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Accidental Communities: Race, Emergency Medicine, and The Problem of PolyHeme

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This essay focuses on emergency medical care in black urban populations, suggesting that the classification of a “community” within clinical trial language is problematic. It references a cultural history of black Americans with pre-hospital emergency medical treatment as relevant to contemporary emergency medicine paradigms.

10 Part I explores a relationship between “autonomy” and “community.” The idea of community emerges as a displacement for the ethical principle of autonomy precisely at the moment that institutionalized medicine focuses on diversity.

15 Part II examines a clinical trial for the blood substitute PolyHeme. It illustrates the ways in which bias in research paradigms and IRB decisions attach to the notion and utility of the language of “community.”

The conclusion’s contemporary anecdote makes apparent the vitality of the issues of prehospital emergency medical care, and the ways in which decisions and practices fall too easily into a narrative of culturally biased treatment.

INTRODUCTION

20 “Keeping us and the American people sick benefits the pharmaceutical industry.”

Minister Louis Farrakhan
Tavis Smiley Presents—“The State of the Black Union 2005” C-Span 2/26/05

25 Minister of Islam Louis Farrakhan was a 2005 panelist on Tavis Smiley’s now annual conference on the “State of the Black Union.”¹ In his remarks on the topic of African American health, Mr. Farrakhan advanced the judgment about the pharmaceutical industry that I have quoted in the epigraph above.
 30 To the surprise of some, perhaps, his indictment elicited standing cheers from the predominantly black audience of over 500. The acclamation earned by this particular assessment is noteworthy.

1. The intuitive reader may note the irony in the title of this conference regarding a “black *union*” in an essay that will critique the presumptions inherent in a notion of “community.” However, the essay’s critique is directed at the way in which the language of community is used in health care to direct actual and active practices rather than the more passive (though nonetheless arguable) use of the term by Tavis Smiley.

Although there is ample evidence that medical cultures have made considerable commitments to extending the benefits of medical research to ethnic and minority communities (Smedley 1999), the response to Mr. Farrakhan reveals that the histories of distrust and misapprehension characterizing the relationship between black America and institutionalized medicine have contemporary currency and vigor. There are also indications that despite interest in outreach and in diversity, medical and research communities (particularly institutional review boards (IRBs) that are formulated to safeguard a relationship between medical research and medical subjects) might not yet fully appreciate the ways in which historical and cultural memory still impede effective outreach to minority populations.

This failure is especially evident, and significant, in the flexibility of protocols and IRB standards in circumstances when minority and urban populations are the subjects of proposed trials. Review board protocols have traditionally been attentive to principles in bioethics that champion autonomy. But the frames of analysis and response that these committees bring to research proposals have evolved away from a traditional protection of individuals toward a focus on “communities.” Although

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 PolyHeme
 race and ethics

60 this shift has paralleled their stated interest in becoming more responsive to and reflective of the diverse publics they serve, it also replicates a troubled historical pattern of racially stratified healthcare.

65 Efforts to make medical research and clinical trials interested in seeking the participation of minority populations is both admirable and correct. However, the risk exists that the outreach to these communities will be presentist in construction and operation, and will fail to appropriately contextualize the weight of historical memory associated with medicine and research. My purpose in this essay is to illustrate, using the clinical trials proposed for a blood substitute, the larger issue of the relationship between research protocols, the boards who develop and execute them and the narrative and experiential histories in lay populations that these medical interventions impact. David Smith writes a compelling analysis of the cultural histories of minorities, medicine, and its institutions that are relevant to the context of this essay (Smith 1999).

80 The issues that have emerged regarding clinical trial protocols for PolyHeme seem appropriately representative of these culturally inflected matters. Without an acknowledgment of the tangible racial and cultural histories that construct the narrative memories in these relationships, any interest in an expanded access to and participation from these populations for research risks beginning at an historically vacant point of scientific interest rather than a substantive point of cultural memory. Successful reconstitution of IRB memberships to reflect a greater diversity, and effective outreach to minorities in clinical trials depend on an acknowledgment of social and cultural histories.

95 One space in particular where cultural history has constructed narratives that still resonate with vigor is within the structures of emergency medical care. In a review of the 1998 National Health Interviews Survey, Craig Walls notes that African American populations continue a trend of using emergency departments for medical care. Lillie-Blanton notes a similar data pattern from 1980s HHS data (Lillie-Blanton, Martinez and Salganicoff 2001; Walls, Rhodes and Kennedy 2002). Given consistency in this pattern, it is not surprising that cultural narratives include these sites of pre-hospital and emergency room care as the space of story. The historical memories associated with these narrative spaces linger and significantly impact the perceptions and judgments about contemporary medical practice, care, and access.

* * *

The purposes of this paper are to discuss, with a particular focus on emergency medical care in black urban populations, the social practices of medicine that emerge as racially specific. Critically important to this consideration is the idea of “community” as it is constructed in discussions of these populations, especially as some from these “communities” become potential subjects for research protocols.

