UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EDMUND EDWARD WARD, **Plaintiff,** **v.** **ERNST J. SCHAEFER, M.D.,** **Defendant.**	**Civil Action No. 16-12543-FDS**

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

SAYLOR, C.J.

This is an action arising out of the use of a drug in a compassionate-use protocol. Plaintiff Edmund Edward Ward suffers from a rare genetic deficiency that has resulted in, among other things, severe kidney disease. He alleges that he was fraudulently induced by defendant Ernst Schaefer, M.D., to participate in what he contends was a non-therapeutic, experimental drug trial. He further contends that he was led to believe that the drug, ACP-501, would reverse his kidney disease, but that Dr. Schaefer's true purpose in treating him was to gain data for research and commercial benefit.

Ward initially filed suit against Dr. Schaefer; the company that originally produced the drug (AlphaCore Pharma, LLC); one of its officers (Bruce Auerbach); the company that later purchased AlphaCore (MedImmune, LLC); a related company (AstraZeneca Biopharmaceuticals, Inc.); and the doctors at the National Institutes of Health involved in the compassionate-use protocol (Robert Shamburek, M.D., and Alan Remaley, M.D.). All claims

against parties other than Dr. Schaefer have previously been dismissed.

Dr. Schaefer has moved for summary judgment. For the following reasons, the motion will be granted as to all of the claims except those based, in substance, on a lack of informed consent. The evidence as those claims, while hardly free from doubt, is sufficient to establish an issue of disputed material fact. Accordingly, the motion will be granted in part and denied in part.

I. Background

A. Factual Background

The following facts are as set forth in the record and are undisputed except as noted.

1. The Parties

Edmund Edward Ward was born with an extremely rare genetic deficiency of a bloodstream enzyme, called lecithin-cholesterol acyltransferase ("LCAT"). (Def. Ex. 2 at ¶ 2; Def. Ex. 6 ("Ward Dep.") at 19; Def. Ex. 5 at 493). LCAT is associated with high-density lipoprotein cholesterol ("HDL-C"), often referred to as the "good cholesterol." (*See* Def. Ex. 3 ("Schaefer Dep. Vol. 1") at 42; Def. Ex. 5 at 496-97). As a result of his deficiency, referred to as "familial LCAT deficiency" or "FLD," Ward produces virtually no cholesterol. (*See* Schaefer Dep. Vol. 1 at 42-43; Def. Ex. 5 at 496-97; Def. Ex. 8 ("Shamburek Dep.") at 18-19). He also suffers from associated health conditions, including kidney disease and a history of atrial fibrillation. (Def. Ex. 2 at ¶ 5; Def. Ex. 5 at 493). He is in stage-five kidney failure and receives dialysis treatment several times a week. (Ward Dep. at 44-45; Pl. Ex. 43).

Ernst J. Schaefer, M.D., is a physician at the Tufts University School of Medicine. (Schaefer Dep. Vol. 1 at 23). He is the founder of the Dyslipidemia Foundation of Boston, which "supports research awards, research, education, and patient care in the area of dyslipidemia." (Pl. Ex. 2 at 2). At all relevant times, he was also one of Ward's regular treating

physicians. (Ward Dep. at 19-20).

Dr. Schaefer is also the founder and chief medical officer of Boston Heart Diagnostics ("BHD"), a company that provides, among other things, laboratory and diagnostic services, focusing on heart-disease prevention. (Schaefer Dep. Vol. 1 at 26-27). Since 2007, BHD has used the HDL Map—a test co-developed and patented by Dr. Schaefer—to examine HDL particles by two-dimensional gel electrophoresis. (Def. Ex. 4 ("Schaefer Dep. Vol. 2") at 283, 306-08; Def. SMF ¶ 90).[1]

2. ACP-501

On October 21, 2003, U.S. Patent Number 6,635,614 ("the '614 Patent") was issued to three scientists associated with the National Institutes of Health ("NIH") within the Department of Health and Human Services. (Pl. Ex. 6). The claims for the patent involve "[a] method for decreasing accumulation of cholesterol in arteries in a human subject not suffering from [LCAT] deficiency syndrome." (Pl. Ex. 6 at col. 21 ll. 2-4). The patent was assigned to the NIH. (*Id.* at 1; Pl. Ex. 7 at 52803). Dr. Schaefer was not listed as an inventor, nor does it appear that he had any involvement in obtaining the patent. (Pl. Ex. 6 at 1; *see* Schaefer Dep. Vol. 1 at 207).

Alan Remaley, M.D., and Robert Shamburek, M.D., are physicians associated with the NIH. (Def. Ex. 7 ("Remaley Dep.") at 15; Shamburek Dep. at 15). They study "lipid and lipoprotein metabolism," including disorders such as LCAT deficiency. (*See* Remaley Dep. at 15-16, 20-21; Shamburek Dep. at 12-15). Dr. Remaley leads the same laboratory that was previously led by the inventors of the '614 Patent. (Remaley Dep. at 41-42).

[1] The parties dispute whether the HDL Map diagnoses LCAT deficiency. (Def. SMF ¶ 90; Pl. Resp. to Def. SMF ¶ 90). According to Dr. Schaefer, the HDL Map helps with diagnosing the disease, but DNA sequencing is necessary to confirm it. (Schaefer Dep. Vol. 2 at 286). According to Ward, the HDL Map provides a "biochemical diagnosis." (Pl. Ex. 76 at 10). It is unclear if a biochemical diagnosis also requires genetic confirmation.

In approximately 2007 or 2008, Bruce Auerbach and Brian Krause approached Dr. Remaley about the '614 Patent. (*Id.* at 41; Pl. Ex. 8). Auerbach and Krause had founded AlphaCore Pharma, LLC, and they were "interested in licensing the patent and potentially trying to develop [it] into a drug." (Remaley Dep. at 41). Dr. Remaley agreed to collaborate, and in 2008 the NIH entered into a research agreement with AlphaCore. (*Id.* at 43-45; Pl. Ex. 12 at 2).[2] Around the same time, AlphaCore licensed the '614 Patent from the NIH. (*See* Shamburek Dep. at 43). The NIH provided a grant of $240,129 to AlphaCore to produce recombinant LCAT enzyme and to conduct animal testing. (Pl. Ex. 9 at 168). AlphaCore then started to make recombinant human LCAT, which it called ACP-501. (Remaley Dep. at 19; Shamburek Dep. at 43).

In approximately 2012, AlphaCore and the NIH conducted a Phase 1 clinical trial of ACP-501 in 16 patients with cardiovascular disease. (*See* Remaley Dep. at 50-52; Def. Ex. 12).[3] That study indicated that ACP-501 was safe for use in humans and could "raise[] HDL" levels. (Remaley Dep. at 52). The NIH shared the study's results with the Food and Drug Administration. (*Id.* at 60-61).

After the Phase 1 study, "a limited supply" of ACP-501 remained. (*Id.* at 70). The parties dispute whether there were plans at one point to use that leftover ACP-501 in another study. (Def. SMF ¶ 33; Pl. Resp. to Def. SMF ¶ 33; *compare* Remaley Dep. at 70, *with id.* at 171). In any event, AlphaCore ultimately donated the leftover ACP-501 so that the NIH could

[2] The 2008 agreement was a Cooperative Research and Development Agreement with the NIH National Heart, Lung, and Blood Institute ("NHLBI"), Lipoprotein Metabolism Section, with Dr. Remaley listed as principal investigator. (Pl. Ex. 11 at 2).

[3] Phase 1 studies typically include "the initial introduction of an investigational new drug into humans." 21 C.F.R. § 312.21. They are designed to "determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness." *Id.*

use it to treat Ward. (First Auerbach Aff. (Dkt. No. 20) ¶ 18).

3. The Proposal to Treat Ward

In May 2010, Ward saw Dr. Om Ganda for a consultation about a lipid disorder. (*See* Pl. Ex. 5). Dr. Ganda concluded that Ward had an LCAT deficiency and referred him to Dr. Schaefer. (*Id.* at 3; Def. Ex. 14). After genetic sequencing performed at BHD in June 2010 confirmed that Ward had FLD, he made an appointment with Dr. Schaefer to "discuss therapeutic options." (Def. Ex. 14 at 1).

Ward and Dr. Schaefer first met on July 1, 2010. (Ward Dep. at 19). Over the next two years, they met "on a monthly basis" to discuss Ward's condition. (*Id.*).

Shortly after Ward was diagnosed with FLD in June 2010, Dr. Schaefer attended a medical conference, where he discussed Ward's condition with Dr. Remaley and Brian Krause of AlphaCore. (*See* Def. Ex. 14 at 1). Dr. Remaley offered to help, and shared the fact that the NIH and AlphaCore were "developing recombinant LCAT as a therapy," presumably for cardiovascular disease, and hoped "to start a clinical trial sometime" in 2011. (*Id.*).

Sometime later, Dr. Schaefer called Dr. Remaley to discuss Ward and ask whether he had plans to use ACP-501 to treat LCAT-deficient patients. (Remaley Dep. at 78-80). Ward was also on the call, but Dr. Remaley "had very limited conversation with him." (*Id.* at 78). Dr. Remaley told them that at the time, AlphaCore and the NIH "had no plan to design a study to systematically treat" LCAT deficiency using ACP-501. (*Id.* at 79).

Over the next year or so, Dr. Schaefer, Ward, and Dr. Remaley continued to correspond about LCAT therapy. In November 2011, Ward told his nephrologist, Bijan Roshan, M.D., that he "may be one of the first to receive an IV injection with the LCAT enzyme." (Def. Ex. 15). In December 2011, he sent an e-mail to Dr. Remaley to thank him for keeping him informed about "the progress of the LCAT enzyme" and to "reiterate [his] desire and willingness to have the

enzyme administered as soon as feasible." (Def. Ex. 16).

In December 2011, Dr. Roshan, Dr. Ganda, Dr. Schaefer, and others published an article about LCAT deficiency in the Journal of Clinical Lipidology, which included Ward's data and information concerning his diagnosis. (Second Auerbach Aff. (Dkt. No. 30-1), Ex. A ; Def. Ex. 5).[4] The article listed Ward as a co-author. (Def. Ex. 5 at 493). It concluded that "[i]n the future, the use of recombinant LCAT may be of value in patients who develop significant renal impairment." (*Id.* at 498). The article included a disclosure that Dr. Schaefer "[is] supported by research grants to the Lipid Metabolism Laboratory at Tufts University from the National Institutes of Health, Bethesda, MD." (*Id.*).

On February 29, 2012, Dr. Schaefer e-mailed Dr. Remaley to inquire "about the status of recombinant LCAT in LCAT deficiency." (Pl. Ex. 16 at 1). Dr. Remaley replied that he needed to collect more safety data before he could obtain the FDA's approval to use ACP-501 in a trial to treat LCAT-deficient patients. (*See id.*). Dr. Schaefer indicated that Ward wanted to participate in such a trial once Dr. Remaley had obtained the FDA's approval. (*See id.*).

In March 2012, Dr. Schaefer and Dr. Remaley again e-mailed about having Ward participate in a trial involving ACP-501. (*See* Pl. Ex. 17). Dr. Remaley indicated that Ward could likely participate in such a trial. (*Id.*). Dr. Schaefer replied that Ward was "ready when you are," copied Ward, and shared Ward's phone numbers and home address. (*Id.*).

On April 10, 2012, Dr. Schaefer sent an e-mail to Dr. Remaley and copied Ward and Dr. Roshan. (Def. Ex. 18). The e-mail stated that due to changes in Ward's condition, Dr. Roshan had "recommended the placement of a fistula so that [Ward] will be ready for hemodialysis." (*Id.* at 1). Thus, he said, "the issue of therapy has now taken on some urgency." (*Id.*). Dr.

[4] Dr. Schaefer had presented a case report about Ward's diagnosis at a conference at the Joslin Diabetes Center on October 4, 2010. (Pl. Ex. 4 at 1). Ward was present at that event. (*Id.*).

Schaefer stated that Ward was "ready anytime," but asked Dr. Remaley to "be realistic – I do not want to raise any false hopes." (*Id.*).

That same day, Dr. Remaley replied to Dr. Schaefer to share the status of his research with AlphaCore on ACP-501 and to say that "perhaps sometime this summer we can treat" Ward. (Pl. Ex. 21). However, he opined that "[u]nless the single treatment does much, which I am not expecting, it may not help [Ward] much." (*Id.*). Dr. Schaefer forwarded that e-mail to Ward. (*Id.*).

On April 12, 2012, Dr. Roshan replied to Dr. Schaefer's April 10 e-mail. (Def. Ex. 18 at 1). He opined that "at this point," Ward's chance of "meaningful renal recovery is low." (*Id.*). He shared that he was "working to convince" Ward that he should be evaluated for a kidney transplant, but that Ward was "refusing" such an evaluation. (*Id.*).

That same day, Ward replied to Dr. Roshan's e-mail. (*Id.*). He acknowledged the "extreme rarity" of his disease and stated that "*nobody* is exactly sure what metabolic pathways are going on inside the kidney and whether recombinant LCAT treatment can reverse or alleviate the renal insufficiency." (*Id.*).

On April 17, 2012, Ward had a fistula put in place in preparation for dialysis. (Pl. Ex. 44).

In May 2012, Ward met with a different nephrologist, Edward Walshe, M.D. (*See generally* Def. Ex. 27). Dr. Walshe noted that Ward had considered a kidney transplant but had rejected it for several reasons. (*Id.* at 1). Dr. Walshe urged him to reconsider. (*Id.* at 4).

On September 27, 2012, Dr. Schaefer e-mailed two physicians at the FDA. (Pl. Ex. 24 at 1). He copied Ward and Dr. Remaley on the e-mail. (*Id.*). Dr. Schaefer told the FDA physicians about Ward's condition and said that according to Ward's nephrologist, "he will

require dialysis in 6 – 12 months." (*Id.*). Dr. Schaefer stated that he had referred Ward to Dr. Remaley for treatment with ACP-501. (*Id.*). The only thing "preventing [Ward] from getting the enzyme replacement," Dr. Schaefer said, was the FDA. (*Id.*). He urged the FDA "to approve giving this very important and potentially life-saving therapy [to] patients" with FLD. (*Id.*). According to Ward, Dr. Schaefer explained this statement to him by saying that ACP-501 was "a treatment and a cure to reverse [Ward's] kidney function loss." (Ward Dep. at 30).

That same day, Dr. Schaefer e-mailed Ward and Dr. Remaley a revised copy of a draft letter addressed to Senator John Kerry. (Pl. Ex. 24 at 2). That letter "urgently request[ed]" that Senator Kerry help Ward "get the FDA to approve the use of ACP-501 in rare patients such as" himself. (*Id.* at 4). It stated that Ward would "probably require dialysis in the next 6 – 12 months unless [he could] get replacement therapy that should help prevent [his] kidneys from failing." (*Id.* at 3). Ward does not recall whether he signed that letter or sent it to Senator Kerry. (Ward Dep. at 31).

