

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
RICHMOND DIVISION**

**BUCKEYE TRANSPLANT SERVICES,
LLC,**

Plaintiff,

-v-

**UNITED NETWORK FOR ORGAN
SHARING,**

Defendant.

Civil Action No. 3:23-cv-00427

COMPLAINT

For its Complaint against Defendant United Network for Organ Sharing (“UNOS”), Plaintiff Buckeye Transplant Services, LLC (“Buckeye”) states and alleges as follows:

INTRODUCTION

1. The organ matching process is a race against time. When an organ becomes available following a tragedy, the hope that the organ might bring new life to a recipient dims with every minute the recipient waits. Over 36,000 deceased donor organ transplants were performed in the United States in 2022. Today, there are over 100,000 adults and children on the national transplant waiting list. Seventeen of them die every day waiting for an organ.¹

2. Many Americans volunteer to be organ donors. When their time comes, medical staff determine that a donor has died, and an organ procurement organization (“OPO”) assists with making the donor’s organs available to potential recipients. The OPO enters data about the donor, such as blood type, height, and location into a national computerized system known as the Organ

¹ <https://www.organdonor.gov/learn/organ-donation-statistics>

Procurement and Transplantation Network (“OPTN”). Transplant centers receive information about available organs through the OPTN. Transplant surgeons and their teams evaluate the organs to determine whether they are suitable for the organ recipients they treat. As UNOS’ website confirms, “[t]iming is especially important at this step and during recovery.”²

3. The efficient, effective operation of OPTN is essential to the functioning of the organ allocation system. UNOS has held a monopoly on operating OPTN nationwide since 1986. UNOS won its first contract because it was the only bidder.

4. UNOS’ information technology has been subject to scathing criticism. The Chair of the U.S. Senate Finance Committee described the UNOS IT system as “outdated, mismanaged and insecure” and observed that “[u]sing such decrepit tech to run the transplant network puts lives in danger and puts sensitive data at risk, and there is no apparent solution in sight.”³ Senator Elizabeth Warren has condemned UNOS in even stronger terms, saying UNOS “should lose this contract,” and UNOS “should not be allowed anywhere near the organ transplant system in this country. Patients and families deserve better than what they are getting from UNOS.”⁴

5. There is bipartisan agreement that the organ transplant system UNOS oversees is desperate for reform. Senator Chuck Grassley has charged that “[t]housands of patients are dying every year and billions of taxpayer dollars are wasted because of gross mismanagement,” and “[t]he system is rife with fraud, waste and abuse, corruption, even criminality.”⁵

² <https://unos.org/transplant/deceased-donation/>

³ <https://www.finance.senate.gov/chairmans-news/wyden-statement-at-finance-committee-hearing-on-the-urgent-need-to-address-failures-in-the-organ-transplant-system>

⁴ <https://www.wbur.org/onpoint/2023/05/02/the-single-organization-that-runs-americas-organ-transplant-system>

⁵ <https://www.washingtonpost.com/health/2023/03/22/transplant-system-overhaul-unos/>

6. Media reports confirm that “[u]nder UNOS, which holds a \$6.5 million annual contract with the U.S. Health Resources and Services Administration (“HRSA”), the network has been plagued by problems: Too many organs are discarded, damaged in transit or simply not collected, faulty technology sometimes jeopardizes transplants, and poor performers face little accountability.”⁶

7. Buckeye is proud to serve an important role in the life-saving work of the medical professionals who labor around the clock to provide organs to patients who need them. Buckeye has developed innovative IT tools to speed up the work those medical professionals do. Buckeye works hand-in-glove with transplant centers to evaluate available organs and maximize the effectiveness of their organ transplant programs, and accesses the OPTN through UNOS’ systems on behalf of the transplant centers to perform these essential services.

8. Buckeye accesses the UNOS system as an authorized third party, in order to perform and facilitate “certain quality assurance and improvement activities related to organ transplantation”—the expressly stated purpose of UNOS providing access to its systems and the OPTN.⁷ Buckeye’s use of the UNOS system is and has always been fully within the scope of its authorized use, for the purposes of facilitating and improving organ transplant coordination as contemplated by UNOS’ terms and the OPTN, and consistent with industry norms for transplant center and third party use of UNOS’ systems.

9. Recently, after years of Buckeye’s fully authorized and compliant use of its systems, UNOS suddenly sought to preclude Buckeye’s continued work. Buckeye was forced to bring this lawsuit—and pursue emergency injunctive relief—because UNOS has threatened to

⁶ <https://www.washingtonpost.com/health/2023/03/22/transplant-system-overhaul-unos/>

⁷ <https://unos.org/wp-content/uploads/2018-UNOS-Systems-Terms-of-Use.pdf>

terminate Buckeye's access to the OPTN on July 5, 2023 unless Buckeye stops performing essential services and deletes years of transplant centers' data, essentially handicapping Buckeye's ability to serve its transplant center clients.

10. On June 21, 2023, UNOS alleged that Buckeye is violating UNOS' OPTN policies and the UNOS Terms of Use, a five-page document UNOS wrote in 2018 describing how it believes OPTN should be used.⁸ Buckeye disagrees with UNOS' interpretations, and UNOS implicitly conceded that its reading of the terms was new by emailing the transplant community on June 30, 2023, adding more words to one of the phrases at issue.

11. UNOS' new interpretation is incorrect, but more importantly, UNOS' demand that Buckeye cease performing essential services and delete data belonging to its client transplant centers before the parties can resolve their dispute requires emergency judicial intervention. Absent emergency injunctive relief, the work at transplant centers Buckeye serves to evaluate potential organs will slow or stop, delaying the organs transplant recipients desperately need. All of those patients will suffer. Some will die.

PARTIES

12. Plaintiff Buckeye Transplant Services, LLC is a limited liability company organized under the laws of Ohio. Its sole member is Transplant Advancement USA Inc., a corporation organized under the laws of Delaware with its principal place of business in Buffalo, New York.

13. UNOS is a nonstock corporation organized under the laws of Virginia. Its principal place of business is in Richmond, Virginia.

⁸ <https://unos.org/wp-content/uploads/2018-UNOS-Systems-Terms-of-Use.pdf>

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. § 1332 because UNOS and the sole member of Buckeye are citizens of different states and the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 as to Buckeye's claims that arise under the laws of the United States, and supplemental jurisdiction over Buckeye's other claims pursuant to 28 U.S.C. § 1367 because they form part of the same case or controversy.

15. This Court is the proper venue for this civil action pursuant to 28 U.S.C. § 1391 because, without limitation, UNOS resides in this district.

FACTS

I. The Organ Donation and Transplant Process

16. In the United States, organ donations and transplants are coordinated through a national network of OPOs, transplant centers, and service providers. UNOS operates the technological system for matching donors with patients waiting for an organ transplant through OPTN.

17. When an organ from a deceased donor becomes available, an OPO facilitates the process at the donor's hospital and gathers detailed information about the available organs to transmit to UNOS. That information is then processed and made available through the OPTN in the form of an "offer" to transplant centers with potential recipient patients on the organ transplant waiting list.

18. Upon receipt of an organ offer, a transplant center must analyze and evaluate the suitability of the organ before making a decision on whether to accept or decline the organ. This decision requires retrieving and analyzing a large volume of information from the OPTN systems. If the organ matches the transplant center's criteria, the information is communicated to the

physicians, decision makers, and surgeons who would ultimately perform the transplant for a final decision. If an organ is declined, it is offered to the next transplant center on the list, and so on, until the organ is either matched, is determined to no longer be viable for transplant, or is declined by every center on the match list.

19. Time is of the essence in this process of transplant coordination, as organs remain viable for only a short period of time following the death of the donor, and delays in transplant centers' response time significantly increases the risk that organs will become unviable or otherwise unavailable for transplant.

20. Transplant centers also must act quickly on organ offers so that the centers can consider more offers. Timely considering more organ offers increases the number of opportunities a transplant center has for their listed recipients. Patients do not have time to waste.

