A Penny for Your Clots? Examining Tax Incentives for Whole Blood Donation under FDA Guidelines

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ABSTRACT

Blood is a valuable commodity, used for scientific research, drug development, and life-saving transfusions into ailing patients. It is also sacred: it cannot be created artificially, and it is considered by some to be a defining feature of one's humanity. But when contaminated, it can be deadly. Acknowledging these realities, the Food and Drug Administration (FDA) regulates blood donation in the United States in a highly nuanced fashion, permitting cash payments to donors of blood used for research while discouraging-to-the-point-of-prohibiting any direct monetary compensation to donors of blood destined for transfusion. FDA's policies, however, create significant ambiguity on what constitutes impermissible "monetary payment" under its guidelines. Facing frequent blood shortages, hospitals and blood banks have embraced this ambiguity, providing donors with an array of valuable incentives just short of cash payments to encourage donations. Sitting squarely in this zone of ambiguity are individual tax incentives-which on the one hand can be as literally valuable as cash to their recipients, but on the other are not immediately redeemable or transferable. Personal tax incentives tied to blood donations have never been used in the United States, but they have been proposed by state legislators, and they have been enacted overseas. This Article analyzes how personal tax incentives would fit into FDA's current regulatory scheme if they were enacted in the United States. Examining the history of blood transfusions, the specific concerns underlying opposition to paying donors, and FDA's regulations, this Article ultimately concludes that tax incentives should not be treated as direct monetary payments to donors and incur the associated labeling requirements. Whether or not their implementation would be a wise policy, tax incentives should be considered permissible non-monetary incentives under FDA guidelines.

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INTRODUCTION

On September 17, 2015, hundreds of smalltime criminal offenders appearing in the packed Perry County Courthouse in Marion, Alabama faced an unusual offer.¹ Before commencing with his "pay-due" docket addressing the offenders' unpaid legal fees, Circuit Judge Marvin Wiggins announced to the crowd that there was a mobile blood drive operating outside the courthouse that day. Adding to this charitable announcement, Judge Wiggins explained, "If you do not have any money, go out there and give blood and bring in a receipt indicating you gave blood."² Defendants choosing this option would receive a "discount" off of their court-ordered expenses. As for those who did not have sufficient funds, nor agreed to donate blood? Well, "the sheriff has enough handcuffs," the judge declared.³

There are many troubling aspects of Judge Wiggins's conduct. Chief among them is coercing indigent individuals into donating parts of their bodies to avoid jail time. The Alabama Court of Judiciary agreed, censuring Judge Wiggins after finding that his behavior violated the state's Canons of Judicial Ethics.⁴ But the episode at the Perry County Courthouse highlights the immense pressures to incentivize blood donation in the United States, especially given the periodic shortages of blood available for transfusion. Every two seconds, someone in the United States needs blood, including one in every seven people entering a hospital.⁵ Unlike other biologics, whole blood cannot be artificially made.⁶ And it has a short shelf life, meaning that keeping up with demand requires a steady supply of healthy blood provided by human donors.⁷ Yet less than ten percent of the people eligible to donate blood do so annually, and shortages are frighteningly common, especially during wintertime.⁸

Judge Wiggins's push to encourage donations may feel wrong not only for the coercive nature of his offer but also for the uncomfortable notion more generally of

⁵ Blood Donation, UCHICAGO MED. (2020), https://www.uchicagomedicine.org/give/give-blood, [https://perma.cc/XP97-M92G].

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¹ Campbell Robertson, *For Offenders Who Can't Pay, It's a Pint of Blood or Jail Time*, N.Y. TIMES (Oct. 19, 2015), https://www.nytimes.com/2015/10/20/us/for-offenders-who-cant-pay-its-a-pint-of-blood-or-jail-time.html [https://perma.cc/H3U4-5AGB].

² Complaint at 3, *In re Marvin Wayne Wiggins*, (Ala. Ct. Jud. 2016) (No. 45), https://www.splcenter. org/sites/default/files/documents/coj45complaint.pdf [https://perma.cc/5TLK-MDP7].

³ *Id.*

⁴ Censure at 1, *In re Marvin Wayne Wiggins*, (Ala. Ct. Jud. 2016) (No. 45), https://www.splcenter. org/sites/default/files/documents/wiggins-censure.pdf [https://perma.cc/9JGJ-YH3Z].

⁶ At least not yet. The quest to develop artificial blood has dragged on for decades, with a viable alternative proving elusive. For a discussion of this history, *see* 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/, [https://perma.cc/F99W-5LYF].

⁷ Whole blood taken from humans can be split into its components, which remain viable for different periods. Red blood cells can be refrigerated for up to 42 days; plasma—the liquid substance that carries cells and is used to develop pharmaceuticals—can be stored for up to a year; and platelets—which create clots that stop bleeding—only last two days after they pass disease screening. As a result of these low shelf lives, even large-scale donations, such as those seen after 9/11 or natural disasters, cannot solve the problem of recurring shortages. *See* Jonathan Thon, *The Polar Vortex Exposed a Major Flaw in our Volunteer Blood Supply System*, STAT (Feb. 28, 2019), https://www.statnews.com/2019/02/28/blood-platelets-shortages.new-approaches/ [https://perma.cc/2KWH-T3VC].

⁸ Blood Donation, supra note 5; Robert Slonim, Carmen Wang & Ellen Garbarino, The Market for Blood, 28 J. ECON. PERS. 179, 190 (2014).

compensating people for their blood—paying out literal *blood money*. This Article will explore in greater detail the United States' inconsistent regulatory stance towards compensating donors for their blood. Based partly on ethical concerns, the current regulatory scheme has the practical effect of precluding directly paying donors for blood when it is destined for transfusion. In contrast, *indirect* compensation—through material prizes, non-transferable gift certificates, etc.—is permitted and encouraged. The following analysis examines how providing individual tax incentives would fit into the current U.S. regulatory system, and it concludes that these incentives should not be treated as direct "monetary payment" along the lines of cash payments. This Article does not promote implementing any specific system of tax incentives; rather, it analyzes one possible impediment to tax incentive schemes and explains why, ultimately, current regulations effectively proscribing paid compensation should not cover tax incentives.

The analysis begins by tracing the historical development of blood transfusions, blood banking, and the prevailing attitudes toward compensating blood donors. Part II frames the debate over paying for blood donations and examines recent scholarship and arguments challenging conventional assumptions. Part III shifts the focus to the current regulations on incentivizing donors in the United States, outlining both what is clear and what is unsettled under FDA guidelines. Part IV addresses tax incentives, situating them in the current regulatory scheme and explaining why they may constitute an acceptable middle ground encouraging more blood donations while avoiding the risks inherent in direct compensation. The Article concludes by suggesting further avenues for research and study.

I. HISTORICAL ROOTS OF BLOOD DONATION REGULATION

To properly assess the current regulation of blood donation and the prevailing attitudes toward acceptable donor incentives, it is critical to acknowledge the historical development of blood transfusion as a medical treatment, altruistic endeavor, and commercial business. Blood transfusions first emerged in the 1600s, following a long history of bloodletting as a medical cure. Jean Baptiste Denis, a physician to King Louis XIV of France, preformed the first recorded transfusion of blood into a human in 1667.⁹ Foreshadowing blood transfusion's occasionally troubled history, the first known blood donor was not a knowing and consenting participant: Denis transfused the blood of a lamb into a young boy suffering from fever and delirium.¹⁰

A well-respected physician in the Paris medical community, Denis accepted the learned theories of the day including "vitalism"—the belief that blood carried the essence of the body in which it flowed.¹¹ Denis believed that the blood of lambs and calves, for example, would evoke tranquility, making them suitable sources of transfusable blood for those suffering mental ailments.¹² Despite considerable progress in the field of hematology (the study of blood) since Denis's day, the notion that our

⁹ Kim A. Janatpour & Paul V. Holland, *A Brief History of Blood Transfusion, in* BLOOD BANKING AND TRANSFUSION MEDICINE 3 (Christopher D. Hillyer et al. eds., 2d. ed. 2007).

¹⁰ Id.

¹¹ DOUGLAS A. STARR, BLOOD: AN EPIC HISTORY OF MEDICINE AND COMMERCE 5 (Alfred A. Knopf 1998).

¹² See id. at 3, 5; Janatpour & Holland, supra note 9, at 3.

blood carries more than just cells and proteins—such as our human dignity—has not disappeared entirely.

Denis performed several of his livestock-to-human transfusions, narrowly avoiding tragedy after some of his patients suffered dangerous episodes of shock when their bodies rejected the non-human blood.¹³ News of Denis's procedures spread across Western Europe, and physicians copied his techniques while adding their own variations, such as using different animals as blood sources.¹⁴ Denis continued his experiments until he was charged with the murder of one of his patients who died shortly after a round of transfusion.¹⁵ Although Denis was acquitted, blood transfusion was condemned in the court of public opinion; the negative publicity from Denis's trial and several deaths outside of France led to a swift ban on transfusions in France and England.¹⁶ Soon after, Pope Innocent XI banned the practice throughout most of Europe in light of the perceived medical risks.¹⁷

Blood transfusion science languished for the next century and a half until a new generation of physicians resurrected the practice. With patients dying in droves and lacking any other viable recourse, British obstetricians in the early nineteenth century began supplying blood from animals and ultimately human donors to women suffering from severe postpartum bleeding.¹⁸ Leading the charge was English doctor James Blundell, who came to be known as the father of human blood transfusion.¹⁹ Blundell performed the first recorded human-to-human blood transfusions in history: drawing blood from husbands to save their dying wives.²⁰ Blundell's endeavors were highly

¹⁵ Denis's trial produced evidence that the deceased man was in fact poisoned by his wife, who killed her husband to protect herself from his repeated fits of violent rage. STARR, *supra* note 11, at 14–15. Apparently, Denis's calming calf's blood failed to work as planned.

¹⁶ Id.

¹⁹ See Sunny Dzik, James Blundell, Obstetrical Hemorrhage, and the Origins of Transfusion Medicine, 32 TRANSFUSION MED. REV. 205, 205 (2018). For a list of Blundell's publications and analysis of their reception, see SWANSON, *supra* note 13, at 26 n.63 and accompanying text.

²⁰ SWANSON, *supra* note 13, at 26. It is possible, however, that an earlier human-human transfusion occurred in 1795 in the United States, although little is known about this possible breakthrough. *See* P.J. Schmidt, *Transfusion in America in the Eighteenth and Nineteenth Centuries*, 279 N. ENGL. J. MED. 1319, 1319–20 (1968).

¹³ STARR, *supra* note 11, at 6. Unbeknownst to Denis, his patients almost certainly suffered from agglutination—where antibodies in a recipient's bloodstream recognize the new blood as foreign and bind themselves to the transfused red blood cells, risking dangerous blockage of veins and arteries. KARA SWANSON, BANKING ON THE BODY 25 (Harvard Univ. Press 2014).