In December 2012, Ward met with another nephrologist, Valerie Price, M.D. (Def. Ex. 28). Dr. Price indicated that she would recommend that Ward start dialysis if his kidney function worsened or if he wanted to do so, but that based on his current condition there was "no rush." (*Id.* at 2). She noted that he was "hesitant" to start dialysis because he was "awaiting FDA approval of recombinant LCAT [that] he hopes will reverse his renal failure" and "worri[ed] that starting dialysis will render him ineligible for the drug." (*Id.* at 1). Ward alleges that in January 2013, Dr. Schaefer told him not to start dialysis because it would "destroy" his remaining kidney tissue and then the ACP-501 "would not work." (Ward Dep. at 45-46).

4. The Protocol

Meanwhile, on October 25, 2012, Dr. Shamburek and AlphaCore employees prepared the first draft of a compassionate-use protocol that proposed how to treat Ward with ACP-501. (Pl.

Ex. 26; *see also* Remaley Dep. at 89; Shamburek Dep. at 226). They did so in order to obtain permission from both the FDA and the NIH's Institutional Review Board ("IRB") to administer ACP-501 to Ward. (Remaley Dep. at 88, 90). Dr. Remaley reviewed the protocol and "may have made some changes or modifications." (*Id.* at 88). On at least one occasion, Dr. Schaefer reviewed a version of the first draft of the protocol, said that it looked "fine" to him, and sent along information on Ward to the drafters. (Pl. Ex. 26).

The first draft of the protocol refers to Dr. Schaefer as Ward's "personal physician[]" and "personal 'home' physician." (*Id.* § 3.5). It indicates that Ward "is currently being treated by" Dr. Schaefer. (*Id.* § 3.4). It states that Ward will visit an NIH hospital for initial observation and to receive his first doses of ACP-501. (*Id.* § 3.5). Then, it states, he will return home, where Dr. Schaefer will continue to monitor him and administer ACP-501. (*Id.*). The protocol says that Ward will "return to the NIH for full clinic assessments every 3 months" after the initial doses. (*Id.*). It lists the total number of study sites as "1," which includes the NIH and "one home physician per subject." (*Id.*). It states that the study will exclude any subject with "[e]stablished chronic kidney disease . . . requiring dialysis (Stage 5)." (*Id.* § 7.4). It also lists AlphaCore as a sponsor. (*Id.* § 2).

On November 26, 2012, an AlphaCore employee e-mailed Dr. Schaefer, Dr. Remaley, and Auerbach the "latest version of the protocol." (Pl. Ex. 27 at 1). Dr. Schaefer forwarded that e-mail and the attached draft protocol to Ward. (*Id.*). He wrote that the protocol would be "submitted this week" and that he hoped it "will be approved" so that Ward could "start therapy after the New Year." (*Id.*).

The second draft of the protocol again listed Dr. Schaefer as Ward's "'[h]ome' personal physician[]." (*Id.* § 3.5). However, it differed from the first draft in several notable ways. First,

it also listed Dr. Schaefer as a "Medical Monitor" along with Dr. Shamburek. (*Id.* § 1.1). Second, it now stated that there are "2" study sites: the NIH and "one '[h]ome' physician." (*Id.* § 3.5). Third, it no longer stated that the study will exclude any subject with chronic kidney disease. (*See id.* § 6.7.2). Finally, it did not list AlphaCore as the study's sponsor. (*Id.* § 2).

A third draft of the protocol was dated December 2012. (Def. Ex. 19; Second Auerbach Aff. Ex. B). In early December, Dr. Shamburek submitted that version to the FDA and the NIH's IRB. (Second Auerbach Aff. ¶¶ 13-14; *see* Shamburek Dep. at 92). Both entities approved the third version of the protocol later that month. (Shamburek Dep. at 67, 93; *see* Second Auerbach Aff. ¶¶ 13-14). On January 16, 2013, the NIH's IRB approved minor amendments to the protocol. (*See* Shamburek Dep. at 93-94).

The approved protocol stated that its primary objective was to "assess the safety and tolerability of ACP-501." (Def. Ex. 19 at § 3.3.1). Its secondary objectives were to "assess the effects of ACP-501 on biomarkers of reverse cholesterol transport, including [HDL-C] elevation," and on "biomarkers of renal function." (*Id.* § 3.3.2). It differed from the second draft in several ways. First, it referred to only one ACP-501 administration site: the NIH. (*Id.* § 3.5). Second, it no longer listed Dr. Schaefer as a "Medical Monitor." (*Id.* § 1). Third, while it referred to Ward's "home physician," it did not say who that person was. (*See id.* § 3.5).

The parties dispute what role Dr. Schaefer had in the study as set forth in the approved protocol. (*See* Def. SMF ¶¶ 43-44; Pl. Resp. to Def. SMF ¶¶ 43-44). Dr. Shamburek has testified that under the protocol, "Dr. Schaefer had no role period" in administering ACP-501 to Ward. (*See* Shamburek Dep. at 50). In contrast, Ward has submitted a report from expert witness James P. Sutton, M.D., who has opined that based on Dr. Schaefer's involvement in the protocol and its drafting, he "was acting in the role of principal investigator," even though he

was "not named as such." (Pl. Ex. 28 at 60).

5. The Informed-Consent Form

On January 6, 2013, Ward was first admitted to the NIH. (Shamburek Dep. at 150). That same day, he signed a "General Admission Consent" form. (Def. Ex. 20 at 13-14). He stayed at the NIH for five to six days. (Shamburek Dep. at 152). During that time, medical staff ran a variety of tests on him, including drawing mineral and liver panels, collecting daily urine samples, taking ultrasound images of his abdomen, and doing an electrocardiogram. (*See id.*). He did not receive any doses of ACP-501 during that visit. (*Id.* at 152-53).

On January 24, 2013, Ward returned to the NIH. (*See* Def. Ex. 20 at 11). That same day, he, Dr. Shamburek, and a witness signed an informed-consent form, which was entitled "Consent to Participate in a Clinical Research Study." (*Id.*).

The parties dispute whether Dr. Shamburek reviewed the form with Ward before he signed it. Dr. Shamburek has testified that he shared the form with Ward on January 6, 2013, during his first visit to the NIH. (Shamburek Dep. at 82). According to Dr. Shamburek, he read through the form twice with Ward, "reviewed all the limitations [and] the potential risks" of the study, and encouraged him to discuss the form with his family before signing it. (*Id.* at 82-83). Ward, however, has testified that he did not recognize the informed-consent form and had no memory of Dr. Shamburek discussing it with him or even signing it. (Ward Dep. at 99, 101, 105-06).

Similarly, there is a dispute as to whether Dr. Schaefer had any role in the reviewing and signing of the informed-consent form. Dr. Shamburek testified that there would have been "no reason" for Dr. Schaefer to obtain Ward's informed consent to the study. (Shamburek Dep. at 82). Dr. Schaefer states that he "was not involved in, nor was he present for, the review and execution" of the document. (Def. SMF ¶ 56). Ward purports to dispute that fact. (Pl. Resp. to

Def. SMF ¶ 56). But there is no evidence in the record stating or suggesting that Dr. Schaefer in fact reviewed the form with Ward or was present for its signing.

The informed-consent form is eleven pages long. (*See generally* Def. Ex. 20 at 1-11). It states, among other things, that "[t]aking part in NIH research is entirely voluntary." (*Id.* at 1). It states that Ward may withdraw at any time, but that "to receive care at the NIH, [he] must be taking part in a study or be under evaluation for study participation." (*Id.*). It also states that he "may receive no benefit from taking part" in the study. (*Id.*).

The form describes Ward's compassionate-use protocol in some detail. It states that the study will provide "expanded use ACP-501 to one subject with FLD and declining renal function." (*Id.* at 2). According to the form, the study "will help determine the ability of this drug to affect the consequences of FLD." (*Id.*). It states that Ward "may not receive any direct benefit from participating in this study," but that "the study will yield knowledge about the use of ACP-501 for future subjects." (*Id.* at 8). The form also notes that Ward "will experience up to a 6-month drug hiatus during the study due to a delay in the availability of ACP-501." (*Id.* at 2).

The form also describes "the risks and discomforts of [the] study." (*Id.* at 6-7). Those include potential complications from "blood draw[s] or [an] intravenous catheter," such as feeling light-headed, nauseated, or experiencing "bleeding, pain, and bruise formation." (*Id.* at 6). They also include several "possible side effects" related to ACP-501 that range from "a mild rash" to "an anaphylactic reaction or death." (*Id.* at 7-8).

The form also states that Ward "will not be compensated for [his] participation in [the] study." (*Id.* at 10). However, the NIH's IRB later approved an amendment to allow Ward to receive compensation for his flights to and from the NIH. (*See* Pl. Ex. 33 at 10; Shamburek Dep.

at 112-13).

Finally, the form states that "none of the researchers on this protocol will receive any compensation." (Def. Ex. 20 at 10). But it also states that because this was a joint study between the NIH and AlphaCore, it was possible that the results "could lead to payments to NIH scientists and to the NIH." (*Id.*). It reiterated, however, that "[Ward] will not receive any money from the development of recombinant human LCAT." (*Id.*).

6. The Study

On January 28, 2013, Ward received his first infusion of ACP-501. (Def. Ex. 22 at 2). He received two more infusions on January 31 and February 7. (*Id.*).[5] On February 10, he had an episode of atrial fibrillation. (*Id.*). Dr. Shamburek and Ward's care team "decided to electively admit him to the Intensive Care Unit" in order to administer an antiarrhythmic medication, amiodarone. (*Id.*). After two days of treatment with amiodarone, Ward "successfully cardioverted to normal sinus rhythm." (*Id.*).

On February 19, 2013, Ward received his first "maintenance dose" of ACP-501 "without any problems and was discharged home" the next day. (*Id.*). Between February and September 2013, he returned to the NIH for 19 additional doses. (Def. Ex. 23 at 1).

It is undisputed that Dr. Schaefer did not administer any infusions of ACP-501 to Ward. (Def. SMF ¶ 61; Pl. Resp. to Def. SMF ¶ 61; *see also* Shamburek Dep. at 46).

On June 19, 2013, Ward visited his nephrologist, Dr. Price. (Def. Ex. 29 at 1). She observed that the ACP-501 infusions "have increased his HDL." (*Id.*). But she noted that while they may "prevent worsening of renal function" and "stav[e] off dialysis," they also "may not be

[5] Ward's medical record from this visit to the NIH states that he received his third ACP-501 infusion on February 17. (Def. Ex. 22 at 2). However, the parties agree that Ward received his third infusion on February 7. (Def. SMF ¶ 58; Pl. Resp. to Def. SMF ¶ 58). In any event, this inconsistency does not appear to be material.

enough to reverse the damage already done" to his kidneys. (*See id.* at 4). She decided that "he does not need to start dialysis yet," but discussed "the process" with him. (*Id.*). Ward continued to receive ACP-501 infusions after that visit. (*See* Def. Ex. 23 at 1).

In June and July 2013, Dr. Schaefer and Dr. Remaley discussed whether to administer ACP-501 to Ward in Massachusetts. (*See* Pl. Ex. 29 at 1-2). Dr. Schaefer also asked whether they could increase Ward's dosage of ACP-501. (*Id.* at 3). He said that if they did not, Ward "may end up on dialysis." (*Id.*). Dr. Remaley replied that if they increased Ward's dosage, they "w[ould] not have enough enzyme to keep treating him until the new batch will be ready, which is still sometime in the fall." (*Id.* at 2). Nevertheless, Dr. Remaley e-mailed employees at AstraZeneca, which had acquired AlphaCore earlier in 2013, to "set[] up a protocol so that [Dr. Schaefer] can treat [Ward] in Boston once the new enzyme is available." (*Id.* at 70). He copied Dr. Schaefer on that e-mail. (*Id.*).

In July 2013, Ward started dialysis. (Ward Dep. at 216).

On September 19, 2013, Ward received his twentieth maintenance dose of ACP-501. (Def. Ex. 23 at 1). The records for that visit stated that he would "return in two weeks for another maintenance" dose. (*Id.* at 3).

However, on September 30, 2013, Dr. Schaefer e-mailed Drs. Remaley and Shamburek and copied Ward. (Def. Ex. 24). He wrote that after "lengthy discussions with [Ward] and [Ward's] family, I have decided that it is no longer worthwhile that he get any more therapy at [the] NIH." (*Id.*). Dr. Schaefer stated that Ward "was making progress on the higher dose with some improvement," but had "deteriorated on the lower [and] less frequent dose." (*Id.*). He also stated that the "NIH treatments interfere[d] with [Ward's] dialysis schedule." (*Id.*).

Another apparent reason why Ward withdrew from the study was that he had "more and

more problems with his veins because of all the venipunctures he had been subjected to at the NIH." (Pl. Ex. 38 at 4). Ward testified that at times his blood clotted during the study, and that as a result he had experienced "very painful" blood draws. (Ward Dep. at 37).

An article about the study that was published later noted that "3 adverse events" had occurred during it. (Def. Ex. 10 at 357-58). The first of these was Ward's episode of atrial fibrillation. (*See id.*; Def. Ex. 22 at 2). The second was that Ward had "presented with a viral syndrome consisting of chills and fatigue that started on day 65" of the study. (Def. Ex. 10 at 358). The third was that Ward had begun "elective hemodialysis" at the end of the study, "per the recommendation of his nephrologist." (*Id.* at 357-58). According to the paper, all three events "were not attributed to ACP-501." (*Id.* at 357).

7. The Disputed Blood Draws

Meanwhile, between November 2012 and November 2013, Ward had his blood drawn twelve times at BHD. (Def. Ex. 32 at No. 12). According to Dr. Schaefer, the purpose of those blood draws was to evaluate Ward's kidney function. (*Id.*). The parties dispute whether those blood draws were related to the ACP-501 study. Dr. Schaefer denies that they were part of the study protocol or that the NIH requested the draws. (Def. SMF ¶ 73). Similarly, Dr. Shamburek testified that any data collected by Dr. Schaefer was not part of the protocol. (Shamburek Dep. at 204-06). Ward, however, alleges that Dr. Schaefer collected those blood samples as part of the study protocol, and that he did not consent in writing to those draws. (Pl. Resp. to Def. SMF ¶¶ 72-73).

In any event, on March 16, 2013, Dr. Schaefer sent Drs. Remaley and Shamburek an e-mail providing a summary of Ward's "laboratory testing at our lab." (Pl. Ex. 64 at 1). He sent a copy of the e-mail to Auerbach, Krause, and one other person at AlphaCore, and then forwarded it to Ward. (*Id.*). On April 12, 2013, he sent another e-mail to Auerbach and Krause, copied to

Ward, attaching the "most recent lab data we have." (Pl. Ex. 65 at 1).[6] On August 20, 2013, Dr. Schaefer sent a further e-mail to Dr. Shamburek, copied to Dr. Remaley, Auerbach, Krause, Ward, and others, enclosing a draft journal article and additional laboratory results. (Pl. Ex. 30).[7]

8. The Sale of AlphaCore

Meanwhile, on April 3, 2013, AlphaCore announced that it had been acquired by MedImmune, LLC, a company affiliated with AstraZeneca. (Def. SMF ¶ 78). The financial details of the acquisition were not made public at that time. (*Id.*).