21. From the time that a transplant center receives notification of an offer, it typically has between 30 minutes to an hour (depending on the status of its potential recipient on the transplant list) to respond to the offer. If a transplant center fails to respond within the allotted time frame, it may be bypassed and the offer moved on to the next candidate. The more transplant centers that decline or fail to respond to an offer, the longer the delay in matching the organ with a recipient, which increases the risk that the organ will not be transplanted at all.

22. Transplant centers may be notified of new organ offers at all hours of the day. Due to the time-sensitive nature of the organ matching process, all transplant centers are required to have transplant personnel—whether an internal employee or a third-party contractor—available at all times to receive, evaluate, and process organ offers.

II. Buckeye Helps Transplant Centers Make Life-Savings Decisions Faster

23. Buckeye is the nation's leading provider of specialized services for transplant centers to facilitate the organ donation process. Buckeye's clients include dozens of prominent

hospitals and medical centers that rely on Buckeye's services at various stages of the donor transplant process. Buckeye began partnering with transplant centers across the United States in 2008.

24. Buckeye has over 150 transplant coordinators on staff and a large dedicated team of technical staff. Buckeye's coordinators have extensive years of organ placement or transplant experience and are made up of Registered Nurses, Respiratory Therapists, and Procurement Transplant Coordinators.

25. Buckeye's industry and technical expertise have enabled it to add significant value to the transplant coordination process. In 2022, Buckeye assisted in the facilitation of 5,906 organ transplants at its client transplant centers—accounting for over 16% of all deceased donor transplants that took place in the United States last year.

26. UNOS' website publicly recognizes Buckeye as one of UNOS' "community partners" whom UNOS thanks for "their generosity," which enables UNOS "to provide patient, public, and professional education and launch high-impact projects in transplant technology to grow ever closer to our vision of a lifesaving transplant for everyone in need."⁹

27. At a high level, Buckeye's services and technological capabilities enable its client transplant centers to screen and respond to offers more quickly and efficiently. Among other services, Buckeye assists its clients in the process of evaluating and responding to organ offers by receiving notifications of new offers, evaluating data regarding the available organ, and identifying acceptable offers based upon the criteria established by the client transplant center.

28. For the clients of Buckeye's offer screening services, Buckeye acts essentially as the transplant center's outsourced transplant personnel, providing front-line intake of new offers,

⁹ <https://unos.org/community/partners/>

retrieving and analyzing information from the OPTN systems, and determining whether the offer meets the transplant center's criteria for potentially acceptable organs. In this capacity, Buckeye accesses the OPTN systems as an authorized third party, on behalf of the member transplant center.

29. In addition to its specialized personnel, Buckeye utilizes technology to optimize and accelerate the process of retrieving and analyzing the volume of data necessary to evaluate an organ offer. Buckeye offers certain pieces of its technology to its clients to enable the transplant centers to more efficiently and accurately access necessary information in the organ offer evaluation process.

30. Buckeye also offers logistical and administrative support to its client transplant centers by facilitating organ intake and delivery, managing the transplant center's recipients on the OPTN waiting list, and supporting the client's reporting and compliance needs as a member of the transplant center network.

31. Many of Buckeye's clients rely on Buckeye to track and report on the transplant center's offer decision data, which are then used by the transplant centers to conduct internal reviews with their transplant physicians and other decision-making personnel in order to analyze and improve their organ offer evaluation process. Buckeye's clients have also relied on Buckeye's data analytics and processing capabilities to provide reports in connection with information that the transplant centers then relay to UNOS and other entities for transplant program improvement.

32. At issue in this dispute are Buckeye's front-line offer screening and decision review services—two of the most important services utilized by Buckeye's clients to facilitate and improve their organ transplant processes. Specifically, UNOS has demanded that Buckeye

discontinue two of its technological tools—the Rapid Organ Assessment Tool and the Operational Assessment Tool.¹⁰

33. As stated in the *first sentence* of the UNOS Terms of Use, UNOS expressly contemplates and authorizes access to its systems for “quality assurance and improvement activities related to organ transplantation.” Buckeye read these terms and, in reliance thereon, Buckeye has invested more than \$1.4 million in recent years in developing its technological tools, and they are essential to the services offered by Buckeye to its clients. They are utilized by Buckeye’s personnel in the provision of its transplant coordination services to transplant centers.

34. As discussed further below, these tools are critical to the organ coordination process and the elimination of Buckeye’s technology would have both immediate and long-term implications for the ability of the organ donation network to successfully transplant deceased donor organs.

A. The Rapid Organ Assessment Tool

35. The Rapid Organ Assessment Tool is a web browser plug-in designed to enable the user to quickly and accurately analyze the large volume of information that needs to be reviewed in the evaluation of an organ offer.

36. The Rapid Organ Assessment Tool is deployed solely on Buckeye’s internal web browser. It does not reside on or through any UNOS system.

37. To use the tool, the organ information is first accessed by an authorized user—*i.e.*, a transplant center employee, contractor, or other person who has permission to access the information—through the OPTN systems website. The user accesses the website through an

¹⁰ In communications with UNOS leading up to this lawsuit, Buckeye used generic names for these services and introduces these easier-to-understand titles to ensure clarity herein.

ordinary internet browser. After the user logs into the OPTN systems and pulls up the information in the user's browser, the Rapid Organ Assessment Tool scans and processes the content of the webpage (which is already visible to the user) to retrieve the data points that the user needs to evaluate the organ offer.

38. The Rapid Organ Assessment Tool is essentially an automated "copy and paste" mechanism that excerpts and compiles pertinent information for the transplant personnel's review. The plug-in operates by quickly and accurately distilling the large volume of information contained on the webpage down to the data points required for transplant personnel to determine whether an organ offer is suitable for the potential recipient.

39. By using the Rapid Organ Assessment Tool to automate administrative labor that would otherwise require time-consuming manual review, the user is able to save substantial processing time in evaluating whether the organ is suitable. The use of the tool therefore directly decreases the transplant center's decision-making and response time in either accepting or declining the offer.

40. In cases where the organ is not suitable, the Rapid Organ Assessment Tool is able to help transplant personnel rule out an offer within minutes, thus permitting the organ to be made available to another transplant center that may be able to make use of it. In cases where an offer passes the initial screening, the coordinator is able to effectively compile the necessary information to afford the decision-maker (*i.e.*, the surgeon) maximum time to review the information and make the best decision for the patient.

41. Additionally, because the tool automates the review and retrieval of pertinent information, it avoids mistakes due to human error that may occur in the manual review process. The tool increases accuracy because it eliminates the need for the user to either retype or manually

copy and paste the data into new locations, both of which risk inadvertent errors. This automation reduces the risk of a transplant center mistakenly identifying an unsuitable organ as acceptable, or vice versa—a devastating mistake that could potentially cost a patient’s life. For example, if a donor’s blood type is “AB” and a user manually copies this information as “A,” the organ may be transplanted into a recipient with A blood type—a potentially fatal error.

42. The continued use of the Rapid Organ Assessment Tool is imperative to Buckeye’s transplant center clients. Buckeye assists transplant centers in assessing and processing over 20,000 organ offers per month. It is impossible for Buckeye or any transplant center Buckeye serves to assess and make timely decisions regarding as many organ offers as efficiently as they can at present without the assistance of Buckeye’s tool.

43. If Buckeye is unable to utilize the Rapid Organ Assessment Tool, evaluation times will be extended, causing longer allocation times and in some cases the inability of the transplant center to timely respond to an offer. These delays in evaluating an organ could result in worse patient outcomes and cause potentially transplantable organs to become unviable or otherwise unavailable.

44. There is no dispute that lower organ utilization would be undesirable and result in the potential loss of life for patients on the waitlist. As UNOS itself has confirmed: “Addressing organ non-use is crucial to saving lives.”¹¹ Buckeye’s tool is designed to help coordinators focus on the pertinent offers, evaluate them quicker, and lessen allocation times to increase organ utilization.

¹¹ <https://unos.org/transplant/organ-acceptance/>

B. Operational Assessment Tool

45. The Operational Assessment Tool is also an automated browser tool that processes and compiles information for the transplant center's use. The Operational Assessment Tool retrieves and compiles data on the outcomes of organs that had been previously declined by the transplant center, in order to identify instances where the declined organ had been successfully transplanted elsewhere.

