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ABSTRACT

There are many components vitally essential to our biological function, and humanity tends to recognize, and often fight against, mounting threats to those very things. As a civilized society, Americans, in general, expect clean air, drinkable water, and safe food on a daily basis. However, a resource equally as essential to each of us is rarely recognized for its utility and necessity until a threat to its viability becomes personal. The blood shortage in the United States grows more critical every day, but for those of us lucky enough to not urgently need blood, the threat feels more removed and less important than similar threats to the air we breathe, the water we drink, and the food we consume. This article looks at the history of blood donation, collection, and supply in the United States, and how changing societal norms, unworkable federal regulation, and misdirected economic influences are impacting the blood shortage crisis. The result is an urgent need to reconsider how the blood supply system could work to more efficiently solve for the even larger, more urgent need for blood.

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I. INTRODUCTION

It may be a well-known television doctor who famously said, "it's a beautiful day to save lives,"[1] but realistically, doctors are not the only people who can save lives.[2] In fact, before medical professionals can ever attempt to save a life, there is an inherent prerequisite that a sufficient blood supply exists for doctors to utilize in order to save the one out of seven patients needing a blood transfusion.[3] Every day, hospitals throughout the country need approximately 41,000 units of blood, and the demand is endless.[4] Therefore, in the United States, blood is a "critical national resource,"[5] so a threat to this resource is a threat to human life. Regrettably, there is an increasingly dire threat to the blood supply that is being felt month after month and year after year—not only by blood donation centers and hospitals, but also by the people waiting for life-saving treatment.[6]

Over the past decade, the United States has routinely found itself dealing with a constantly vulnerable blood supply.[7] During 2008, blood collection and transfusion peaked, with over 17 million units of red blood cells being collected.[8] But by 2015, blood collections had dropped 27.2% compared to 2008.[9] The National Blood Collection and Utilization Survey concluded that the significant declines between 2008 and 2015 resulted in an insufficient blood supply to meet routine demands nationwide.[10] Although figures for collection rates are not yet available for 2016-2018, projections expect the blood supply to continue to dwindle, weakening an already fragile system.[11] Even without statistical data, concern over a persistent

1. Top 10 Grey's Anatomy Quotes, FAMOUS QUOTES & QUOTATIONS, http://www.famous-quotes-and-quotations.com/greysanatomyquotes.html (last visited Mar. 25, 2019).

2. Jill Poet, *Blood Donation: You Don't Have to be a Doctor to Save Lives*, HEALTHY LIFE ESSEX (Feb. 28, 2018), https://healthylifeessex.co.uk/2018/02/blood-donation-save-lives/ (citing the infographic published by Study Medicine Europe).

3. ANDREW W. MULCAHY ET AL., RAND CORP., TOWARD A SUSTAINABLE BLOOD SUPPLY IN THE UNITED STATES: AN ANALYSIS OF THE CURRENT SYSTEM AND ALTERNATIVES FOR THE FUTURE iii (2016), https://www.rand.org/content/dam/rand/pubs/research_reports/RR1500/RR1575/RAND_RR1575.pdf; Joseph A. Ibrahim, *Why Blood Donations are so Important*, ORLANDO HEALTH (Jan. 25, 2018), https://www.orlandohealth.com/blog/why-blood-donations-are-so-important; *Blood Transfusions are Vital to Saving Lives*, CARTER BLOODCARE (Aug. 1, 2013), http://www.carterbloodcare.org/blood-transfusions-are-vital-to-saving-lives/.

4. *Make a Difference Through Blood Donation*, DRS. OSTEOPATHIC MED., https://doctorsthatdo.org/blood-donation-can-save-lives (last visited Mar. 25, 2019); Ibrahim, *supra* note 3.

5. Jay E. Menitove, *The U.S. Blood System: Under Pressure*, 15 HEMATOLOGIST 4, 4 (May 2018), https://www.hematology.org/Thehematologist/Past-Issues/8570.aspx.

6. Joe Severino, *Red Cross Officials Call Blood Shortage 'Dire'*, CHARLESTON GAZETTE-MAIL (July 9, 2018), https://www.wvgazettemail.com/news/health/red-cross-officials-call-blood-shortage-dire/article_aba5b311-9d54-5b40-b087-47a5ccf8983e.html.

7. Anne Lodge, *Bioengineering Solutions to the Blood Supply Shortage*, ASTARTE BIOLOGICS (Nov. 30, 2017), https://astartebio.com/bioengineering-solutions-blood-supply-shortage/; *see also* Menitove, *supra* note 5, at 4.

8. Menitove, *supra* note 5, at 4 ("Red cell collections and transfusions peaked in 2008 at approximately 17,286,000 units collected, 17,159,000 units distributed, and 15,014,000 units transfused.").

9. *Id.* (showing roughly 12.5 million red blood cells units were collected in 2015).

10. Katherine D. Ellingson et al., *Continued Decline in Blood Collection and Transfusion in the United States–2015*, 57 TRANSFUSION 1588, 1589 (June 2017), https://onlinelibrary.wiley.com/doi/epdf/10.1111/trf.14165.

11. Menitove, *supra* note 5, at 4.

shortage is evidenced by the pleas of national and regional collection organizations and hospitals that are desperate for more donors.[12]

With the country nearing a decade of continued blood shortage, there are multiple reasons why the United States cannot stay ahead of the need for blood. One factor, which is the most prominently and generally known, is how the lack of donations from eligible donors has dramatically worsened.[13] Whether the source of this decline is from the older generation of reliable donors beginning to age out[14] or past blood donors lapsing and reducing their donation frequency,[15] the blood industry's response needs to be revisited.[16] Three additional factors that contribute to the blood shortage crisis stem from how the Food and Drug Administration ("FDA") regulates the blood supply. First, donor deferrals, although necessary for a safe blood supply in general, have been temporarily or permanently assigned—often erroneously, and usually avoidably—to a growing proportion of otherwise willing donors.[17]

Second, the FDA currently accepts no substitutions for human blood despite the availability of alternative synthetic products that are not only universally compatible and more readily available but also increasingly safe.[18] This regulation consequently results in a less flexible blood supply system, putting more pressure on collection organizations to recruit new or recruit lapsed donors—a lone strategy that has been empirically ineffective at curbing the blood shortage.[19] A final component of the decade-long shortage stems from another regulatory shortcoming; the FDA

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12. *Significant Shortages Impact U.S. Blood Supply*, AM. RED CROSS (July 11, 2016), https://www.redcross.org/about-us/news-and-events/press-release/Significant-Shortages-Impact-US-Blood-Supply.html [hereinafter *Significant Shortages Impact*]; *Emergency Blood Shortage: Red Cross Issues Urgent Call for Blood Donors*, AM. RED CROSS (July 9, 2018), https://www.redcrossblood.org/local-homepage/news/article/emergency-blood-shortage--red-cross-issues-urgent-call-for-blood.html.

13. Ryan Patterson, *National Drop in Blood Donors Hits Sheridan*, CASPER STAR TRIB. (Aug. 3, 2018), https://trib.com/news/state-and-regional/national-drop-in-blood-donors-hits-sheridan/article_2c6608b8-4208-5faa-921c-543cb6cf40c1.html.