On September 23, 2014, Dr. Schaefer e-mailed Auerbach and other AlphaCore employees to ask if the company would compensate Ward for his involvement in the study. (*See* Def. Ex. 33). Dr. Schaefer said that Ward and his sister had pointed out that Ward "spent considerable time an[d] effort" on the study and had asked Dr. Schaefer about compensation. (*Id.*). He also shared that they had asked whether Ward's data was "used for getting the company sold, and what was the price of the sale." (*Id.*). Dr. Schaefer wrote that "the price of the sale cannot be found in the public domain." (*Id.*).[8]

Dr. Schaefer testified that he never received a response from "any of the addressees" on that e-mail. (Schaefer Dep. Vol. 1 at 187-88). However, it appears that on September 23, 2014, one AlphaCore employee replied to him, saying that she "[did] not know how to answer" his inquiry because she had not profited from the company's sale. (Pl. Ex. 22 at 1). Dr. Schaefer forwarded that response to Ward. (*Id.*).

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[6] In the same e-mails, Dr. Schaefer requested that he receive reimbursement for Ward's travel costs, which Dr. Schaefer had been funding. (Pl. Ex. 64 at 2; Pl. Ex. 65 at 1).

[7] Dr. Schaefer testified that he had provided Ward's BHD blood-draw data to Dr. Remaley, who may have shared it with AlphaCore. (*See* Schaefer Dep. Vol. 1 at 188).

[8] Ward has testified that Dr. Schaefer told him it was $20 million. (Ward Dep. at 54-55).

Dr. Remaley reported, in an NIH Annual Intramural Research report dated September 30, 2014, that AstraZeneca acquired AlphaCore "[b]ased on [the] results" of the Ward study and "a promising Phase I study done at the NIH." (Pl. Ex. 63 at 1).[9]

There is no evidence that Dr. Schaefer has ever owned any financial interest in AlphaCore, MedImmune, or AstraZeneca, or that he directly profited from the sale of AlphaCore.

In 2014, after Ward withdrew from the study, Dr. Schaefer paid him as a consultant for $500 a month. (Ward Dep. at 64-65; Def. Ex. 32 at No. 12). Ward testified that he performed no specific duties for Dr. Schaefer, but that he would visit his office once a month for one to three hours. (Ward Dep. at 65-66). During that time Ward was listed as a co-author on a draft manuscript about corneal abnormalities associated with lipid metabolism disorders. (Pl. Ex. 39 at 2). Ward was also named the Director of the Dyslipidemia Foundation, on which Dr. Schaefer served as a medical consultant and BHD served as the sponsor. (*Id.*). Dr. Schaefer stopped paying Ward in October 2015, after Ward chose to cease his monthly visits to Dr. Schaefer's office. (Pl. Ex. 41).

9. Subsequent Use of Data

On October 16, 2013, Dr. Schaefer e-mailed Dr. Remaley and several employees of AlphaCore and AstraZeneca. (Pl. Ex. 67). He said that Dr. Shamburek had recently shared new data from Ward's study with him of which he had not been aware. (*See id.* at 1). Based on that data, he proposed that MedImmune "offer this therapy to LCAT deficient patients," including Ward, "in the future." (*Id.*). He stated that "enzyme therapy could become lifelong to treat the

[9] Some years later, in 2017, the NIH National Heart, Lung, and Blood Institute issued a publication stating that AstraZeneca acquired AlphaCore "on the strength of [ACP-501's] potential as a treatment for [coronary heart disease]." (Pl. Ex. 10 at 1).

renal insufficiency and the anemia," and that without it, such patients "are consigned to either dialysis or a kidney transplant." (*Id.*).

At some point after Ward withdrew from the study, BHD acquired 20 frozen samples of his serum from the NIH. (Schaefer Dep. Vol. 2 at 241-42). Dr. Schaefer and others at BHD wanted to analyze how the "enzyme replacement that [Ward] received would affect the HDL particles over time." (*Id.* at 241). But after they analyzed the samples, they destroyed their results at the request of the NIH. (*Id.* at 242). According to Dr. Schaefer, that was because Dr. Shamburek did not want BHD to use or publish the results and felt that doing so "might be some protocol violation." (*Id.*).

The parties dispute whether Dr. Schaefer ever saw the complete data from the NIH on Ward's treatment. (Def. SMF ¶ 83, Pl. Resp. to Def. SMF ¶ 83). Dr. Shamburek testified that he had not. (Shamburek Dep. at 254). However, Ward alleges that a draft paper that Dr. Remaley shared with Dr. Schaefer in August 2015 included data concerning him gathered by the NIH. (Pl. Resp. to Def. SMF ¶ 83; Pl. Ex. 58).

10. Collaboration between MedImmune and BHD

Between October 2013 and September 2014, Dr. Schaefer communicated several times with a MedImmune employee, Sotirios Karathanasis, about "a potential collaboration" between BHD, MedImmune, and the Dyslipidemia Foundation. (Pl. Ex. 69 at 1; s*ee also* Pl. Exs. 67-72).

In November 2014, BHD and MedImmune entered into a clinical research agreement. (*See generally* Pl. Ex. 73). Their research plan was to "screen all patients who have blood samples sent to" BHD with HDL-C values below a certain threshold for FLD. (*See id.* Ex. A § I). Under the terms of the agreement, MedImmune was to pay BHD $150,000 that was to be used "solely for activities required for the conduct of the Research Plan." (*Id.* at § 4.1). Dr. Schaefer and several co-investigators later published results from the study in 2018 in the Journal

of Lipid Research. (Schaefer Dep. Vol. 2 at 248-49; *see also* Pl. Ex. 62).

11. Subsequent Publications

In 2016, Dr. Shamburek, Dr. Remaley, Auerbach, Krause, and other NIH and AlphaCore employees published an article about Ward's treatment. (*See* Def. Ex. 10). The article was published in the Journal of Clinical Lipidology and was entitled "Familial lecithin: cholesterol acyltransferase deficiency: First-in-human treatment with enzyme replacement." (*Id.* at 356). It concluded that after treatment with ACP-501, Ward's "HDL-C rapidly increased" and his "anemia improved, as did most parameters related to renal function in spite of advanced disease." (*Id.*). A supplemental appendix stated that his "[h]emodialysis was delayed pending the trial of rhLCAT." (Pl. Ex. 50 at 2).

Dr. Schaefer was not listed as an author on the article, but he is thanked "for advice and referring the patient." (Def. Ex. 10 at 356, 366).

As noted, in 2018 Dr. Schaefer and several co-authors published an article setting forth the results from BHD's study with MedImmune entitled "Genetic and secondary causes of severe HDL deficiency and cardiovascular disease." (Pl. Ex. 62). Ward's data was included in the article. (Schaefer Dep. Vol. 2 at 318). The parties dispute, however, whether the data included was collected from Ward's blood draws at BHD that occurred during the protocol. Ward alleges that it was. (Pl. Resp. to Def. SMF ¶ 77). Dr. Schaefer has testified that the only data from Ward that he relied on for the 2018 article was data that he had previously collected for the 2011 paper he co-authored with Ward. (Schaefer Dep. Vol. 2 at 318-19).

B. Procedural Background

Ward filed the complaint in this action in July 2016, in Massachusetts state court. The complaint alleged claims for fraud (Count One); lack of informed consent (Count Two); unjust enrichment (Count Three); violations of the Due Process Clause of the United States

Constitution, the Massachusetts Declaration of Rights, and the Nuremberg Code (Count Four); violation of the Massachusetts Civil Rights Act (Count Five); and civil conspiracy (Count Six). It named as defendants Dr. Schaefer, Dr. Shamburek, Dr. Remaley, Auerbach, AlphaCore, MedImmune, and AstraZeneca. Drs. Shamburek and Remaley removed the action to this Court on the basis of 28 U.S.C. § 2679(d)(2).

On June 23, 2017, the Court granted the motion to dismiss of MedImmune and AstraZeneca under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. *See generally Ward v. Auerbach*, 2017 WL 2724938 (D. Mass. June 23, 2017). That same day, the Court also granted the motion to dismiss of AlphaCore and Auerbach under Fed. R. Civ. P. 12(b)(2) for lack of personal jurisdiction. *See generally id.*

On July 10, 2017, the Court granted in part and denied in part a motion by Drs. Shamburek and Remaley to substitute the United States as defendant as to all claims against them. *See generally Ward v. Schaefer*, 2017 WL 2951889 (D. Mass. July 10, 2017).

On November 16, 2017, the Court referred the matter to Massachusetts Superior Court to convene a medical malpractice tribunal. *See generally Ward v. Schaefer*, 2017 WL 5505405 (D. Mass. Nov. 16, 2017). On April 20, 2018, a medical malpractice tribunal concluded that there was sufficient evidence, if properly substantiated, to raise a legitimate question of liability appropriate for judicial inquiry. (Findings of the Medical Malpractice Tribunal (Dkt. No. 85) at 1).

On February 27, 2018, the Court granted a motion to dismiss by the United States and Drs. Shamburek and Remaley under Fed. R. Civ. P. 12(b)(1) for lack of subject-matter jurisdiction and under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. *See generally Ward v. Schaefer*, 2018 WL 1096829 (D. Mass. Feb. 27, 2018).

Dr. Schaefer has now moved for summary judgment on all counts.

II. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 822 (1st Cir. 1991) (quoting *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990)). Summary judgment shall be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine issue is "one that must be decided at trial because the evidence, viewed in the light most flattering to the nonmovant, would permit a rational factfinder to resolve the issue in favor of either party." *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990) (citation omitted). In evaluating a summary judgment motion, the court indulges all reasonable inferences in favor of the nonmoving party. *See O'Connor v. Steeves*, 994 F.2d 905, 907 (1st Cir. 1993). When "a properly supported motion for summary judgment is made, the adverse party must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (quotations omitted). The nonmoving party may not simply "rest upon mere allegation or denials of his pleading," but instead must "present affirmative evidence." *Id.* at 256-57.

III. Analysis

Because the analysis of the fraud claim (Count One) involves issues largely similar to that of the informed-consent claim (Count Two), the latter will be addressed first.

A. Breach or Lack of Informed Consent (Count Two)

Count Two alleges that Dr. Schaefer breached his duty to obtain Ward's informed consent regarding his participation in the ACP-501 study. Under Massachusetts law, "[f]or a plaintiff to prevail on a theory of informed consent, '(1) the physician must have a duty to

disclose the information at issue to the patient, and (2) the breach of that duty must be causally related to the patient's injury.'" *Bradley v. Sugarbaker*, 809 F.3d 8, 16 (1st Cir. 2015) (quoting *Halley v. Birbiglia*, 390 Mass. 540, 548 (1983)).[10] As a general matter, a physician has a duty to make appropriate disclosures concerning a particular procedure if there is "a sufficiently close doctor-patient relationship." *See Bradley*, 809 F.3d at 16.

As noted, Ward and Dr. Shamburek executed a fairly detailed informed-consent form on January 24, 2013, prior to his participation in the study. (Def. Ex. 20 at 1-11). That form is eleven pages long and describes the potential risks and experimental nature of the study in considerable detail. (*Id.*). Dr. Shamburek testified that he read through the form twice with Ward, that he reviewed "all the limitations [and] the potential risks" of the study with him, and that he encouraged him to discuss the form with his family before signing it. (Shamburek Dep. at 82-83). It is undisputed that Ward did, in fact, sign the form. (Def. Ex. 20 at 11). It is also undisputed that Dr. Schaefer did not personally explain the form to Ward, or otherwise obtain his informed consent.

The parties dispute whether Dr. Schaefer had a duty to obtain Ward's informed consent before he participated in the study. Ward contends that Dr. Schaefer had such a duty, and that he "failed to reasonably and adequately disclose and explain the risks and complications of the [study]" and "the unproven nature and effectiveness of the treatment." (Pl. Opp. at 18). Ward also contends that he was not competent to execute the informed-consent form, that the form was misleading and inadequate, and that Dr. Schaefer failed to disclose various "financial and professional" conflicts of interest of the researchers. (*Id.*).

[10] The parties agree that Massachusetts law governs this case. (*See* Def. Mem. at 3 n.2; Pl. Opp. at 10).

1. Whether Dr. Schaefer Was Required to Obtain Ward's Informed Consent

The first question is whether Dr. Schaefer had a duty to obtain Ward's informed consent. Dr. Schaefer contends that under Massachusetts law, "only *one* physician" is responsible for obtaining the informed consent of a patient. (Def. Mem. at 9). In support of that proposition, he relies principally on the decision in *Harnish* v. *Child.'s Hosp. Med. Ctr.*, 387 Mass. 152 (1982).

In *Harnish*, the Massachusetts Supreme Judicial Court held that one of three individual defendants, a surgical assistant, did not have a duty to obtain the plaintiff's informed consent to a particular procedure. 387 Mass. at 159. One of the other two defendants was the admitting physician and surgeon in charge, and one had "discussed with the plaintiff the potential consequences, risks and side effects of the surgery." *Id.* at 158-59. The third physician had "only assist[ed] in the operating room." *Id.* at 159. The SJC held that the mere fact that the assistant had participated in the surgery was not sufficient "to create a doctor-patient relationship with a concomitant duty of disclosure," and that "[i]t would not be reasonable to require all of the individuals who only assist in the operating room to obtain the informed consent of the patient." *Id.*; *see also Grassis v. Retik,* 25 Mass. App. Ct. 595, 604 (1988) (concluding that an assisting physician who acted under the attending physician's orders did not have a duty to obtain informed consent because "he was not shown to stand in such a relation to the parents [of the patient] that he would be bound to inform them of the risks").

Similarly, in *Halley*, the SJC concluded that a physician who was only a "neurological consultant" did not have a "sufficiently close doctor-patient relationship" and therefore had no duty to obtain a patient's informed consent to the performance of an arteriogram. 390 Mass. at 548-49. That physician saw the patient only "intermittently during the period prior to the performance of the arteriogram," was "not the admitting or attending physician," was "not the

physician who formally ordered the arteriogram (although he did recommend its performance)," did not "perform the arteriogram," and was "not one of the medical personnel who spoke with [the patient's] parents and assured them of the safety of the test." *Id.* According to the SJC, that physician was only "tangentially involved in the performance of [the] medical procedure." *Id.* at 549. By contrast, the physician who both performed the arteriogram and "was also in a position to discuss the procedure" with the parents and "to highlight the risks associated with the test" did have such a duty. *Id.*

That case law thus indicates that only certain physicians—those with a sufficiently close doctor-patient relationship—have a duty to obtain informed consent for a particular procedure. More specifically, those cases address, in substance, the following issue: when multiple physicians are involved in the diagnosis and treatment of a patient, which of them have a duty to obtain consent from the patient, such that they can be found liable if that consent is inadequate? In simple terms, the SJC found that the lead physicians generally have such a duty, and that assisting, peripheral, or consulting physicians do not.