46. The Operational Assessment Tool is deployed solely on Buckeye's internal web browser. It does not reside on or through any UNOS system. Buckeye voluntarily paused its use of the Operational Assessment Tool in May when UNOS questioned its use.

47. The primary purpose of the Operational Assessment Tool is to enable transplant centers to analyze retrospective data for the purpose of improving their clinical practices and procedures. For example, if a large number of the transplant center's declined organs were ultimately successfully transplanted elsewhere, that trend may indicate to a transplant center that it needs to re-evaluate its offer filter criteria and provide guidance to the transplant center on areas of improvement for their donor screening policies.

48. This type of retrospective review is not only within the contemplated use of the OPTN systems, but is specifically encouraged by UNOS as best practices for increasing organ utilization. UNOS has recognized that the rate of organ non-use is an issue for the organ donation and transplant community, and claims to be "actively developing solutions to address it."¹²

49. In fact, UNOS offers a "collaborative improvement" program in which it expressly recommends that transplant centers "perform a retrospective review . . . to review offers declined but accepted and successfully transplanted elsewhere" in order to assess its donor criteria and offer

¹² <https://unos.org/transplant/organ-acceptance/>

screening process. A number of Buckeye's clients participate in UNOS' collaborative improvement program, and many of those clients rely on Buckeye's reporting capabilities to provide the transplant center's data as needed for the program.

50. As with the Rapid Organ Assessment Tool, the data captured by the Operational Assessment Tool for each of Buckeye's clients is information that is already available to that transplant center. The Operational Assessment Tool is accessed through a user's ordinary internet browser and compiles only information that the user is authorized to access on the OPTN systems.

51. As noted further below, UNOS also offers a very similar data analytics tool that also compiles retrospective data regarding organ outcomes for transplant center review, including reports of "transplant-specific and aggregate outcomes" for the organs declined by a transplant center—*i.e.*, essentially the same data that is compiled by the Operational Assessment Tool.¹³

III. In March 2023, the Federal Government Announced that UNOS' Thirty-Year Monopoly May End

52. On March 22, 2023, HRSA announced a modernization initiative, including stating "HRSA's intent to issue contract solicitations for multiple awards to manage the OPTN in order to foster competition and ensure OPTN Board of Directors' independence," that is, solicit bids to potentially replace UNOS as the monopolist operator of OPTN.¹⁴

53. Losing its monopoly represents an existential threat to UNOS. UNOS collected over \$68 million in revenue in 2022, over \$53 million of which was from fees UNOS charges for patients to be listed for a potential transplant.¹⁵ UNOS spent over half of that revenue in salaries,¹⁶

¹³ <https://unos.org/solutions/research-data-analytics-transplant/#CARE>

¹⁴ <https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative>

¹⁵ <https://unos.org/wp-content/uploads/2022-Audited-Financial-Statement.pdf>

¹⁶ <https://unos.org/wp-content/uploads/2022-Audited-Financial-Statement.pdf>

including paying nearly \$600,000 in 2022 to its former CEO.¹⁷ Indeed, UNOS paid a total of nearly \$4 million to its top dozen executives that year.

54. The same day that HRSA announced its intention to accept bids to potentially replace UNOS, UNOS trumpeted its own perceived abilities and suggested that it would bid to continue as the contractor. UNOS wrote: “[W]e believe it is critical that the future transplantation system include bidders with OPTN operations experience. We believe we have the expertise required to best serve the nation’s patients and to help implement HRSA’s proposed initiatives. We look forward to demonstrating our ongoing commitment to saving lives and how our expertise should remain an integral part of the system.”¹⁸

55. UNOS’ desire to retain its monopolist role creates an incentive for UNOS to undermine the public perception and operational abilities of any entity that might compete with UNOS in this fall’s contract bidding process. UNOS also has a unique ability, as the incumbent operator of the system, to abuse its position in furtherance of its own competitive goals.

IV. UNOS is Targeting Its Potential Competitor Buckeye

56. On Friday, May 5, 2023, at 9:56 p.m. Eastern Time, Jason Livingston transmitted two cease-and-desist letters to counsel for Buckeye.

57. One letter purported to be on behalf of UNOS and the other on behalf of OPTN, but Livingston signed both letters as “General Counsel” and both letters appeared on UNOS letterhead.

58. The letters expressed concern about what UNOS characterized as “automated pulls” of data from the OPTN and a Buckeye PowerPoint marketing presentation. The letters

¹⁷ <https://unos.org/wp-content/uploads/FY-2022-990-Final.pdf>; <https://unos.org/news/unos-in-the-news/unos-ceo-brian-shepard-to-leave-organization-after-a-decade-of-service/>

¹⁸ <https://unos.org/news/unos-welcomes-competitive-bidding-process-for-next-optn-contract/>

characterized these concerns as potentially indicating violations of the UNOS Terms of Use and the Health Insurance Portability and Accountability Act (“HIPAA”).

59. The letters demanded that Buckeye respond by Monday, May 8 and provide certain assurances about Buckeye’s use of the UNOS system and OPTN data.

60. Buckeye timely responded, transmitting letters at 12:12 p.m. on May 8, 2023, to Livingston as general counsel for UNOS and OPTN. Buckeye provided the assurances requested in the UNOS and OPTN letters and pledged its full cooperation with providing whatever additional information UNOS and OPTN might request.

A. UNOS Contacted Buckeye’s Customers Before Gathering the Facts

61. Later that day—and before UNOS or OPTN made any additional requests of Buckeye—UNOS told Buckeye that UNOS planned to inform Buckeye’s customers of UNOS’ view of the situation.

62. Buckeye wrote to UNOS on May 9 and objected to UNOS or OPTN “raising unfounded and speculative allegations against Buckeye” in any communications with Buckeye’s customers.

63. In calls with Buckeye’s counsel on May 9, Livingston stated that UNOS intended to send Buckeye additional requests for information but planned to communicate with Buckeye’s customers imminently before requesting any additional information from Buckeye.

64. Indeed, UNOS did just that, transmitting an email in the evening of May 9 to Buckeye’s customers, with the subject line “Important: Update to users of Buckeye Transplant Services,” which read:

A message from Dr. Jerry McCauley and Dr. Maureen McBride

Dear colleagues,

The Organ Procurement and Transplantation Network takes the stewardship of OPTN data very seriously.

We wanted to let you know we are in an ongoing investigation of a potential privacy incident. We are working collaboratively with the contractor to identify the scope of the potential incident. While we continue our investigation, we have taken immediate steps to mitigate any risk to the OPTN Computer System and OPTN data.

As a best practice, you should review your current privacy and security arrangements with any vendors to whom you provide access to OPTN data to confirm that they have appropriate privacy and security controls.

65. The email was signed by Maureen McBride, Ph.D., who was identified as “Acting Executive Director, OPTN” and Jerry McCauley, M.D, M.P.H., FACP, identified as “President, OPTN Board of Directors.”

66. Using OPTN titles, UNOS attempted to obscure the fact that the email actually came from (or in addition to OPTN came from) UNOS. In addition to her role at OPTN, Dr. McBride is the chief executive officer of UNOS, and Dr. McCauley is the president of the UNOS board of directors.

67. HRSA recognizes that this overlap in leadership decreases oversight and accountability. HRSA stated in May 2023 that its fall solicitation for bids to run a modernized transplantation system “will seek multiple vendors for distinct functions – including supporting a separate OPTN Board of Directors – to ensure service continuity and increase oversight and accountability.”¹⁹

B. Buckeye’s Clients Reacted with Concern, Damaging Buckeye’s Reputation and Goodwill

68. Just as Buckeye feared, Buckeye’s clients reacted to UNOS’ email with alarm. Within three hours of the email’s transmission, the director of clinical services for a prominent

¹⁹ <https://www.hrsa.gov/organ-procurement-transplantation-modernization>

transplant center on the West Coast emailed Buckeye's president, asking "can you let us know what this is regarding and if there is any action required from our end?"