¹⁴ STARR, *supra* note 11, at 12. One German surgeon, Johann Elsholtz, proposed blood transfusions as a remedy for marital strife—suggesting that married couples swap blood to balance out clashing personalities. *See* BILL HAYES, FIVE QUARTS: A PERSONAL AND NATURAL HISTORY OF BLOOD 53 (2006).

¹⁷ *Id.* at 15. Among the dangers involved in early transfusions, physicians had yet to understand the risks in trans-species transfusions, which cause severe reactions in the bodies of recipients. Moreover, early transfusions were clumsy and imprecise; in particular, exposure to air triggers blood to begin clotting, which prevents the free flow of blood from supplier to recipient. Early transfusion methods almost always guaranteed that significantly more blood was lost by the donor than gained by the recipient, often putting both parties at risk—especially when the procedure followed bloodletting. *See* SWANSON, *supra* note 13, at 25.

¹⁸ SWANSON, *supra* note 13, at 25–26. The success of these experiments depended on the groundbreaking research conducted by Barbados scientist John Henry Leacock, who discovered that donors and recipients must be from the same species to avoid disastrous complications, including agglutination. *See* P.J. Schmidt & A.G. Leacock, *Forgotten Transfusion History: John Leacock of Barbados*, 325 BMJ 1485 (2002).

controversial—especially in an era that still embraced bloodletting as a common medical treatment, even for blood hemorrhaging. Blundell was assisted by the advancements made at the University of Edinburgh, which was pioneering hematology in the early nineteenth century.²¹ And Blundell made important technical contributions of his own, moving from first directly connecting humans together during transfusion—putting both participants at risk—to inventing a process called "mediate," where blood was collected from a donor in a glass vial and then inserted into the recipient's veins.²²

True blood banking and storage would not arrive on the scene until several decades into the twentieth century, dependent on a few more critical scientific advancements. Substantial credit belongs to Austrian scientist Karl Landsteiner, who, at the turn of the century, discovered and catalogued chemical differences in blood—coining the term "blood groups" for the distinctions we today know as blood types O, A, B, and AB.²³ Landsteiner also demonstrated that human-to-human transfusion involving different blood types could trigger the same dangerous side effects as cross-species transfusion, which had plagued early transfusion efforts.²⁴ Developments accelerated during World War I out of wartime necessity. In particular, American doctors Francis Peyton Rous and J. R. Turner developed a citrate-glucose solution that permitted blood to be viably stored for several days or even weeks for later transfusion.²⁵ This advancement prompted the British to create the first blood "depots" to store blood for future use.²⁶

Despite the medical advancements in preserving blood's viability, logistical challenges to storing blood on a mass scale hindered systematic donation and storage capabilities in the United States and Europe.²⁷ Accordingly, during the "blood-on-the-hoof" era (approximately 1914 to 1937), blood transfusion remained largely dependent on suppliers being physically present to provide blood shortly before transfusion— occasionally still directly into the recipient.²⁸ Faced with an ailing patient, physicians

²⁴ *Id.* Landsteiner would later earn the Nobel Prize in Physiology or Medicine in 1930 for his research. *Karl Landsteiner*, NOBEL PRIZE, https://www.nobelprize.org/prizes/medicine/1930/landsteiner/ biographical/ [https://perma.cc/DHC9-PTF8] (last visited June 8, 2020).

²⁵ PETRA SEEBER & ARYEH SHANDER, BASICS OF BLOOD MANAGEMENT 227 (Blackwell ed., 1st ed. 2007). For more information on hematological advances during World War I, see Lynn G. Stansbury & John R. Hess, *Blood Transfusion in World War I: The Roles of Lawrence Bruce Robertson and Oswald Hope Robertson in the "Most Important Medical Advance of the War,"* 23 TRANSFUSION MED. REV. 232 (2009).

²⁶ See SEEBER & SHANDER, *supra* note 25, at 227. For more on developments in Britain during the war and in the years afterward, see ROSE GEORGE, NINE PINTS: A JOURNEY THROUGH THE MONEY, MEDICINE, AND MYSTERIES OF BLOOD 84–94 (2018).

²⁷ The one exception was Russia, where the experiences of World War I spurred deliberate efforts to improve blood access and storage. By 1930, the Soviet Union had a network of "blood centers" operating around the country and managed from the military's institute for transfusion in Moscow. *See* SEEBER & SHANDER, *supra* note 25, at 227–28.

 28 "On the hoof" is a British expression similar in meaning to "on the fly," and this era was characterized by the need for donors to be corralled near the moment of donation. *See* STARR, *supra* note 11, at 53–71.

²¹ Kim Pelis, Blood Clots: The Nineteenth-Century Debate over the Substance and Means of Transfusion in Britain, 54 ANNALS SCI. 331, 334 (1997).

²² Id. at 336. For more on Blundell's inventions and advancements, see id. at 336–38.

²³ SWANSON, *supra* note 13, at 27.

often recruited donors in an ad hoc manner from hospital personnel, relatives of sick patients, and strangers off the street.²⁹ Transfusion still contained substantial risk and inconvenience for recipient and donor alike; accessing veins required minor surgery that carried risk of infection, improper healing, and scarring.³⁰ And blood types needed to be matched, often necessitating the screening of multiple would-be donors.³¹

As a result, transfusions in this era relied on both unpaid and compensated donors. Paying for blood was not peculiar at a time when selling breastmilk was accepted by many as a "legitimate trade" for healthy women.³² In cities such as New York, healthy individuals could earn around \$50 per blood donation-an even more significant sum at the time.³³ Congress passed legislation in 1927 explicitly authorizing government hospitals to pay donors up to \$50 per donation when both the donor and recipient were either an active servicemember or a veteran.³⁴ Congress ostensibly desired to put military hospitals on equal footing as those in the private sector, because without an ability to pay donors, transfusions would be limited.³⁵ Publicity campaigns in the private sector emphasized the dignity and heroism of "professional donors" who "graciously pour[ed] out their blood in the interests of science" as a "unique way of providing bread and butter for the family table."36 Indeed, in 1923 the New York Times hailed blood donation as the "1,001st Way to Make a Living."³⁷ New York City had a particularly sophisticated system supervised by the New York Blood Transfusion Betterment Association (BTBA), which kept accounts of donors' health and giving histories.38

The compensation, however, was not entirely wholesome in every case, as some doctors pressured impoverished young men into donating.³⁹ According to one doctor of the era, "the chief trouble with the system" was donors' habit of taking their compensation straight to the nearest tavern after the transfusion to get "rip-roaring drunk"—perhaps one of the least healthy post-procedure habits.⁴⁰ And despite scattershot efforts at improving safety-such as the BTBA's private sector oversight

³⁶ Id. at 43.

³⁸ STARR, supra note 11, at 60–61. Under this highly commercialized system, transfusions soared. Id.

³⁹ One doctor recounted how he targeted "rovers of the unskilled type." In at least one system, individuals were paid \$1 for a blood sample (for matching purposes) and would receive \$50 if selected for the transfusion procedure. SWANSON, supra note 13, at 40.

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⁴⁰ Id.

²⁹ See SWANSON, supra note 13, at 39. Once blood transfusions became relatively safe, doctors used them to treat a host of maladies, some relevant (hemophilia, anemia, carbon monoxide poisoning) and some not (typhoid, tuberculosis, cancer). See id. at 30.

³⁰ Id. at 39.

³¹ Id. at 40.

³² Id. at 38-39.

³³ See Slonim et al., supra note 8, at 181.

³⁴ An Act Relating to the Transfusion of Blood by Members of the Military Establishment, Pub. L. No. 69-595, 44 Stat. 1066 (1927).

³⁵ Even so, the initial restriction of payment to only military personnel-rather than to any citizenis a notable limitation. SWANSON, supra note 13, at 42.

³⁷ Our 1001st Way to Make a Living; Men Who, Sell Their Blood for Transfusion Have a Close Knit Union. Must Keep at Top Form; Most of Them Are Working Men, and Clean Living Is a First Essential., N.Y. TIMES (Feb. 11, 1923) at 10, https://www.nytimes.com/1923/02/11/archives/our-1001st-way-to-makea-living-men-who-sell-their-blood-for.html [https://perma.cc/VFK6-2YUC].

in New York—there was minimal regulation in the industry, fostering over-donation by desperate individuals.⁴¹ Screening for diseases was also neither as comprehensive nor as encouraged by physicians and advocates as it is today.⁴²

On the other hand, early blood donation arguably had some advantages to today's environment. Requiring blood suppliers to be physically present at or near the time of transfusion, though inefficient, permitted donors to see their blood being used to help real people in real time. The human connection forged in these moments stands in contrast to the more clinical nature of typical donations today, with anonymous donors supplying blood to unknown recipients receiving it in an unknown place at an unknown time.⁴³ Donation in this era also led to innovative altruistic campaigns to corral volunteer donors. In London, Dr. Percy Oliver organized one of the first blood volunteer groups in 1922, which quickly exploded to nearly 900 donors four years later.⁴⁴ In this system, donors were often summoned by police or neighbors, given the scarcity of telephones in private homes.⁴⁵ Around the same time, the Mayo Clinic in Minnesota had over 1,000 donors on its roster, categorized by blood type, with an "active pool" of donors available to donate directly to patients on short notice.⁴⁶

The advent of true "blood banking"—with blood systematically stored for future use by unknown recipients—emerged in the late 1930s.⁴⁷ The term's connection to financial banking was no accident; at one of the earliest blood banks in Chicago, donors received a "credit" when donating healthy blood, and transfusion accounts kept strict records of the individual credit or debit amounts of donors and recipients.⁴⁸ Both the Spanish Civil War and World War II spurred demand and funding for large-scale blood storage, as pioneered by pre-war blood banks. During World War II, the American Red Cross alone drew more than 13 million pints of blood.⁴⁹ Altruistic campaigns, such as "Blood for Britain," evolved into nationwide, patriotic donation drives in the United States.⁵⁰ The invention of "blood fractionation"—splitting blood into its components, such as red blood cells, platelets, and plasma—permitted the military to collect blood plasma in prodigious quantities, as it was easier to store and

⁴⁴ Id.

⁴⁵ Paul L.F. Giangrande, *The History of Blood Transfusion*, 110 BRIT. J. HEMATOLOGY, 758, 762 (2000).

⁴⁶ SWANSON, *supra* note 13, at 44.

⁴¹ See Slonim et al., supra note 8, at 181.

⁴² As early as 1915, reports surfaced of transfusion-transmitted diseases, including measles, malaria, and syphilis. SUSAN E. LEDERER, FLESH AND BLOOD: ORGAN TRANSPLANTATION AND BLOOD TRANSFUSION IN THE TWENTIETH-CENTURY AMERICA 48 (Oxford Univ. Press 2008).