14. JoNel Aleccia, *As Loyal Blood Donors Age, Industry is out for Young Blood*, USA TODAY (Sept. 24, 2017, 12:01 AM), https://www.usatoday.com/story/news/health/2017/09/24/loyal-blood-donors-age-industry-out-young-blood/683714001/.

15. Johanne Charbonneau et al., *Why Do Blood Donors Lapse or Reduce Their Donation's Frequency?*, 30 TRANSFUSION MED. REVS. 1, 1 (Jan. 2016), https://ac.els-cdn.com/S0887796315001169/1-s2.0-S0887796315001169-main.pdf?_tid=979cd3a3-c81e-4b14-bb97-e4341f798d89&acdnat=1538241592_636c4aca3fb009f7bf044c11554ce070.

16. C.K. Lee, *Update on Donor Recruitment Management in Blood Service*, 11 INT'L SOC'Y BLOOD TRANSFUSION 69 (June 28, 2016), https://onlinelibrary.wiley.com/doi/full/10.1111/voxs.12265.

17. *See generally* Suhailur Rehman et al., *The Evaluation of Blood Donor Deferral Causes*, 3 J. BLOOD DISORDERS & TRANSFUSION 1 (Oct. 2012), https://www.omicsonline.org/the-evaluation-of-blood-donor-deferral-causes-a-tertiary-care-centrebasedstudy-2155-9864.1000131.pdf (showing data explaining possible reasons why donors may be deferred by collection centers); Brian Custer et al., *Quantifying Losses to the Donated Blood Supply due to Donor Deferral and Miscollection*, 44 J. AABB: TRANSFUSION 1417 (Sept. 22, 2004), https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1537-2995.2004.04160.x; Kusum D. Jashnani & Laxmi N. Patil, *Blood Donor Deferrals: Can This be Reduced?*, 5 ASIAN J. TRANSFUSION SCI. 60 (Jan. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3082725/; P. A. Tomasulo et al., *A Study of Criteria for Blood Donor Deferral*, 20 J. AABB: TRANSFUSION 511 (Sept. 1980), https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1537-2995.1980.20581034503.x?sid=nlm%3Apubmed.

18. Nina Notman, *Red Blood Cell Substitutes*, CHEMISTRY WORLD (Feb. 16, 2018), https://www.chemistryworld.com/feature/artificial-blood/3008586.article.

19. Custer et al., *supra* note 17.

does nothing to combat widespread "misuse of the blood supply" by hospitals, including doctors' tendencies to overprescribe blood transfusions.[20]

Regardless of the exact combination of factors causing the blood shortage, the enormous impacts of the ongoing crisis are at the great expense of patients and their families. Usually, the human cost and the economic cost go hand-in-hand, where

> [a]n inadequate blood supply may pose a danger to patients if the proper amount and type of blood is not available when needed. It may lead to longer hospital stays if elective procedures must be postponed in order to wait for an adequate blood supply. This leads to increased costs, as well as potential risks for patients.[21]

In much more severe circumstances, "blood shortages become so critical that major surgeries and other hospital procedures that require blood transfusions will halt entirely. For patients who need urgent surgery, this can mean the difference between life and death."[22] Here, the potential human cost does not need to be supplemented with an associated economic cost for the impact to be disastrously unacceptable.

In addition to the impact on patients, the negative impacts of consistent blood shortages are also felt by the healthcare industry. The U.S. Department of Health and Human Services contracted the RAND Corporation to assess instability within the blood supply system, aiming to understand the economic implications of the crisis on the industry.[23] The shortage from 2008 to 2015, in conjunction with other trends,[24] resulted in over 90% of blood providers' expenses exceeding revenues in 2016.[25] Obstacles created by the shortage result in cost increases for hospitals, which relatedly increases the financial pressure on blood centers when they absorb the associated costs.[26] Simply put, when there is less blood collected, there is less blood to sell; when there is less blood to sell, blood centers lose revenue and hospitals incur greater costs to buy whatever blood is available. However, the Advisory Committee on Blood and Tissue Safety distinguishes that normal "supply and demand economic principles do not fully address the societal value of" blood as a "critical national resource."[27] This important distinction surely adds further complexity and uniqueness to the problem at hand, but neither the complex nor unique

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20. Colin Hemez, *Blood Transfusion Costs*, YALE GLOBAL HEALTH REV. (Dec. 21, 2016), https://yaleglobalhealthreview.com/2016/12/21/blood-transfusion-costs/.

21. Jeffrey McCullough, *Blood Supply Fluctuations*, *in* BLOOD DONORS AND THE SUPPLY OF BLOOD AND BLOOD PRODUCTS 9, 9 (Frederick J. Manning & Linette Sparacino eds., 1996), https://www.ncbi.nlm.nih.gov/books/NBK233132/pdf/Bookshelf_NBK233132.pdf.

22. *The Impact of Blood Shortages on American Healthcare*, RATE HOSPS. (Jan. 21, 2014), https://web.archive.org/web/20170731190327/http://www.ratehospitals.com/blog/the-impact-of-blood-shortages-on-american-healthcare/.

23. Menitove, *supra* note 5, at 4 (The RAND Corporation is a global nonprofit think tank, funded privately and by the U.S. government to research and develop solutions to public policy challenges, including the blood shortage.).

24. *Id.* (detailing how additional factors are influencing the industry, such as a declining number of transfusions).

25. *Id.*

26. *Id.*

27. *Id.*

nature of the problem excuses the urgent obligation of relevant officials and agencies to find and implement a near-term solution.[28]

Despite the obviously troublesome situation, the FDA boldly noted in early 2018 how "the blood supply is *safer than it ever has been*."[29] While that may be true for the supply of blood which is physically collected and transfused, the sustainability of the blood supply faces great risks. One may argue, as this article does, that because the blood supply system lacks sufficient resiliency, the blood supply is thereby *less safe than it ever has been*.[30] Leaders of transfusion medicine—those who navigate and deal with the blood supply shortage on a daily basis—agreed with this point in 2017 when they

> conclude[d] that 'allowing the U.S. blood system to function as it has while it is losing stability, resilience, and surge capacity is not a responsible option,' and caution[ed] that 'a constructive intervention to stabilize the U.S. blood system, although urgently needed, has yet to be envisioned.' The importance of addressing these issues . . . is obligatory. . . .[31]

After analyzing the social and legal history of the industry in Part II, this article further reveals the unfortunate status quo of the blood supply industry in Part III. Then, Part IV suggests various reconsiderations of the current system in order to revitalize and stabilize the blood supply, drawing upon a creative combination of social, political, legal, economic, and scientific perspectives.

First, subsection A of Part IV discusses how blood collection organizations must make greater, more focused use of social media marketing. Strategically utilizing modern advertising tools will allow easier dissemination of relevant information to the public. Because social media is a relatively easy approach to revamping an organization's marketing, and the public is the inherent pool of potential donors, this change is both practical and necessary.

Second, subsections B and C of Part IV discuss how the remainder of necessary changes lies in altering current FDA regulations and guidance. Among these changes are: (1) popularizing blood donor incentivization through tax credits or direct payments to draw in new donors and retain current/past donors; (2) clarifying both the standards and process for donor requalification, following either temporary or indefinite donor deferrals; and (3) allowing the regular use of synthetic blood alternatives beyond the limited, exceptional uses allowed currently.