69. By the next morning, Buckeye had received communications from eight other clients similarly expressing their alarm. For example, around 7:30 a.m. EDT on May 10, 2023, the director of transplant operations at a prominent East Coast transplant center emailed Buckeye's president to inquire about the UNOS email, stating that the transplant center was "very alert to breaches with IT and concerns for patient information," and further requesting that Buckeye validate that a list of 41 individuals were properly authorized to access the transplant center's data for its heart and kidney transplant programs.

70. Buckeye's senior personnel spent the next several days speaking with senior administrators and physicians from ten different transplant centers to explain the situation and address their concerns following the UNOS email.

71. Buckeye's clients have had more than questions: over the past two months, they have decreased their usage of Buckeye's tools, causing hundreds of thousands of dollars in lost billings and stalled contracts since the UNOS email, and several of Buckeye's clients have initiated termination of its services.

72. In addition, the UNOS email caused internal concern and uncertainty among Buckeye's personnel, who feared that UNOS' position had put their jobs in jeopardy. Additionally, Buckeye's attempts to respond to UNOS' demands by modifying its operations over the past two months have resulted in a significantly increased burden on its personnel. As a result, multiple Buckeye employees have quit in response to the changing demands, uncertainty, and increased workload. Buckeye will spend tens of thousands of dollars in recruiting and training new employees to fill these roles.

C. Despite UNOS' Interference, Buckeye Cooperated with UNOS' Exhaustive Investigation of Buckeye

73. Hours *after* the email to Buckeye's customers on May 9, Livingston transmitted a three-page (single spaced) document entitled "OPTN Questions for Buckeye Transplant Services" to Buckeye's counsel. The document was a list of 35 questions, relating to Buckeye's privacy and security controls for protecting OPTN data.

74. On the morning of May 10, 2023, outside counsel to "UNOS/OPTN" contacted Buckeye counsel to "get some update information so that we can provide an update to HRSA on a call today at 3:00 ET."

75. Within two hours, Buckeye counsel provided UNOS/OPTN counsel with a risk assessment addressing a PowerPoint slide deck that Buckeye presented that contained some UNOS identification numbers, and concluded that no HIPAA data breach resulted from that presentation. UNOS/OPTN counsel then responded that "I'll stay tuned for the additional information, but I believe this will help folks to cool down in the meantime."

76. Outside counsel for UNOS/OPTN again followed up on May 10 and also asked if Buckeye counsel would be provided a similar risk assessment about the use of automated systems to "pull UNet information that was separate from the real-time coordination that Buckeye does for its clients?" and again on May 11 with questions about data flow. On Friday, May 12, 2023, UNOS/OPTN counsel provided further reactions from the UNOS technical team and said "we expect responses to above and to the remaining questions from Jason's message on Tuesday (attached for convenience) by noon ET, on Monday, May 15."

77. On the morning of Monday, May 15, Buckeye counsel provided UNOS/OPTN counsel with answers to all of the questions from May 9, as well as responding to the reactions of the UNOS technical personnel.

78. Buckeye counsel provided UNOS/OPTN counsel on Tuesday, May 16 with a risk assessment addressing the use of an electronic tool to gather data used to address the backlog of offer status/quality assurance data, and concluded that there was no data breach.

79. Late in the afternoon of Tuesday, May 16, Livingston sent Buckeye counsel an additional list of 60 questions, in spreadsheet form, and asked for responses by “close of business on Thursday so that we can review and discuss those responses during our daily meeting with HRSA on Friday afternoon.”

80. On Thursday, May 18, Buckeye counsel provided Livingston with answers and responses to all of the questions provided on May 16, and stated that “Buckeye is happy to provide a demo of the plug-in tool referenced in these responses. Any remaining questions may be best answered through a call among the technical teams, perhaps at the same time as the demo.” (The “plug-in tool” refers to the Rapid Organ Assessment Tool described above.)

81. Buckeye also provided UNOS/OPTN counsel with redacted copies of the forms of services agreement that Buckeye holds with its transplant center customers on Friday, May 19.

82. On the afternoon of Wednesday, May 24, Buckeye demonstrated the Rapid Organ Assessment Tool for UNOS personnel. A second demonstration was scheduled for May 31, 2023. On the evening of May 30, 2023, UNOS/OPTN counsel provided a list of over 40 questions that was suggested should be answered during the demo the next day.

83. The second demonstration was held on May 31, 2023 and Buckeye answered numerous questions about its operations and its privacy and security framework. UNOS indicated that it would provide any other final questions it may have to conclude its investigation.

84. After hearing nothing from UNOS for over a week, Buckeye counsel provided correspondence to UNOS/OPTN counsel on June 8, 2023 stating Buckeye’s position that the

UNOS inquiry should end. In addition, Buckeye stated that: (1) the same UNOS leadership that sent the communication of May 9, 2023 to Buckeye customers should send another communication to the same set of Buckeye customers indicating that OPTN has ended its investigation and found no privacy or security breach, no compromise of the OPTN Computer System or OPTN data, and no material privacy or security issues with regard to the activities of the contractor being reviewed; (2) UNOS should confirm that Buckeye may continue to utilize the “plug-in tool” that was demonstrated to UNOS and HRSA personnel on May 24, 2023; and (3) UNOS should confirm that Buckeye may resume use of what we have referred to as the “automated script” that Buckeye has halted using in response to the initial demands of UNOS in early March. Buckeye expressed willingness to agree to volume limitations or other reasonable conditions on the use of this tool upon UNOS’ request.

D. Having Gathered Extensive Information About Buckeye, UNOS Demanded that Buckeye Stop Serving Its Customers

85. Instead of complying with Buckeye’s requests or engaging further, UNOS sent another cease and desist letter to Buckeye on June 21 alleging that Buckeye is violating the 2018 UNOS Terms of Use and the OPTN Policies in two respects.

86. First, the June 21 letter alleges that Buckeye’s Rapid Organ Assessment Tool violates section 6(c) of the terms, which states: “You may not ... use data mining, robots, or other data gathering devices on or through UNOS Systems, unless specifically allowed by these Terms,” as well as section 7 of the terms, which states: “You may not use, copy, store, reproduce, transmit, distribute, display, modify, alter, license, sublicense, or commercially exploit UNOS Systems or any contents, information, data or materials provided through UNOS Systems in any manner not expressly permitted by these Terms of Use.”

87. Second, the June 21 letter alleges that Buckeye's Operational Assessment Tool violates section 3.1.A of the OPTN Policies, entitled "Non-member Access," and which states "Members may not use the match system for non-members or allow non-members access to the match system unless all of the following requirements are met: ... 1. The non-member is assisting the member with facilitating organ transplants, placing organs for purposes other than transplantation, or reporting data to the OPTN." The letter asserted that "Because after-the-fact reviews of information falls into none of the categories above, it is, inherently, impermissible."

88. The June 21 letter continued: "For the avoidance of doubt, despite the availability of the OPTN data at issue, Buckeye is not authorized to access it or to use such OPTN data in any way. Instead, for any information other than in-the-moment information necessary for the evaluation and placement of organs, all OPTN data and information must be obtained using a specific data request to the OPTN." The letter further stated: "We hereby demand that Buckeye cease any use of UNOS Systems that violate the UNOS Systems Terms of Use that would constitute the use of any data other than that which relates, narrowly, to contemporaneous facilitation, placement, and reporting to the OPTN."

89. The June 21 letter demanded that Buckeye "certify destruction of all identifiable OPTN data, including all electronic copies of data wherever stored, to include on all Buckeye employee devices."

90. The June 21 letter instructed that Buckeye could no longer use its Operational Assessment Tool because after the client's decision about whether to accept an organ, "any further information about a particular case must be obtained from OPTN by specific request." The letter provided a URL for Buckeye "to submit requests for data on behalf of members using the UNOS Service Portal."

91. The June 21 letter concluded with a demand that Buckeye reply confirming that it would comply with the letter by Monday, June 26, or “UNOS will consider taking any and all remedies available to secure the integrity of UNOS Systems, including revoking the access rights of all users related to Buckeye.”