⁴³ See Slonim et al., supra note 8, at 180.

⁴⁷ While Russia was leagues ahead of the rest of the world on systematic blood banking, see *supra* note 27, credit for the first blood bank in the United States has been attributed to Dr. Bernard Fantus at the Cook County Hospital in Chicago. *See* SWANSON, *supra* note 13, at 49–60.

⁴⁸ Writing about blood transfusions at his hospital, Dr. Fantus noted: "A strict accounting of the amount of blood deposited and withdrawn is kept for each service. The service is given credit for the blood as soon as it is deposited in the bank, but if it should be [syphilis] positive or badly clotted this credit is withdrawn." Bernard Fantus, *The Therapy of The Cook County Hospital*, 111 J. AM. MED. ASSOC. 320, 320–21 (1938).

⁴⁹ J.R. Hess & M.J.G. Thomas, *Blood Use in War and Disaster: Lessons from the Past Century*, 43 TRANSFUSION 1622, 1623 (2003).

⁵⁰ See SWANSON, supra note 13, at 68–79; Slonim et al., supra note 8, at 181.

ship overseas.⁵¹ While the national blood program was dismantled as part of demobilization at the end of the war, the civilian sector benefitted from the logistical solutions to mass transportation and storage that had been developed in the meantime.

The donation campaigns during World War II also ushered in new social norms around blood donation that endured long after the fighting ceased. In countries such as the United States, England, and France, where patriotic volunteerism had thrived during the war, altruistic donation became the dominant form of blood donation.⁵² In the United States in particular, donation campaigns shifted from valorizing the hardy "professional donors" who were paid for their brave service in the pre-war era to lionizing the everyday citizens who could altruistically save a life or two during their lunch hour.⁵³ In certain areas, however, compensation remained a vibrant practice; during the mid-1950s, over forty percent of New York City's donations came from paid donors.⁵⁴ But New York was an outlier, and by 1957, the Joint Blood Council estimated that only about one-sixth of whole blood suppliers nationwide were compensated for their donation.⁵⁵

The commitment to volunteerism persisted into the late twentieth century, even as the total and per-capita demand for whole blood and its components rose. Since the 1950s, rising life expectancy and new medical procedures requiring vast amounts of transfusable blood have elevated demand for whole blood.⁵⁶ The demand for blood plasma has also risen dramatically based on newfound uses and a steadier stream of supply given the advent of plasmapheresis, which allows donors to give approximately twenty times more plasma per year than whole blood.⁵⁷

The latter half of the twentieth century also saw a growing awareness of the safety risks of blood transfusion. Even before the AIDS crisis in the 1980s, bloodborne diseases such as hepatitis triggered increased emphasis on screening procedures and helped fuel an aversion towards compensated blood donation in countries such as the United States.⁵⁸ But the outbreak of the AIDS epidemic established safety as a predominant concern for blood collection in the late twentieth and early twenty-first centuries. An estimated 14,000 Americans contracted AIDS from HIV-contaminated

⁵¹ See Giangrande, supra note 45, at 763; Thon, supra note 7.

⁵² Slonim et al., *supra* note 8, at 182. In contrast, countries where the link between patriotism and blood donation was weaker, such as Russia, China, and Japan, continued to rely primarily on paid donors in the years following World War II. *Id.*

 $^{^{53}}$ See SWANSON, supra note 13, at 74–75. This shift is partly attributable to wartime necessity. With a large portion of able-bodied men fighting overseas, blood centers turned to women and others on the home front unable to serve. Indeed, women provided about half of the blood collected by the American Red Cross during the war. *Id.* at 75.

⁵⁴ See STARR, supra note 11, at 189.

⁵⁵ SWANSON, *supra* note 13, at 143 (citing JOINT BLOOD COUNCIL, THE NATION'S BLOOD FACILITIES AND SERVICES 28 (1960)).

⁵⁶ Slonim et al., *supra* note 8, at 182. The procedures include heart surgery, organ transplants, advanced natal care, and many cancer treatments. *Id.*

 $^{^{57}}$ *Id.* at 183. The plasmapheresis process uses centrifuges to extract plasma from whole blood donations and then return the red cells and platelets to the donor's veins. As a result, donors have a much smaller chance of developing anemia and can thus donate much more frequently.

 $^{^{58}}$ *Id.* at 185–86. AIDS (acquired immunodeficiency syndrome) is a set of symptoms that can develop after infection with the human immunodeficiency virus (HIV). HIV travels in blood as well as other bodily fluids. For more on the safety precautions adopted in the 1980s, see *id.* at 183.

blood transfusions in the 1980s and 90s.⁵⁹ Reactions to that crisis led the bloodbanking community to embrace comprehensive safety precautions for whole blood donations, which continue to this day.⁶⁰ These safety measures include extensive testing for bloodborne diseases, as well aggressive donor screening to prevent donations by individuals with certain high-risk behaviors, travel histories, or medical backgrounds.⁶¹

The renewed focus on safety also coincided with a growing public debate over the ethics of compensating blood donors. In particular, British philosopher Richard Titmuss' 1971 book, *The Gift Relationship*, forcefully argued against paid donation on ethical and practical grounds.⁶² The substance of Titmuss' concerns will be explored in greater detail in Part II *infra*, along with studies bolstering and criticizing his theories, while specific regulatory policies emanating from those debates will be detailed in Part III. Suffice it to say that his book ratcheted up the ongoing debate over blood donation incentives and crystallized many pre-existing objections to the then-prevailing regulation of blood products in the United States.⁶³

Change came swiftly after Titmuss' book hit the shelves. Under the leadership of Bernice Hemphill, the "Mother of Blood Banking," the American Association of Blood Banks (AABB) set a goal of eliminating the use of compensated donors by its member banks by 1975.⁶⁴ Between 1970 and 1975, Congress introduced around forty bills addressing the blood supply.⁶⁵ Although none of these led to direct federal legislation overhauling the regulatory scheme, the Department of Health, Education, and Welfare established a National Blood Policy that encouraged budding efforts to establish an all-volunteer donation system in the country and to "eliminate commercialism in the acquisition of whole blood and blood components for transfusion purposes."⁶⁶ In accordance with this policy, the U.S. Food and Drug Administration (FDA) issued strict labeling requirements distinguishing "paid" and "volunteer" donations—a policy that will be examined in greater detail in Parts III and IV *infra*. Even before this last development, the percentage of whole blood obtained from paid donors was only three percent in 1976, down from twenty-five percent a mere five years earlier.⁶⁷

⁶² RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY *passim* (1971).

⁶³ See SWANSON, supra note 13, at 151–53.

⁶⁴ Id. at 154.

⁶⁶ Hemophila [sic] and Other Chronic Blood Disorders, 39 Fed. Reg. 9329 (Mar. 8, 1974).

⁵⁹ Elizabeth Donegan, Transmission of HIV by Blood, Blood Products, Tissue Transplantation, and Artificial Insemination, HIV InSite Knowledge Base Chapter, HIVINSITE (Oct. 2003), http://hivinsite.ucsf.edu/InSite?page=kb-07-02-09#S2X [https://perma.cc/AW6F-VANU].

 $^{^{60}\,}$ Differences in the testing and screening of whole blood donations versus plasma donations will be outlined in further detail in Part III.

 $^{^{61}}$ For more details on screening and testing procedures, see SEEBER & SHANDER, supra note 25, at 230–34.

⁶⁵ *Id.* at 153. Some of these efforts pushed for a national blood exchange supervised by the federal government, but the legislation failed to gain traction, and responsibility for blood drawing, storage, and coordination remains with blood banks and hospitals today. For more on such legislation, see STARR, *supra* note 11, at 250–56.

⁶⁷ Oversight on Implementation of National Blood Policy: Hearing Before the Subcomm. on Health and Sci. Research, Comm. on Labor and Human Res., 96th Cong. 2 (1979).

The history of blood transfusion recounted in this section reveals the practice's deeply-rooted connections to both altruistic and commercial donations. While once a conventional practice, compensated donation at times exploited desperate, impoverished donors. But in some limited instances, like in New York during the blood-on-the-hoof era, compensation operated in a generally safe and professional environment. Most importantly, the history of blood transfusion in the United States demonstrates that the debate cannot operate on only one axis: societal norms, safety concerns, and practical limitations such as blood storage and transportation heavily influence the efficacy—and the public reception—of any donation regime. Viewing donation incentives as merely an ethical issue, merely a medical issue, or merely an economic issue may be useful in framing specific options, but it risks missing the mark on the practical effects that any one change in technology or policy can have.

II. THE DEBATE OVER COMPENSATED BLOOD DONATION

Before determining where tax incentives for whole blood donations might fit in the current regulatory scheme, it is crucial to review the underlying justifications for prohibiting or at least discouraging monetary payments to donors. After all, in the face of periodic blood supply shortages around the country and the globe, there must be compelling reasons to steer clear of the most ubiquitous incentive (cash). The opposition to paid blood donation can be separated into three lines of argument, which will be addressed in turn.

A. Ethical Considerations

First, there are ethical and moral concerns intrinsic to the commodification of blood. When questions first arose over the propriety of giving money for blood, they were focused on whether or not it was appropriate to charge the *recipient* for a life-saving infusion of blood—rather than on the donor, for whom payment seemed generally acceptable.⁶⁸ Arguments against paying donors on moral grounds gained traction in the twentieth century. Ethicists such as Richard Titmuss contended that paying for blood constitutes an "instrumentalisation" of people and their bodies.⁶⁹ Indeed, the notion that blood carries human dignity stretches back to the earliest days of transfusion. So putting a price on a physical human "good" could lead to the commodification of the human body and even dehumanization.⁷⁰ The thrust of this argument parallels objections in related contexts, such as opposition to markets for human organs.⁷¹

It is true that the very first human blood donors acted out of altruism: husbands giving blood to save their dying wives and physicians aiding their ailing patients.⁷² But what is a familiar feature of a practice—historically or currently—should not be confused with what is necessary. Commentators have pointed out that compensation

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⁶⁸ SWANSON, *supra* note 13, at 120–21.

⁶⁹ Alena M. Buyx, Blood Donation, Payment, and Non-Cash Incentives: Classical Questions Drawing Renewed Interest, 36 TRANSFUSION MED. & HEMOTHERAPY 329, 331 (2009).

⁷⁰ See David Archard, Selling Yourself: Titmuss's Argument Against a Market in Blood, 6 J. ETHICS 87, 87 (2002).

⁷¹ See, e.g., Mario Morelli, Commerce in Organs: A Kantian Critique, 30 J. Soc. PHIL. 315, 322 (2002).

