blood from high-risk donors. Instead, there may remain a need to replenish the blood supply. If this is the case, priority should be placed in replenishing the supply with blood from low-risk donors. High-risk donations should be taken and kept only if necessary to alleviate the emergency. On the same note, as the emergency comes to an end, blood banks should transition back to using previous methods of donor filtration. That is, deferring high-risk donors per FDA regulation and reintegrating normal operations as quickly as possible.

253. See *supra* Part 0, Sec. 0.

254. See *supra* Part 0, Sec. 0.

255. *Advincula v. United Blood Servs.*, 678 N.E.2d 1009, 1026 (Ill. 1996) (“The application of a professional standard of care to the conduct of blood banking organizations in collecting blood comports with a majority of jurisdictions which have considered this issue, in a variety of contexts.”); see *Zaccone*, 872 F. Supp. at 460 (finding that because the defendant (a blood manufacturer) utilized extensive medical expertise and personnel in providing its service of (1) collecting and processing of blood, which, in turn, was carried out by trained health care professionals, (2) testing blood through various laboratory processes, (3) separating the blood into components by trained medical professionals, and (4) conducting examinations of donors, the defendant was subject to professional standard of care); see also *Doe v. Am. Nat’l Red Cross*, 848 F. Supp. 1228, 1233 (S.D. W. Va. 1994) (“[The defendant] had the

whether the defendant breached that duty of care by not acting as a reasonably prudent blood manufacturer would still need to be answered. In a negligence case, the blood manufacturer would not assert necessity as an affirmative defense but, instead, would challenge the breach element of the plaintiff's *prima facie* case.

D. A Benefit to All

Altruism is one of the most beautiful compassions of humanity. It permeates in times of need, alleviates sorrow and suffering, and makes possible great endeavors that many believe to be impossible. Truly, even if this philanthropic nature is only shared amongst a small group, we should never doubt for a second that a small group of thoughtful, committed people can change the world because, indeed, it is the only thing that ever has.²⁵⁶

In the years following the HIV/AIDS epidemic, medical and societal advances have allowed many individuals the opportunity to give a part of themselves for the benefit of others. From today onward, policy shifts in the United States and advancements in medical technology may, one day, make moot the need for the label of “high-risk.” In the present, extending the defense of necessity to encompass situations like those herein described opens new opportunities for people to share the one gift that is all too hard to give in the first place—that of life itself.

duty to exercise the degree of care commonly practiced by the ordinary skillful, careful, and prudent blood bank or equivalent personnel in the same or similar circumstances.”).

256. Credit for this altered quote must necessarily and rightfully be given to Margaret Mead, a leading voice in the cultural shift and sexual revolution that, in the opinion of this author, greatly and positively shaped the way women's, LGBTQ, and other minorities' rights have shifted for the better in the past century.