92. Absent from UNOS and OPTN’s June 21 letter was any suggestion that Buckeye’s services and data practices violated HIPAA, other than stating “We understand that certain OPTN data was utilized without authorization in a marketing PowerPoint presentation, and we appreciate that Buckeye has already remediated that use of OPTN data.” UNOS has not sought to transmit a data breach notification to patients or take any of the other steps normally associated with a privacy incident. UNOS has thus implicitly conceded that its exhaustive investigation of Buckeye yielded no evidence of a privacy incident.

93. Buckeye counsel responded the next day asking UNOS to reconsider the manner it was seeking to enforce its interpretation of the terms and policies, and, for purposes of ensuring continued patient care, asking UNOS to engage in good faith discussions to develop conditions under which Buckeye could continue to operate its tools by mutual agreement.

94. UNOS responded through counsel on Wednesday, June 28 via email rejecting any further discussion with Buckeye and stating that Buckeye must follow UNOS’ demands no later than July 5 or its users’ account access will be terminated. UNOS’ counsel stated: “please note that the last day that Buckeye will be able to use the clinical tool is July 5, 2023 (14 days from my June 21, 2023) letter. Additionally, we expect to receive the Declaration of Data Destruction form to be returned promptly, but in no case later than July 5, 2023.” UNOS dismissed Buckeye’s concerns about the impact of UNOS’ demands on patient care: “To the degree that suspending or

unwinding certain elements of Buckeye's operations is necessary in order to comply with the UNOS Systems Terms of Use, it is, regrettably, an issue of Buckeye's own making."

V. UNOS' Interpretation of Its Terms of Use Is Incorrect, and Until June 30, 2023, Was Applied Only to Buckeye

95. In Buckeye's counsel's letter transmitted June 22, Buckeye articulated its position as to why UNOS' interpretation of its terms of use was incorrect. Buckeye explained that UNOS' position rested on—at best—an unpromulgated new interpretation of its Terms of Use being applied solely to Buckeye.

96. Buckeye explained that the initial paragraph of the Terms of Use states that "UNOS provides access to UNOS Systems and other software and data to approved transplant professionals in order to match organ donors with recipients as well as for certain quality assurance and improvement activities related to organ transplantation." Buckeye accesses and uses the UNOS system and data solely for those allowed and permitted purposes.

97. Buckeye explained that UNOS was interpreting its Terms of Use in two new ways that are contrary to standard practice in the transplant community and, to Buckeye's knowledge, had not been provided to the transplant community previously.

98. UNOS' new interpretation and rejection of Buckeye's Rapid Organ Assessment Tool to automate an otherwise manual process is especially striking because in early 2021, the White House's U.S. Digital Service completed a confidential government review of UNOS' systems and concluded that among other problems, UNOS' systems demonstrated "overreliance on manual input of data."²⁰

²⁰ <https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/>

99. As described in a subsequent media report published in July 2022: “Transplant doctors have complained for years about archaic aspects of the technology for sharing data and getting organs to the right place as quickly as possible. ‘When nearly 100 percent of hospitals use electronic records, the notion that we rely on human beings to enter data into databases is crazy. It should be 85 to 95 percent automatic,’ said University of California at San Francisco surgery vice chair Ryutaro Hirose, a former chair of the UNOS liver transplant policy committee. ‘We could concentrate more on improving patient care.’”²¹

100. Regarding UNOS’ interpretation of its Terms of Use to prohibit any user from using any data for purposes other than “narrowly” for “contemporaneous facilitation, placement, and reporting to OPTN,” Buckeye contested UNOS’ position that after-the-fact reviews of UNOS data are inherently impermissible because those reviews do not facilitate organ transplants.

101. To the contrary, in Buckeye’s view and those of its transplant center customers, review of post-transplant data is a critical (and nearly universal) part of the transplant process at every transplant center, and is absolutely essential to the facilitation of transplants.

102. To that end, many (if not all) OPTN members access post-transplant OPTN data for a variety of purposes. Indeed, the OPTN network permits post-transplant access to the organ and donor data. It would be anomalous for the UNOS Terms of Use to prohibit accessing this data when UNOS makes that data available. Further, many (if not all) OPTN members store and/or transmit UNOS data in some form.

103. Buckeye requested that if UNOS’ new interpretations were to apply to all transplant centers, transplant service providers, OPOs, and all other OPTN members, then UNOS should

²¹ <https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/>

apply and enforce these interpretations of the Terms of Use fairly, consistently, and appropriately. UNOS should first promulgate public guidance setting forth these interpretations. UNOS should then set a deadline for the entire transplant community to come into compliance. This would treat all OPTN members equally and give the entire transplant community consistent guidance and a consistent timeframe in which to modify current practices to comply with UNOS' interpretation of the Terms of Use. Buckeye pledged that it would certainly comply if UNOS took this approach.

104. Consequently, to avoid patient harm, Buckeye requested that UNOS agree to provide additional time for UNOS and Buckeye to discuss what assurances and conditions can be applied to Buckeye's continued use of the Rapid Organ Assessment Tool. Buckeye expressed its willingness to engage in discussions with UNOS to agree on reasonable conditions under which Buckeye can continue to utilize the tool in accordance with UNOS' interpretation of the Terms of Use.

VI. UNOS Finally Announced Its New Interpretation of its Terms of Use to a Broader Audience—on June 30, 2023.

105. On June 30, 2023, OPTN emailed its members with the subject line "Important reminder for review of vendor security and data privacy." Among other things, the email states "As an OPTN member, you are ultimately responsible for safeguarding the privacy and security of the OPTN Computer System and data, and this responsibility extends to any third party to whom you may provide access to OPTN systems and associated OPTN data." The email continued: "The use of unauthorized automated tools (e.g., data mining, robots, and other data gathering devices commonly referred to as screen scraping) to extract OPTN data directly from the OPTN computer system is not permitted."

106. A portion of the foregoing sentence is drawn from section 6(c) of the UNOS Terms of Use, which reads: "You may not: ... use data mining, robots, or other data gathering devices on

or through UNOS Systems, unless specifically allowed by these Terms.” The phrase “commonly referred to as screen scraping” does not appear in the UNOS Terms of Use; rather, this phrase apparently reflects UNOS new interpretation of its Terms of Use.

107. Even if any such tools were used, Buckeye’s use would be “specifically allowed by these Terms” because all of Buckeye’s access to the UNOS’ systems is for the purpose of “quality assurance and improvement activities related to organ transplantation” on behalf of its transplant centers client.

108. UNOS’ June 30, 2023 email, which adds additional language to the UNOS Terms of Use confirms that—as written—those terms do not explicitly prohibit what UNOS has termed “screen scraping.”

109. A ban on “screen scraping” is not implied by the language actually in the Terms of Use—“data mining, robots, or other data gathering devices on or through UNOS Systems”—because unlike “data mining,” “robots” or other devices that operate “on or through UNOS Systems,” so-called “screen scraping” has no impact on the technological workload the UNOS Systems must bear, and is deployed solely on the user’s internal web browser.

110. Buckeye’s Rapid Organ Assessment Tool illustrates this point. The tool is a plugin that operates on the ordinary internet browser utilized by the transplant center or Buckeye personnel acting on their behalf. The tool copies and pastes data that is visible to the transplant center personnel on their internet browser, and thus speeds up the otherwise manual process of copying essential information for the transplant center’s use. For that reason, Buckeye’s tool is not even properly characterized as “screen scraping,” a pejorative term seemingly intended to sound nefarious. Buckeye’s tool merely facilitates a user’s rapid capture of data the user is authorized to see and must communicate to others on the transplant team.

111. Buckeye's tool does not burden UNOS Systems because the tool merely copies data that the user has already requested be sent to the user's internet browser. This makes the tool unlike "data mining" or "robots" because the tool does not operate "on or through UNOS Systems."

112. UNOS is thus attempting to change the nature of that prohibition from a prohibition on automated tools based on where the tools are deployed, into a prohibition based on a certain purpose (i.e., to extract OPTN data from the OPTN computer system regardless of on what or whose systems the tool is deployed).