⁷² See supra note 20 and accompanying text.

does not inherently degrade other forms of socially beneficial activities that some people pursue altruistically; we generally do not, for example, denigrate nurses, counselors, or caretakers because they are paid for services that other people sometimes perform for free.⁷³ Arguments along these dimensions are inexorably intertwined with more general conceptions of personal morality and societal norms.

Some scholars have also expressed concern that paid donors disproportionally come from lower socioeconomic groups.⁷⁴ Impoverished donors might sell their blood into a market that they themselves could never access, should they need blood—a fact that violates notions of interpersonal fairness.⁷⁵ A related ethical argument stresses the inescapable risk of coercion presented by paid donation; offering life-sustaining payment in exchange for blood invites coerced consent in the absence of more dignified options for those in extreme material need, encouraging some donors to compromise their personal autonomy.⁷⁶

Critics of these positions point out that payment motivating someone to donate does not necessarily mean that the donor is misinformed, jeopardizing her own dignity, or lacking autonomy over her body; the risk only arises if under different financial circumstances the donor would have refused to donate on moral grounds.⁷⁷ This moral risk is context dependent and more palpable in less developed societies that have fewer economic safety nets and alternative sources of non-coercive income. And unlike non-regenerative human biologics such as organs, blood typically regenerates quickly and the side effects of a typical donation are short-lived.

B. "Crowding Out" and Economic Considerations

In contrast to the moral and ethical concerns listed above, some objections to compensated donation focus on its extrinsic effects, including its propensity to actually *decrease* the number of donors and the amount of blood collected. Titmuss devoted much of his 1971 book to presenting the argument that paying blood donors destroys altruistic donation and that it was already hindering donation in the United States.⁷⁸ Other scholars in the decades since have agreed, contending that paid donation crowds out unpaid donations by alienating altruistic donors who see payment as cheapening their donations or signaling that they are unneeded.⁷⁹

Although researchers have studied the effects of incentives on blood donation extensively, definitive conclusions are elusive given difficulties inherent in this field of study. At the highest level, simply comparing the donation rates between countries that do and do not pay donors is too crude, skipping over numerous confounding factors; for example, do some countries that directly pay donors but have low donation rates only pay donors *because* donation rates are low and must be encouraged through payment? Likewise, once compensation is stigmatized in a given society, that stigma

⁷³ Buyx, *supra* note 69, at 331.

⁷⁴ See R. W. Beal & W. G. van Aken, *Gift or Good?*, 63 VOX SANGUINIS 1, 3–4 (1992); see also TITMUSS, *supra* note 62.

⁷⁵ Buyx, *supra* note 69, at 331.

⁷⁶ Id. at 330.

⁷⁷ Pablo Rodriguez del Pozo, *Paying Donors and the Ethics of Blood Supply*, 20 J. MED. ETHICS 31, 32 (1994).

⁷⁸ TITMUSS, *supra* note 62 *passim*.

⁷⁹ See, e.g., Archard, supra note 70, at 90.

may not easily be erased—even if the country shifts to an alternative system. Those studies that do offer more specific findings tend to examine only developed economies, such as the United States and Europe, which largely confine acceptable compensation to indirect, non-monetary forms.⁸⁰ Unfortunately, tax incentives have not yet been studied for their effect on motivating blood donation.⁸¹

Research into certain economic incentives is often limited by the ability to only *ask* donors about their expected reactions to hypothetical incentive systems, rather than field testing the efficacy of different incentives.⁸² Donors' answers may also be susceptible to a social desirability bias, whereby participants are motivated to appear selfless in their answers.⁸³ These experiments sometimes fail to interview non-donors who could donate with the correct incentives. And donors or potential donors interviewed in studies may prefer whatever system they inhabit because it is self-selected (i.e., representative governments tend to choose policies preferred by their citizens) or based merely on familiarity. Either way, empirical studies confirm this intuition: donors and non-donors in countries where payment is permitted have generally more positive attitudes toward incentives of all kinds (including cash payments) than citizens of countries that require all donations to be unpaid.⁸⁴

Advocates of the crowding-out theory point to research demonstrating that potential donors have a clear aversion to cash payments.⁸⁵ More recent studies do not disagree, but they paint a more complicated picture. Incentives of all kinds (material or otherwise) are generally ineffective in *recruiting* new donors but have some success in boosting donor *retention*; some people are simply more inclined to start donating than others.⁸⁶ When given economic incentives short of cash (e.g., gift cards), individuals have been found to donate more often—and increasingly so the higher the

⁸³ Kathleen Chell et al., *A Systematic Review of Incentives in Blood Donation*, 58 TRANSFUSION 242, 247 (2018).

⁸⁴ Id. at 246.

⁸⁰ These policies will be examined in greater detail below. See infra Part III.

⁸¹ There have, however, been a few studies assessing the effect of tax incentives on bone marrow and organ donation. *See, e.g.*, Nicola Lacetera, Mario Macis & Sarah S. Stith, *Removing Financial Barriers to Organ and Bone Marrow Donation: The Effect of Leave and Tax Legislation in the U.S.*, 33 J. HEALTH ECON. 43, 43 (2014). All of the published studies reported no effect on organ or bone marrow donations. *See id.* at 45, 54 (discussing prior research and presenting findings). The authors of the most recent study (Nicola Lacetera et al.) suggest that the incentives may have been too small to affect such invasive procedures as organ and marrow donations, contrasting them with blood donations, which are significantly less invasive for donors and thus could be affected. *Id.* at 55.

⁸² See Nicola Lacetera et al., *Economic Rewards to Motivate Blood Donations*, 340 SCI. 927, 927 (2013) [hereinafter Lacetera et al., *Economic Rewards*].

⁸⁵ See, e.g., Danielle Chmielewski et al., A New Perspective on the Incentive-Blood Donation Relationship: Partnership, Congruency, and Affirmation of Competence, 52 TRANSFUSION 1889, 1889 (2012) (citing RICHARD M. TITMUSS, THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY (1970); S.A. Glynn et al., Attitudes Toward Blood Donation Incentives in the United States; Implications for Donor Recruitment, 43 TRANSFUSION 7 (2003); Nicola Lacetera & Mario Macis, Do All Material Incentives for Pro-Social Activities Backfire? The Response to Cash and Non-Cash Incentives for Blood Donations, 31 J. ECON. PSYCHOL. 738 (2010)) ("The one clear, uniform message to emerge from past research on the incentives-donation relationship is that monetary, compensation-payment incentives seem to 'crowd out' donors' intrinsic motivations (including donors feeling good about themselves or gaining social approval) and thus decrease their blood donation behavior.").

⁸⁶ Chell et al., *supra* note 83, at 247.

value of the rewards.⁸⁷ These results suggest that cash itself is a pariah, but economic rewards a "step removed" from cash evade the same stigma.⁸⁸

Of course, this research rests alongside a robust cash-based plasma donation industry currently operating in the United States.⁸⁹ Given the design of that industry, discussed in Part III *infra*, it seems unlikely that its cash payments are crowding out an even greater number of altruistic-focused donors who are refraining from donating plasma out of distaste for the cash-based system. It may just be the case that the multitude of donors and potential donors are all motivated by a combination of factors including payment, altruism, and social rewards such that any one system has the potential to repulse some individuals. Accordingly, some commentators have pushed for a "pluralistic approach" that attempts to accommodate many different incentive schemes to match the heterogeneous landscape of donor preferences.⁹⁰

C. Safety Concerns

Lastly, a strong extrinsic objection to compensated blood donation is the risk it poses to blood safety. Given the history of blood transfusion summarized in Part I *supra*, keeping transfusable blood free from communicable infections is of paramount importance for regulators. Although donated blood undergoes extensive testing between donation and transfusion, FDA admits that those steps are meant to be redundant—"like layers of an onion"—to other precautions such as donor screening.⁹¹ Opponents of compensated donation since Titmuss have rightfully highlighted the danger that cash or other economic rewards will attract at-risk donors or encourage donors to lie about their medical histories to pass the initial screening.⁹² Paid incentives could also lead to *overdonation*—with donors misrepresenting their donation histories to donate more often than is healthy to earn more money.

The empirical results on the safety effects of incentivized donation are mixed. Some research has shown that paid donors have a higher risk of transfusion-transmitted infections and are more likely to conceal risk factors, such as habitual drug use.⁹³ A number of these studies rely on disparate rates between paid plasma donors and unpaid whole blood donors, but at least one longitudinal study examined donations from paid and unpaid whole blood sources, finding higher infection rates in the former.⁹⁴ On the

⁸⁷ Lacetera et al., *Economic Rewards, supra* note 82; *see also* Lorenz Goette & Alois Stutzer, *Blood Donations and Incentives: Evidence from a Field Experiment*, 170 J. ECON. BEHAV. & ORG. 52, 54 (2020), https://doi.org/10.1016/j.jebo.2019.11.021 [https://perma.cc/T8RU-KY2L] (discussing lottery tickets and free medical tests).

⁸⁸ Lacetera & Macis, *supra* note 85, at 746.

⁸⁹ See infra note 118 and accompanying text.

⁹⁰ Albert Farrugia et al., *Payment, Compensation and Replacement—The Ethics and Motivation of Blood and Plasma Donation*, 99 VOX SANGUINIS 202, 202 (2010).

⁹¹ The precise testing requirements for relevant transfusion-transmitted infections are specified in 21 C.F.R. § 610.40 (2016). Testing Requirements for Relevant Transfusion-Transmitted Infections, 21 C.F.R. § 610.40 (2016); *FDA Regulation of Blood and Blood Components in the United States*, FOOD & DRUG ADMIN., https://www.fda.gov/media/81654/download [https://perma.cc/SAV5-XWSL] (last visited June 8, 2020).

⁹² See Chell, supra note 83, at 247.

⁹³ See Buyx, supra note 69, at 332 (summarizing research and collecting sources).

⁹⁴ C. L. Van der Poel et al., Review, *Paying for Blood Donations: Still a Risk?*, 83 VOX SANGUINIS 285, 285 (2002).

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other hand, some studies have found no effect on safety by the addition of non-cash economic incentives such as prepaid gift cards, free medical tests, token gifts, and supermarket vouchers.⁹⁵ Unfortunately, there have been no published studies addressing the incidence of disease for tax-incentivized donations.