Finally, the conclusion in Part V synthesizes how urgently a solution is needed, whether it involves the solutions discussed in Part IV or involves an entirely different idea yet to be discovered and developed. Regardless, a "robust, sustainable blood system is a crucial component of every health care system."[32] In order for medical professionals to ensure the safety of current and future patients' lives, the nation must first ensure the safety of our at-risk blood supply.

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28. *Id.*

29. *Blood & Blood Products*, FDA, https://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/default.htm (last updated Feb. 2, 2018) (emphasis added).

30. Menitove, *supra* note 5, at 4 (citing to the U.S. Department of Health and Human Services, Advisory Committee on Blood and Tissue Safety and Availability (Nov. 2016)).

31. *Id.*

32. MULCAHY ET AL., *supra* note 3.

II. OVERVIEW OF RELEVANT BLOOD COLLECTION AND SUPPLY LAW IN THE UNITED STATES

Blood banking in the United States first began in 1936 and has since developed into a sophisticated blood supply system.[33] Essential to the development of the system was a 1972 report from the U.S. Department of Health, Education, and Welfare, stating

> several problems within the blood supply system, including an inadequacy in the quantity of blood supplied, an unreliability in the quality of blood owing to the high rates of transfusion-related hepatitis, an inefficiency in the system itself owing to waste in some areas and shortages in others, and excessive costs of blood and blood services.[34]

The corresponding result was the creation of the National Blood Policy in 1973, which nationally standardized all blood donation and collection practices and became "the focal point around which blood banking policy has evolved" over time.[35] It was this policy that first encouraged efforts to end paid blood donations and, instead, establish a purely volunteer blood donation system that hoped to eliminate commercialism in the acquisition of transfusable blood.[36]

Presently, the U.S. blood system has grown into a complex function of multiple moving parts: "donors; blood centers; suppliers of equipment, goods, and services used in the blood system; hospitals and clinics; and patients."[37] In addition, the FDA is a key component of the blood supply process because it authorizes the regulation of all biologic products, "including blood and blood-components."[38] The process of supplying blood in the United States begins with the blood collected from donors at blood collection organizations, hospitals, or the like, all of which are registered and licensed by the FDA.[39] Using the 2016 data collected under the research contract with the Department of Health and Human Services, The RAND Corporation determined there were 786 registered blood collection organizations on top of another 725 hospital and nonhospital blood banks.[40]

A few large, national organizations comprise and operate the majority of blood collection organizations: AABB, The American Red Cross, and America's Blood Centers.[41] Formerly titled the American Association of Blood Banks, AABB is an

33. *Blood Banking and Donation*, AM. SOC'Y HEMATOLOGY, https://www.hematology.org/Patients/Basics/Banking.aspx (last visited Mar. 25, 2019).

34. INST. OF MED. (U.S.) COMM. TO STUDY HIV TRANSMISSION THROUGH BLOOD AND BLOOD PRODUCTS, HIV AND THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 41 (Lauren B. Leveton et al. eds., 1995), https://www.ncbi.nlm.nih.gov/books/NBK232409/#_ddd00056_ [hereinafter HIV AND THE BLOOD SUPPLY].

35. *Id.* (citing OTA 1985); *see also History of Blood Transfusion*, AM. RED CROSS, https://www.redcrossblood.org/donate-blood/blood-donation-process/what-happens-to-donated-blood/blood-transfusions/history-blood-transfusion.html (last visited Mar. 25, 2019).

36. HIV AND THE BLOOD SUPPLY, *supra* note 34, at 41 (citing the Federal Register 1975).

37. MULCAHY ET AL., *supra* note 3, at 7.

38. *Id.* at 10.

39. *Id.* at 11.

40. *Id.* at 12; *see also* Menitove, *supra* note 5, at 4.

41. *Significant Shortages Impact*, *supra* note 12.

international, not-for-profit association that represents individuals and accredits institutions involved in blood donation and transfusion medicine.[42] The American Red Cross is also a not-for-profit organization, and alone it supplies "about 40% of our nation's blood and blood components" among its other numerous humanitarian aid missions.[43] America's Blood Centers was founded in 1962 and is the largest network of independent and community blood programs in North America.[44] As indicated by The RAND Corporation's research, some hospitals also have their own blood collection centers but supplement their supplies with blood from national or regional organizations.[45]

As a whole, the blood industry is a $4.5 billion-a-year business, accounting for the operating expenses of collecting blood and the revenue gained from its sale.[46] Although the costs of collecting and supplying blood for transfusions vary around the country,[47] the blood shortage and its associated financial burdens on the blood industry are causing concern nationwide.[48] Of primary concern is that the cost of blood continues to increase,[49] prompting industry experts to suggest that this knowledge of rising prices "should be used by organizations and policy makers to improve financing and utilization management."[50] A preliminary understanding of the current policies governing the management and regulation of the blood supply system, as well as the agencies and organizations authorized to control it, is an essential foundation that must be laid out before undertaking any construction of potential solutions to the blood shortage crisis.

A. Statutory Influence on the Blood Supply

The main statutory sources regulating blood collection and supply in the United States, as well as authorizing the agencies and regulations discussed below,[51] are the Public Health Service Act ("PHSA"),[52] and the Federal Food, Drug, and Cosmetic Act ("FDCA").[53]

Concerned primarily with giving "a policy framework for federal [and] state cooperation in [advancing] public health," the PHSA includes provisions about

42. *Id.*

43. *Blood Needs & Blood Supply*, AM. RED CROSS, https://www.redcrossblood.org/donate-blood/how-to-donate/how-blood-donations-help/blood-needs-blood-supply.html (last visited Mar. 25, 2019).

44. *Significant Shortages Impact*, *supra* note 12.

45. MULCAHY ET AL., *supra* note 3, at 9; Menitove, *supra* note 5.

46. Erin Carlyle, *The Guys Who Trade Your Blood for Profit*, FORBES (June 27, 2012, 1:13 PM), https://www.forbes.com/sites/erincarlyle/2012/06/27/blood-money-the-guys-who-trade-your-blood-for-profit/#4bfa6c24282e; *see also* Kathleen M. Berry, *All About/Blood Banks; A Multibillion-Dollar Business in a Nonprofit World*, N.Y. TIMES (July 7, 1991), https://www.nytimes.com/1991/07/07/business/all-about-blood-banks-a-multibillion-dollar-business-in-a-nonprofit-world.html.

47. Hemez, *supra* note 20.

48. MULCAHY ET AL., *supra* note 3, at xiii.

49. Richard W. Toner et al., *Costs to Hospitals of Acquiring and Providing Blood in the US*, 9 APPLIED HEALTH ECON. & HEALTH POL'Y 29 (2011), https://link.springer.com/article/10.2165/11530740-000000000-00000.

50. *Id.*

51. *See infra* Part II.A.