120 Part I details and critiques this matter of language and culture, indicating the ways in which the classification of a “community”—especially as it has emerged within the clinical trials language—is problematic. It references a cultural history of black Americans with pre-hospital emergency medical treatment to indicate the way in which contemporary issues in medical research have an opportunity to re-inscribe the experience of that history. These experiences frustrate the expressed goals of medicine to develop the trust and confidence of historically underserved populations.

To make this argument, I propose a relationship between the language of “autonomy” and “community,” and suggest how the notion of community emerges as a displacement for the traditionally ethically powerful principle of autonomy precisely at the moment that institutionalized medicine and research focus on diversity as a desirable goal.

140 Part II examines a particular clinical trial proposed for a blood substitute. The articulation and construction of this trial traces a memorable cultural history. The evolution of this protocol illustrates the ways in which bias in research paradigms and IRB decisions emerges in a manner that might seem facially neutral, but that is instead attached to the notion and utility of the language of “community.”

The conclusion offers a contemporary anecdote that makes apparent the vitality of the issues of pre-hospital emergency medical care, and the ways in which decisions and practices that seem to be discrete fall too easily into a narrative of culturally biased treatment.

I. AN IDEA OF COMMUNITY AND POPULATION: THE SOURCE OF NARRATIVE

155 Since the 1970s the goals of institutionalized medicine have included an aggressive effort to develop culturally sensitive approaches to the medical issues of discrete populations. In these contexts, the idea of “community” has less ability to cohere populations than the arguably empathetic use of the term suggests. This language functions as a utilitarian construction that paradoxically serves the interests, but not the goals, of institutionalized medicine and

165 medical research. Although it might seem neutral in
 its indications of location and identity, former Sur-
 geon General Satcher’s embrace of the importance of
 “creating real and meaningful partnerships as essen-
 tial to achieving a balanced community health sys-
 tem” is extracted from a longer discussion focused
 170 on reducing “health care disparities in our nation”
 (Satcher 2001). The disparities that are Satcher’s
 focus become evident at the boundaries of racial
 identification, gender, and ethnicity. Satcher’s essay
 makes this apparent, when, in exploring the “role
 175 of the community,” he notes that sensitivity “to the
 diverse cultural norms and beliefs of the people”
 and appropriateness for “people of all races, ethnici-
 ties, genders, sexual orientations, ages, and disabili-
 ty statuses, members of the populations served, and
 180 their gatekeepers, must be involved in the *community*
 assessment and planning process” (Satcher 2001, 2–
 4). Paradoxically, Satcher’s list of objectives argues
 for the multiple and complex identities inherent in
 a population and points out the difficulty in sustain-
 185 ing a coherent, that is, a stable and uncomplicated
 notion of community, with these varied categories
 of differences in play.

The analytical over inclusiveness resident in an
 idea of community is engaged as well by researchers
 190 whose effort it is to call attention to the diverse needs
 of medical populations. Consider the point made
 by Marsha Lillie-Blanton who writes of Latino and
 African American populations in the United States that

195 reside largely in racially segregated neighborhoods
 and have poverty rates three times those of whites.
Both have cultural beliefs and practices that sometimes con-
flict with western medicine, and thus, may result in a lack
 of confidence in the medical system (Lillie-Blanton,
 200 Martinez and Salganicoff 2001, X, emphasis added).

Despite the focus of this culturally interested es-
 say, the authors make a strategic error in locating
 some bodies within, and others outside of “west-
 205 ern” medicine. The bias implicit in cultural notions
 that distinguish “the West and the rest of us”
 are too easily incorporated into otherwise thought-
 ful considerations of difference. Instead, scholars
 who focus on the distinctions of cultural practices
 and experiences within Western populations might
 210 certainly distinguish between majority and non-
 majority experiences—and in doing so, complicate
 the membership of the West in ways would forward
 a critical interrogation of the spaces that have
 been assigned to or occupied by various members
 215 and practices within western civilization. It is crit-

ical to see the long history of African Americans in
 the United States as a part of a western tradition—
 rather than apart from it and instead of efficiently
 positioning perspectives from diverse populations
 as something outside of a norm of citizenship. 220
 Certainly efficiency is a necessary and proper goal
 in medical and legal matters. But to the extent that
 efficiency encourages institutions to approach pop-
 ulations as aggregate bodies, both the legal doctrine
 of privacy and the bioethics’ principle of autonomy 225
 are sacrificed.

A. The Plural that Constitutes Story

Although something seems coherent, accessible,
 and possibly even desirable with this affective lan-
 guage of community, especially in the way in which 230
 it seems to advance an ethical interest to historically
 underserved populations, the idea of community is
 complex and intangible. In the romanticized frame
 in which it is used in social medicine especially, the
 term community connotes what cultural theorist 235
 Benedict Anderson understands as an “imagined
 community” rather than some actual space of de-
 mographic and ethnographic coherence (Anderson
 1991). Anderson’s “imagined community” is posi-
 240 tioned as a tangible ideal where membership and
 identity are an exterior overlay providing some lo-
 cation for ethnic populations that are differentiated
 in many of the ways that matter in socioeconomic
 and demographic categories. In medical research
 and arguably in legal studies, the efficacy in spec- 245
 ifying a ‘discrete’ population in ways that elide a
 foregrounding of racial identification to imply a co-
 herence of judgments, perspective, preference and
 even appearance encourages a troubling displace-
 ment of individual autonomy—an otherwise nearly 250
 sacred principle of biomedical ethics. Given the
 once sacrosanct principle of autonomy, what then
 is the romance and appeal of community?