Some commentators stress that blood quality depends far more on the donor population and donation setting than on the incentives offered.⁹⁶ Studies analyzing the effects of donor incentives often gather data from settings in which would-be donors receive rewards just for showing up to donate, whether or not they pass health screening and ultimately give blood, meaning donors would not have a financial incentive to provide false information about their risk factors.⁹⁷ That disparities in usable blood between paid and unpaid donors nonetheless still appear in some studies suggests that blood safety risks may be grounded less in motivating at-risk individuals to lie during pre-donation screening and more in encouraging unknowingly at-risk individuals to show up to donate when they otherwise would not have. So some commentators have argued that drawing a strict line between "volunteer" and "paid" donations is actually counterproductive, as it suggests that donations from the former are inherently safe or at least safer—when in reality the particular geographic area or source population is a much more important factor.⁹⁸

III. CURRENT POLICIES CONCERNING INCENTIVIZED BLOOD DONATION

As recounted in Part I *supra*, blood donation operated for most of its history without much formal government regulation. This changed rapidly in the mid-twentieth century, as many governments around the world began to advocate for and ultimately mandate volunteer-only blood donation. Even before FDA acted in the United States, the World Health Organization (WHO) adopted a resolution in 1975 urging member states to "promote the development of national blood services based on voluntary nonremunerated donation of blood."⁹⁹ And in conjunction with the International Federation of Red Cross and Red Crescent Societies, WHO released the "Melbourne Declaration" in 2009, setting a goal for all blood donations worldwide to be collected from unpaid volunteer donors by 2020.¹⁰⁰

⁹⁵ Victor Iajya et al., *The Effects of Information, Social and Financial Incentives on Voluntary Undirected Blood Donations: Evidence from a Field Experiment in Argentina*, 98 SOC. SCI. & MED. 214 (2013); *see also* Chell, *supra* note 83, at 247–51 (cataloging and analyzing studies).

⁹⁶ Buyx, *supra* note 69, at 332.

⁹⁷ See Nicola Lacetera, Mario Macis & Robert Slonim, On the Importance of Unconditional Rewards for Blood Donations, 60 CLINICAL CHEMISTRY 423 (2014).

⁹⁸ Ronald G. Strauss, Editorial, *Blood Donations, Safety, and Incentives*, 41 TRANSFUSION 165, 166– 67 (2001). One example provided was the French practice of liberally accepting voluntary donations from prison inmates, who were at a much higher risk for infectious diseases, but whose donations were classified as "volunteer" and thus were assumed to be safer than any donations from compensated sources. *Id.* at 165.

⁹⁹ WORLD HEALTH ASSEMBLY, UTILIZATION AND SUPPLY OF HUMAN BLOOD PRODUCTS (1975), https://www.who.int/bloodsafety/en/WHA28.72.pdf?ua=1 [https://perma.cc/BW8C-K7MD].

¹⁰⁰ This policy was launched on World Blood Donor Day in 2009 as a result of WHO's Global Consultation on "100% Voluntary Non–Remunerated Donation of Blood and Blood Components" in Melbourne, Australia. Although it has missed its 2020 target, WHO also published a "global framework for action" in 2010 to help serve as a justification and long-term blueprint for the move to exclusively voluntary, uncompensated donations. *See* WORLD HEALTH ORG., TOWARDS 100% VOLUNTARY BLOOD DONATION: A

The United States needed no international encouragement to move toward regulating blood transfusions more heavily. Although in the 1960s the Federal Trade Commission (FTC) started to consider "the blood business" a type of commerce worthy of FTC oversight, today the U.S. blood supply and blood banking are directly regulated by FDA.¹⁰¹ This legal authority stems from two national laws: the Federal Food, Drug, and Cosmetic Act—which considers blood and blood products falling within the definition of "drug"¹⁰²—and the Public Health Service Act—which classifies blood, blood components, and blood derivatives as "biologic products."¹⁰³ FDA exercises its authority through its Center for Biologics Evaluation and Research (CBER), which mandates rules for blood bank licensing, blood testing, and donor screening that are ultimately published in the *U.S. Code of Federal Regulations* (CFR).¹⁰⁴ FDA's policies, in place since the 1970s, have largely curtailed the practice of paying for whole blood donation.¹⁰⁵

It is, however, inaccurate to say that FDA currently *bans* paid blood donations. Rather, FDA's stance emanates from its simple yet impactful labeling regulations that require blood bags destined for transfusion to be marked as either "paid donor" or "volunteer donor" to signify the source of the donated blood.¹⁰⁶ Whether this policy was intended to merely be a compromise position in the face of stalwart opposition to more stringent rules, or if it was a knowingly ingenious resolution from the start, the policy immediately combined with free market reactions to have wide-ranging effects.¹⁰⁷ No hospital buying whole blood for transfusion would risk having purchased *inferior* blood—with labels on the bag attesting to that fact; as one blood bank director explained when the policy was announced, "If you label it [paid], you

¹⁰⁴ Regulation of the Blood Supply, FOOD & DRUG ADMIN. (Sept. 18, 2018), https://www.fda.gov/vaccines-blood-biologics/blood-blood-products/regulation-blood-supply [https:// perma.cc/5CNJ-9MYN]. Practically, this regulatory process is quite laborious. FDA places a notice of any new, proposed regulation in the Federal Register, where the proposed rule is available for public notice and comment, as well as discussion at meetings of the Blood Products Advisory Committee, industry roundtables, etc. If FDA approves the final rule, it is placed in the Federal Register along with FDA responses to public comments, while the final rule gets published in the Code of Federal Regulations (CFR). The regulations relating to human blood generally fall under "Biologics" (21 C.F.R. Subchapter F) and can be found at 21 C.F.R. § 600 (2016).

 105 See infra note 121 and accompanying text for discussion of the differences in whole blood and plasma donations.

¹⁰⁶ This policy was first proposed in 1975 and culminated in a final rule published in 1978. *See* Whole Blood and Components of Whole Blood Intended for Transfusion; Donor Classification Labeling Requirements, 43 Fed. Reg. 2142 (Jan. 13, 1978).

¹⁰⁷ FDA's first proposal, released in 1975, mandated more explicit warnings on blood bags about the risk of hepatitis in the blood from paid donors. FDA altered this policy after many comments in protest from blood banks and industry advocates. For a summary of the comments and an explanation of the shift in FDA's proposed language, see Whole Blood and Components of Whole Blood Intended for Transfusion, 42 Fed. Reg. 11018, 11020 (Feb. 25, 1977). For more background on the development of the labeling policy, see *Transfusion Blood Soon Must Indicate Volunteer Donors*, N.Y. TIMES (Jan. 14, 1978), https://www.nytimes.com/1978/01/14/archives/transfusion-blood-soon-must-indicate-volunteer-donors.html [https://perma.cc/YU8S-GRVW].

GLOBAL FRAMEWORK FOR ACTION 27 (2010), https://www.who.int/bloodsafety/publications/ 9789241599696/en/ [https://perma.cc/X5PE-FT5B].

¹⁰¹ See SWANSON, supra note 13, at 130–33.

¹⁰² 21 U.S.C. § 321(g)(1) (2016).

^{103 42} U.S.C. § 262(i)(1) (2019).

might as well pour it down the drain."¹⁰⁸ Responding to this policy shift and the evolving social norms detailed in Part I *supra*, compensation for whole blood donations dried up quickly.¹⁰⁹

While straightforward in sentiment, FDA's policy immediately becomes murkier once one departs from the extremes—such as, on the one hand, a donor who gives blood and leaves a clinic without getting anything at all for her trouble or, on the other hand, a donor who is handed a predetermined amount of cash. So it is critical to examine the exact wording of the current regulations:¹¹⁰

Section 606.121 Container label

(c) The container label must include the following information, as well as other specialized information as required in this section for specific products:

(8) If the product is intended for transfusion, the statements:

(v) The appropriate donor classification statement, *i.e.*, "paid donor" or "volunteer donor," in no less prominence than the proper name of the product.

(A) A paid donor is a person who receives monetary payment for a blood donation.

(B) A volunteer donor is a person who does not receive monetary payment for a blood donation.

(C) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.

FDA's "donor classification" requirement sits among an array of hypertechnical blood labeling provisions, but the text leaves much to be desired in terms of clarification. Indeed, a paid donor is someone who "receives monetary payment" for donating, while a volunteer donor is one who "does not receive monetary payment."¹¹¹ The term "monetary payment" is not explicitly defined, and the only clues provided as to its meaning are in the short, non-exhaustive list of examples of in-kind remuneration that do not count as monetary payment.

Fortunately, CBER has since provided some additional guidance on what constitutes monetary payment under the labeling regulations via its "Compliance Policy Guide on the Blood Donor Classification Statement" (CPG).¹¹² Last updated in

¹⁰⁸ Constance Holden, Blood Banking: Tangled System Resists Swift Change, 175 SCI. 1444 (1972).

¹⁰⁹ See supra note 67 and accompanying text; Kara W. Swanson, *Rethinking Body Property*, 44 FLA. ST. U. L. REV. 193, 244 (2016); Slonim et al., *supra* note 8, at 185–86.

¹¹⁰ 21 C.F.R. § 606.121(c)(8)(v)(A)-(C) (2019).

¹¹¹ Id.

¹¹² The CBER first issued this guidance in 2002, with two updates between that issuance and its most recent update. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE CPG SEC. 230.150: BLOOD DONOR CLASSIFICATION STATEMENT, PAID OR VOLUNTEER DONOR (2019), https://www.fda.gov/media/75039/ download [https://perma.cc/P5CQ-HCJR].

December 2019, the CPG confirms that a monetary payment made "to a group to which the donors belong" would also "generally be considered a monetary payment" to those donors, foreclosing a possible loophole in the policy.¹¹³ In addition, the CPG provides other examples beyond those listed in the regulation to illustrate what incentives would constitute "monetary payment" and thus require a "paid donor" classification." The distinctions can be broken down as follows:¹¹⁴

Monetary Incentives	Non-Monetary Incentives
 Cash payments High-value gifts (e.g., televisions) that are readily convertible to cash Tickets or vouchers for entertainment events where the tickets are transferable or where a secondary market exists Vouchers for future medical tests, if transferable to other people Scholarship funds paid directly to a student 	 Paid time off work Gifts of nominal value (e.g., mugs, t-shirts) Tickets or vouchers for entertainment events where the tickets are not transferable Medical tests performed on the donor at the time of their blood donation Scholarship funds paid directly to an educational institution on a student's behalf Discount hotel room rates that are not transferable or redeemable for cash Gift cards or certificates bearing the donor's name that are not transferable or redeemable for cash Frequent flyer miles

Even with the additional distinctions listed above, the line between "monetary" and "non-monetary" incentives is not entirely clear. But the CPG also identifies three factors important to making the distinction. First, is the incentive refundable or redeemable for cash? With direct cash payments occupying the heartland of "monetary payment," FDA understandably includes items that are readily convertible to cash within the same category, making the recipient a "paid donor." FDA highlights as an example gift certificates from a store that can be refunded for cash. Second, does a market exist for the incentive given? If so, here again the item given could be readily converted into cash by selling it to another person (e.g., selling a ticket to another event attendee), hence FDA's examples of concert tickets or even high-value items like television sets. Third, is the incentive transferable? The issue here, according to the CPG, is yet again a concern over the ultimate conversion into cash—even if no established market exists. High-value rewards, such as discounted hotel rooms, are nonetheless acceptable incentives for voluntary donors if they benefit only the recipient and cannot be readily exchanged with third parties.

