No. 14-4162

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

BRENT LEVORSEN,

Plaintiff-Appellant

v.

OCTAPHARMA PLASMA, INC.,

Defendant-Appellee

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, NO. 2:14-CV-00325,
THE HONORABLE DUSTIN B. PEAD

REPLY BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* SUPPORTING APPELLANT AND URGING REVERSAL

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INTRODUCTION

The United States submits this reply brief to address Octapharma's argument that Food and Drug Administration (FDA) regulations interpreting the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act conflict with the position set forth in the United States' initial *amicus* brief that plasma donation

centers are public accommodations covered by Title III of the Americans With Disabilities Act (ADA).[1]

ARGUMENT

1. Much of Octapharma's argument presumes a scenario in which a potential plasma donor is turned away because he or she does not meet the donor eligibility criteria defined by FDA regulations. That is not this case. The district court's opinion states that "[t]he basis for [Octapharma's refusal to allow Levorsen to donate plasma] was Octapharma's assertion that during the donation process Mr. Levorsen might have a schizophrenic episode and 'pull the needle collecting blood out of his arm and hurt him-self and/or others.'" Aplt. App. 31 (citation omitted). At this stage of the litigation, there is no indication that Octapharma turned Levorsen away because it was attempting to follow FDA regulations or written donor eligibility criteria developed in accordance with FDA regulations. Thus, Octapharma obscures the factual basis for the district court's decision by focusing on the purported inconsistency between ADA coverage and the donor eligibility

[1] Octapharma also suggests (Appellee Br. 31) that FDA regulations are entitled to *Chevron* deference for purposes of interpreting the ADA. But the FDA has not issued ADA regulations. The FDA regulations Octapharma cites interpret other statutes, not the ADA. Moreover, *Toomer* v. *City Cab*, 443 F.3d 1191 (10th Cir. 2006), does not support Octapharma's claim that this Court should rely to FDA regulations in order to interpret the ADA. In *Toomer*, this Court deferred to the *ADA regulations* issued by the Department of Transportation. *Id.* at 1195-1196.

criteria, which are developed in accordance with the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and are designed to protect donor health and assure the safety of blood products.[2]

But the United States agrees with Octapharma that this Court should not interpret the ADA in a way that would endanger public health. And so on this point we want to be very clear: ADA coverage of plasma donation centers would *not* impair their ability to establish and follow donor eligibility criteria developed in accordance with FDA regulations to protect donor health and assure the safety of blood products. Indeed, the Department of Justice's Title III regulations make that plain.

Title III regulations provide that "[a] public accommodation may impose legitimate safety requirements that are necessary for safe operation." 28 C.F.R. 36.301(b). The regulations explain that these requirements "must be based on actual risks and not on mere speculation, stereotypes, or generalizations about individuals with disabilities." *Ibid.* The Department of Justice has explained that this regulation permits public accommodations to "impose neutral rules and criteria that screen out, or tend to screen out, individuals with disabilities, if the criteria are

[2] Octapharma's brief contends (Appellee Br. 9-10 n.4 & n.5) that the United States' *amicus* brief misstates certain immaterial facts. But the United States' brief simply sets out the facts reported in the district court's opinion. See U.S. Br. 3 (citing Aplt. App. 31).

necessary for the safe operation of the public accommodation." 56 Fed. Reg. 35,544-01 (July 26, 1991); see also 28 C.F.R. 36.301(a).

Certainly, establishing donor eligibility criteria in accordance with FDA regulations to protect donor health and assure the safety of blood products is "necessary for the safe operation" of a plasma donation center. See 28 C.F.R. 36.301(b); 56 Fed. Reg. 35,544-01. FDA regulations require establishments to have written standard operating procedures addressing all steps to be followed in the collection of blood. These procedures must establish the criteria used to determine donor eligibility, including acceptable medical history criteria. See 21 C.F.R. 606.100(b)(1). If an individual with a disability is not "in good health" within the meaning of FDA regulations and the donor eligibility criteria established in accordance with FDA regulations, the center clearly should prohibit that individual from donating. See 21 C.F.R. 640.63(c). Just as clearly, the plasma donation center would not be liable under the ADA for doing so.