113. UNOS' interpretation of the OPTN Policies in its June 21 letter is even less cogent. UNOS cited section 3.1.A of the OPTN Policies, entitled "Non-member Access," and which UNOS claims makes "after-the-fact reviews of information ... inherently, impermissible." First, Buckeye is not a "non-member" of OPTN, Buckeye is a business member, rendering section 3.1.A facially inapplicable. Second, UNOS' interpretation is illogical insofar as Buckeye's Operational Assessment Tool merely enables more accurate and efficient use of data that Buckeye's transplant center customers already have access to. It is undisputed that UNOS makes so-called "after-the-fact" information available to transplant centers. There is no reason for UNOS to do that if the transplant centers—and their agents, such as Buckeye—are never allowed to use the data. (Data that, as described below, UNOS will sell to the centers itself.)

114. UNOS' June 30 email is also notable for what it does not say. The email does not say that a transplant center or other OPTN user cannot access post-transplant data. UNOS did not include its admonishment to Buckeye prohibiting access to "any data other than that which relates, narrowly, to contemporaneous facilitation, placement, and reporting to the OPTN."

115. Such a public admonishment to all involved in organ transplant would raise serious alarms about the appropriateness and legality of UNOS' new interpretation. Consequently, UNOS' June 30 email does not (even remotely) prohibit after-the-fact review of data or limit use of the OPTN systems solely for contemporaneous activity. Instead, UNOS has confined communicating that position in the form of threats to shut down the operations of its competitor, Buckeye.

116. UNOS went so far as to highlight its own competing tool in the June 30 email, writing: "If you need data to assess the performance of your institution, there are tools within Secure Enterprise to request such data, as well as a number of helpful reports." A public website confirms that UNOS can receive fees for responding to data requests. Indeed, "If required, the requester will be invoiced via PayPal or directly by the UNOS Finance Department."²²

117. UNOS' interference with Buckeye's customer relationships thus provides UNOS a direct competitive benefit by forcing Buckeye's customers to come directly to UNOS for data that UNOS can control and charge for.

VII. UNOS Offers Tools with the Very Same Features It Now Claims Buckeye Cannot Offer

118. Far from believing that the tools Buckeye offers its customers are not consistent with a well-functioning transplant system, UNOS itself offers (or attempts to offer) tools with similar features.

119. For example, UNOS offers what it calls the "CARE tool," which UNOS describes as an "interactive tool allows transplant centers to review their own organ acceptance rates for

²² <https://optn.transplant.hrsa.gov/data/view-data-reports/request-data/data-request-instructions/>

specific types of donors, along with transplant specific and aggregate outcomes information on the organs they refused that were transplanted elsewhere.”²³

The screenshot displays the UNOS 'Liver Matches' interface for the period July 1, 2017, to June 30, 2019, with offers to ABCD-TX1. The interface includes various filters for donor and recipient characteristics, such as Match Has an Accepter, Organ Tied, Center Accepted, Distance to Donor Hospital, Donor Age Years, Donor ABO, DCD, BMI Group, Donor ID, WL ID, Match Date, Donor COD, HCV Serology, HCV NAT, Hep B Surface NAT, Hep B Core, PHS Increased Risk, % Micro Vesicular Fat, % Macro Vesicular Fat, Heavy Alcohol, and Primary Refusal Code. A table titled 'Liver Offers' is shown below the filters, listing donor IDs, recovery OPO, organ tied, donor ABO, donor age, BMI, PHS increased risk, HCV, heavy alcohol, match ID, accept sequence(s), match classification, match sequence, offer ID, offer accepted, and primary refusal code. The table contains multiple rows of data, with some rows highlighted in blue and others in white. The UNOS logo is visible in the bottom right corner.

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120. Among other data points, the UNOS Care tool displays specific donor IDs and the details of organs that became available from those donors. This appears identical to the dataset that UNOS claims its terms preclude Buckeye from directly providing to transplant centers about their patients. Other UNOS webpages confirm that it will provide “Donor, candidate, and recipient-specific records”²⁵ and “Post-transplant follow-up data”²⁶ through its data portal.

121. UNOS also permits recipients of data it provides to retain local copies of that data, that is, UNOS does not restrict use of its data to IT systems UNOS operates. In a February 14, 2023, email from UNOS’ manager of data products, UNOS informed transplant centers and others that UNOS was changing the file format for Organ Offers reports in UNOS’ data services portal

²³ <https://unos.org/news/in-focus/new-care-tool-visualizes-organ-acceptance-and-refusal/>

²⁴ Screen shot of the video available on UNOS’ webpage timestamped at 7:14.

²⁵ <https://unos.org/technology/technology-for-transplantation/>

²⁶ <https://unos.org/technology/unet/>

to .csv from Excel files. Both .csv and Excel files are downloaded to a computer and utilized on that computer, not accessed exclusively through an internet portal.

122. The February 14 email informed recipients that “you may need to update connections or import processes to link to the new csv file format.” (There would be no need for “import processes” if the data UNOS was providing did not reside on the recipient’s hardware.) The email continued – “[o]ne thing to note is that the date-time fields in the csv files may auto-format to your computer settings.” (Files do not “auto-format” to a new computer’s settings unless those files reside on that computer.)

123. UNOS has also expressed public willingness to work with third-party software vendors. For example, UNOS’ website states that UNOS also welcomes the development of third-party Application Programming Interfaces (“APIs”) that “provide seamless integration between UNOS and other systems, eliminating duplicate data entry and improving data quality and operational efficiency.”²⁷ UNOS claims that “Becoming a software partner is easy!” and that UNOS will grant access to its API portal to, among others, “Clinical software vendors with an established business relationship to an OPTN member organization.”²⁸

124. UNOS’ API features sometimes handle donor and recipient-specific information, such as an API feature that “allows the retrieval of organ offer acceptance information for a given Waitlist candidate; including the donor ID, organ type and laterality, and other match related

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https://developer.unos.org/?utm_source=email&utm_medium=email&utm_campaign=oarelease&_gl=1*yg7wgv*_ga*MTMyMzE4NDgwLjE2ODczNjUwMzM.*_ga_43RGFTP89W*MTY4ODIxMTAyNC43LjEuMTY4ODIxMzM5OS4wLjAuMA..

²⁸ <https://developer.unos.org/setup-developer-account>

data.”²⁹ However, there does not exist any API that is able to integrate with and access data in UNOS’ systems in the same manner as Buckeye’s Rapid Organ Assessment Tool.

VIII. Buckeye’s Customers Prefer Its Operational Assessment Tool to Other Available Alternatives

125. Buckeye’s transplant center clients prefer that Buckeye provide them with data regarding the centers’ past decisions to accept or not accept organs for transplant.

126. In 2019, one of Buckeye’s clients in a mid-Atlantic state wrote in response to receiving data from Buckeye that “This is excellent information, much better than our previous vendor.”

127. Buckeye’s clients use its services to comply with CMS demands. One New England client wrote in July 2021: “Is it possible to also get the heart organ offer reports? I am not sure who they are being sent to since [employee] has retired as well as I am complying everything for our impending CMS transplant re-certification survey.”

128. Another of Buckeye’s clients—an academic teaching hospital on the West Coast—emailed Buckeye in January 2023 seeking Buckeye’s assistance gathering data to “assist me with a UNOS/OPTN project I am working on.” The client continued: “We are working on how to increase DCD transplants and improve workflows.” The client requested “# of DCD donors for 2020, 2021 and 2022,” “# of DCD donors that were DRY RUNS for each year,” and “# of DCD donors that were OCS cases for each year.” The client could request some of this data from UNOS if it wanted to, but UNOS does not record certain of the transplant center’s decision-making data; the client thus chose to use Buckeye’s services instead.

²⁹ <https://unos.org/news/unet%e2%84%a0-api-now-available-for-waitlist%e2%84%a0-organ-acceptance-data/>

129. Even when Buckeye experienced some delays in providing data during the summer of 2022 because of a high volume of requests, one of its clients confirmed that it wished for Buckeye to press forward and continue providing services, writing: “Like [] the other centers, we are desperate to have the report. The report is being asked [for] by our physicians pretty frequently.”