¹¹³ Id.

¹¹⁴ This list is not intended to exhaustively report all of the examples listed in the CPG but instead to illustrate the most salient distinctions.

In this uncertain environment, blood collection organizations in the United States have carefully attempted to toe the line between monetary and non-monetary incentives. After all, violations of these provisions can lead to FDA sanctions against culpable organizations, such as suspension or the revocation of relevant licensing.¹¹⁵ Despite this liability, collection organizations have experimented with a wide array of rewards and incentives to potential donors.¹¹⁶ For example, the American Red Cross operates a robust rewards program with many different material gifts for whole blood donors, including t-shirts and baseball game ticket vouchers, as well as near-cash incentives such as Amazon.com gift cards.¹¹⁷

One conspicuous exception to this non-cash incentive system is blood plasma donation. Unlike whole blood or platelet donations, plasma donors in the United States are regularly compensated in cash.¹¹⁸ Plasma collected through plasmapheresis¹¹⁹ is predominantly broken down into its protein products and used to make pharmaceuticals; this "Source Plasma" is not intended for transfusion, thus it need not adhere to the strict labeling requirements of 21 C.F.R. § 606.121.¹²⁰ The process of breaking down the Source Plasma as well as converting it into usable pharmacological components kills viruses and contaminants in the blood, considerably lowering the risk of infection.¹²¹ Plasma collection is a multibillion-dollar industry in the United States—"the OPEC of plasma collections"—which exports around sixty percent of the plasma it collects, supplying between fifty-five and seventy percent of the world's plasma.¹²² Donors may give up to two donations per week, and donations typically pay out between \$30 and \$50.¹²³

¹¹⁸ A 2004 study found that over eighty percent of plasma products in the United States were derived from compensated donors. *See* Slonim et al., *supra* note 8, at 178.

¹¹⁹ See supra note 57.

¹²⁰ The CBER Compliance Guide definitively states that "[t]he donor classification labeling requirement does not apply to blood and blood components intended for further manufacturing, such as Source Plasma and recovered plasma." FOOD & DRUG ADMIN., *supra* note 112.

¹²¹ 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/ [https://perma.cc/26HZ-9HE7].

¹¹⁵ 21 C.F.R. §§ 601.5, 601.6 (2019). For a summary of FDA's authority on regulatory options, see FOOD & DRUG ADMIN., COMPLIANCE PROGRAM GUIDANCE MANUAL ch. 42, pt. IV (2016), https://www.fda .gov/media/84887/download [https://perma.cc/44FV-E432].

¹¹⁶ A 2001 study found that 56% of American blood donors received some kind of incentive, including items of appreciation (26.8%) and paid time off work (22.4%). Ana M. Sanchez et al., *The Potential Impact of Incentives on Future Blood Donation Behavior*, 41 TRANSFUSION 172, 174 (2001).

¹¹⁷ See, e.g., Mary Hanbury, 6 Great Rewards You Can Get for Giving Blood This Summer, MONEY (July 27, 2016), http://money.com/money/4424283/rewards-donating-blood-amazon/ [https://perma.cc/ K79P-F8N3].

¹²² Farrugia et al., *supra* note 90, at 202; Darryl Lorenzo Wellington, *The Twisted Business of Donating Plasma*, ATLANTIC 1, 3 (May 28, 2014), https://www.theatlantic.com/health/archive/2014/05/ blood-money-the-twisted-business-of-donating-plasma/362012/ [https://perma.cc/DEP5-X779]; H. Luke Shaefer & Analidis Ochoa, *How Blood-Plasma Companies Target the Poorest Americans*, ATLANTIC 1, 4 (Mar. 15, 2018), https://www.theatlantic.com/business/archive/2018/03/plasma-donations/555599/ [https:// perma.cc/HQ2C-JTFK]; Philip Flood et al., *Review of Australia's Plasma Fractionation Arrangements*, AUSTRALIAN GOV'T DEP'T HEALTH 194 (Dec. 13, 2006), https://www1.health.gov.au/internet/main/ publishing.nsf/Content/B3B4E1D741764DD2CA257BF000193A6F/\$File/plasma_FINAL%20as%20at% 2030%20November%202006.pdf [https://perma.cc/6X4Y-GHMU].

¹²³ See Shaefer & Ochoa, supra note 122 at 2.

The plasma donation industry has, however, faced the same criticisms that traditional blood banks faced in the early twentieth century. Plasma has historically been collected in the most marginalized communities.¹²⁴ Some studies have found that the incidence of disease is higher in plasma donations, presumably in part because donors conceal medical conditions or risky behavior so they can donate and receive cash.¹²⁵ The plasma collection industry has taken steps in recent years to professionalize collection and combat charges of exploitation, but concerns persist.¹²⁶ At the very least, the thriving plasma donation market exhibits the enduring stubbornness of compensated blood donation in the United States, ethical and safety concerns notwithstanding.

The mixed attitude toward donation incentives places the United States somewhere in the middle of the international community on the question of compensating blood donors. Despite WHO's resolutions encouraging reliance on solely unpaid donors, countries are all over the map on the issue, so to speak.¹²⁷ As of June 2020, seventynine countries collect more than ninety percent of their blood supply from voluntary unpaid donations, including sixty-two countries (predominantly high- and middleincome) that report at or near 100 percent of their donations are uncompensated.¹²⁸ In contrast, in fifty-six countries more than half of donations come from paid donors or replacement donors (e.g., family members donating to replenish the amount of blood given to a relative).¹²⁹

A full survey of the incentives used in countries worldwide is beyond the scope of this Article, but a few points are worth highlighting. Even those countries committed to collecting blood exclusively from uncompensated volunteer donors have different conceptions of what amounts to compensation—even when ostensibly adhering to the same regulations. For the European Union, the Council of Europe's definition is very similar to FDA's stance, but has led to disparate national policies.¹³⁰ In Denmark, for example, no compensation of any kind is permitted, even to offset time and travel

¹²⁷ For more on WHO's position, see *supra* note 100 and accompanying text.

¹²⁸ Blood Safety and Availability, WORLD HEALTH ORG. (June 10, 2020), https://www.who.int/news-room/fact-sheets/detail/blood-safety-and-availability [https://perma.cc/F3ND-TW2T].

¹²⁹ *Id.* Replacement donors are also referred to as "reciprocal donors." Reciprocal donation systems are popular in many developing countries that have not been able to fully transition to all-volunteer systems. One such country is China, which outlawed paid donations in 1998 but has struggled to meet the demand for blood in recent years. *See Clot Hoppers: China Bungles Changes to its Blood-Donation System*, ECONOMIST (Mar. 22, 2018), https://www.economist.com/china/2018/03/22/china-bungles-changes-to-its-blood-donation-system [https://perma.cc/WGW6-5M74].

¹²⁴ See Robert C. James & Cameron A. Mustard, Geographic Location of Commercial Plasma Donation Clinics in the United States, 1980–1995, 94 AM. J. PUB. HEALTH 1224 (2004).

¹²⁵ Blood Safety: Enhancing Safeguards Would Strengthen the Nation's Blood Supply: Hearing Before the Subcomm. on Hum. Resources of the H. Comm. on Gov't Reform & Oversight, 5–7 (1997) (testimony of Bernice Steinhardt).

¹²⁶ Farrugia et al., *supra* note 90, at 206–07.

¹³⁰ The Council of Europe definition states: "Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation." EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE, GUIDE TO THE PREPARATION, USE, AND QUALITY ASSURANCE OF BLOOD COMPONENTS, 120–21 (20th ed. 2020) (quoting Council of Europe Recommendation No. R (95) 14 Art. 2).

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expenses, unlike next door in Germany where reimbursement along these lines is permitted.¹³¹ And in Italy no donors are paid but they can qualify for paid leave of absence from work on days that they donate.¹³² One study found that while the Czech Republic, Croatia, Greece, Italy, Macedonia, and Romania—among other European countries—reported that their donors are entirely voluntary and uncompensated, typically all (Greece, Macedonia, and Romania) or some (Croatia, Czech Republic, and Italy) of their donors receive some sort of valuable, if not material, incentive.¹³³

Among this confusing patchwork of policies that all embrace "unpaid donation," the Czech Republic actually allows a personal income tax deduction for each donation of blood—a policy that will be examined in greater detail in Part IV *infra*. The message from this brief look outside the United States is that—to the extent FDA's policy is less than crystal clear on what qualifies as unacceptable "monetary incentives" for whole blood and what does not—it is certainly no outlier compared to other regulatory regimes. And apart from those governments still permitting direct cash payments for blood, countries around the world have experimented with near-monetary incentives such as generous travel reimbursements, paid days off of work, and tax benefits. Should regulators and blood drive operators in the United States consider fresh incentives, they would be in good company.

IV. PERSONAL TAX INCENTIVES AND WHOLE BLOOD DONATIONS

Although blood banking as a practice began with deliberate imitations of the financial industry and traditional banking, personal tax relief may seem like an odd incentive to encourage donation. As detailed in Part III, the most popular incentives employed by blood centers involve material rewards given to donors at the donation site, such as token gifts. But precisely because tax benefits are a step removed from the point of donation—and a step removed from literal cash—they might make an acceptable incentive under current regulations.

As mentioned above, tax incentives are not an entirely novel proposal. The Czech Republic offers a personal income tax deduction to citizens who donate blood. Under Section 15(1) of the Income Tax Act, for each donation "of blood or its donor components" given in a year, a taxpayer may deduct CZK 3,000 (approximately \$130) from his tax base.¹³⁴ Both the usage of this tax incentive by Czech citizens and its efficacy in spurring donations are unclear. But one study asserted that sixty percent of Czech donors later requested tax relief under this provision, and it predicted that the number was not higher only because a significant portion of donors do not have

¹³¹ See C.P. Engelfriet & H. W. Reesink, *Paid vs. Unpaid Donors*, 90 VOX SANGUINIS 63, 65–66 (2006) (discussing Denmark and Germany).

¹³² Nouva Disciplina delle Attivitá Transfusionali e della Produzione Nazionale delgi Emoderivati, Legge 21 Ottobre 2005, n.219, Gazzetta Ufficiale n.251 (2005) (It.). (Italian law providing for paid leave); *see also* Lacetera & Macis, *supra* note 85, at 740–41 (describing the blood donation system in Italy).

¹³³ L. Mascaretti et al., *Comparative Analysis of National Regulations Concerning Blood Safety Across Europe*, 14 TRANSFUSION MED. 105 (2004). This study was conducted before the release of the Council on Europe's 2005 definition, but the broader disparity in attitudes towards "compensation" still holds.