The SJC did not, however, suggest that only *one* physician on any particular medical team had a duty to obtain informed consent to a procedure. Indeed, in *Harnish*, it concluded that both the surgeon and one of the two assistants had such a duty. *See Halley*, 390 Mass. at 548. But neither did it hold that *every* physician who has such a duty is obligated to have a separate conversation with the patient, and to execute a separate informed-consent form. Such a rule would create a pointless and redundant requirement that multiple physicians must disclose the same risks to the same patient.[11] Rather, it appears that the law follows a common-sense

[11] *See Wilson v. Merritt*, 142 Cal. Rptr. 3d 630, 640 (Cal. Ct. App. 2006) (noting that either physician involved in a procedure "could have obtained informed consent from [the patient] and the consent so obtained would have been legally sufficient" to preclude liability for a claim for failure to obtain informed consent against one of the defendants).

approach, which may be summarized as follows: multiple physicians may have a duty, based on their relationship with a particular patient, to obtain the informed consent of that patient for a particular procedure. Normally, only one of those physicians actually needs to make the required disclosure and obtain the required consent.[12] But if there is only a single disclosure to a patient, the question of whether the duty of *all* physicians was discharged will depend on the adequacy of that single disclosure and the patient's subsequent consent.

Thus, under that framework, the relevant issues here may be framed as follows. First, did Dr. Schaefer have "a sufficiently close doctor-patient relationship" with Ward as to the ACP-501 study, such that Dr. Schaefer had a duty to obtain Ward's informed consent to participating in that study? If he *did not* have such a relationship, he stands in the position of the assistant surgeon in *Harnish*, or the consulting neurologist in *Halley*, and had no duty to obtain that consent. If he *did* have such a relationship, he had such a duty. But that duty might be discharged by the consent obtained by Dr. Shamburek, if that consent was appropriately informed; conversely, he could be found liable if that consent was not so informed.[13] In other words, if Dr. Schaefer had such a duty, and Dr. Shamburek failed to make adequate disclosures to Ward, that failure may be attributed to Dr. Schaefer, at least as a general matter.

Again, the initial question is whether Dr. Schaefer had a sufficiently close doctor-patient relationship with Ward as to matters concerning the study such that he had a duty to obtain Ward's informed consent to participate in it. Certainly, Dr. Schaefer and Ward had a doctor-

[12] Of course, there may be circumstances where different physicians may be required to make the necessary disclosures. For example, a surgeon may be better situated to disclose the risks of surgery, and the anesthesiologist for the same procedure may be better situated to disclose the risks of anesthesia. *See Foster v. Traul*, 175 P.3d 186, 191 (Idaho 2007) ("One would not expect an ophthalmologist to be present when the anesthesiologist discusses with his patient the potential risks that anesthesia care might pose to his eyesight during a surgery . . . . After all, the anesthesiologist is in the best position to inform and protect the patient and certainly should know of the type of risks that may exist.").

[13] Ward does not appear to contend that Dr. Schaefer had a separate duty to make disclosures to him that arose independently of the study.

patient relationship for some purposes. By the time of Ward's first visit to the NIH, he had seen Dr. Schaefer about his FLD on a monthly basis for more than two years. (*See* Ward Dep. at 19). And as part of those consultations, Dr. Schaefer put Ward in touch with Drs. Remaley and Shamburek and repeatedly asked them to treat Ward with ACP-501. (*See, e.g.*, Def. Ex. 14; Def. Ex.18; Pl. Ex. 16; Pl. Ex.17).

There is certainly substantial evidence that Dr. Schaefer's role in the study was relatively limited, and that his relationship was more of a referring physician or a consultant than a treating or a research physician. The written protocol approved by the FDA and the NIH's IRB did not list him as a "Medical Monitor," nor did it explicitly name him as Ward's "home physician." (*See* Def. Ex. 19 §§ 1, 3.5). He did not design the study. And he did not administer the treatment, nor was he present when it was administered. *See Halley*, 390 Mass. at 548-49 (declining to find a doctor-patient relationship when a physician acted as a consultant on a procedure and was not the admitting or attending physician).

However, Ward's expert witness, Dr. Sutton, has opined that given Dr. Schaefer's involvement in the protocol and in obtaining Ward's participation in the study, Dr. Schaefer was essentially "acting in the role of principal investigator." (Pl. Ex. 28 at 60); *see Zeman v. Williams*, 2014 WL 3058298, at *3 (D. Mass. July 7, 2014) ("[T]he investigator has a major, if not the major, role in obtaining a properly informed consent."); *see also Darke v. Est. of Isner*, 2005 WL 3729113, at *5 (Mass. Super. Ct. Nov. 22, 2005) (noting that a doctor-patient relationship for informed-consent purposes can arise even if the physician does not physically perform the patient's treatment). As further evidence that Dr. Schaefer was a central figure in the ACP-501 study, Ward points to the fact that Dr. Schaefer had blood draws performed of him at BHD between November 2012 and November 2013, which he contends were done as part of

the study.[14] Dr. Schaefer stated in an interrogatory that Ward presented to BHD "to have his blood drawn after receiving the enzyme replacement ACP-501 at the NIH." (Def. Ex. 32 at No. 12). The forms ordering the labs state "Research" on the top of the form. (*See, e.g.*, Pl. Ex. 51 at 3, 8, 13). Presumably, that suggests that the blood was not drawn in the ordinary course of Dr. Schaefer's care as Ward's regular treating physician. In addition, Dr. Schaefer also sent Dr. Remaley, Dr. Shamburek, and AlphaCore employees e-mails on three separate occasions that appear to include Ward's results from those blood draws. (*See* Pl. Ex. 64 at 1; Pl. Ex. 65 at 1; Pl. Ex. 30).

Under the circumstances, there is a genuine dispute of material fact as to whether Dr. Schaefer played a non-peripheral role in conducting the ACP-501 study, and thus had a duty to obtain Ward's informed consent to participate in the study. *See Harnish*, 387 Mass. at 159. It is undisputed that Dr. Shamburek did, in fact, obtain Ward's signature on an informed-consent form. The question then becomes whether there is sufficient evidence to establish that the consent was not informed.

2. Whether Ward Was Competent to Give Consent

Ward contends that although he signed the informed-consent form, he was not mentally competent to give a knowing and willing consent. Ward is a law-school graduate, although not a practicing attorney, and presumably has a reasonably high level of intelligence and capability. (Ward Dep. at 13-14). He nonetheless contends that because of his medical condition at the time, his cognitive abilities were impaired, and therefore any consent he may have given should be deemed invalid.

Dr. Shamburek testified that he gave Ward the written informed-consent form, explained

[14] Dr. Shamburek testified that any data collected by Dr. Schaefer was not part of the protocol. (Shamburek Dep. at 204-06).

it at some length, and suggested that Ward discuss it with his family before signing it. (Shamburek Dep. at 82-83). Two weeks later, he went over the form with Ward again, and they both then signed it on that same day. (*See id.*; Def. Ex. 20 at 11).[15]

Ward has testified, however, that he did not recognize the form nor recall discussing it with Dr. Shamburek. (Ward Dep. at 99, 105-06). Of course, his failure to remember discussing or signing the form is not sufficient, without more, to establish a lack of consent. *See Benson v. Mass. Gen. Hosp.*, 49 Mass. App. Ct. 530, 532 n.3 (2000) ("To the extent [the plaintiff] cannot remember what happened and has no other admissible evidence relating thereto, his allegation regarding [the defendant hospital's] purported nondisclosure cannot be based on personal knowledge and amounts to speculative averment based upon information and belief insufficient to defeat a well-pleaded summary judgment motion."). A party to a written instrument cannot avoid its terms simply by claiming not to remember ever having signed it.

Ward further contends, however, that he may have been cognitively impaired at the time he executed the form. His expert witness, Dr. Sutton, alleges that he should have been evaluated to see if he had the cognitive ability to give his consent to the study in the first instance. (Pl. Ex. 28 at 60). He notes that Ward suffered from chronic kidney disease before he entered the study and that one of the effects of that disease is cognitive impairment. (*Id.* at 14-15). No provision in the protocol provided for Ward's cognitive ability to be evaluated before or during the study. (*Id.* at 60). Thus, he contends that Ward's ability to provide informed consent to the study was inadequately assessed by his physicians. (*Id.*).

Dr. Sutton does not actually opine that Ward was cognitively impaired, and Ward himself

[15] Ward also apparently signed a "General Admission Consent" form on January 6, 2013. (Def. Ex. 20 at 13). Dr. Schaefer does not contend that form was sufficient to obtain Ward's informed consent to the ACP-501 study. (*See* Def. Reply at 7-8).

simply claims to have no memory. Nonetheless, if Ward should have been evaluated for cognitive impairment and was not, a clear answer to the question of whether he was impaired may not be possible. "Only a competent person may give informed consent for medical care," and thus "where a patient's cognitive impairments call into question her ability to make treatment decisions, medical treatment may not be administered without adequate and judicially supervised protection." *Rudow v. Comm'r of Div. of Med. Assistance*, 429 Mass. 218, 223-24 (1999). Under the circumstances, there is sufficient evidence to establish that Ward may have been unable to provide informed consent to the study. If that was the case, then Dr. Schaefer could be liable based on a lack of informed consent, notwithstanding the fact that Ward executed the NIH consent form.

3. Whether the Informed Consent Form Adequately Described the Risks and Benefits of the Study

Ward further contends that the form itself was inadequate to describe the risks and potential benefits of the study. As noted, the NIH form is eleven pages long, describes the compassionate-use protocol in some detail, and details the "risks and discomforts of [the] study" in fairly straightforward language. (Def. Ex. 20 at 6-7). It also states that several "possible side effects" could result from the ACP-501 treatment, and notes that "there could be side effects that we have not thought about" because "[s]ide effects after multiple doses of ACP-501 are not known" as "this is the first time multiple doses will be given to [a] human[]." (*Id.* at 7-8). It states that the "experimental infusion could contribute to your death." (*Id.* at 8). It also states that the purpose of the study is to determine a safe and tolerable dose of ACP-501 in order to determine "the ability of [the] drug to affect the consequences of FLD." (*Id.* at 2). Finally, it warns that Ward "may not receive any direct benefit from participating" in the study, but that the "information obtained from the study will yield knowledge about the use of ACP-501 for future

subjects." (*Id.* at 8).

As noted, Dr. Shamburek testified that he went over the form with Ward twice. (Shamburek Dep. at 82-83). The information provided to Ward was not limited to that set forth in the form. It is also undisputed that Ward was made aware on other occasions that a principal objective of the study was to conduct research on ACP-501, not necessarily treat his condition. For example, he was provided with drafts of the study protocol on at least two separate occasions. (*See* Pl. Ex. 26; Pl. Ex. 27). The final draft of that document stated that the study's objective was "[t]o assess the safety and tolerability of ACP-501," not to provide medical treatment. (Def. Ex. 19 § 3.3). It also noted that "[*i*]*f* ACP-501 is determined as safe and tolerable and produces a clinically meaningful effect on HDL-C during . . . (Period 1), the subject will be offered continued treatment at the NIH." (*Id.* § 3.5) (emphasis added). Ward participated in a variety of telephone calls and e-mail exchanges concerning the study over a period of many months. And Ward himself told Dr. Roshan that he may be one of the first FLD patients to receive ACP-501 and that "[w]e are all standing in the forefront of medicine." (Def. Ex. 15).

Ward's expert witness, Dr. Sutton, has nonetheless opined that the informed-consent form "was fatally flawed in its construction," and that as a result Ward did not give informed consent to participate in the study. (Pl. Ex. 28 at 57). According to Dr. Sutton, the form "failed on multiple counts to serve the required purpose of human subject protection," such as by offering false promises, making care contingent on research participation, and including "biased language." (*See id.* at 57-60 (enumerating alleged failures)).

Dr. Sutton identifies multiple specific problems with the form.[16] Some of those,

[16] Two of the criticisms—concerning disclosure of potential financial conflicts and performing an assessment of Ward's cognitive abilities—are discussed elsewhere in this opinion.

however, are relatively trivial, or even irrelevant. For example, he contends that the form was given to Ward before being approved by the NIH's IRB. (*Id.* at 57). But even if true, at worst there was a violation of some (unidentified) NIH procedure; it is unclear, to say the least, how that would vitiate Ward's consent. He further states that the form was "ambiguous" concerning Ward's compensation, even though it states fairly directly that Ward will not be paid for taking part in the research and that "[r]eimbursement of travel and subsistence will be offered consistent with NIH guidelines." (*Id.* at 60).

Dr. Sutton also takes issue with the statement in the form that "to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation." (*Id.* at 57). He argues that "[c]are contingent on research participation is not 'care,' it is human subject research." (*Id.*). But that statement simply conveys the obvious fact that the NIH is not an acute-care hospital, but a research facility, and that patients who are not willing to participate in research must obtain their medical care elsewhere. No objectively reasonable reader would interpret that statement to represent a threat that Ward would not receive medical care of any kind from any source unless he consented to participate in the study.

Dr. Sutton also contends that the form offered "[f]alse hope" and contained "biased language," including "misleading and conflicting statements regarding the possibility of stabilizing renal disease, improving renal disease or reversing renal disease, or delaying the need to begin dialysis." (*Id.* at 58). However, the only language in the form that he points to is the statement that "[t]here are no drugs that increase LCAT" and "[b]ecause of this, LCAT has been artificially made so that it can be directly infused into the body, in the hope that it will increase HDL and reverse the corneal opacities, anemia, and protein in the urine and/or kidney dysfunction." (*Id.*). He complains that the reference to kidney dysfunction is "lumped together

with other hopes, and listed at the end," and "there is no qualification of any sort that a reversal of kidney dysfunction was unlikely." (*Id.*). But that complaint amounts to little more than technical wordsmithing. No reasonable person, reading that language, would conclude that the reversal of kidney dysfunction was anything other than a "hope"; put another way, no reasonable person would read "hope" to mean "certainty" or "probability" or "likelihood." Furthermore, that language must be read in light of the context of the entire document, which makes clear that the process is highly experimental, and that the outcome was uncertain at best.[17]

That leaves two other criticisms leveled by Dr. Sutton: an alleged "[f]ailure to obtain a signed [consent form] before beginning study-related procedures" and an alleged "[f]ailure to explain clearly the details of study conduct." (*Id.* at 57-58). As to the former, he contends, in substance, that various study procedures, including blood draws, occurred before consent was given, or at least before the consent form was signed. (*Id.*). As to the latter, he contends that the form does not "explain what is meant by 'home physician,' identify who this is, explain where this part of the [study] will be conducted, and what will be done in this part of the [study]." (*Id.* at 58). He also points to an apparent discrepancy between the study protocol and the informed-consent form, in that the latter did not make clear that Ward was required to meet with his "home physician" every two weeks throughout the study. (*Id.*). As to those criticisms, the evidentiary record appears to be disputed, and it is difficult to assess whether they are substantial or not. In

[17] Similarly, Dr. Sutton contends that there was an "[i]nadequate discussion of treatment alternatives," (Pl. Ex. 28 at 60), even though the document makes clear that FLD is a genetic disease that normally leads to kidney failure and that there are no known drugs that increase LCAT. Indeed, Dr. Sutton does not suggest that there were, in fact, treatment alternatives. He further contends that the consent form made "[f]alse promises" because it stated that "[i]f you have shown benefit with ACP-501 with no safety concerns, you will be offered continued treatment with the drug in an extension study"; according to Dr. Sutton, this statement "was false from the onset, as there was no plan in place that would allow this to occur." (*Id.*). In other words, Dr. Sutton seems to be suggesting that the researchers had no intention of continuing Ward's treatment with ACP-501 *even if the treatment were successful*, because there was no explicit plan in place to permit that to occur. Surely there was nothing unreasonable about leaving such planning to a later stage, once the study was underway and there were results (or a lack of results) to analyze.

other words, the present record does not permit a finding one way or the other that those criticisms are valid, and accordingly summary judgment cannot be granted to Dr. Schaefer as to those issues.