130. Buckeye’s clients use Buckeye’s services to improve patient care. One of Buckeye’s mid-Atlantic transplant center clients wrote to Buckeye in November of 2022 about a data request and tied the request to that purpose: “We finally started to have an increase in organ offer(s) and acceptance rate. I do not want to lose momentum. We are still behind in our transplant volume for this calendar year and need to catch up.”

131. Another client, in the Southeastern U.S., tied the need for data from Buckeye to the client’s efforts to provide UNOS with information it requires, writing in April 2023: “Good morning, I was wondering if I can get list of all donor offers (Donor ID and Match ID) from January 2022 through May 2022. This is preparation for the upcoming UNOS site visit. One of our patient’s record is being reviewed.”

132. Just last month, one of Buckeye’s clients responded to a Buckeye data report with effusive praise, writing:

This is perfect!!!-and I am so very appreciative that you pulled this together for me. I can’t thank you enough.

This is a lifesaver for tomorrow evening’s presentation.

I have been asked to do monthly organ offer review meetings with our transplant physicians and the executive physician team for the entire cardiac division of [the center] and without reports, I have to do all of the extrapolation manually.

Thanks again for pulling this together!

133. Buckeye's clients clearly prefer Buckeye's services to those of UNOS. Only through improper anti-competitive means can UNOS force Buckeye's clients to choose UNOS' data delivery services. UNOS' behavior described above appears calculated to do exactly that.

CLAIMS

Count I – Declaratory Judgment

1. Buckeye incorporates the allegations in the preceding paragraphs as if fully set forth herein.

2. Buckeye and UNOS dispute the meaning of the 2018 UNOS Terms of Use and the OPTN Policies.

3. The parties' dispute is definite and concrete insofar as Buckeye's interpretation of the 2018 UNOS Terms of Use and OPTN Policies is consistent with the plain meaning of those documents and prevailing standards within the industry. UNOS' interpretation is neither.

4. UNOS has demanded that Buckeye accede to UNOS unilateral interpretation by ceasing its work for transplant centers, including disabling the Rapid Organ Assessment Tool and the Operational Assessment Tool. UNOS has also demanded that Buckeye irreversibly delete years of data that originated from Buckeye's transplant center customers no later than July 5, 2023, or UNOS will cut off Buckeye's access to the OPTN.

5. The parties' dispute is real and substantial because UNOS is demanding that Buckeye accede to UNOS' incorrect and novel interpretation of the 2018 UNOS Terms of Use and OPTN Policies through irreversible actions without permitting time for a third-party neutral's adjudication of the dispute.

6. The parties' dispute can be resolved through a decree of a conclusive character because the Court can, and should, resolve the questions underlying the dispute, including whether

Buckeye's tools and practices are consistent with the 2018 UNOS Terms of Use and the OPTN Policies.

Count II – Tortious Interference with Contract and Business Expectancy

7. Buckeye incorporates the allegations in the preceding paragraphs as if fully set forth herein.

8. Buckeye has valid contractual relationships with its client transplant centers for Buckeye's provision of various services to the transplant centers, including technology-assisted organ offer screening services and data reporting.

9. Buckeye has a valid business expectancy that its clients will continue to use Buckeye's services consistent with their historical usage.

10. UNOS is well aware of Buckeye's contractual relationships, including because Buckeye specifically informed UNOS that UNOS' planned course of conduct would harm those relationships and because Buckeye provided UNOS with redacted examples of Buckeye's contracts with its customers.

11. UNOS intentionally interfered with Buckeye's contractual relationships with its customers and business expectancy that those customers will continue to use Buckeye's services, in at least two ways.

12. First, UNOS emailed "users of Buckeye Transplant Services" on March 9, 2023, announcing "an ongoing investigation of a potential privacy incident" when, in truth, UNOS had not even transmitted the questions about the supposed "privacy incident" that it wanted Buckeye to answer when it emailed Buckeye's customers. UNOS also encouraged Buckeye's customers to "review your current privacy and security arrangements with any vendors to whom you provide access to OPTN data," thus instructing Buckeye's customers that the "privacy incident" should

cause the customers to “review” their business relationship with Buckeye. Further, UNOS has ignored Buckeye’s requests that UNOS send a corrective communication to Buckeye’s customers confirming that UNOS’ investigation confirmed that there was no “privacy incident” in the first place.

13. Second, UNOS has purported to use its role as enforcer of the 2018 UNOS Terms of Use and the OPTN Policies to force Buckeye to deactivate its tools and delete transplant center data. The circumstances under which UNOS has issued its demands to Buckeye described herein provide strong evidence that UNOS’ purpose is not a good faith enforcement of applicable rules, but rather to hobble potential competition UNOS will face in the upcoming bid process that will determine whether UNOS retains its thirty-six year monopoly on running the U.S. organ transplant system.

14. UNOS’ intentional interference with Buckeye’s contracts and business expectancy has induced or caused some of Buckeye’s customers to breach or terminate their relationships and damages Buckeye’s business expectancy.

15. Buckeye has sustained monetary damages as a result of UNOS’ interference.

16. UNOS has interfered with Buckeye’s business expectancy employing improper methods, including threats, intimidation, undue influence, unfair competition, violating established standards of the parties’ trade and profession, sharp dealing, and overreaching.

Count III – Breach of Contract

17. Buckeye incorporates the allegations in the preceding paragraphs as if fully set forth herein.

18. Having accepted Buckeye’s request to become a business member of UNOS and permitted Buckeye to perform services for its transplant center clients, UNOS accepted a legally

enforceable obligation to Buckeye to apply the 2018 UNOS Terms of Use and OPTN Policies in a legally correct manner.

19. UNOS has breached its obligation to Buckeye, including by applying the 2018 Terms of Use and OPTN Policies to Buckeye via unsupportable interpretations of those documents, singling out Buckeye for arbitrary treatment not consistent with prevailing standards in the industry, and targeting Buckeye to squash competition.

20. Buckeye was and is damaged by UNOS' breach of obligation insofar as Buckeye's customer relationships have been harmed by UNOS' inaccurate public statements about Buckeye, UNOS' insistence that Buckeye exhaustively share information about its services with UNOS for UNOS' improper purpose of damaging Buckeye. Further, Buckeye will be damaged if UNOS compels Buckeye to either accede to UNOS' incorrect interpretation of the 2018 UNOS Terms of Use and OPTN Policies by refraining from providing lifesaving services for Buckeye's customers and irreversibly deleting data gathered for the transplant centers that Buckeye serves.

Count IV – Attempted Monopolization Under § 2 of the Sherman Act

21. Buckeye incorporates the allegations in the preceding paragraphs as if fully set forth herein.

22. Buckeye and UNOS are competitors in the market for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant.

23. This data is valuable to transplant centers because they use it for quality assurance and quality improvement purposes, as well as to comply with regulatory requirements imposed by the Centers for Medicare & Medicaid Services ("CMS").

24. Not only do Buckeye and UNOS compete insofar as each can provide transplant centers with the data that they need, Buckeye and UNOS compete in how the information is

presented because the presentation of data in an efficient and useful manner can save transplant centers time and resources and is thus valuable to them.

25. The relevant geographic market for these services is the United States because both Buckeye and UNOS offer the services throughout this geographic area.

26. UNOS is using anticompetitive conduct to attempt to monopolize this market, including by issuing directives to Buckeye to stop providing its services to transplant centers based on legally erroneous interpretations of the 2018 UNOS Terms of Use and the OPTN Policies. UNOS is also targeting Buckeye, such as by communicating supposed concerns about a “privacy incident” specifically to Buckeye’s customers and then ignoring Buckeye’s request for a corrective communication after UNOS’ privacy concerns were resolved.

27. UNOS has the specific intent to monopolize because it continues to promote its own ability to offer the services it demands that Buckeye refrain from offering with no technical, privacy, or other reason why only UNOS can offer these services and Buckeye cannot. UNOS has not and cannot offer any rationale for reserving for itself the right to offer these services while denying that right to Buckeye other than UNOS’ desire to monopolize the market.