 $^{^{134}}$ Č. 586/1992 Sb (Income Tax Act) § 15(1). The same provision also allows a CZK 20,000 deduction for each donation of hematopoietic (bone marrow) cells. *Id*.

income tax from which to deduct (e.g., unemployed students).¹³⁵ Perhaps more indicative of the incentive's importance is the Czech government increasing the value deductible for each donation from CZK 2,000 to 3,000 in 2018.¹³⁶

The Czech tax code contains no cap on the number of donations that can be claimed. Rather, the total tax *savings* in this manner are capped at CZK 3,000.¹³⁷ The incentive per donation is only a tax *deduction*—not a tax *credit*—meaning that a donor reaps a benefit far lower than CZK 3,000 per donation. So there is a lower risk that donors will abuse the system to over-donate than they would for, say, direct cash payments. And even if a donor were so inclined, the CZK 3,000 annual savings cap acts as a deterrent.

While a unique reward, the Czech tax incentive has yet to be systematically studied. But one similar proposal emerged recently in the United States.¹³⁸ In 2016 and 2017, several legislators introduced bills in the New Jersey (NJ) Assembly and State Senate that would provide "gross income tax credits for certain taxpayers who provide blood donations."¹³⁹ In providing a rationale for the legislation and its proposed tax credit, the bills contained the following identical statement:

[New Jersey] has sought to encourage residents to make regular blood donations. The need for blood is ever-present, and simply put, it saves lives. Donations are used to aid individuals battling cancer, trauma victims, surgical patients, premature infants, and American soldiers serving in battlefields. According to the American Red Cross, every two seconds someone in the United States is in need of blood, though less than 5 percent of the American population that is eligible to donate blood actually does so each year.¹⁴⁰

As for specific provisions, the proposed legislation stated:

A taxpayer shall be allowed a credit against the tax otherwise due under the "New Jersey Gross Income Tax Act" . . . in an amount equal to \$100 per taxable year if the taxpayer makes four or more blood donations, as defined by this section, through a [licensed] blood bank operator . . . or a [licensed] hospital . . . that maintains blood donor facilities and provides blood donation services to the public. For purposes of this section, one "blood donation" equals one whole blood donation, platelet donation, or plasma donation; one double red cell donation shall be considered two

¹³⁵ Hassan Abolghasemi et al., *Blood Donor Incentives: A Step Forward or Backward*, 4 ASIAN J. TRANSFUSION SCI. 9 (2010).

¹³⁶ ACCACE, SUMMARY OF THE MOST SIGNIFICANT CHANGES AFFECTING EMPLOYMENT TAXATION IN 2018 4 (2018), https://accace.com/wp-content/uploads/2018/04/GL-2018-04-26-Summary-of-the-most-significant-changes-affecting-employment-taxation-in-2018-EN.pdf [https://perma.cc/Y3DB-X4ZL].

¹³⁷ Id.

¹³⁸ The IRS has explained that blood donations are considered a "Time and Services" donation rather than an asset donation and thus do not qualify as deductible charitable contributions under the federal tax code. *See Publication 526, Charitable Contributions, Value of Time or Services,* IRS, https://www.irs.gov/publications/p526 [https://perma.cc/P6HW-ZYF4] (last updated Mar. 25, 2020).

¹³⁹ N.J. Leg. Assemb. A4665, 217th Sess. (N.J. 2017); N.J. Leg. S. S2515, 217th Sess. (N.J. 2016). Introduced at the same time were bills providing similar \$1,000 tax credits for donating organs. *See* N.J. Leg. Assemb. A4664, 217th Sess. (N.J. 2017); N.J. Leg. S. S2516, 217th Sess. (N.J. 2016).

¹⁴⁰ N.J. Leg. Assemb. A4665, 217th Sess. (N.J. 2017).

blood donations.... A credit allowed under this section shall be claimed for the taxable year in which four or more blood donations occur.¹⁴¹

In brief, the legislation would grant a \$100 income tax credit to taxpayers who donate blood, platelets, or plasma at least four times in a year. Other language in the bills mandates that the Director of the NJ Division of Taxation promulgate procedures and tax forms that donors could use to verify that at least four donations have been made. The proposed legislation received minor attention in the press but was overshadowed by companion bills offering state tax credit for donating an organ.¹⁴² The legislation was not voted on during the 217th legislative session and has not been reintroduced since.

The NJ legislation differs from the Czech incentive through its reliance on a tax credit rather than a tax deduction. But unlike in the Czech provision, a taxpaying donor in New Jersey would only receive an economic benefit once he has donated four times in a year, and this reward does not increase upon further donations thereafter. So one could characterize the NJ legislation as incentivizing habitual donating as a behavior, rather than financially rewarding any one donation.

Either way, both the Czech provision and the proposed NJ legislation raise questions as to how they would be treated by FDA regulations. The labeling requirements under 21 C.F.R. § 606.121(c) require donations to be labeled as sourced from a "paid donor" when the supplier received "monetary payment" for the donation—an uncertain term with many possible boundaries, as explored in Part III supra. On the one hand, a tax incentive is in some ways a paradigmatic form of monetary payment: the reward entails increasing the financial assets of the donor as a result of his donation. Adopting the guideposts for "monetary payments" provided by FDA,¹⁴³ tax savings are easily "refundable or redeemable for cash," given that taxes are paid with financial assets. To claim otherwise would suggest that perhaps wiring funds to someone's bank account would not be sending a "monetary payment." This logic would eschew accepted notions of financial banking, especially in an increasingly cashless society. Once one recognizes that tax incentives are readily redeemable for cash, it is not difficult to see how those savings are "transferable" and that a "market" exists for them; just like cash, tax savings can be spent on anything or nothing.

On the other hand, tax incentives are in some ways decidedly unlike cash payments. The benefits accrued by donating—even if given on a per donation basis—depend on the donor having a tax liability (in the future) and on the donor filing taxes, which many donors would not do (e.g., students without income). To that end, potential tax savings cannot be transferred to someone else, nor is there a market for the savings as a good; they only become valuable once converted into usable funds—which only occurs at the moment that less tax is paid during the following year.

¹⁴¹ Id.

¹⁴² Matt Friedman, *Bills Would Offer Tax Relief for Blood, Organ Donations*, POLITICO (Mar. 3, 2017), https://www.politico.com/states/new-jersey/story/2017/03/tax-relief-for-blood-and-organ-donations -proposed-in-nj-110022 [https://perma.cc/CQ8P-N5WL]; Emily Smith, *NJ Proposal to Offer Tax Credits for Organ Donation Met with Skepticism*, CBS N.Y. (Apr. 3, 2017), https://newyork.cbslocal.com/2017/04/ 03/organ-donor-tax-credit/ [https://perma.cc/9EZM-5FBH].

¹⁴³ Namely: (1) Is the incentive refundable or redeemable for cash? (2) Does a market exist for the incentive? And (3) Is the incentive transferable? *See* FOOD & DRUG ADMIN., *supra* note 112 and accompanying text.

The tax incentive schemes provided by the Czech and NJ examples are even less akin to monetary payments than tax savings in the abstract. For the former, the incentive is a tax *deduction*, meaning that it alters the calculation of how much personal income tax someone might owe, which is not in any way transferable to another person. And it might provide a given donor no value at all if, for example, she has already maxed out the allowable deduction based on other charitable contributions. The proposed NJ system provides a tax credit, but one that only materializes for someone who donated four times in the preceding year. So for at least the first three donations, the earned incentive is merely the opportunity to be closer to achieving four donations in a year; the marginal benefit accrued for each of these donations is not transferable, marketable, or redeemable for cash.

Analogizing tax incentives to other forms of currently acceptable rewards also weighs in favor of not treating tax incentives as a "monetary payment" under FDA guidelines. To be sure, some material incentives seemingly further removed from cash are considered monetary payments, such as tickets to entertainment events, vouchers for free medical tests, or high-value gifts such as television sets.¹⁴⁴ But here again, the touchstone is transferability: similar vouchers and items that are non-transferable do not trigger a "paid donation" classification. Gift cards are likewise not considered monetary incentives provided that they bear the donor's name and are thus non-transferable. Similarly, tax incentives are person-specific, but they have even more of a temporal delay than gift cards, which can be converted into value much more quickly.¹⁴⁵

FDA's distinction on scholarship payments is instructive. Scholarship money paid directly to a student counts as "monetary payment," while funds transferred instead to a school "would not be considered to be readily convertible to cash" even if it thereby saves a student tuition money that she would have otherwise paid.¹⁴⁶ Similarly, tax incentives would not provide cash or a cash-equivalent directly to a donor but could be characterized as a payment to the government on behalf of a donor who reaps the savings. And for tax incentives, in theory no funds actually change hands, as the government would merely forgive some money that would otherwise be owed as tax. Of course, the majority of U.S. taxpayers actually receive refunds from the government, at least from their federal filings.¹⁴⁷ So one could stretch to say a tax credit often ultimately involves money changing hands from the government to the taxpayer in the form of an increased tax refund. This logic would be even more strained for tax deductions, which would only alter a person's tax base, and thereby only marginally change the calculations on the amount of any refund received. Either way, both tax deductions and credits involve a significant temporal delay between donating and reaping any reward. And, like scholarship payments, any reward runs through an

¹⁴⁴ See FOOD & DRUG ADMIN., supra note 112 and accompanying text.

¹⁴⁵ In some instances, redemption of the gift card requires follow-up by the donor via instructions sent by email shortly after the donation. *See, e.g., Get a \$5 Amazon Gift Card, AM. RED CROSS (2019), https://www.redcrossblood.org/local-homepage/events/help-save-lives--get-a--5-amazon-com-gift-card-.html [https://perma.cc/7PEA-EV69].*

¹⁴⁶ FOOD & DRUG ADMIN., *supra* note 112 and accompanying text.

¹⁴⁷ See Filing Season Statistics for Week Ending April 19, 2019, IRS, https://www.irs.gov/newsroom/ filing-season-statistics-for-week-ending-april-19-2019 [https://perma.cc/77XX-MUBL] (last updated Apr. 3, 2020).

intermediary (i.e., a school or the government), with the value dependent on how much, if at all, the donor happens to already owe that intermediary.

Frequent flyer miles provide another helpful analogy. Also known as "airline miles" or "travel points," frequent flyer miles are accumulated by would-be travelers, typically by using a certain credit card or flying a certain airline often. Travelers can then use the accumulated miles to purchase whole or discounted tickets. Some airlines permit transferring miles to other account holders on a limited basis or for a fee.¹⁴⁸ FDA's guidance states that incentivizing donations with frequent flyer miles "would generally not require a 'paid donor' label," despite the CPG acknowledging that "a market may exist for the miles."¹⁴⁹ These accumulated rewards ultimately save donors money, provided that they decide to use them, just as tax incentives (credits or deductions) would ultimately save donors money should they choose to claim them on their tax filings (and assuming they file tax returns at all).