In short, there is certainly a strong argument that the informed-consent form, taken as a whole, described the study as experimental, disclosed the material risks of the procedure, and stated the likelihood that Ward would receive no benefit from participating. Nonetheless, under the circumstances, Ward has succeeded in establishing that there is a genuine dispute of material fact as to whether the form, and the related disclosures made to him from multiple sources, adequately disclosed all information necessary to obtain his informed consent to participate in the ACP-501 study, and whether his consent was given in a timely manner. Summary judgment as to that issue will therefore be denied.

4. Whether the Form Disclosed Financial and Professional Conflicts

Ward further alleges that Dr. Schaefer failed to inform him about various "financial and professional interests and conflicts" of interest related to the study. (Pl. Opp. at 18).

As a general matter, a physician has a duty to disclose information to a patient concerning any financial interest the physician may have in the treatment, if that information would be material to a reasonable person in the patient's position. *See Heinrich v. Sweet*, 308 F.3d 48, 69 (1st Cir. 2002) (applying Massachusetts law and citing to the finding in *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 483 (1990), that "a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment" when discussing a physician's duty to disclose "all significant medical information that the physician possesses") (quotation omitted); *Darke v. Est. of Isner*, 2004 WL 1325635, at *2 (Mass. Super. Ct. June 3, 2004) (finding that a physician has a duty to disclose non-medical information concerning a financial interest in the treatment recommended; "[t]he

touchstone to the inquiry" of what a physician must disclose to a patient is "whether the information is material: if it is information which would be significant to a reasonable person in the patient's position, then the physician has a duty to disclose it"); *see also D.A.B. v. Brown*, 570 N.W.2d 168, 170 (Minn. Ct. App. 1997) (finding that "patients deserve medical opinions about treatment plans and referrals unsullied by conflicting motives"). The *Darke* court found that a physician could be held liable for failing to disclose an ownership interest in the corporation responsible for an experimental treatment he recommended to a patient. *Darke*, 2004 WL 1325635, at *3.[18]

Here, there is an initial question as to whether the obligation to disclose medical information and the obligation to disclose financial information should be treated identically in all respects. As noted, Dr. Schaefer may be held responsible for Dr. Shamburek's failure (if any) to adequately disclose the medical risks and benefits of a procedure, if in fact they are part of the same medical team. And perhaps he could be held responsible for any failure of Dr. Shamburek to reveal potential financial conflicts, if he were aware both (1) that Dr. Shamburek had a material financial conflict and (2) that Dr. Shamburek had failed to disclose that conflict to Ward. But it is unclear why Dr. Schaefer should be held responsible for another physician's failure to disclose financial conflicts of which he was not aware and could not reasonably be expected to know. If there is a public policy reason for such a rule, it is not obvious, and counsel has not cited any case law holding to that effect.

In any event, Ward contends, in substance, that Dr. Schaefer failed to disclose the

[18] That principle is necessarily limited by concepts of reasonableness and materiality, taking into account the many demands and constraints on the medical profession, including the limited time in which physicians normally have available to interact with their patients. Surely, for example, a surgeon need not disclose to every patient that he or she will be paid more if surgery is performed than if it is not. Nonetheless, it is also clear that in some circumstances, such as where the financial interest of the physician would not be reasonably obvious to the patient, disclosure of material financial incentives or interests may be required.

following "financial and professional motives and conflicts of interest": (1) that "Dr. Schaefer's case report [in the Journal of Clinical Lipidology] of [Ward's] diagnosis disclosed NIH research funding"; (2) that AlphaCore entered into a research and development agreement with Dr. Remaley and the NHLBI; (3) that "Dr. Remaley knew that [AlphaCore] intended to be acquired by another company"; (4) that "Dr. Schaefer intended to and attempted co-publication with Drs. Shamburek and Remaley regarding the [p]rotocol"; (5) that MedImmune entered into a clinical research agreement with Dr. Schaefer that resulted in funding to the Cardiovascular Nutrition Laboratory at Tufts, where Dr. Schaefer is a Senior Scientist; and (6) that "Dr. Schaefer attempted co-publication with Drs. Shamburek and Remaley, and co-published with [MedImmune]." (Pl. Mem. at 15). None of those claims, however, are sufficient to sustain a claim for failure to disclose a financial conflict.

First, it is difficult to see how a case report by Dr. Schaefer that *disclosed* the fact—in November 2011, before the study had even begun—that he had NIH research funding could support a claim for *failing to disclose* such funding. Again, Ward was listed as an author of the article in question. (*See* Def. Ex. 5 at 493). But even assuming that the existence of that funding was somehow kept from Ward, it is unclear how it represented a potential conflict of interest for Dr. Schaefer; certainly Ward does not provide an explanation. It is undisputed that Ward knew that scientists from the NIH were involved in the study—Ward traveled to the NIH on multiple occasions to participate in it—and that it involved clinical research. A reasonable person under the circumstances would surely draw the inference that the study was financed at least in part, if not entirely, by the NIH. The fact that Dr. Schaefer also received one or more grants from the NIH to conduct his research is unremarkable, and there is no obvious reason why that posed a material conflict of interest requiring disclosure.

Second, the fact that *Dr. Remaley* had entered into a research agreement with AlphaCore, and allegedly knew that AlphaCore intended to be acquired by another company, is not evidence that *Dr. Schaefer* knew that fact and failed to disclose a potential financial conflict.[19] Again, if there is a case to be made that Dr. Schaefer should be responsible for the acts or omissions of Dr. Remaley, Ward has failed to make it.

Third, the fact that Ward "intended to" or "attempted to" publish one or more articles about the study in a peer-reviewed publication cannot form the basis of a failure to obtain informed consent claim due to inadequate disclosure. It is hardly a secret that most medical researchers hope or intend to publish the results of their work in a medical journal. Indeed, as Ward is aware, Dr. Schaefer has been a contributor to more than 400 such articles. (Ward Dep. at 172-73). The authors of articles in medical journals are not normally compensated for their submissions, and the marginal prestige or renown that may accrue to their benefit by publication is not the type of financial interest that requires disclosure to a patient. Furthermore, and in any event, Dr. Schaefer was not even one of the eight listed authors of the article describing the study; he received only a brief acknowledgement at the end of the article thanking him for "advice and referring the patient." (Def. Ex. 10 at 366). And there is no evidence that any of the data drawn from Ward's blood draws at BHD were used in any publication of any kind.

That leaves the claim that Dr. Schaefer wrongfully failed to disclose the existence of the MedImmune clinical research agreement prior to Ward's participation in the study. The principal problem with that argument is that the agreement in question was not executed until November 2014, and Ward had withdrawn from the study in September 2013, more than a year

[19] Ward cannot credibly claim that the fact Dr. Remaley had entered into a research agreement with AlphaCore was not disclosed to him—Ward was copied on an e-mail sent by Dr. Remaley in which he specifically stated that he and the NIH had a "collaboration with AlphaCore for developing recombinant LCAT as a therapy." (Def Ex. 14 at 1). In addition, the informed-consent form stated that the ACP-501 used in the study was "developed by [AlphaCore] through a joint study with" the NIH researchers. (Def. Ex. 20 at 10).

earlier. (*See* Pl. Ex. 73 at 17 (showing that the research agreement was executed in November 2014)). Ward does not argue, and there is no evidence, that Dr. Schaefer was secretly negotiating with MedImmune during the study, or that somehow the existence or outcome of the study might have affected the nature or scope of that agreement. Indeed, the earliest e-mail exchange presented by Ward involving Dr. Schaefer and Dr. Karathanasis of MedImmune did not occur until October 2013, after Ward had left the study. (*See* Pl. Ex. 67). Moreover, the subject matter of the agreement was to "determine the approximate prevalence of LCAT deficiency in a large population," and thus did not involve the Ward ACP-501 study at all. (Schaefer Dep. Vol. 2 at 245). That evidence is therefore insufficient to sustain a claim for failure to obtain a properly informed consent.

In short, there is insufficient evidence from which a jury could reasonably conclude that Dr. Schaefer failed to disclose financial arrangements or incentives to Ward, prior to his participation in or completion of the study, that would have been material to a reasonable person in Ward's position. Accordingly, summary judgment will be granted in favor of Dr. Schaefer to the extent that the claim of lack of informed consent is based on a theory that he failed to disclose material financial conflicts of interest.

5. Conclusion

In summary, genuine factual disputes exist as to whether Dr. Schaefer had a duty to obtain Ward's informed consent to the ACP-501 study and whether Dr. Shamburek successfully did so, which would discharge Dr. Schaefer's corresponding obligation. Accordingly, Dr. Schaefer's motion for summary judgment will be denied with respect to Count Two, except to the extent that Ward is proceeding on a theory that Dr. Schaefer failed to disclose material financial conflicts of interest.

B. Fraud (Count One)

Count One is a claim for fraud or intentional misrepresentation. Under Massachusetts law, to prove fraud, a plaintiff must show that a defendant "(1) 'made a false representation of material fact'; (2) 'with knowledge of its falsity'; (3) 'for the purpose of inducing the plaintiff[] to act on this representation'; (4) 'that the plaintiff[] reasonably relied on the representation as true'; and (5) 'that [the plaintiff] acted upon it to their damage.'" *AcBel Polytech, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 928 F.3d 110, 122 (1st Cir. 2019) (quoting *Cumis Ins. Soc'y, Inc. v. BJ's Wholesale Club, Inc.*, 455 Mass. 458, 471 (2009)) (emphasis omitted).

Ward has identified four categories of alleged misrepresentations and non-disclosures by Dr. Schaefer. He contends that Dr. Schaefer affirmatively represented (1) that "ACP-501 would effectively reverse [his] advanced kidney disease" and (2) that later batches of ACP-501 "would be produced at a higher dose," which "could either prevent, remove, or reduce the need for dialysis." (Pl. Opp. at 12-13). He also contends that Dr. Schaefer failed to disclose (3) that "the [p]rotocol was for research only and was not therapeutic" and (4) that he had "financial and professional motives and conflicts of interest" related to the protocol. (*Id.* at 14-16).

Dr. Schaefer has moved for summary judgment on the fraud claim. He contends that Ward cannot show (1) that he made any actionable misrepresentations; (2) that Ward reasonably relied on any of those misrepresentations; or (3) that Ward did so to his detriment.

1. Whether Dr. Schaefer Made Any Affirmative Misrepresentations to Ward

First, Ward alleges that Dr. Schaefer affirmatively represented (1) that "ACP-501 would effectively reverse [his] advanced kidney disease" and (2) that later batches of ACP-501 "would be produced at a higher dose," which "could either prevent, remove, or reduce the need for dialysis." (*Id.* at 12-13).

"A statement on which liability for misrepresentation may be based must be one of fact, not of expectation, estimate, opinion, or judgment." *von Schönau-Riedweg v. Rothschild Bank AG*, 95 Mass. App. Ct. 471, 497 (2019) (quoting *Zimmerman v. Kent*, 31 Mass. App. Ct. 72, 79 (1991)). A fact is something "susceptible of knowledge." *Zimmerman*, 31 Mass. App. Ct. at 79. Therefore, "statements of a purely promissory nature, as well as predictions regarding future events, are not actionable as misrepresentations." *Comley v. Media Plan. Grp.*, 108 F. Supp. 3d 6, 15 n.13 (D. Mass. 2015) (citing *Commonwealth v. Drew*, 36 Mass. 179, 185 (1837)); *see also Hallmark Inst. of Photography, Inc. v. CollegeBound Network, LLC*, 518 F. Supp. 2d 328, 332 (D. Mass. 2007) (stating that "[w]here a statement is of a 'fundamentally predictive nature,' a defendant cannot be said to be making a representation regarding any present fact that the plaintiff can then reasonably rely on") (internal quotation omitted). Similarly, "statements of conditions to exist in the future" are not normally actionable. *Nationwide Books Indus., LLC v. A&S Booksellers, Inc.*, 950 F. Supp. 2d 264, 269 (D. Mass. 2013) (internal quotation omitted); *see also Child.'s Hosp. Corp. v. George Washington Univ.*, 750 F. Supp. 2d 239, 251 (D. Mass. 2010) (finding that "mere projection[s] of possible future capacity" and "predictions about an untested, novel technology" that fail to materialize do not constitute fraud).

Under that standard, Dr. Schaefer's representations about ACP-501's therapeutic potential cannot form the basis of a claim for fraud. According to Ward, Dr. Schaefer told him that ACP-501 was "a treatment and a cure to reverse [his] kidney function loss." (Ward Dep. at 30). In support of that assertion, he identifies several specific instances where Dr. Schaefer allegedly made that promise. (*See* Pl. Opp. at 12-14). But it is clear, in context, that all of those statements represent Dr. Schaefer's expectations and predictions about the effect ACP-501 *may* have on Ward.

For example, in Dr. Schaefer's 2011 report concerning Ward's diagnosis, he wrote that the "use of recombinant LCAT *may* be of value in patients who develop significant renal impairment." (Def. Ex. 5 at 498) (emphasis added). He later wrote in an e-mail, copied to Ward, that treatment with ACP-501 was a "very important and *potentially* life-saving therapy for patients with documented [FLD]." (Pl. Ex. 24 at 1) (emphasis added). Similarly, he wrote, in a draft letter to Senator Kerry that he shared with Ward, that therapy with ACP-501 "*should* help prevent [Ward's] kidneys from failing" and avoid the need for dialysis. (*See id.* at 3) (emphasis added). In a June 28, 2013 e-mail, he asked Dr. Remaley if it was possible for Ward to receive more of the enzyme because "otherwise [he] *may* end up on dialysis." (Pl. Ex. 29 at 3) (emphasis added). And in an August 14, 2014 e-mail to Dr. Karathanasis discussing whether Ward should receive the new preparation of ACP-501 that MedImmune was developing, he noted that "[*i*]*f* [Ward] has a great response we may *try to see* if one could improve his kidney disease or have him be dialyzed less frequently." (Pl. Ex. 71 at 2) (emphasis added). All of those statements about ACP-501's effect on Ward's kidney disease are simply "estimate[s] or judgment[s]." *Hallmark Inst. of Photography, Inc.*, 518 F. Supp. 2d at 332 (internal citation omitted); *see also Harris v. Delco Prods., Inc.*, 305 Mass. 362, 365-66 (1940) (finding that the defendant's assurances that "[t]here would be definitely no chance" of a future event occurring "amount[ed] to nothing more than an expression of strong belief" and thus was not a misrepresentation for fraud purposes).[20]

Ward also alleges that Dr. Schaefer made misrepresentations concerning the future availability of ACP-501 and the impact that a lower dose of the enzyme would have on his

[20] Ward also identifies a September 25, 2012 e-mail in which Dr. Schaefer stated that "[t]he therapy of choice is enzyme replacement." (Pl. Ex. 20). But stating that ACP-501 was the "therapy of choice" is not an affirmative representation that the drug would reverse Ward's kidney disease. Thus, that statement can also not serve as the predicate misrepresentation for Ward's fraud claim.

condition. (*See* Pl. Opp. at 13; Pl. Surreply at 5). He testified that Drs. Schaefer, Remaley, and Shamburek all told him while he was participating in the study that more of the enzyme was to be produced in the fall of 2013, and that if he dropped out of the study he would lose his "rights to the new batch" of the enzyme. (Ward Dep. at 47-48). In a June 28, 2013 e-mail to Dr. Remaley, copied to Ward, Dr. Schaefer wrote, "[p]ease let me know when you can send me the protocol so that we can submit for approval and begin treating [Ward] here in Boston once new enzyme becomes available after October 1, 2013." (Pl. Ex. 29 at 1). But a statement that more of the enzyme would be available in the fall of 2013 is a "statement[] of conditions to exist in the future," and is not actionable as a fraudulent misrepresentation. *A&S Booksellers, Inc.*, 950 F. Supp. 2d at 269 (internal citation omitted).

