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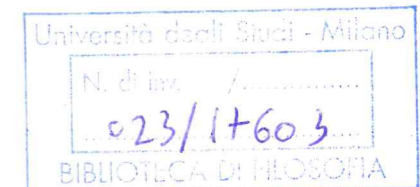
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#### EDITORIAL

## The Limits of Individualism: Potential Societal Harms from the EAP for Convalescent Plasma

David Magnus

Stanford University

This issue features a set of articles addressing allocation issues for drugs for COVID-19 that have not been approved by the FDA but are available through either Emergency Use Authorization or Expanded Access Programs (EAP). Webb et al. (2020) propose a framework to guide these decisions. Of particular note, the authors point out that a requirement for EAP programs is that they do not interfere with clinical development, including clinical trials, and that the larger the number of participants, the greater the evidence required for an EAP.

Convalescent plasma (CVP) is a promising and plausible candidate as a treatment for COVID-19. CVP has a long history as a treatment for a wide range of diseases and is based on a plausible biological mechanism, namely that neutralizing antibodies circulating in the blood could provide either immunity in the uninfected or treatment for those who are. There is some evidence, mostly from case reports, case series, and retrospective analyses, that suggests that CVP is safe and possibly effective for other viral infections, including other coronavirus infections. There is non-human primate data supporting the development of protective immunity after recovery from acute infection. Taken together, there is ample evidence that CVP is a plausible candidate for trials to determine whether or not CVP is a safe and effective treatment for COVID-19, and if so, when in the course of the disease it is effective. The available clinical evidence and biological intuition particularly point to potential benefits early in the course of disease or even as a prophylactic, but it is not unreasonable to explore its benefits for sicker patients, those who require hospitalization and are critically ill (even if there may be somewhat less hope that there will be benefit in this population).

One would expect, given this background, that a major priority would be the rapid design and execution of large, multi-center randomized clinical trials of CVP for both hospitalized patients and outpatients. But in the U.S., randomized trials of CVP have received less attention, funding, and governmental support than we might have hoped. Instead, the FDA approved a large multicenter EAP on April 7th, administered through the Mayo

Clinic, which made CVP available in a non-randomized fashion to over 20,000 hospitalized, critically ill patients at over 2,000 sites. Given the heterogeneity of outcomes for critically ill COVID patients across hospitals, what has been learned from the significant number of patients who have been given CVP through the EAP? Very little. There is perhaps more support for the safety of the intervention. And there is enough evidence so that it remains a plausible target of study. However, it remains unknown whether the intervention provides benefit to the patients it is being provided to. Had the federal dollars (through BARDA) that went to this EAP been spent on a randomized, placebo-controlled trial, we would already know whether the intervention works. In contrast, large multi-center randomized clinical trials of CVP in hospitalized patients have been much more rapidly initiated in a coordinated fashion both in the UK and Canada, and are likely to be able to provide us with a definitive answer regarding whether or not this is an effective intervention.

Why did Mayo (the lead for the CVP EAP) and other institutions choose to focus on an objectively inferior research design that was likely going to be unsuccessful in answering the critical question of whether there was benefit to the intervention? Why did BARDA fund the effort? Why was the EAP program approved by the FDA?

Part of the answer can be found in a growing trend in the U.S. to drop research standards for seriously ill patients when there are no effective treatments available. In the Abigail Alliance case, the parents of a terminally ill patient with head and neck cancer (and the advocacy group they created on her behalf) sued the commissioner of the FDA for the right to access an unapproved drug that was then in clinical trials for colon cancer. They argued that there is a constitutional right to access drugs after Phase I. The court eventually found that there is no right to unproven, unapproved drugs, but the battle over access has continued. The FDA has made it easier to access unproven drugs through EAPs, and most states have adopted "right to try laws," that make it easier to