The Department of Justice's publically available settlement agreement with Bio-Medics (another plasma donation center), which the United States cited in its initial brief (U.S. Br. 2), confirms that the United States does not interpret the ADA to require action that would threaten donor health or the safety of the plasma supply. Paragraph fourteen of that agreement states that individuals with disabilities should be permitted to donate plasma "*as long as they pass the physical*

examination that all donors are required to pass." *Settlement Agreement Between The United States Of America And Bio-Medics*, available at http://www.ada.gov/bio-medics.htm (emphasis added). Similarly, the agreement states that "[a] person who is blind or has low vision is not prevented from donating plasma, *as long as he or she meets all other set requirements needed to donate*." *Id.* at Appendix B (emphasis added); see also *id.* at Appendix C ("A person who is deaf or hard of hearing is not prevented from donating plasma, *as long as he or she meets all other requirements for being a donor*.") (emphasis added).

Certain individuals with disabilities will not qualify (or will be less likely than other individuals to qualify) as plasma donors. But that is not a reason that plasma donation centers should be exempt from ADA coverage. Many individuals with disabilities are "in good health" and otherwise qualified to donate plasma under FDA regulations and establishments' donor eligibility criteria developed in accordance with FDA regulations. For example, many individuals who are blind or deaf or have certain mobility impairments will be able to meet all the requirements for being a donor. Though ADA coverage *will not* prevent plasma donation centers from establishing donor eligibility criteria in accordance with FDA regulations, exemption from ADA coverage *would* permit discrimination against individuals with disabilities who clearly are eligible to donate. ADA

coverage simply ensures that individuals with disabilities will be allowed to donate plasma when they meet the same eligibility criteria that apply to everyone else.

2. Octapharma also posits a conflict between the United States' position that it qualifies as a service establishment for purposes of the ADA and its status as a manufacturer under FDA regulations interpreting other statutes. Appellee Br. 16-19. Octapharma is correct that it is a manufacturer for purposes of these FDA regulations, but mistaken in its belief that this fact means that it cannot be a "service establishment" for purposes of 42 U.S.C. 12181(7)(F). That an entity is engaged in manufacturing does not mean that it cannot also – even as part of the manufacturing process – be engaged in service.

Hospitals provide a straightforward illustration. The FDA definition of "manufacture" that applies to plasma donation centers like Octapharma also applies to many hospital divisions. Specifically, that regulation defines "manufacture" to include "the collection, preparation, processing or compatibility testing by chemical, physical, biological, or other procedures of any blood product which meets the definition of a drug as defined in section 201(g) of the [Federal Food, Drug, and Cosmetic Act], and including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process." 21 C.F.R. 607.3(d). And since many hospitals engage in some of these activities, the divisions that perform these activities are often subject to FDA regulation. But

hospitals are also service establishments; indeed, a hospital is one of the listed examples. See 42 U.S.C. 12181(7)(F). Quite obviously then, the status of these divisions as manufacturers does not prevent the hospital from being a service establishment. Similarly, certain recycling centers (entities Octapharma rightly concedes are service establishments (Appellee Br. 15 n.7)) manufacture new products from recyclable materials. That fact does not prevent them from providing a service. The same is true for plasma donation centers like Octapharma.

CONCLUSION

This Court should reverse the district court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type volume limitation imposed by Federal Rule of Appellate Procedure 29(d). This brief was prepared with Microsoft Word 2007 and contains 1322 words of proportionately spaced text. The typeface is Times New Roman, 14-point font.

s/ Nathaniel S. Pollock
NATHANIEL S. POLLOCK
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Dated: June 26, 2015

CERTIFICATE OF DIGITAL SUBMISSION

I certify that the electronic version of the foregoing REPLY BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* SUPPORTING APPELLANT AND URGING REVERSAL, prepared for submission via ECF, complies with all required privacy redactions per Tenth Circuit Rule 25.5, is an exact copy of the paper copies submitted to the Tenth Circuit Court of Appeals, and has been scanned with the most recent version of Trend Micro Office Scan (version 8.0) and is virus-free.

s/ Nathaniel S. Pollock
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Dated: June 26, 2015

CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing REPLY BRIEF FOR THE UNITED STATES AS *AMICUS CURIAE* SUPPORTING APPELLANT AND URGING REVERSAL with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system. Seven copies of the same were sent by Federal Express to the Court. All participants in this case who are registered CM/ECF users will be served by the appellate CM/ECF system.

I further certify that on June 26, 2015, I served a copy of the foregoing reply brief on the following counsel by certified U.S. mail, postage prepaid:

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