Ward's claims based on representations about how effective a lower dose of ACP-501 would be in treating his kidney disease likewise cannot form the basis of a fraud claim. On August 20, 2013, Dr. Schaefer wrote in an e-mail to Dr. Shamburek, copied to Ward: "[m]y understanding is that the patient will continue therapy at the lower dose every two weeks until the enzyme runs out, and that as soon as new enzyme became available he would be a candidate for the enzyme *in order to see if* we can get him off dialysis." (Pl. Ex. 30 at 1) (emphasis added). Again, that statement is a "prediction[] regarding future events," not a fact, and therefore cannot support a fraud claim. *Comley*, 108 F. Supp. 3d at 15 n.13.

It is true that predictive statements can constitute fraud under some relatively narrow circumstances. *See, e.g.*, *Glassman v. Computervision Corp.*, 90 F.3d 617, 627 (1st Cir. 1996) (noting that a prediction may be actionable if it is "not reasonably based on, or [is] inconsistent with, the facts at the time the forecast is made"). Ward points out that Dr. Schaefer testified that "it was unlikely that" using ACP-501 "would reverse [Ward's] disease, but it might stabilize it."

(Schaefer Dep. Vol. 1 at 69-70). But the exception is not applicable where, as here, the defendant "simply could not have known when it made its prediction" what the outcome would actually be. *Hallmark Inst. of Photography, Inc.*, 518 F. Supp. 2d at 332. As Ward was made aware, ACP-501 had never been used to treat patients with FLD, and thus all that Dr. Schaefer could do was predict what its effect would be. In an e-mail to Drs. Schaefer, Roshan, and Remaley, Ward himself acknowledged that due to the "extreme rarity" of his disease, "*nobody* is exactly sure what metabolic pathways are going on inside the kidney and whether [ACP-501] can reverse or alleviate the renal insufficiency." (Def. Ex. 18). Nor has Ward identified any evidence that Dr. Schaefer's prediction that more of the enzyme was going to be produced in the fall of 2013 was "not reasonably based on" the facts at the time he made that representation. *See Glassman*, 90 F.3d at 627. Accordingly, the statements do not fall within the exception to the general rule that estimations and projections cannot be actionable as fraud.

In short, because Dr. Schaefer's statements concerning the ability of ACP-501 to reverse Ward's kidney disease and the future availability and effectiveness of the enzyme at different doses were not statements of fact, they cannot form the basis of a claim for fraud.

2. Whether Dr. Schaefer Omitted Materially Relevant Facts

Ward also contends that Dr. Schaefer committed fraud by omitting materially relevant facts that he had a duty to disclose. Specifically, he alleges that Dr. Schaefer failed to disclose (1) that "the [p]rotocol was for research only and was not therapeutic" and (2) that he had "financial and professional motives and conflicts of interest" related to the protocol. (Pl. Opp. at 14-16).

"It is well-settled law in Massachusetts that there is no liability for bare nondisclosure." *Hopkinton Friendly Serv., Inc. v. Global Cos. LLC*, 384 F. Supp. 3d 179, 191 (D. Mass. 2019) (citing *Swinton v. Whitinsville Sav. Bank*, 311 Mass. 677, 679 (1942)). Thus, a fraud claim that

is predicated on alleged omissions can succeed only if there is evidence of "both concealment of material information and a duty requiring disclosure." *Sahin v. Sahin*, 435 Mass. 396, 402 n.9 (2001). Here, the parties dispute whether Dr. Schaefer had such a duty as Ward's physician.[21]

"Massachusetts courts generally rely on the Restatement (Second) of Torts § 551 to determine the circumstances giving rise to a duty to disclose." *Smith v. Zipcar, Inc.*, 125 F. Supp. 3d 340, 344-45 (D. Mass. 2015) (citing *Nota Constr. Corp. v. Keyes Assocs., Inc.*, 45 Mass. App. Ct. 15, 19 (1998)). One such circumstance is "a fiduciary or other similar relation of trust and confidence" between the parties. *Taylor v. Am. Chemistry Council*, 576 F.3d 16, 31 (1st Cir. 2009) (citing *Knapp v. Neptune Towers Assocs.*, 72 Mass. App. Ct. 502, 507 (2008)); *see also* Restatement (Second) of Torts § 551(2)(a). One of those "other relations of trust and confidence" is that of a physician and patient. *See* Restatement (Second) of Torts § 551 cmt. f.

"The [Massachusetts] Supreme Judicial Court has recognized that the doctor-patient relationship has fiduciary aspects." *Bourassa v. LaFortune*, 711 F. Supp. 43, 46 (D. Mass. 1989) (citing *Warsofsky v. Sherman*, 326 Mass. 290, 292 (1950)). In *Chace v. Curran*, 71 Mass. App. Ct. 258 (2008), patients alleged that their physicians failed to disclose certain material facts for the purpose of hiding the mistakes they made while treating them, and thus to conceal a potential cause of action from them. *Id.* at 267. The court found that the plaintiffs' claim "sound[s] in fraud and allege[s] the existence of a fiduciary relationship that gave rise to a duty on the defendants' part to disclose adequately to the plaintiffs facts that would give rise to knowledge of a cause of action for substandard care," and therefore it was "viable." *Id.* at 263-64.[22]

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[21] Both parties correctly point out that "a party who discloses partial information that may be misleading has a duty to reveal all the material facts he knows to avoid deceiving the other party." *V.S.H. Realty, Inc. v. Texaco, Inc.*, 757 F.2d 411, 414 (1st Cir. 1985); (*see* Def. Mem. at 4; Pl. Opp. at 11). It is unclear whether Ward contends that such a duty existed here. (*See* Pl. Opp. at 14-16). Because the Court finds that Dr. Schaefer had a duty to disclose material information about the study to Ward, it does not reach that issue.

[22] A similar approach has been adopted in other jurisdictions. For example, in *Lujan v. Mansmann*, 956 F.

Accordingly, because Dr. Schaefer and Ward had a physician-patient relationship, Dr. Schaefer had a duty to disclose information to him about his treatment, if that information would be material to a reasonable person in Ward's position. Any material omission of such information could serve as the predicate misrepresentation for a claim of fraud. *See Sahin*, 435 Mass. at 402 n.9.

a. Whether the Protocol Was for Research Purposes Only

Ward alleges that Dr. Schaefer failed to disclose that "the [p]rotocol was for research only and was not therapeutic." (Pl. Opp. at 14 ("Dr. Schaefer knew that it was unlikely [Ward's] kidney disease would be reversed by recombinant LCAT and that it was therefore unlikely to be therapeutic for [Ward].")). He thus contends that Dr. Schaefer did not provide him with all of the relevant medical information before he agreed to enroll and remain in the protocol.

The alleged facts underlying that claim are essentially the same as those underlying the claim that Dr. Schaefer failed to obtain Ward's informed consent to participate in the study, which is the basis of Count 2. In other words, Ward claims that Dr. Schaefer failed to provide sufficient information concerning the potential risks and benefits of the study before he gave his consent. To sustain a fraud claim, of course, Ward must show more than simply that Dr. Schaefer did not properly obtain his informed consent. *See AcBel Polytech, Inc.*, 928 F.3d at 122. Among other things, fraud requires an intentional act or omission, not mere negligence. *Id.* But assuming Ward can prove the other elements of fraud, there is sufficient evidence in the record to establish a dispute of material fact as to whether Dr. Schaefer provided Ward with

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Supp. 1218 (E.D. Pa. 1997), a patient alleged that her therapist failed to tell her the entirety of what her therapy entailed. *Id.* at 1229. The court found that "[b]ecause the relationship involved matters known to [d]efendants that [the plaintiff] was entitled to know because of a fiduciary relation of trust and confidence between her and [d]efendants, allegations of 'omissions' will support [the plaintiff's] claim for fraudulent misrepresentation." *Id.*; *see also Lynch v. Waters*, 256 Ga. 389, 390 (1986) (finding that "[t]he physician-patient relationship is a confidential one and silence or failure to disclose what should be said or disclosed can amount to fraud").

sufficient information concerning the study before Ward consented to participate.

There is, to be sure, considerable evidence that Ward was not told that ACP-501 would reverse his condition and that he was not misled as to the certainty of any therapeutic benefit. And he even expressly acknowledged that it was difficult to predict what effect ACP-501 would have on his kidneys. (*See, e.g.*, Def. Ex. 18 at 1). There is also a substantial question as to whether a reasonable person would believe with any degree of certainty that this experimental process would cure his severe medical condition. But the Court cannot make a credibility determination at this stage of the proceeding.

Accordingly, there is a genuine issue of fact as to whether Dr. Schaefer omitted any material facts as to the therapeutic benefits of ACP-501 in his discussions with Ward.

b. Whether Dr. Schaefer Had Financial and Professional Motives Related to the Protocol

Ward further alleges that Dr. Schaefer failed to inform him about various "financial and professional motives and conflicts of interest" related to the protocol. (Pl. Opp. at 15). Again, the basis of the fraud claim in that respect is essentially identical to the basis for the claim for lack of informed consent. For the reasons outlined above, there is insufficient evidence that Dr. Schaefer had material financial and professional conflicts that he failed to disclose, and therefore summary judgment will be granted on the claim of fraud to the extent it is based upon that theory.

3. Whether Ward Reasonably Relied on Any Omissions

Dr. Schaefer next contends that Ward cannot show that he reasonably relied on any alleged misrepresentation.

As described above, there is substantial evidence that Ward was made aware that the protocol he participated in was a research study. (*See, e.g.*, Def. Ex. 18 at 1). Accordingly, a

jury could conclude that Ward did not reasonably rely on any omission by Dr. Schaefer concerning the nature of the study, and whether it would be therapeutic for him.

But a jury could also find that Ward could reasonably have relied on the assumption that Dr. Schaefer was providing him with all of the relevant medical information about the study. Ward considered Dr. Schaefer to be "the world's foremost expert" on FLD and the "top man in the field." (Ward Dep. at 46, 172-73). He testified that he relied on Dr. Schaefer when making several decisions, such as when to start hemodialysis and whether to withdraw from the ACP-501 study. (*Id.* at 45-46, 60).

Accordingly, genuine issues of fact also exist with respect to the reasonable reliance element of the fraud claim.

4. Whether Ward Relied on Any Omissions to His Detriment

Finally, Dr. Schaefer contends that "[t]here is absolutely no evidence in the record that [Ward] suffered any detriment as a result of the alleged misrepresentations." (Def. Mem. at 8). He contends that there is no evidence that Ward's "participation in the [p]rotocol delayed the beginning of dialysis, reduced his life expectancy, or changed his outcome in any way." (*See id.*).

To be sure, it is very doubtful whether all of the harm Ward has allegedly suffered was caused by his participation in the ACP-501 study. It is undisputed that he had an episode of atrial fibrillation during the study. (Def. Ex. 22 at 2). But according to the 2016 article about Ward's treatment that was published by Dr. Shamburek and others, that episode was "not attributed to ACP-501." (Def. Ex. 10 at 357). Although Ward disputes whether Dr. Shamburek properly classified the atrial fibrillation as "not attributed" to ACP-501 based on the terms of the approved study protocol, he does not offer any expert testimony to that effect. (*See* Pl. Resp. to Def. SMF ¶ 59).

Similarly, it is also unclear whether Ward's participation in the study has harmed him by affecting his dialysis treatments. There is evidence that it may have delayed his starting dialysis. For example, the 2016 article states in a supplemental appendix that his "[h]emodialysis was delayed pending the trial of rhLCAT." (Pl. Ex. 50 at 2; *see also* Def. Ex. 28 at 1 (noting that Ward was "hesitant" to start dialysis because he believed it would "render him ineligible for" the study). But even assuming that is true, it is not entirely clear—at least on the present record—whether that delay harmed him or negatively impacted his course of treatment. Again, he does not offer any expert testimony to that effect.

Nevertheless, there is at least some evidence in the record that Ward suffered some harm as a result of his participation in the ACP-501 study. Ward has testified that he was subjected to 731 venipunctures as a result of the study. (*See* Ward Dep. at 51). And he has testified that due to the study, his blood clotted, which caused "very painful" blood draws. (*Id.* at 37). Dr. Schaefer himself acknowledged that Ward had "more and more problems with his veins because of all the venipunctures he had been subjected to at the NIH." (Pl. Ex. 38 at 4). Based on that evidence, at the very least, a jury could reasonably find that Ward has suffered a detriment because of his participation in the ACP-501 study.

In summary, several genuine issues of material fact preclude summary judgment on at least a portion of Ward's fraud claim. Those include whether Dr. Schaefer omitted material information as to the nature of the study, whether Ward reasonably relied on any such omission, and whether he did so to his detriment. Accordingly, Dr. Schaefer's motion for summary judgment on Count One will be denied as to that portion of the fraud claim that is based on a failure to disclose the nature of the study.

C. Unjust Enrichment (Count Three)

Count Three alleges a claim for unjust enrichment. Massachusetts law defines unjust

enrichment as the "retention of money or property of another against the fundamental principles of justice or equity and good conscience." *Santagate v. Tower*, 64 Mass. App. Ct. 324, 329 (2005). To succeed on a claim for unjust enrichment, a plaintiff must show (1) a benefit conferred upon the defendant by the plaintiff; (2) an appreciation or knowledge by the defendant of the benefit; and (3) that acceptance or retention of the benefit under the circumstances would be inequitable without payment for its value. *Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 552 F.3d 47, 57 (1st Cir. 2009). Here, plaintiff cannot establish the first element—that is, Ward cannot show that he conferred a benefit upon Dr. Schaefer.