# ROBERT SMITHSON

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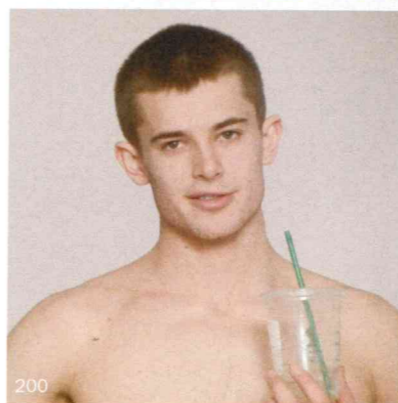
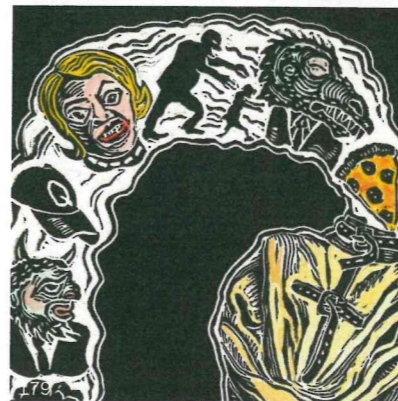
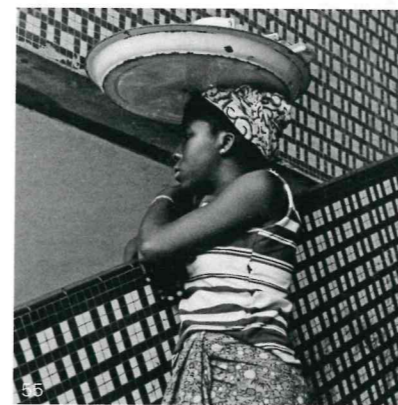
Robert Smithson in the UK working on a *Mirror Displacement* in 1969, photographed by Nancy Holt.  
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Cover: Adam Pendleton, *US/U.S.*, 2020, spray paint on paper.

From top: Ming Smith, *Symmetry on the Ivory Coast, Abidjan, Ivory Coast (detail)*, 1972, gelatin silver print, 4 1/2 x 3 1/4". Sue Coe, *QAnon (detail)*, 2020, linocut with hand-coloring on paper, 10 1/2 x 8 1/2". Ken Okiishi, *Vital Behaviors*, 2019, HD video, color, sound, 64 minutes. Brian Altamus, Masaharu Sato, *Stairs (detail)*, 2018, acrylic on board, 35 1/2 x 25 1/2".



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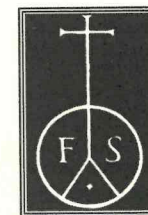
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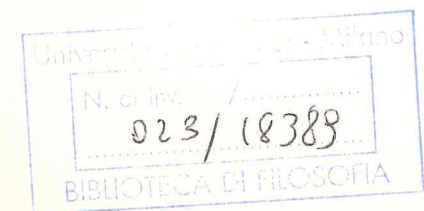