52. Public Health Service Act, 42 U.S.C. §§ 201-300 (2018).

53. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (2018).

blood donation and transfusion.[54] Consistent with its policy aim, the PHSA established "a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply."[55] An additional relevant section allows authorized persons to have access to a Blood Donor Locator Service, which provides such persons with the mailing address of previously eligible donors determined to be infected with, or at risk of, blood related infections.[56] The FDCA authorizes the FDA to oversee the safety of foods, drugs, and cosmetics,[57] including the duty to oversee the safety of the U.S. blood supply.[58]

B. Regulation of the Blood Supply

The growing complexity of the modern blood supply system since its institution in 1973 is apparent in the regulatory authority which authorizes and governs it. Conveniently, the Code of Federal Regulations sections relevant to blood collection and supply can be categorized fairly neatly into two broad areas: (1) the general nature and types of a *blood donation*, which trigger specific, individualized language necessary for any analysis; and (2) the role of the *blood donor* in the blood supply system, encompassing the necessary determination of eligibility to donate. Before discussing these two areas, this subsection begins with a brief discussion of the agencies authorized to act in relation to the blood supply.

The Center for Biologics Evaluation and Research ("CBER") and its parent agency, the FDA, are responsible for regulating and overseeing the blood supply in the United States.[59] Both the CBER and the FDA, in conjunction with the Public Health Service ("PHS"), are also responsible for identifying and responding to threats against blood safety or supply.[60] The authority outlining the nature and scope of these responsibilities is found in federal statutes discussed above in subsection A and in the federal regulations discussed in the remainder of this subsection.[61] Viewed comprehensively, the CBER and the FDA work with other PHS organiza-

54. *Public Health Service Act Law and Legal Definition*, US LEGAL, https://definitions.uslegal.com/p/public-health-service-act/ (last visited Mar. 25, 2019); *see also* HIV AND THE BLOOD SUPPLY, *supra* note 34, at 48.

55. 42 U.S.C. § 300cc-19 (1988).

56. *Id.* § 1320b-11 (1994) (enabling relevant blood collection organization personnel to follow the FDA regulations requiring the notification of donors who test reactively for transfusion-transmitted infections).

57. *Federal Food, Drug, and Cosmetic Act of 1989 Law and Legal Definition*, US LEGAL, https://definitions.uslegal.com/f/federal-food-drug-and-cosmetic-act-of-1938/ (last visited Mar. 25, 2019).

58. *Food and Drug Administration*, WEST'S ENCYCLOPEDIA AM. L. (2005), https://www.encyclopedia.com/social-sciences-and-law/political-science-and-government/us-government/food-and-drug-administration; *see also* Theodore W. Ruger, *Federal Food, Drug, and Cosmetic Act (1938)*, ENCYCLOPEDIA.COM (2004), https://www.encyclopedia.com/social-sciences-and-law/economics-business-and-labor/businesses-and-occupations/drug-and-cosmetic (stating the FDA's general authority to govern the safety of "blood and tissue products").

59. *Regulation of the Blood Supply*, FDA, https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/RegulationoftheBloodSupply/default.htm (last updated Sept. 18, 2018) [hereinafter *Regulation of the Blood Supply*] (the FDA, as part of its responsibilities, "promulgates and enforces standards for blood collection and for the manufacturing of blood products.").

60. *Id.*

61. Public Health Service Act, 42 U.S.C. § 201 (1993); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938); *Regulation of the Blood Supply*, *supra* note 59.

tions, governmental agencies, "volunteer health organizations, universities, . . . scientists, nongovernmental laboratories, and" biological product manufacturers to control the blood supply system in the United States.[62] Even with so many entities sharing the responsibility, regulating the blood supply is no simple task. The proceeding discussion breaks down the two most fundamental areas of blood collection and supply regulation.

First, blood donation and collection regulations are located in Title 21 of the Code of Federal Regulations under the Biologics Subchapter, most recently amended in 2015.[63] Briefly, blood is defined as "a product that is a fluid containing dissolved and suspended elements which was collected from the vascular system of a human."[64] A blood component is "a product containing part of blood separated by physical or mechanical means."[65] These definitions imply the FDA does not authorize the use of synthetic blood alternatives because they are not collected from a human.[66]

The humans who allow their blood to be collected are each identified as a "blood donor."[67] Consistent with its colloquial use, the FDA's use of the word "volunteer donor" denotes an individual "who does not receive monetary payment for a blood donation."[68] Since 1974, "the near-universal practice in the U.S.A. has been to collect blood and blood components for transfusion from volunteer donors who are not paid, consistent with the long-standing national policy" adopted around that time.[69] Although there is no outright prohibition against instances of paid donation, the FDA requires whole blood and red blood cell donations that are "intended for transfusion" to be prominently labeled as either "paid donor" or "volunteer donor."[70] Unfortunately, Johns Hopkins economist, Mario Macis, explains that while blood donations labeled "paid donor" are normally as usable and safe as donations labeled "volunteer donor," hospitals still rarely use "paid donor" blood because of a generally unsupported, archaic determination that doing so would be unethical.[71]

Whole blood donations, primarily composed of red blood cells, will eventually be transfused directly into the human patient—again, this type of donation must be labeled as "paid" or "volunteer."[72] Aside from red blood cells, whole blood also include platelets and plasma, all which can be separated out for unique purposes, but must still be labeled as "paid" or "volunteer."[73] Conversely, the FDA allows

62. HIV AND THE BLOOD SUPPLY, *supra* note 34, at 45.

63. Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 80 Fed. Reg. 29841 (May 22, 2015).

64. 21 C.F.R. § 630.3(a) (2016).

65. *Id.* § 630.3(b); *see About Blood: Blood Facts*, COMMUNITY BLOOD CTR., http://givingblood.org/about-blood/blood-facts.aspx (last visited Mar. 25, 2019) ("One unit of blood can be separated into several components: red blood cells, plasma, platelets, and cryoprecipitate.").

66. 21 C.F.R. § 630.3(a)-(b).

67. *Id.* § 630.3(c).

68. *Id.* § 606.121(c)(8)(v)(B)-(C) (2016) (stating that benefits which "are not readily convertible to cash" are not "monetary payments").

69. *Paid vs. Unpaid Donors*, 90 VOX SANGUINIS 63, 69–70 (2006), https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1423-0410.2005.00708.x (referring to the National Blood Policy).

70. 21 C.F.R. § 606.121(c)(8)(v).

71. Elizabeth Preston, *Why You Get Paid to Donate Plasma but not Blood*, STAT (Jan. 22, 2016), https://www.statnews.com/2016/01/22/paid-plasma-not-blood/.

72. *Id.*; 21 C.F.R. § 606.121(c)(8)(v).

73. *Whole Blood Donation*, AM. RED CROSS, https://www.redcrossblood.org/donate-blood/how-to-donate/types-of-blood-donations/whole-blood-donation.html (last visited Mar. 5, 2019); 21 C.F.R. § 606.121(c)(8)(v).

targeted plasma donations to be compensated without any such labeling because plasma collections are never directly transfused into another person;[74] rather, plasma is broken down in different parts and protein products, and it is then sold for pharmaceutical use.[75]

In general, the controls for labeling, as well as for storage and testing, are individualized for the type of donation being collected (e.g., red blood cells, plasma, platelets) and the way the donation was collected (i.e., voluntarily or paid).[76] Therefore, regulations also control the storage and testing of donated blood products before they can be sold for use because there are varying types of donations.[77] Knowing the nature of the donation is only one piece of the regulatory puzzle, though. Next, examining the role of the human donor in the blood supply system, including the donor's eligibility or ineligibly to donate, completes the puzzle.