Aside from interpreting the regulatory text and its corresponding guidance, it is critical to also consider the effect that tax incentives might have given the longstanding objections to paid donation. After all, FDA's policy was implemented based on certain assumptions about the pitfalls of compensated blood donation. Tax incentives would sidestep some of the gravest concerns about paid donation, providing a strong reason to read FDA's safe harbor for non-monetary incentives to apply to tax incentives as well.

As identified in Part II supra, one of the chief concerns about paid donation is the risk that it crowds out some would-be donations by alienating altruistic donors. The limited conclusive research on the subject demonstrates that potential donors tend to dislike direct cash payments, which discourage further donations.¹⁵⁰ But economic incentives a "step-removed" from cash, such as personal gift cards, do boost donations—especially by encouraging occasional donors to donate more frequently.¹⁵¹ Tax incentives are even more removed from cash payments than gift cards, at least logistically. Unlike gift cards received at a blood center or a few days later, tax benefits would be redeemed weeks or even months later, upon the filing of tax documents. This may make the incentive less potent-being too remote or too much of a hassle to incentivize as many donors as more immediate rewards would. But it likely also protects against significant crowding out. Donors for whom a tax reward is motivating could file the necessary paperwork to redeem it down the line, while those for whom it is negligible or even discouraging could ignore it. Unlike cash payments handed out in person, which could be repulsive for donors to be given or to watch others receive, even well-publicized tax incentives are redeemed individually, in private, at a later date, and only by a donor who so desires. In that sense, they embrace a more pluralistic approach to incentives, as promoted by some industry advocates.¹⁵²

Economics aside, safety concerns are appropriately one of the most important factors motivating FDA's specific rules on clearly labeling blood as either "paid" or

¹⁴⁸ Johnny Jet, *Can You Transfer Airline Miles to Someone Else's Account?*, FORBES (Dec. 15, 2017), https://www.forbes.com/sites/johnnyjet/2017/12/15/can-you-transfer-airline-miles-to-someone-elsesaccount/#4e3a0f616a73 [https://perma.cc/4XML-PYBL].

¹⁴⁹ FOOD & DRUG ADMIN., *supra* note 112 and accompanying text.

¹⁵⁰ See supra note 82 and accompanying text.

¹⁵¹ See Lacetera et al., Economic Rewards, supra note 82, at 927.

¹⁵² See Farrugia et al., supra note 90, at 207-08.

"volunteer." Indeed, the FDA commissioner cited reducing the risk of transfusing infected blood as one of the principal motivations in first implementing the labeling policy back in 1978.¹⁵³ Adding any incentive to shift donor behavior should be eyed with caution, especially given the widespread, tragic consequences when blood supplies were compromised in the late twentieth century. But the empirical research, discussed above, suggests that today the greatest risk comes from varying the populations donating rather than the incentives offered to individuals within those groups.¹⁵⁴ Populations attracted to certain incentives can have distinct risk profiles: some research suggests that "unlike cash payment, which is more attractive to low-income groups with higher transmission risks, [other] incentives are not problematic in terms of blood safety, because they are not necessarily tied to such groups with problematic risk profiles."¹⁵⁵

Of course, it is important to avoid generalities about certain groups based merely on one or a few characteristics. But even if groups attracted to cash payment carry the greatest risk factors for infected blood, as seen with infection rates in the plasma industry, it does not necessarily mean that tax incentives would attract these donors.¹⁵⁶ First, to the extent that at-risk individuals would seek out compensated donation, the plasma donation industry already fills that demand. Controversial as they are, plasma donation centers pay cash directly to donors at the time of donation.¹⁵⁷ It seems unlikely that a significant number of vulnerable, cash-seeking donors are currently forgoing plasma donation or would switch from cash-paying plasma donation to taxincentivized whole blood donation for the much more delayed economic benefit of income tax savings. Indeed, given the demographic patterns of plasma donors, concerning as they are, these donors are less likely to have high personal income tax burdens or be paying income tax at all.¹⁵⁸ Second, as mentioned above, research on economic rewards has shown that they primarily motivate occasional donors-already motivated by altruism, social benefits, etc.-to donate more frequently, rather than attracting droves of new donors.¹⁵⁹ And studies have shown that repeat donors have lower rates of transfusion-transmitted diseases than new donors, meaning safer blood.¹⁶⁰

The ethical considerations underlying FDA's policy also cannot be ignored. The current system of blood donation in the United States is a far cry from the ideal envisioned by Titmuss and his fellow ethicists.¹⁶¹ Of course, if one views the current state of incentives as objectionable, adding yet another mode of remuneration for blood donation is unwelcome. But tax incentives are less crudely transactional than

¹⁵⁵ Id.

¹⁵⁶ Van der Poel et al., *supra* note 94, at 285–86, 289, 291–92.

¹⁵⁷ See Shaefer & Ochoa, supra note 122, at 2, 5.

¹⁵³ Whole Blood and Components of Whole Blood Intended for Transfusion; Donor Classification Labeling Requirements, 43 Fed. Reg. 2142 (Jan. 13, 1978). At the time, transmission of the hepatitis B virus was the chief concern.

¹⁵⁴ See Buyx, supra note 69, at 333.

¹⁵⁸ See James & Mustard, *supra* note 124, at 1225–27.

¹⁵⁹ See Lacetera et al., Economic Rewards, supra note 82, at 928.

¹⁶⁰ Simone A. Glynn et al., *Repeat Whole-Blood and Plateletpheresis Donors: Unreported Deferrable Risks, Reactive Screening Tests, and Response to Incentive Programs,* 41 TRANSFUSION 736 (2001).

¹⁶¹ See Titmuss, supra note 62 and accompanying text.

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gift cards redeemed at the point of donation, for example—and certainly less distasteful than the cash-paying plasma donation industry, with its many questionable practices.¹⁶² At the very least, tax incentives do not push donation rewards into more blatantly anti-altruistic territory than they currently reside.

Some of the ethical concerns described in Part II focus on the coercive nature of paying for blood, which may compel destitute individuals into donating—or overdonating—when they would refrain from doing so if they were financially secure. But it seems unlikely that tax incentives would add to this risk, especially when overdonation motivated by tax incentives could be easily deterred. The proposed NJ legislation, for example, gives a tax credit once four donations are made in a year and then gives *no reward for donations thereafter*. Tax incentives—whether deductions or credits, and whether accumulating on a per donation basis like in the Czech Republic or upon reaching a certain threshold like in the NJ legislation—could be capped in such a way to avoid encouraging unhealthy donation practices.¹⁶³

A more pertinent ethical concern may be the fact that tax incentives would be regressive insofar as they would benefit only those who expect to pay income tax—excluding, for example, unemployed students, low-income earners, or the destitute. (Indeed, these may be the very populations who have the time and motivation to donate more often, especially where economic incentives are offered.) This is a fair criticism, but it does not suggest that tax incentives are incorrigible. Already, some tax credits are available to individuals who do not owe any income tax and otherwise would not need to file.¹⁶⁴ And some incentives provided by blood centers are not useful for all potential donors; frequent flyer miles are only valuable for those who expect to travel by air, and gift cards to certain stores might not appeal to all donors. Recognition of tax incentives they might be used, rather than justifying rejecting them out of hand.

In fact, tax incentives could also be used creatively to address specific shortages in the blood supply. For example, whole blood and platelets are often in short supply at certain times of the year, such as during holidays and the winter months, while arriving in surplus at other times.¹⁶⁵ Tax legislation could address this imbalance by offering incentives only—or for a greater amount—during periods of the year where there have historically been supply shortages. Even if zero new donors responded to the tax incentives and existing donors did not donate any additional times, simply shifting the behavior of existing donors (e.g., when they donate) could pay dividends in managing the blood supply and, ultimately, in saving lives.

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¹⁶² Wellington, *supra* note 122.

¹⁶³ The Red Cross explains that donors for their own health "must wait at least eight weeks (56 days) between donations of whole blood and 16 weeks (112 days) between Power Red donations," while "[p]latelet apheresis donors may give every 7 days up to 24 times per year." *Frequently Asked Questions*, AM. RED CROSS (May 1, 2019), https://www.redcrossblood.org/faq.html [https://perma.cc/3FUA-FCVN]. So a tax incentive scheme could set rewards to only accumulate for at most six donations of whole blood in a taxable year—or fewer, to be even more cautious.

¹⁶⁴ See, e.g., Earned Income Tax Credit (EITC), IRS (June 5, 2020), https://www.irs.gov/credits-deductions/individuals/earned-income-tax-credit [https://perma.cc/689M-MPVR].

¹⁶⁵ Slonim et al., *supra* note 8, at 190; *see also Winter Storms and Flu Prolong Blood Shortage*, AM. RED CROSS (Jan. 31, 2019), https://www.redcross.org/about-us/news-and-events/news/2019/winter-storms-and-flu-prolong-blood-shortage.html [https://perma.cc/3W4U-2KSH].

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To be sure, it may be difficult to predict exactly how tax incentives would be treated under FDA's regulatory regime. The labeling requirements are ambiguous, and tax savings uniquely straddle the winding line between "monetary" and "non-monetary" compensation. But as has been shown, there are good reasons to treat tax incentives as fulfilling both the letter and the spirit of volunteer donations. This conclusion is reinforced by comparing tax incentives to alternative forms of near-cash incentives that have been deemed acceptable, as well as by acknowledging the assumptions behind attempts to distinguish transfusable blood from paid and volunteer donors.

CONCLUSION

This Article set out to examine how tax incentives would fit into the current regulatory scheme that distinguishes between "paid" and "volunteer" blood donations, as well as to explain why tax incentives should not be treated as monetary payments. Two distinct questions loom: Would tax incentives work in encouraging donations? Should they be implemented? Even if the answer to both questions is "yes," one could argue over whether the state or federal government would be the better jurisdiction to adopt such an incentive program. Similarly, this Article addresses both potential tax credits and tax deductions, but the case could be made for either system as superior.

Unfortunately, scholarship has yet to analyze the effect of tax incentives on blood donations to help answer these questions, despite possibly fertile ground to study the issue in the Czech Republic. Additional research might compare blood donations to markets for other replenishable biologics, such as bone marrow and human hair.¹⁶⁶ Or perhaps what deserves more pressing reexamination are not the incentives offered to blood donors but instead hospitals' continuing rejection of blood collected from "compensated donors" for use in transfusions.

There remains much room for creativity both in further research and in potential donation incentives, especially in the face of routine shortages of whole blood and platelets. Of course, not *all* creativity is beneficial, as Judge Wiggins demonstrated in his Perry County courtroom. But as has been seen since the days of James Blundell treating desperate patients with the previously condemned treatment of blood transfusion, out of necessity can flow ingenuity and innovation.

 $^{^{166}}$ For some commentary addressing the effect of tax incentives on bone marrow donations, see *supra* note 81.