Ward contends that there are multiple ways in which his participation in the study benefitted Dr. Schaefer, which largely track his claim for failure to disclose alleged financial and professional conflicts of interest. Specifically, he alleges that he conferred a benefit on Dr. Schaefer from his involvement in the study when (1) Dr. Schaefer published his 2011 article in the Journal of Clinical Lipidology on his diagnosis; (2) Dr. Schaefer received professional recognition from the article published on the study's results; (3) BHD and MedImmune entered into a clinical research agreement; (4) Dr. Schaefer published an article on that research agreement's results, which may have included Ward's data from blood draws performed at BHD between 2012 and 2013; (5) Dr. Schaefer utilized Ward's biochemical diagnosis when trying to justify the medical necessity of the HDL Map, a genetic test that generates significant income for BHD, to insurers; and (6) BHD paid Dr. Schaefer a higher salary that was based in part on Dr. Schaefer's research activities, including those that involved Ward. (Pl. Opp. at 22-24; Pl. Surreply at 8-9).

To start, any benefit that Ward may have conferred on Dr. Schaefer when Dr. Schaefer co-authored the 2011 article could not have resulted from Ward's participation in the ACP-501

study—the study was not approved until 2012 and did not begin until 2013. (Shamburek Dep. at 67; Def. Ex. 22 at 2).

Ward also contends that he conferred a benefit on Dr. Schaefer in the form of professional recognition when the article published on the ACP-501 study thanked Dr. Schaefer for "advice and referring the patient." (Def. Ex. 10 at 366). "A 'benefit' for purposes of an unjust enrichment claim is any form of advantage that has a measurable value." *Kerr v. Vince*, 2010 WL 1416511, at *19 (D. Mass. Apr. 1, 2010) (quoting *Mass. Eye & Ear Infirmary*, 552 F.3d at 59). Similarly, "[r]estitution is concerned with the receipt of benefits that yield a measurable increase in the recipient's wealth." Restatement (Third) of Restitution and Unjust Enrichment § 1 cmt. d (Am. L. Inst. 2011). There is no evidence in the record that the "thank you" Dr. Schaefer received in the article measurably increased his wealth or provided him with any kind of measurable advantage. Therefore, it cannot serve as the requisite "benefit conferred" for a claim of unjust enrichment.

Ward next points to the clinical research agreement between BHD and MedImmune that resulted in funding to the laboratory at Tufts where Dr. Schaefer is a Senior Scientist, and to the article on the study's results co-authored by Dr. Schaefer. It is far from clear whether a benefit to Dr. Schaefer's place of employment constituted a benefit to Dr. Schaefer personally. But even assuming that it did, there is sufficient evidence that the research agreement was sufficiently unrelated to Ward's participation in the ACP-501 study such that any benefit it conferred on Dr. Schaefer could not be attributed to Ward.

Dr. Schaefer testified that the research agreement was created to "determine the approximate prevalence of LCAT deficiency in a large population." (Schaefer's Dep. Vol. 2 at 245). The agreement proposal itself notes that its purpose is to screen patients whose blood

samples were sent to BHD with a certain HDL value for the presence of LCAT deficiency. (Pl. Ex. 73 at 18). No supplemental work was done with Ward or with any of his data as part of the agreement. (Schaefer's Dep. Vol. 2 at 249).

Ward, however, contends that Dr. Schaefer initially only spoke with the MedImmune representative who became the principal contact under the agreement, Dr. Sotirios Karathanasis, to discuss further treating him after he withdrew from the study. (Pl. Mem. at 23; Pl. Resp. to Def. SMF ¶ 82). But in the earliest email exchange presented by Ward involving Dr. Karathanasis, Dr. Schaefer writes that he spoke with him not only about Ward, but also about the number of people in the general population who suffered from LCAT deficiency based on the blood samples received at BHD—the focus of the resulting agreement. (Pl. Ex. 67 at 2). Thus, the agreement cannot constitute the basis of Ward's unjust enrichment claim because it did not result from Ward's participation in the ACP-501 study.

Furthermore, while Ward alleges that data from his blood drawn between 2012 and 2013 at BHD was included in the 2018 publication on the agreement's results, there is no evidence of that in the record. (Pl. Resp. to Def. SMF ¶ 77). Dr. Schaefer testified that the only data of Ward's that was included in the 2018 article was the same data published in the 2011 article on Ward's diagnosis. (Schaefer's Dep. Vol. 2 at 318-19). That data was procured by Dr. Schaefer before Ward's participation in the ACP-501 study. Dr. Schaefer further testified that he did not save any of the samples from the BHD blood draws. (*Id.* at 319). Ward has not identified any evidence that his data from those blood draws was used by Dr. Schaefer in any publication, including the 2018 article. (Pl. Resp. to Def. SMF ¶ 77). Therefore, neither that article nor Ward's data in general from the 2012-2013 BHD blood draws constitute benefits conferred by

Ward on Dr. Schaefer from his participation in the ACP-501 study.[23]

Similarly, the HDL Map cannot form the basis of an unjust enrichment claim. The parties dispute whether the HDL Map can "diagnose" LCAT deficiency. (Def. SMF ¶ 90; Pl. Resp. to Def. SMF ¶ 90). Regardless, it was developed by BHD and has been used by BHD since at least 2007, before Dr. Schaefer even met Ward. (Schaefer Dep. Vol. 2 at 308). Even if Ward's allegation that it generates income for BHD is true, Ward was not involved in its development and therefore cannot have conferred that "benefit" upon Dr. Schaefer. Similarly, even if Dr. Schaefer used the HDL Map's biochemical diagnosis of Ward's LCAT deficiency as an example of the Map's utility in order to justify its medical necessity to insurers, that biochemical diagnosis happened in 2010, when Ward first met Dr. Schaefer. (Def. Ex. 14). It was thus unrelated to Ward's participation in the ACP-501 study.

Finally, Ward alleges that he conferred a benefit on Dr. Schaefer in the form of a higher salary from BHD. (Pl. Opp. at 23-24; Pl. Surreply at 8-9). He contends that Dr. Schaefer's salary took into account research activities, including those that involved him.[24] But even assuming that fact is true, Ward has not shown how his participation in the ACP-501 study affected those research activities of Dr. Schaefer.

Ward identifies (1) Dr. Schaefer's work with the HDL Map and (2) the BHD-MedImmune research agreement and its resulting publication as activities that were considered as part of Dr. Schaefer's salary determination. (Pl. Opp. at 24). But as previously noted, any

[23] For these purposes, the Court need not determine whether the blood draws were done as part of the ACP-501 study protocol.

[24] As Ward points out, Dr. Schaefer has not identified evidence showing that his salary was completely unrelated to his research activities. (*See* Def. SMF ¶ 7; Schaefer Dep. Vol. 1 at 26, 195). In fact, in Dr. Schaefer's 2017 Annual Performance Planning Review Form, he included in the "annual objectives for past review year" section: "[t]o carry out research and to publish on the value of our proprietary testing . . . (done and completed)." (Pl. Ex. 75 at 4). Notably, it is not explicitly stated in that form (or elsewhere) that Dr. Schaefer's self-evaluation was a factor in BHD's determination of his salary.

utilization of Ward's data by the HDL Map occurred in 2010, before the ACP-501 study. (Def. Ex. 14). And again, the research agreement between BHD and MedImmune did not result from Ward's participation in the ACP-501 study, nor was Ward's data from his time as a study participant included in the agreement's resulting publication. Therefore, even if Dr. Schaefer's salary was based on his research activities, Ward has not identified how those activities can be attributed to his involvement in the ACP-501 study.

In summary, Ward has not shown how his participation in the ACP-501 study conferred a cognizable benefit on Dr. Schaefer. Accordingly, the motion for summary judgment as to Count Three will be granted.

D. Due Process (Count Four)

Count Four alleges violations of Ward's due process rights as set forth in the Nuremburg Code, the Massachusetts Declaration of Rights, and the United States Constitution.

As a preliminary matter, there is no private right of action for violations of the Nuremberg Code. *Heinrich ex rel. Heinrich v. Sweet*, 49 F. Supp. 2d 27, 42 (D. Mass. 1999); *Robertson ex rel. Robertson v. McGee*, 2002 WL 535045, at *3 (N.D. Okla. Jan. 28, 2002) (collecting cases). Ward concedes this. (Pl. Opp. at 25 n.9). Thus, Dr. Schaefer is entitled to summary judgment on Count Four to the extent that it alleges violations of the Nuremberg Code.

Similarly, the Massachusetts Declaration of Rights does not provide a private right of action. The Massachusetts Supreme Judicial Court has "never held" that such a right exists. *See Pimentel v. City of Methuen*, 323 F. Supp. 3d 255, 273 (D. Mass. 2018). "It did suggest, 35 years ago, in dicta, that such a right 'may' be available." *Id.* (citing *Phillips v. Youth Dev. Program, Inc.*, 390 Mass. 652, 657-58 (1983)); *see also Layne v. Superintendent, Mass. Corr. Inst., Cedar Junction*, 406 Mass. 156, 159-60 (1989). But in the time since, no Massachusetts appellate court has ever held that such a right exists—at least in suits for money damages such as this one. *See,*

e.g., *Doe v. Sex Offender Registry Bd.*, 94 Mass. App. Ct. 52, 64 (2018) (recognizing a private right of action for injunctive relief but "declin[ing] to recognize one" for claims for money damages); *Rodriguez v. Bos. Pub. Schs.*, 2019 WL 3409982, at *6 (D. Mass. July 29, 2019). Whether to recognize such a right of action is a decision that "is up to the courts of Massachusetts, not this Court." *Pimentel*, 323 F. Supp. 3d at 274. Accordingly, the motion for summary judgment as to Count Four will be granted to the extent that the claims are based on alleged violations of the Massachusetts Declaration of Rights.

That leaves Ward's claims under the United States Constitution. He alleges that Dr. Schaefer violated his constitutional due-process right to be free from the "unlawful deprivation of his liberty interest, his right to bodily integrity, and the freedom to care for one's health and person" by enrolling him in the ACP-501 study. (Compl. ¶ 90). He further contends that Dr. Schaefer's conduct was "intentional, extreme, outrageous, and shocks the conscience." (*Id.* ¶ 92).

The Constitution, however, prohibits only actions by local, state, or federal government actors, and "erects no shield against merely private conduct." *Shelley v. Kraemer*, 344 U.S. 1, 13 (1948). For Ward to recover monetary damages for a constitutional violation, he must assert a claim under either 42 U.S.C. § 1983 or against a government actor. *See Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388, 397 (1971).

Section 1983 claims can be brought only against defendants acting "under [the] color of" state or local law. 42 U.S.C. § 1983. Ward does not allege that Dr. Schaefer was so acting—rather, he contends that Dr. Schaefer is a government actor due to his interactions with the NIH, a *federal* government agency. (Pl. Opp. at 25-26). Federal officials are not liable under section 1983. *See Wheeldin v. Wheeler*, 373 U.S. 647, 650 (1963); *McCloskey v. Mueller*, 385 F. Supp.

2d 74, 86 (D. Mass. 2005) ("It is well-established that a [s]ection 1983 action cannot lie against federal officers acting under color of federal law.").

Nor can Ward's claim be sustained as a *Bivens* action. *Bivens* provides monetary damages to a plaintiff for certain constitutional violations by federal officials. Only federal government actors are liable under *Bivens*. *Bivens*, 403 U.S. at 397. At all relevant times, Dr. Schaefer has been a private citizen, employed by Tufts University and BHD. (*See* Pl. Ex. 2 at 2-3; Schaefer Dep. Vol. 1 at 23, 26). He has not been an employee, contractor, member, or held a panel position at the NIH during that time period. (*See* Pl. Ex. 2).

Ward, however, contends that Dr. Schaefer was *acting* as a federal official due to his contacts with the NIH. (Pl. Opp. at 25-26). But even that were true—which is highly doubtful—that would not be sufficient. Under section 1983, a private person acting "under [the] color of" state law may be considered a state official and a proper party to sue. But there is no analogue for claims brought under *Bivens*. In *Minneci v. Pollard*, 565 U.S. 118 (2012), the Supreme Court declined to extend *Bivens* to claims against employees of a privately-operated federal prison due to the adequacy of state-law remedies. *Id.* at 120; *see also Fletcher v. R.I. Hosp. Tr. Nat'l Bank*, 496 F.2d 927, 932 n.8 (1st Cir. 1974) ("[T]here is no cause of action against private parties acting under color of federal law or custom."); *Acosta v. U.S. Marshals Serv.*, 445 F.3d 509, 514 (1st Cir. 2006) (affirming dismissal of a *Bivens* action against a doctor who treated a plaintiff in federal custody because he was a private party); *Cabi v. Bos. Child.'s Hosp.*, 161 F. Supp. 3d 136, 148 (D. Mass. 2016) (dismissing plaintiffs' claims against doctors who worked for a private hospital because "*Bivens* is unavailable against private actors"); *Holz v. Terre Haute Reg'l Hosp.*, 123 F. App'x 712, 713 (7th Cir. 2005) ("A *Bivens* claim cannot be brought against a private . . . individual . . . ."); *O'Neil v. Anderson*, 372 F. App'x 400, 404 (4th Cir. 2010) (finding

no liability under *Bivens* for a private individual). *But see Kulkarni v. Upasani*, 659 F. App'x 937, 940-41 (9th Cir. 2016) (implying that a *Bivens* action may be brought against private individuals when there is a sufficient link between the individual and the government). Thus, because Dr. Schaefer was not a government official, he cannot be liable for money damages for his alleged violation of Ward's constitutional rights under a *Bivens* action.

Indeed, even assuming that Dr. Schaefer could be considered a federal officer due to his relationship with the NIH, and thus could be liable under *Bivens*, Ward's claim would still fail. The Supreme Court has only endorsed a damages remedy for constitutional violations by federal officers in three circumstances: (1) violations under the Fourth Amendment; (2) violations of the Fifth Amendment Due Process Clause right to equal protection of the laws; and (3) violations of the Eighth Amendment right to be free from cruel and unusual punishment. *See Bivens*, 403 U.S. at 397; *Davis v. Passman*, 442 U.S. 228, 248-49 (1979); *Carlson v. Green*, 446 U.S. 14, 16-18 (1980). Ward's claims do not fall within any of those categories. *See Ziglar v. Abbasi*, 137 S. Ct. 1843, 1864 (2017) (noting that a case can present a new context for *Bivens* purposes "if it implicates a different constitutional right"). And "expanding the *Bivens* remedy is now a 'disfavored' judicial activity." *Id.* at 1857 (internal citation omitted); *see also González v. Vélez*, 864 F.3d 45, 52 (1st Cir. 2017).

Accordingly, the motion for summary judgment as to Count Four will be granted to the extent Ward's claims are based on alleged violations of the U.S. Constitution.

E. Massachusetts Civil Rights Act (Count Five)

Count Five alleges a violation of the Massachusetts Civil Rights Act ("MCRA"), which provides a right of action to any person whose exercise or enjoyment of rights secured by the federal or state constitution or laws has been interfered with by "threats, intimidation or coercion." Mass. Gen. Laws ch. 12, §§ 11H & 11I. Under Massachusetts law, a "threat" means

"the intentional exertion of pressure to make another fearful or apprehensive of injury or harm"; "intimidation" means "putting in fear for the purpose of compelling or deterring conduct"; and "coercion" means "the application to another of such force, either physical or moral, as to constrain him to do against his will something he would not otherwise have done." *Planned Parenthood League of Mass., Inc. v. Blake*, 417 Mass. 467, 474 (1994) (quotation omitted). On its face, the MCRA contemplates a two-part sequence: "(1) the defendant threatens, intimidates, or coerces the plaintiff, in order to (2) cause the plaintiff to give up something that she has the constitutional right to do." *See Thomas v. Harrington*, 909 F.3d 483, 492 (1st Cir. 2018) (quoting *Goddard v. Kelley*, 629 F. Supp. 2d 115, 128 (D. Mass. 2009)).