The second major area begins with the term "blood donor," which includes both a person who successfully gives blood as well as "a person who . . . [p]resents as a potential candidate for such donation."[78] This naturally leads to the question: what makes an individual eligible to donate blood? The basic standard is that a donor must be in good health and not present any factors that may negatively affect the "safety, purity, or potency of the blood or blood component."[79] To test a donor's ability to meet this standard, blood collection organizations determine eligibility based on (1) the donor's medical history, and (2) the donor's performance during the physical assessment made immediately prior to the expected donation.[80] Therefore, a satisfactory medical history and physical assessment on the day of a planned donation means the donor is eligible to donate; an unsatisfactory medical history or physical assessment means the donor is ineligible to donate. Limiting eligibility for blood donation is an extremely effective way to ensure a safe blood supply, but it is also one of the more contentious issues surrounding blood donation regulation.[81]

When circumstances deem a donor ineligible to donate blood, 21 C.F.R. § 630.10(h) instructs blood collection organizations to defer the potential donor and "notify the donor of the deferral."[82] There are two types of deferral: (1) pre-donation, up-front deferrals determined by screening out donors prior to donating based on the physical assessment, and (2) post-donation deferrals based on testing the donated blood sample for certain infections.[83] Depending on which type of deferral is issued and its causal basis, people who had volunteered to donate blood will be prohibited from doing so either temporarily or permanently.[84] Temporary deferrals

74. Preston, *supra* note 71; *see* 21 C.F.R. 606.121(e)(5).

75. Preston, *supra* note 71.

76. *How can One Donation Help Multiple People?*, AM. RED CROSS, https://www.redcrossblood.org/donate-blood/how-to-donate/types-of-blood-donations/blood-components.html (last visited Mar. 5, 2019).

77. 21 C.F.R. § 606.121; *see also* 21 C.F.R. § 610.40 (2016) (outlining the initial testing requirements that must be conducted on all donations of human blood or blood components).

78. 21 C.F.R. § 630.3(c) (2016).

79. *Id.* § 630.10(a)(2) (2016).

80. *Id.* § 630.10(d)-(f) (describing the specific medical history and physical health findings that must be obtained in order to donate blood); *see id.* § 630.10(g) (stating the "additional requirements for determining the eligibility of a donor . . . on the day of donation").

81. *See generally* Rehman et al., *supra* note 17.

82. 21 C.F.R. § 630.10(h) (citing to 21 C.F.R. § 630.40 (2016)).

83. 21 C.F.R. § 610.41 (2016); *see* 21 C.F.R. § 630.10(g)(i), (h).

84. 21 C.F.R. § 610.41; 21 C.F.R. § 630.10(h). *See also* FDA, REQUALIFICATION OF DONORS PREVIOUSLY DEFERRED FOR A HISTORY OF VIRAL HEPATITIS AFTER THE 11TH BIRTHDAY (Sept. 2017),

are characterized by the donor being prohibited from donating on the specific occasion they are deemed ineligible but do not automatically preclude the donor from future donations if the reason for the prior deferral is no longer applicable.[85] A temporary deferral also covers a deferral that only prohibits donation for a fixed period of time.[86] On the other hand, a permanent deferral prohibits the donor from any future blood/blood component donation absent some explicit exception provided for in the regulation.[87] This more serious deferral is enforced after the post-donation testing yields evidence of infection from one of the relevant transfusion-transmitted infections described in § 630.3(h)(1), including Human Immunodeficiency Virus ("HIV"), strains of hepatitis, syphilis, West Nile virus, and malaria.[88] Narrow exceptions to permanent deferral can be found if the donor tested reactive to a certain infections on only one occasion prior to the current donation.[89] Regardless of allowing an exception, every establishment involved in the collection and supply of donated blood must maintain comprehensive records of all deferred donors upon determination of a donor's prior ineligibility.[90]

As noted above, further regulation also provides for certain exceptions or re-qualification of deferred donors.[91] However, beyond defining which donors may potentially be excepted or re-qualified, 21 C.F.R. § 610.41(b) does not provide any further instruction for *how* organizations can assist indefinitely deferred donors toward future eligibility to donate.[92] The language states that "a deferred donor may be subsequently found to be eligible as a donor of blood or blood components by a requalification method or process found acceptable for such purposes by the FDA. Such a donor is considered no longer deferred."[93] Although the FDA has, on occasion, offered additional guidance regarding re-qualification of donors, it is often narrowly targeted, circularly reasoned, and left to the discretion of establishments.[94] At most, these regulations put blood collection organizations in a position to enter a maze of deferred donor policy without a voice or a light to guide them—and most organizations opt to leave the deferred donor issues alone rather than blindly navigate the maze.

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https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM574574.pdf [hereinafter REQUALIFICATION OF DONORS PREVIOUSLY DEFERRED] (noting that permanent deferrals are also identified as "indefinite" deferrals).

85. 21 C.F.R. § 630.35(a) (2016).

86. *Id.*

87. *Id.* § 610.41(a).

88. 21 C.F.R. § 610.40(a)(1)-(3) (2016); *see* 21 C.F.R. § 630.3(h)(1)(i)–(x) (2016) (enumerating all other relevant transfusion-transmitted infections and strains: HIV types I and II, Hepatitis B virus, Hepatitis C virus, Human T-lymphotropic virus types I and II, syphilis, West Nile virus, Chagas disease, Creutzfeldt-Jakob disease, Variant Creutzfeldt-Jacob disease, and malaria).

89. 21 C.F.R. § 610.41(a)(1) (stating "a donor who tests reactive for anti-HBc or anti-HTLV types I and II" qualify for this exception. An additional exception exists under § 610.41(a)(3)-(4) for reactive donors who only donate plasma for pharmaceutical uses rather than for direct transfusion.).

90. 21 C.F.R. § 606.160(e) (2016).

91. REQUALIFICATION OF DONORS PREVIOUSLY DEFERRED, *supra* note 84, at 3.

92. 21 C.F.R. § 610.41(b).

93. *Id.*

94. *See* REQUALIFICATION OF DONORS PREVIOUSLY DEFERRED, *supra* note 84; *see also* FDA, RECOMMENDATIONS FOR REQUALIFICATION OF BLOOD DONORS DEFERRED BECAUSE OF REACTIVE TEST RESULTS FOR ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPES I AND II (ANTI-HTLV-I/II) (Sept. 2018), https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM621245.pdf.