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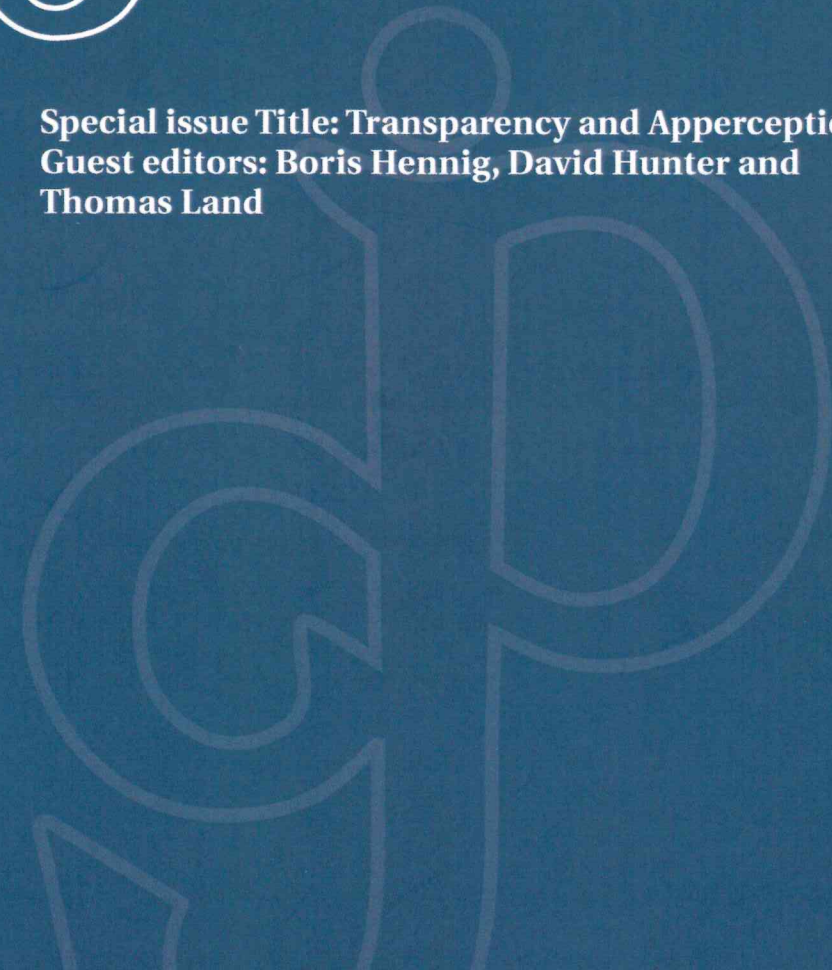
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**Special issue Title: Transparency and Apperception**  
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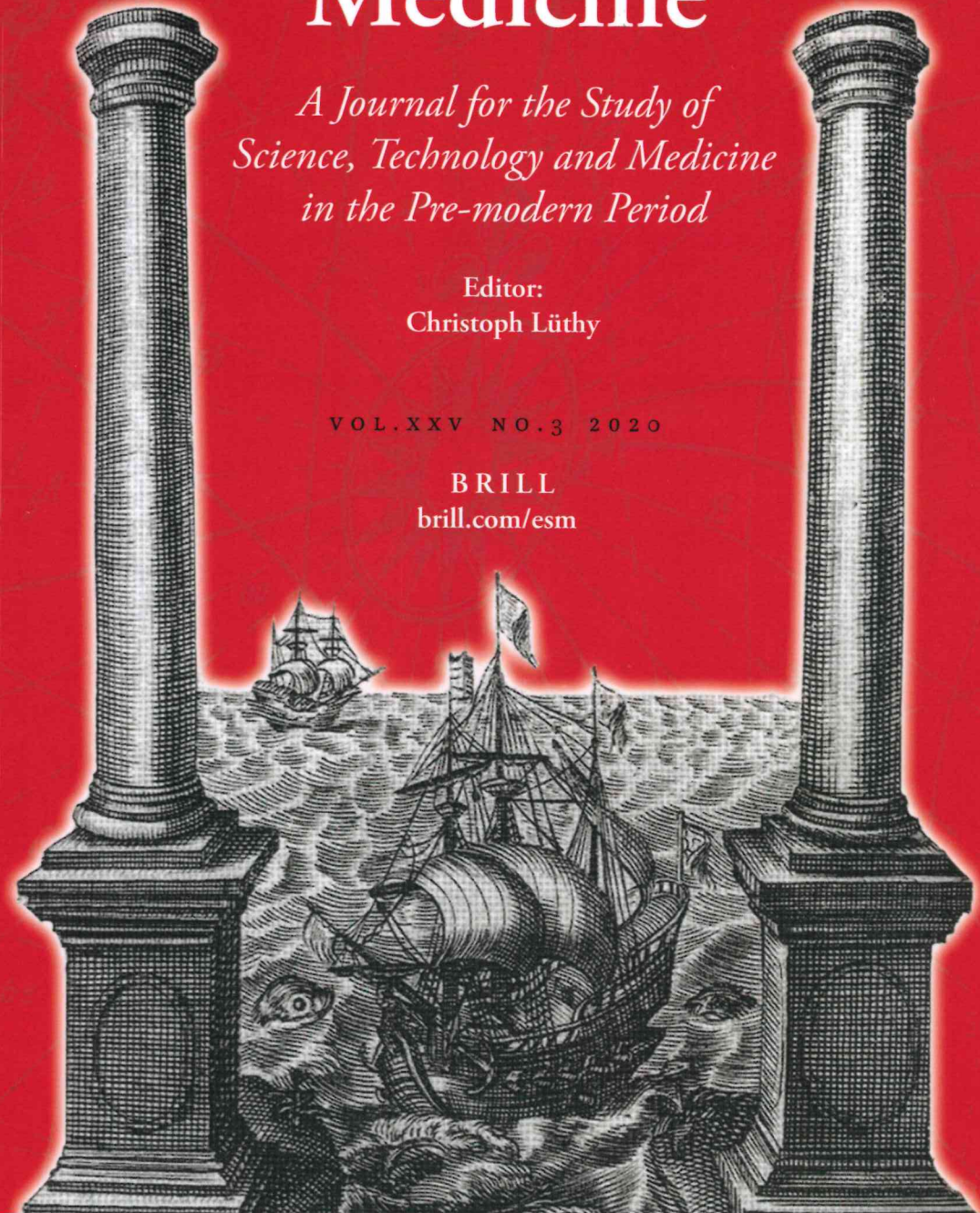
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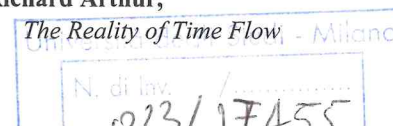
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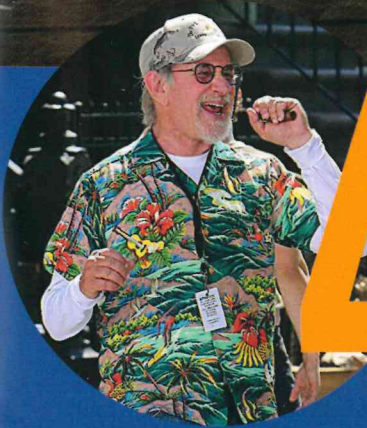
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