"The question of whether coercion, threats, or intimidation has occurred is based on an objective 'reasonable person' standard, rather than on whether the plaintiff themselves felt coerced, threatened, or intimidated." *Doe ex rel. Doe v. Cavanaugh*, 437 F. Supp. 3d 111, 118 (D. Mass. 2020) (quoting *Meuser v. Fed. Express Corp.*, 564 F.3d 507, 521 (1st Cir. 2009)). "Furthermore, the alleged threat, intimidation or coercion must be aimed at a particular individual or group of individuals and the harm involved must be sufficiently serious." *Kappa Alpha Theta Fraternity, Inc. v. Harvard Univ.*, 397 F. Supp. 3d 97, 107 (D. Mass. 2019).

Ward contends that Dr. Schaefer violated his "constitutional right to bodily integrity" by coercing him to submit to the ACP-501 study. (Pl. Opp. at 27). The parties disagree as to what conduct constitutes "coercion." Dr. Schaefer alleges that only situations that involve an "actual or potential physical confrontation accompanied by a threat or harm" are actionable, and that there is no evidence of such coercion. (Def. Mem. at 17). Ward, on the other hand, contends that coercion can consist of a physician committing "boundary violations" with a patient, which he alleges happened here. (Pl. Opp. at 27-28 ("By crossing boundaries from separate reasonable

and appropriate professional conduct to unacceptable personal relations, Dr. Schaefer was able to exert control and a moral force on [Ward] . . . .")).

The record contains no evidence that Dr. Schaefer verbally threatened or intimidated Ward. (Def. Ex. 21 ("Second Ward Dep.") at 73-74). It is also devoid of any evidence that Dr. Schaefer physically threatened or attempted to force Ward to participate in the ACP-501 study. (Second Ward Dep. at 74). To the contrary, there is evidence that Ward himself actively took steps to ensure the study, and his participation in, it would be approved. (*See id.* at 66-67; Def. Ex. 16).

Ward's claim thus rests on the contention that Dr. Schaefer coerced him into participating in the study by violating "professional boundaries" with him. A physician must maintain a professional objectivity and distance from his patients and avoid unacceptable personal relations with them, and failing to do so may constitute misconduct in the practice of medicine. *Bd. of Registration in Med. v. Julian Abbey*, RM-06-962 (Mass. Dep't Admin. L. Appeals Mar. 7, 2008). Ward alleges that Dr. Schaefer overstepped professional boundaries by (1) naming him a co-author on the 2011 article reporting his diagnosis that he alleges he did not actually co-write; (2) paying him a monthly fee for, among other things, helping to publish a manuscript on corneal opacification; (3) appointing him the director of the Dyslipidemia Foundation, for which Dr. Schaefer served as a medical consultant and BHD served as the sponsor; and (4) inviting him to his home for events. (Pl. Opp. at 27-28). Allegedly, these led to a personal relationship with Ward in which Dr. Schaefer could "exert control and a moral force" over him. (*Id.* at 28). According to Ward, Dr. Schaefer's advising Ward to enroll and remain in the ACP-501 study allegedly constituted coercion due to their inappropriate relationship. (*Id.*).

It is true that coercion under the MCRA encompasses more than physical threats—it also

includes moral or economic coercion. *Kennie v. Nat. Res. Dep't of Dennis*, 451 Mass. 754, 763 (2008). However, "[i]t is rare for a MCRA claim to involve no physical threat of harm." *Thomas*, 909 F.3d at 492. Furthermore, "the exception for claims based on non-physical coercion remains a narrow one." *Id.* at 492-93 (quoting *Nolan v. CN8*, 656 F.3d 71, 78 (1st Cir. 2011)). "Massachusetts courts have required 'a pattern of harassment and intimidation' to support a finding of non-physical coercion under the MCRA." *Thomas*, 909 F.3d at 493 (quoting *Howcroft v. City of Peabody*, 51 Mass. App. Ct. 573, 594 (2001)).

This record here does not support such a finding. Ward has not identified any "pattern of harassment and intimidation" by Dr. Schaefer necessary to support his claim of non-physical coercion. *Thomas*, 909 F.3d at 493. Moreover, Dr. Schaefer did not pay Ward a monthly fee or appoint him the director of the Dyslipidemia Foundation until *after* he ended his participation in the study. (Ward Dep. at 64-65; Pl. Ex. 39 at 2). That conduct could not, therefore, have contributed to Dr. Schaefer coercing Ward to *enter* the study. Furthermore, no Massachusetts appellate court has endorsed Ward's theory that "boundary violations" by a physician, without more, can constitute moral coercion under the MCRA.

Accordingly, there is insufficient evidence of coercion by Dr. Schaefer to satisfy the definition of the MCRA as it has been interpreted by Massachusetts courts. The motion for summary judgment as to Count Five will therefore be granted.

F. Civil Conspiracy (Count Six)

Count Six alleges a claim for civil conspiracy. "To establish a civil conspiracy, a plaintiff must demonstrate that 'a combination of persons [acted] pursuant to an agreement to injure the plaintiff.'" *Gutierrez v. Mass. Bay Transp. Auth.*, 437 Mass. 396, 415 (2002) (quoting J.R. Nolan & L.J. Sartorio, Tort Law § 99, at 136 (2d ed. 1989)). In other words, "[i]t is not sufficient to prove joint tortious acts of two or more persons"; rather, a plaintiff must show that

those acts were taken in furtherance of an agreement to cause injury. *Gutierrez*, 437 Mass. at 415 (internal quotation marks omitted). Massachusetts recognizes two types of civil conspiracy, "so-called 'true conspiracy[,]' and conspiracy based on section 876 of the Restatement (Second) of Torts." *Taylor*, 576 F.3d at 34 (citing *Kurker v. Hill*, 44 Mass. App. Ct. 184, 188 (1998)).

"True conspiracy" is itself an independent tort—no other tortious acts must be shown. *See Fleming v. Dane*, 304 Mass. 46, 50 (1939); *Mass. Laborers' Health & Welfare Fund v. Philip Morris, Inc.*, 62 F. Supp. 2d 236, 244 (D. Mass. 1999). To rise to the level of an independent tort, the "mere force of numbers acting in unison" must "make a wrong." *Fleming*, 304 Mass. at 50 (quotation omitted). This Court has previously concluded that Ward could not procced on a "true conspiracy" cause of action. *Ward v. Auerbach*, 2017 WL 2724938, at *12 (D. Mass. June 23, 2017) ("[N]o Massachusetts case has ever permitted a plaintiff to proceed on a civil conspiracy theory on facts remotely close to those presented here.").

Alternatively, civil conspiracy based on section 876 of the Restatement (Second) of Torts extends liability for the torts of another when there has been a "concerted action." *Thomas*, 909 F.3d at 490 (quoting *Kurker*, 44 Mass. App. Ct. at 188). It is, in essence, a form of vicarious liability. "Because it is vicarious liability, this type of civil conspiracy requires an underlying tort and the conspiracy consists in agreeing to, or assisting in, this underlying tort." *Thomas*, 909 F.3d at 490 (quoting *Taylor*, 576 F.3d at 35). A plaintiff must "show that defendants either (1) acted 'in concert with or pursuant to a common design with' the tortfeasor or (2) 'gave substantial assistance to' the tortfeasor's conduct." *Thomas*, 909 F.3d at 490 (citing *Kyte v. Philip Morris Inc.*, 408 Mass. 162, 166 (1990)).

The parties disagree as to whether the record supports liability under either theory. As a preliminary matter, Ward contends that there are two instances of underlying tortious conduct for

which Dr. Schaefer should be held vicariously liable: he alleges (1) that Dr. Remaley, Dr. Shamburek, and Bruce Auerbach fraudulently enrolled him in the ACP-501 study and (2) that Drs. Remaley and Shamburek failed to obtain his informed consent to the study and therefore breached a duty owed to him. (Pl. Opp. at 29).

1. Common-Design Theory

For a defendant to be liable under the common-design theory, "there must be, first, a common design or an agreement, although not necessarily express, between two or more persons to do a wrongful act and, second, proof of some tortious act in furtherance of the agreement." *Aetna Cas. Sur. Co. v. P & B Autobody*, 45 F.3d 1546, 1564 (1st Cir. 1994). Under the first prong, "an inference of an implied agreement [can] properly be drawn from the conduct of two or more parties." *Kyte*, 408 at 167. The "plaintiff must establish a common plan to commit a tortious act where the participants know of the plan and its purpose and take affirmative steps to encourage the achievement of the result." *Bettencourt v. Town of Mendon*, 334 F. Supp. 3d 468, 486-87 (D. Mass. 2018) (quotation omitted).

Ward alleges that Dr. Schaefer acted pursuant to an agreement with Dr. Remaley, Dr. Shamburek, and Auerbach to enroll him in the ACP-501 study by means of fraudulent misrepresentation. (Pl. Opp. at 29). He alleges that Dr. Schaefer took active steps to create the study and secure his ongoing participation in it, such as revising the drafts of the study's protocol and booking Ward's travel to the NIH. (*Id.*). Dr. Schaefer, on the other hand, contends that the evidence shows only that he spoke with the others about Ward's participation, but not that there was any sort of agreement between them or that he controlled or directed the acts of anyone else. (Def. Mem. at 19-20).

Ward "must present evidence creating a genuine issue of fact as to whether an agreement existed between [the defendant and the others] to cause injury to [him]." *Grant v. John Hancock*

Mut. Life Ins. Co., 183 F. Supp. 2d 344, 363 (D. Mass. 2002). Dr. Schaefer, the NIH doctors, and Auerbach would have had to have "agreed to take steps" toward violating Ward's rights. *Blake v. Pro. Coin Grading Serv.*, 898 F. Supp. 2d 365, 393 (D. Mass. 2012). It is undisputed that Dr. Schaefer discussed the ACP-501 study with the others and referred Ward to the NIH for "treatment with potential enzyme replacement." (Pl. Ex. 24 at 1). But Ward has not produced evidence that Dr. Schaefer "agreed to take steps" with the others to misrepresent to Ward the alleged true purpose of the study—that is, to gain data on ACP-501 that would be beneficial in selling AlphaCore—in order to secure his enrollment and continued participation in it. *See Blake*, 898 F. Supp. at 393. Even if there is a genuine issue of material fact as to whether Dr. Schaefer individually defrauded Ward, the evidence does not support a reasonable inference that there was an agreement between Dr. Schaefer and others to do so.

Similarly, there is no evidence of an agreement between Dr. Schaefer and the NIH doctors to breach Ward's right to informed consent. "Because a conspiracy requires an agreement to commit a wrongful act, none can exist where an alleged participant lacks knowledge that a wrongful act is being perpetrated." *Grant*, 183 F. Supp. 2d at 364 (D. Mass. 2002). Ward has not identified any evidence that Dr. Schaefer knew that he or any of the other doctors failed to obtain Ward's informed consent to the study and thus violated his rights. Dr. Schaefer therefore cannot be found to have engaged in a civil conspiracy with the NIH doctors to have done so.

In summary, there is no evidence to reasonably support a finding that Dr. Schaefer is liable under the common-design theory of civil conspiracy for the tortious acts of fraudulently enrolling Ward in the study or breaching Ward's right to informed consent.

2. Substantial-Assistance Theory

Under the "substantial-assistance theory," a plaintiff must show that the defendant "(1)

knew that the conduct of [others] constituted a breach of fiduciary duty and (2) substantially assisted in or encouraged that conduct." *Baker v. Wilmer Cutler Pickering Hale & Dorr LLP*, 91 Mass. App. Ct. 835, 847-48 (2017). The defendant must both know that the other's conduct is tortious and intend to assist or encourage that conduct, and such assistance must be a "substantial factor" in causing the resulting tort. *Thomas*, 909 F.3d at 491 (quoting *Taylor*, 576 F.3d at 35).

Ward contends that Dr. Schaefer gave substantial assistance to the NIH doctors in enrolling and maintaining him in the ACP-501 study, even though he knew that the actual purpose of the study was to conduct research on the enzyme and not to treat him. (Pl. Opp. at 30). But he has not produced evidence of the requisite mental state. Under the substantial-assistance theory, "courts should consider 'the nature of the act encouraged, the amount of assistance given by the defendant, his presence or absence at the time of the tort, his relation to the other and *his state of mind*." *Taylor*, 576 F.3d at 35 (quoting Restatement (Second) of Torts § 876 cmt. d) (emphasis added). Ward must show that Dr. Schaefer had "knowledge that the other's conduct is tortious, and an intent to substantially assist or encourage that conduct." *Taylor*, 576 F.3d at 35. Ward has produced evidence that Dr. Schaefer took steps to ensure that the ACP-501 study would be approved, that Ward could participate in it, and that its results would be published. (Pl. Opp. at 30). But the record does not contain evidence that Dr. Schaefer took those actions with the intent of aiding Auerbach and Drs. Shamburek and Remaley in a plan to misrepresent the true purpose of the study to Ward. *See Taylor v. Airco, Inc.*, 503 F. Supp. 2d 432, 448-49 (D. Mass. 2007) (granting defendants' motion for summary judgment on a civil-conspiracy claim under the substantial-assistance theory when the plaintiffs failed to identify evidence demonstrating defendants knew of another's tortious activities, because "no reasonable jury could conclude that [d]efendants knowingly and intentionally participated in any civil

conspiracy").

Similarly, Ward has identified no evidence that Dr. Schaefer intended to assist the NIH doctors in breaching his right to informed consent. A "[p]laintiff[] must proffer 'evidence of the defendant['s] knowledge of its substantial supporting role in an unlawful enterprise.'" *Airco*, 503 F. Supp. 2d at 448 (citing *Kyte*, 408 Mass. at 168). Furthermore, a civil-conspiracy claim promulgated under the substantial-assistance theory must fail when "there is no allegation that [the defendant] did anything to encourage [the tortfeasor] to breach a duty." *Blake*, 898 F. Supp. 2d at 392. There is no evidence in the record that Dr. Schaefer did anything to discourage the NIH doctors from obtaining Ward's informed consent.

In summary, Ward has not produced evidence of a civil conspiracy between Dr. Schaefer and the others under a substantial-assistance theory for the alleged underlying torts of fraud or breach of informed consent. Accordingly, the motion for summary judgment as to Count Six will be granted.

IV. Conclusion

For the foregoing reasons, defendant's motion for summary judgment is DENIED as to Count 1 to the extent it asserts a claim for fraud based on a theory that Dr. Schaefer did not fully disclose the nature, purpose, and/or risks of the study, and otherwise GRANTED as to Count 1; DENIED as to Count 2 to the extent it asserts a claim for a breach of plaintiff's right to informed consent based on a theory that he was not adequately informed of the nature, purpose, and/or risks of the study, and otherwise GRANTED as to Count 2; and otherwise GRANTED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: March 29, 2021