Since the federal government's institution of the National Blood Policy in the 1970s, each component of the policies, regulations, and statutes discussed above, as well as their drafters and authorities, have strived to maintain a blood supply that is adequate, high quality, accessible to its servicers, and efficient.[95] Unfortunately, the good faith means used to pursue a strong blood supply—policies and statutes authorizing regulations that explicitly limit use of viable synthetic blood, implicitly limit transfusion of safe "paid donor" blood, and silently limit access to improperly deferred donors—may not justify the end. The success of that pursuit must be scrutinized in light of the ongoing blood supply shortage that has amounted into an undeniable threat to one of our most "critical national resources."[96]

III. THE CURRENT STATE OF BLOOD COLLECTION AND SUPPLY

"The tragedy of life is often not in our failure, but rather in our complacency; not in our doing too much, but rather in our doing too little. . . ."[97] As the blood supply becomes increasingly unstable, the real tragedy is the system's complacency regarding the status quo. Dr. Arthur Caplan, the chairman of a 1999 Department of Health and Human Services committee to examine the country's blood supply, stated, "Complacency is completely inappropriate with respect to the blood supply."[98] In the 1990s, the executive director of America's Blood Centers gave credence to the analysts who believed that if trends did not change, the blood supply would soon fail to keep up with the demand for blood.[99] In 2019, it is clear that this prediction came true, and it continues to remain an issue inadequately addressed by those in a position to create change.

A similarly prescient statement, made by industry leaders attempting to curtail a potential shortage in the 1990s, conceded how "repeated appeals for blood . . . could deafen potential donors to the point where, one day, they simply might not respond."[100] This prediction has also come to fruition in 2019 as blood collection establishments seem to inundate potential donors with marketing strategies and express pleas, urging "donors to give now"[101] to build a sufficient supply and save

95. Derek J. Jones, *Ethical & Legal Issues in the Supply of Blood Products*, BAYER ADVISORY COUNCIL ON BIOETHICS 34 (Dec. 1999), https://www.mcgill.ca/healthlaw/files/healthlaw/Jones_DJ_ Issues_BloodSupply_1999.pdf.

96. Menitove, *supra* note 5.

97. Benjamin E. Mays, *Complacency Quotes*, BRAINY QUOTE, https://www.brainyquote.com/topics/complacency (last visited Mar. 25, 2019).

98. Eric Nagourney, *Blood Shortage: Answers Scarce, Too*, N.Y. TIMES (Oct. 5, 1999), https://www.nytimes.com/1999/10/05/health/blood-shortage-answers-scarce-too.html.

99. *Id.*

100. *Id.* (identifying the head of the FDA's blood-supply operation and the chief medical officer of the Red Cross at the time as industry leaders).

101. *Blood Shortage Continues: Red Cross Urges Donors to Give Now*, AM. RED CROSS (July 28, 2016), https://www.redcross.org/about-us/news-and-events/news/Blood-shortage-continues-Red-Cross-urges-donors-to-give-now.html.

patients in need.[102] Despite such a heavy reliance on marketing and emotional appeals to encourage donors to give blood,[103] more and more blood collection organizations report that far too few potential donors respond to the call and donate.[104] Consequently, less than 10% of people eligible to give blood actually do so.[105]

Focusing on this trend, ineffective approaches to marketing that are currently relied on may be seen as one of the reasons voluntary blood donation is not producing a sufficient blood supply. "Blood donation is a voluntary act and different organizations have to run rigorous campaigns to motivate the blood donors to make them realize how their contribution can save precious human lives."[106] Blood collection organizations admittedly understand the importance of these campaigns but are shockingly reluctant to adapt to the social media platforms that would help communicate their message most successfully.[107] Social media, more so than traditional platforms, can quickly and effectively distribute information to target audiences during critical situations.[108] Considering how young people will necessarily be the future pool of potential donors, targeting them through various forms of social media and interactive outreach must become part of an organization's best marketing practice.[109] Relevant studies from Europe, Australia, and Arab regions concluded that targeting young people with mobile apps and social media will specifically increase the amount of new, young donors, as well as increase their sustained loyalty.[110]

Complacency with the blood supply shortage in the United States is also perpetuated by continued reliance on altruism and volunteerism alone, which is currently proven to be insufficient to supply the amount of blood demanded.[111] There is a lack of personal connection in the current system because most blood donors do not know who will receive their blood.[112] Generally, blood from paid donors is

102. *Red Cross: Blood Donors Needed*, TIMES NW. IND. (Oct. 21, 2018), https://www.nwitimes.com/news/local/lake/red-cross-blood-donors-needed/article_7bba51e2-fbbb-52b5-b12c-7a33b235b81f.html.

103. Ashwin Aravindakshan, Oliver Rubel & Oliver Rutz, *Managing Blood Donations with Marketing*, 34 MARKETING SCI. 1 (Mar. 2015), https://www.researchgate.net/publication/270220057_Managing_Blood_Donations_with_Marketing.

104. John R. Hackett Jr., *A Plea to Young Americans: Donate Blood*, U.S. NEWS (June 14, 2018, 6:00 AM), https://health.usnews.com/health-care/for-better/articles/2018-06-14/a-plea-to-young-americans-donate-blood.

105. *Facts & Figures*, AM.'S BLOOD CTRS., https://www.americasblood.org/about-blood/facts-figures.aspx (last visited Mar. 24, 2019).

106. Rabeeh Ayaz Abbasi et al., *Saving Lives Using Social Media: Analysis of the Role of Twitter for Personal Blood Donation Requests and Dissemination*, 35 TELEMATICS & INFORMATICS 892, 895 (2017).

107. *Id.*

108. *Id.*

109. Marcus Foth et al., *Social and Mobile Interaction Design to Increase the Loyalty Rates of Young Donors*, PROC. 6TH INT'L CONF. ON COMMUNITIES & TECH. 64 (2013), https://eprints.qut.edu.au/59928/14/59928a.pdf.

110. *Id.*; *see also* Covadonga Aldamiz-echevarria & Maria Soledad Aguirre-Garcia, *A Behavior Model for Blood Donors and Marketing Strategies to Attract Them*, 22 REV. LAT. AM. ENFERMAGEM 467 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4292625/; Abbasi et al., *supra* note 106, at 910; John Healy & Maurice Murphy, *Social Marketing: The Lifeblood of Blood Donation?*, *in* THE CUSTOMER IS NOT ALWAYS RIGHT? MARKETING ORIENTATIONS IN A DYNAMIC BUSINESS WORLD 811 (Colin L. Campbell ed., 2017), https://link.springer.com/chapter/10.1007/978-3-319-50008-9_222.

111. Kathleen Chell et al., *A Systematic Review of Incentives in Blood Donation*, 58 J. AABB: TRANSFUSION 242, 242 (Jan. 2018), https://onlinelibrary.wiley.com/doi/10.1111/trf.14387.

112. *Donating Blood*, AM. CANCER SOC'Y, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/blood-transfusion-and-donation/donating-blood.html (last updated Apr. 7, 2017)

not used in the United States for transfusions.[113] Although the FDA does not entirely prohibit the paid blood donation,[114] direct payment and any other type of economic incentive are widely discouraged by the FDA's published guidance, which impacts hospitals' policies regarding paid donor blood.[115] Aside from economist Mario Macis's reasoning above that a hospital's anti-paid donor policy is driven by ethical perceptions,[116] a pragmatic, common sense perspective may simply reason that hospital boards are hesitant to openly deviate from the FDA's stance. Regardless of why the FDA and hospitals continue to advance a strong preference for volunteer blood, the reality is that they do—creating a constriction on the blood supply that is not workable as the nation's shortage reaches more critical levels.