28. UNOS also has monopolistic intent to squash the development of technology that could eventually supplant UNOS’ system. Public reports indicate that UNOS considers its computer software code to be a trade secret, and those reports state that UNOS has said the U.S. government would have to buy the code for \$55 million if it ever gave UNOS’ contract to another entity.³⁰ By abusing its claimed position as sole arbiter of the meaning of the 2018 UNOS Terms

³⁰<https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/>

of Service and the OPTN Policies to target competitors like Buckeye, UNOS is thwarting entry into the market for providing organ transplant network services.

29. UNOS has a dangerous probability of succeeding in its attempt to monopolize the U.S. market for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant because UNOS is using coercive methods to force Buckeye to comply with UNOS' demands, including the customer communication discussed above and UNOS' threat to remove Buckeye's access to the OPTN on July 5, 2023 if Buckeye does not accede to UNOS' demands and not providing for any opportunity for a neutral third-party to determine whether UNOS' interpretation of its 2018 UNOS Terms of Use and OPTN Policies is correct and consistent with prevailing industry practices.

30. UNOS' attempts to exclude Buckeye from the market will harm Buckeye, competition, and consumers of the services UNOS and Buckeye offer because absent Buckeye's competition, there will be no market pressure on UNOS to charge lower prices or deliver a higher quality product. This harm to the transplant centers Buckeye serves will in turn harm patients in need of organ transplants because the centers' ability to improve their practices and approaches depends on the quality assurance and improvement practices informed by the data Buckeye provides.

31. Buckeye is losing customers, and as such, market share, it otherwise would have won by virtue of its investment in, and adoption of, innovative tools for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant.

REQUEST FOR RELIEF

WHEREFORE based on the foregoing Plaintiff Buckeye respectfully requests that the Court grant the following relief:

1. Temporarily,³¹ preliminarily, and permanently enjoining UNOS, as well as its officers, agents, servants, employees, and attorneys, and all other persons who are in active concert or participation with any of them, from (a) requiring Buckeye to cease operation of its Rapid Organ Procurement Tool, (b) requiring Buckeye to cease operation of its Operational Assessment Tool, (c) requiring Buckeye to delete data, (d) suspending Buckeye's access to the OPTN, or (e) attempting to monopolize the U.S. market for providing transplant centers with data regarding the centers' past decisions to accept or not accept organs for transplant.

2. Awarding Buckeye its damages, trebled, costs of suit, pre- and post-judgment interest, and attorney's fees.

3. Granting such additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Buckeye demands a jury trial on all issues so triable.

Dated: July 3, 2023

Respectfully submitted,

/s/

Ellis L. Bennett (Virginia Bar No. 71685)
Stephen D. Graeff (Virginia Bar No. 77720)
DUNLAP BENNETT & LUDWIG
8300 Boone Boulevard, Suite 550
Vienna, VA 22182
Telephone: (703) 636-1667
Facsimile: (703) 777-3656

³¹ Buckeye voluntarily paused its use of the Operational Assessment Tool in May. Buckeye does not include the Operational Assessment Tool in its request for a temporary restraining order, although Buckeye does request that any preliminary injunction bar UNOS from prohibiting Buckeye from resuming use of this tool.

E-mail: ebennett@dbllawyers.com
sgraeff@dbllawyers.com

Ben D. Kappelman (*pro hac vice* application
forthcoming)

Ellie Soskin (*pro hac vice* application
forthcoming)

DORSEY & WHITNEY LLP

50 South Sixth Street

Minneapolis, MN 55402

Telephone: (612) 340-2600

E-mail: kappelman.ben@dorsey.com
soskin.ellie@dorsey.com

Wendy M. Feng (*pro hac vice* application
forthcoming)

DORSEY & WHITNEY LLP

701 Fifth Avenue, Suite 6100

Seattle, WA 98104-7043

Telephone: (206) 903-8800

E-mail: feng.wendy@dorsey.com

*Counsel for Plaintiff Buckeye Transplant
Services, LLC*

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Buckeye Transplant Services, LLC

(b) County of Residence of First Listed Plaintiff Erie County, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Ellis L. Bennett and Stephen D. Graeff, DUNLAP
BENNETT & LUDWIG, 8300 Boone Boulevard, Suite 550
Vienna, VA 22182 Telephone: (703) 636-1667

DEFENDANTS

United Network for Organ Sharing

County of Residence of First Listed Defendant Henrico County, VA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF
THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | ☐ 1 | ☐ 1 | Incorporated or Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated and Principal Place of Business In Another State | ☐ 5 | ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 151 Medicare Act ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholders' Suits ☐ 190 Other Contract ☐ 195 Contract Product Liability ☐ 196 Franchise	PERSONAL INJURY ☐ 310 Airplane ☐ 315 Airplane Product Liability ☐ 320 Assault, Libel & Slander ☐ 330 Federal Employers' Liability ☐ 340 Marine ☐ 345 Marine Product Liability ☐ 350 Motor Vehicle ☐ 355 Motor Vehicle Product Liability ☐ 360 Other Personal Injury ☐ 362 Personal Injury - Medical Malpractice	PERSONAL INJURY ☐ 365 Personal Injury - Product Liability ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability ☐ 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY ☐ 370 Other Fraud ☐ 371 Truth in Lending ☐ 380 Other Personal Property Damage ☐ 385 Property Damage Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881 ☐ 690 Other LABOR ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Management Relations ☐ 740 Railway Labor Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Employee Retirement Income Security Act IMMIGRATION ☐ 462 Naturalization Application ☐ 465 Other Immigration Actions	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal 28 USC 157 INTELLECTUAL PROPERTY RIGHTS ☐ 820 Copyrights ☐ 830 Patent ☐ 835 Patent - Abbreviated New Drug Application ☐ 840 Trademark ☐ 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY ☐ 861 HIA (1395ff) ☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g)) ☐ 864 SSID Title XVI ☐ 865 RSI (405(g)) FEDERAL TAX SUITS ☐ 870 Taxes (U.S. Plaintiff or Defendant) ☐ 871 IRS—Third Party 26 USC 7609	☐ 375 False Claims Act ☐ 376 Qui Tam (31 USC 3729(a)) ☐ 400 State Reapportionment ☒ 410 Antitrust ☐ 430 Banks and Banking ☐ 450 Commerce ☐ 460 Deportation ☐ 470 Racketeer Influenced and Corrupt Organizations ☐ 480 Consumer Credit (15 USC 1681 or 1692) ☐ 485 Telephone Consumer Protection Act ☐ 490 Cable/Sat TV ☐ 850 Securities/Commodities/Exchange ☐ 890 Other Statutory Actions ☐ 891 Agricultural Acts ☐ 893 Environmental Matters ☐ 895 Freedom of Information Act ☐ 896 Arbitration ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision ☐ 950 Constitutionality of State Statutes
REAL PROPERTY ☐ 210 Land Condemnation ☐ 220 Foreclosure ☐ 230 Rent Lease & Ejectment ☐ 240 Torts to Land ☐ 245 Tort Product Liability ☐ 290 All Other Real Property	CIVIL RIGHTS ☐ 440 Other Civil Rights ☐ 441 Voting ☐ 442 Employment ☐ 443 Housing/Accommodations ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other ☐ 448 Education	PRISONER PETITIONS Habeas Corpus: ☐ 463 Alien Detainee ☐ 510 Motions to Vacate Sentence ☐ 530 General ☐ 535 Death Penalty Other: ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 555 Prison Condition ☐ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
15 U.S.C. §§ 15(a), 26

Brief description of cause:

Declaratory judgment, tortious interference, breach of contract, and antitrust claim

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____ DOCKET NUMBER _____

DATE

7/3/2023

SIGNATURE OF ATTORNEY OF RECORD

/s/ Ellis L. Bennett

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
 - (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
 - (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
- United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
- Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
- Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
- Original Proceedings. (1) Cases which originate in the United States district courts.
- Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
- Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
- Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
- Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
- Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
- Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
- PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
- Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
- Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.