A study conducted in Germany, one of the first countries to allow direct cash payments for blood donation, found that blood donations decrease when payment to donors is stopped.[117] Importantly, donation levels did not recuperate after payment was ceased.[118] The study concluded that direct incentivization is a powerful tool to prevent and mitigate blood shortages.[119] At a minimum, the FDA and American hospitals should concede the potential for economic incentives to positively influence blood donation. However, mere recognition of a potential solution without subsequent action is the exact type of complacency that the current blood shortage is rooted in.

Another basis for the suffering blood supply is current FDA regulation—first, the prohibition against synthetic blood products and second, the disgraceful conduct regarding some types of deferred donors. Currently, no oxygen-carrying blood substitutes are approved for use by the FDA.[120] The resistance against funding and using a substitute for human blood is due to one "poorly designed clinical trial" in 2008.[121] Since then, the FDA has not changed its official position even though "There has been a need for blood replacements for as long as patients have been bleeding to death because of a serious injury"; the FDA does recognize the potential for its use as an alternative to human blood, though.[122] Reconsidering this stance

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[hereinafter *Donating Blood*]. *See generally Directed Blood Donations*, MAYO CLINIC, https://web.archive.org/web/20080828202500/http://www.mayoclinic.org/donate-blood-rst/directed.html (last visited Mar. 25, 2019) (defining that a "directed blood donation," which is not the norm in the U.S., occurs when "the patient identifies family members or friends who will donate blood for the patient's surgery").

113. *Donating Blood*, *supra* note 112.

114. VOX SANGUINIS, *supra* note 69, at 69.

115. *See id.* at 70; Preston, *supra* note 71; FDA, CPG SEC. 230.150 BLOOD DONOR CLASSIFICATION STATEMENT, PAID OR VOLUNTEER DONOR (Nov. 11, 2011), https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm122798.pdf.

116. Preston, *supra* note 71.

117. David M. Becker et al., *The Impact of Direct Cash Payments on the Whole Blood Supply*, SSRN (Aug. 8, 2017), https://poseidon01.ssrn.com/delivery.php?ID=872119091124112031024111003125093087049073070064025021111113066102071087101118112000120032062006006027002112104105108065030005000029026049019123078083025089090011034006054125066098006065097123066072026002118073091096098103086119107076119096075116086&EXT=pdf.

118. *Id.*

119. *Id.* at 27.

120. A.I. Alayash, *Evaluating the Safety and Efficacy of Hemoglobin-Based Blood Substitutes*, FDA, https://www.fda.gov/biologicsbloodvaccines/scienceresearch/biologicsresearchareas/ucm127061.htm (last visited Mar. 25, 2019).

121. Notman, *supra* note 18.

122. Suman Sarkar, *Artificial Blood*, 12 INDIAN J. CRITICAL CARE MED. 140 (July 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2738310/; Andrew Joseph, *The Quest for one of Science's Holy Grails: Artificial Blood*, STAT (Feb. 27, 2017), https://www.statnews.com/2017/02/27/artificial-blood-substitute/.

has the potential of alleviating the threats facing the blood bank system as well as surging the economy with an estimated $7.6 billion in estimated sales.[123]

The approach toward blood donor deferral regulations in the United States is also complacent and serves as another avoidable cause of the blood shortage. Casually stated, "[w]hen a person is turned away from a blood donation, he or she" does not usually return.[124] For donors who are deferred temporarily, a lack of educational material reminding them to come back and donate again could represent why the United States is consistently unable to put the blood supply on more stable footing.[125] Donors who are deferred indefinitely, whether correctly or not, are more turned off from pursuing re-qualification for future donations.[126] Ignoring the actual, negative impacts of improperly applied donor deferral regulation is not an option for the FDA while the consequences of the blood shortage loom large.

Doctors with a policy-minded focus agree that "balance is key for any change in blood-donation policy, keeping in mind the dual goals of increasing the pool of eligible donors in the U.S. and maintaining the safety of anyone who receives donated blood."[127] Fortunately, solutions that emphasize achievement of these dual goals exist for each of the shortcomings present in the status quo. A reconsideration of the system is more vital now than ever to secure the blood supply—and therefore the nation's public health—now and in the future.[128]

IV. RECONSIDERING THE CURRENT SYSTEM TO SOLVE FOR THE BLOOD SHORTAGE

Although express efforts in the 1970s helped render it functional and effective for many decades, the time has come for focused and intentional changes in the blood supply system; it is time to modernize and realize new, actionable goals necessary to strengthen one of our country's most important yet vulnerable resources. It cannot be overstated that regaining and maintaining a safe, adequate blood supply (1) is fundamental to the nation's public health, (2) is a "priority for the medical community,"[129] and (3) should be a priority to the executive agencies capable of creating the change that is needed. Notably, there are various changes that can be made to solve for the inadequate supply without sacrificing the safety of donors and patients.

123. Sarkar, *supra* note 122.

124. Shalmali Pal, *Blood Donation: Separating Myth from Fact*, AM. SOC'Y HEAMATOLOGY CLINICAL NEWS (Jan. 1, 2018), https://www.ashclinicalnews.org/features/blood-donation-separating-myth-fact/.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Significant Shortages Impact*, *supra* note 12.

129. *Id.*

A. Modernizing Blood Collection Organizations' Approach to Marketing

Focusing on younger generations who are the future of the blood supply means that marketing tactics must also shift to the platforms utilized by these generations.[130] Studies have consistently shown that the use of applications like Twitter or Snapchat have the potential to disseminate information more rapidly and consistently to its audiences.[131] There are multiple factors that can increase the impact of social media marketing, and blood collection organizations have, at best, a weak argument for not taking advantage of them. Mentioned above, these organizations only state a reluctance to adopt modern marketing techniques available through social media.[132] Despite feeling reluctant, there are many ways for blood collection organizations in the United States to slowly find their footing in the modern marketing realm, especially because countries around the world have been doing so for years.

One example is found in Sweden. A Swedish blood service noticed consistently declining blood donation rates in developing countries all around the world and they decided to try utilizing automatic text messages to increase blood donations.[133] Something as simple as an automated message, which efficiently connects all the essential people within the blood supply industry, was found to boost donations greatly.[134] Additionally, campaigns like this were widely popular on social media and effectively generated awareness with the young audience about donating blood.[135] Organizations in the United States could realistically utilize these same tactics and reap the benefit of increased donation without impacting safety.

B. Normalizing Economic Incentives to Attract and Retain Donors

Empirical data from studies conducted in other countries shows the effectiveness of direct payment for blood donation. In the United States, payment is already authorized for plasma donations, and it is not an unreasonable leap to allow payment for red blood cell donation.[136] Although the FDA has put great effort into publishing their concern over payment for donated blood (e.g., paying donors may incentivize infected donors to hide their medical history in order to receive the donation payment),[137] the reality of the blood supply shortage outweighs their arguments.

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130. Liis Hainla, *21 Social Media Marketing Statistics You Need to Know in 2018*, DREAM GROW, https://www.dreamgrow.com/21-social-media-marketing-statistics/ (last updated Feb. 7, 2019) (stating that "social media has grown to become an even more crucial element of digital communications strategies"); *see also* Jon Stone, *Mobile Communication Helps Increase Blood Donations*, MOBILE CAUSE (June 15, 2015), https://www.mobilecause.com/mobile-communication-to-increase-donations/ (reporting "85% of young adults are smartphone users" as of 2015, which has only grown in recent years).

131. Abbasi et al., *supra* note 106.

132. *Id.*

133. Stone, *supra* note 130.

134. *Id.*

135. *Id.*

136. VOX SANGUINIS, *supra* note 69.

137. Hassan Abolghasemi et al., *Blood Donor Incentives: A Step Forward or Backward*, 4 ASIAN J. TRANSFUSION SCI. 9 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2847338/.

Considering that the FDA has such extensive, secure testing requirements for the blood that is donated, the minor flux in tainted blood can and would be screened out, while the increase of transfusable blood will be passed along to waiting patients.[138] Additionally, in Germany, a fairly similar developed country to the United States, direct payment has been shown to allow the blood supply to be adequately maintained without compromising the safety of the blood transfused.[139] Regardless of the opportunity to aid the blood supply, the FDA officially commented that paid donation risks the safety of blood.[140] Therefore, the FDA refuses to endorse paid donations because it intends for all screening of donated blood to be redundant, "like layers of an onion."[141]

A consistent compensation scheme will also allow for the existence of the compensation to become more widely known, and, over time, blood will be supplied more willingly. Although volunteerism and altruistic values supported the blood supply for decades, the waning level of current donations proves that is simply not the case anymore.[142] This is not to say that blood donation should cease to be recognized as a good deed. Rather, donors can be more effectively drawn in by combining people's tendency to take altruistic action with a direct, external incentive that increases the likelihood of getting donors in the door.

Potential economic incentives, such as cash payment, tax deductions, or coupons,[143] would require changes in U.S. statutory authority and in the tone of the FDA's guidance. Upheld by the Supreme Court in *Lary v. U.S.*, the Internal Revenue Service ("IRS") does not allow a donor to "claim a charitable deduction" based on either "performance of a service" or "contribution of property. . . ."[144] Interestingly, if an individual receives payment for a blood donation, they must report that income to the IRS.[145]

To allow for maximum attraction and retention of donors, the government and blood collection organizations should mandate direct payments, even if subject to income tax; or the system could maintain its altruistic nature but provide donors a tax incentive. Either way, the safety of the blood supply is minimally compromised, and the blood supply could be bolstered.

C. Necessary Changes to Current FDA Regulations of Blood Collection and Supply

i. Clarification of Deferred Donor Requalification

The FDA needs to either provide internal clarification and guidance for how blood collection organizations can assist deferred donors in re-qualifying, or it must relax some of the standards that are based on false-positive reactivity. Once a donor is turned away—whether the determination of their deferral was erroneous or not—

138. Preston, *supra* note 71.
139. Becker et al., *supra* note 117.
140. Preston, *supra* note 71.
141. *Id.*
142. *See, e.g.*, Patterson, *supra* note 13.
143. Chell et al., *supra* note 111.
144. Lary v. U.S., 787 F.2d 1538, 1549 (11th Cir. 1986).
145. Julian Block, *The Strange Case of the Blood Deduction*, ACCT. WEB (July 14, 2014), https://www.accountingweb.com/tax/irs/the-strange-case-of-the-blood-deduction.

it is unlikely they will return to donate again.[146] This is a significant loss in the amount of willingly donated blood that the status quo cannot bear to part with unless the deferral is better explained to the people impacted by it.

In 2014, the author of this article was indefinitely deferred by one of the large blood collection organizations following a false-positive reactivity to Hepatitis-B. Prior to the deferral, the author donated blood as often as allowed and never had any issues—she was, and planned to remain, a loyal, repeat donor. Since the deferral, though, the author's personal experience seeking requalification has proved confusing and futile. Although the author takes issue with the fact that inaccurate reactivity testing led to her deferral, it is more concerning that blood organizations were seemingly comfortable losing a reliable donor at a time when knowledge of the shortage was first emerging.

If the FDA provides greater, clearer guidance to blood organizations, the author may not still be deferred. If the FDA required blood organizations to follow up on improperly deferred donors, the author would no longer be deferred and, accordingly, would be donating regularly. While investigating this issue, the author realized that her situation was not a rarity. To the contrary, a handful of the author's personal acquaintances have dealt with the same improper deferral and a similar lack of follow-up by the organizations.

ii. Regular Use of Synthetic Blood Alternatives

Synthetic blood has been tested tirelessly, and, although it would be a dramatic shift in the blood supply's historic reliance on human blood,[147] such utilization may have positive impacts on the threatened blood supply. The FDA has recognized this alternative's potential to be lifesaving in situations where blood transfusions are necessary, but where human-donated "blood is not available or can't be used."[148] Debates over the efficacy of synthetic blood is holding the FDA back from seriously considering its approval for transfusion,[149] despite scientific proof that synthetic blood alternatives at least work as a short-term replacement.[150]

Not only will a product like synthetic blood be practically available in every instance it is needed, it could also surge the economy greatly.[151] One existing alternative to human blood is a hemoglobin-based oxygen carrier ("HBOC"). The pragmaticism of HBOCs is that they are universally compatible, meaning the patient's blood type will not be an issue when performing transfusions.[152] Further, a unit of HBOC is "stable at room temperature for at least three years," undoubtedly creating a much more secure blood supply than refrigerated human-donated red cells that are only viable for a maximum of 42 days.[153]

The benefits that this product would practically provide, plus the scientific assertions promoting the product's reliability and the economic assertions predicting a boost in the nation's economy, as mentioned earlier, make it a solution that cannot

146. Pal, *supra* note 124.
147. *See* Joseph, *supra* note 122; *see also* 21 C.F.R. § 630.3(a) (2016).
148. Joseph, *supra* note 122.
149. *See generally* Notman, *supra* note 18.
150. Sarkar, *supra* note 122.
151. *Id.*
152. Notman, *supra* note 18.
153. *Id.*

be ignored any longer.[154] At the very least, limited approval of synthetic blood could serve to alleviate the tension of a low blood supply while the FDA and blood collection organizations work to implement the other changes necessary to save the industry and the lives that depend on it. It is the author's assertion that mandating funds for research of synthetic blood alternatives is equally as necessary to expedite future approval of their wide-spread use in transfusions.

V. CONCLUSION

The shortage of a critical national resource has never been taken lightly in the United States, and the blood supply should be no different. After a decade of increasing vulnerability in the supply of a life-giving resource, the complacency of blood supply actors and the inflexibility of its controls must be reevaluated. Blood collection organizations *can* abandon improper, unwarranted reluctance toward marketing strategies that will successfully increase donations; the FDA's guidance and hospitals' policies *can* abandon archaic theories encouraging pure volunteerism while discouraging economic incentives shown to increase donations; the FDA *can* abandon unnecessarily restrictive regulations against certain deferred donors and synthetic blood products that would otherwise increase donations. Therefore, our blood supply *can* realistically regain its vitality. Most glaring is that these are specific solutions that could address the significant problems of the blood supply while maintaining its safety. Whether one or all of these solutions are adopted, it is time to return the favor of a life-giving transfusion to the blood supply system that has been saving our lives for decades.

154. *See* Sarkar, *supra* note 122.