The interest in community may partly be lo-
 cated in the language of bioethics itself, where 255
 phrases like “ethics of caring” and “caring com-
 munity” have emerged. “Care,” “community,” and
 “ethics” imply an affect more resonant through their
 visible associative value than in any substantive re-
 lationship that might inhere. The associative nexus 260
 conveys a role for an identified population that is
 linked to basic principles of bioethical inquiry—
 beneficence and justice in particular. In this shift to-
 wards a medical humanism and in a discussion that
 makes apparent the subtext of diversity, Patricia 265
 Martin claims pluralism as the foundation of ethics’

focus on “approaches based on caring and narrative evidence” (Martin 1999). A focus on narrative—the act, and art, of story—is one particular approach that links these interdisciplinary interests.

Theories of narrative that seem of increasing interest to medicine and humanities scholars depend in significant measure on a consideration of text that makes coterminous the act of interpretation and reading. Literary theorist and semiologist Roland Barthes writes:

To interpret a text is not to give it a meaning, but on the contrary to appreciate what plural constitutes it. . . . In this ideal text, networks are many and interactive . . . we gain access. . . by several entrances, none of which can be authoritatively declared to be the main one (Barthes 1974, X).

Barthes poses a warning here that seems especially helpful when we recall that authorship (and *authorship*) are critical positions to acknowledge within narrative theory. Narrative theory in bioethics has appropriately considered this critical positionality, in investing in and making apparent that the teller of the story has the stature and responsibility of author. I suggest this is a position that weds authority to autonomy—a singular independence and self-sovereignty that emerges in how the narrative story is both constructed and claimed. Authority and autonomy incorporate each other such that someone’s telling the story and laying claim to it share critical points of intersection. However, when we consider Barthes’ point regarding a “plural that constitutes” story as a fundamental presumption of narrative, it poses a difficulty for bioethics.

The focus on narrative in medical humanities underscores the long-standing and highly valued principle of autonomy. The narrator is, finally, the storyteller, and an intimate relationship between autonomy and narrative is implicit in the attention to a “patient’s story” (Nelson 1997). However, this relationship is encumbered when the patient’s individual narrative is culturally inflected—that is, when the “plural” that Barthes acknowledges emerges. This certainly implicates the context of a broader cultural story that makes room for this narrative, but, what is more important to my argument, is Barthes’s suggestion that *the narrative telling is itself plural*.

In cultural studies, a multiple and layered narrative voice is a given. But in bioethics, tension between an aggregate cultural story that may reside both alongside *as well as* within an individual patient story positions a critical disjuncture between

two humanistic trends in medicine—one of which champions narrative and, by default, a certain singularity and independence, and the other that urges a collective cultural community.

Ironically, the erosion of and contradictions in the principle of autonomy emerged at the same time that medical professionals began to urge recognition of the diverse communities of medical patients and the United States began to integrate medical hospitals (Katz 1977). While the interest in narrative apparently reifies a value placed on autonomy and places the patient into a critically interlocutive relationship to medical institutions, autonomy becomes a fragile principle when placed into correspondence with diversity.

Bioethics arguably appreciates that an implicit relationship between communitarianism and social justice, and between the ways in which “the existing formal codes and frameworks of bioethics continued to give priority to autonomy [are] a poor fit for public health practitioners seeking ethics guidance for their community-oriented work” (Kass 2004). But the failure to make an explicit connection to the racialized construction of these new values, and the absence of critical inquiry regarding the ethics of a reformulated notion of autonomy when bodies that are traditionally non-white and public become the subject, is troublesome.² Kass, noting Beauchamp’s consideration of community as a “commitment to the common life” links her assessment of his interests to a foundational development in “public health ethics” that has, she understands, “its own set of moral priorities” (Kass, 2004). One might anticipate an interrogative around the two-tiered notion of subjectivity that emerges from the “moral priorities” specific to public health—one body that is private, autonomous and arguably white, and the other reserved for “public health,” located in the aggregate space of a community, and, as the research paradigms illustrate, non-white. If we place the evolving fiction of autonomy within the racialized social history that accompanies it, the consequence of a ‘community’ category is, it seems, inevitably associated with the populations that public health policies targets.

When public health → community → racial otherness, each category comes to signify the other.

2. “Racialized” focuses consideration of how issues like education, health care, housing or even careers engage a different set of issues when, in a consideration of diversity, we make a point of regarding these matters in terms that include race.

Similarly, the autonomous value that whiteness retains for itself is uncritically protected, safely located within the realm of the private. In this formula-
 370 lary, 'community' is a plural residency distinguished from the singularity of whiteness.

B. Blood, Body, and the Persistence of Story

Despite what is finally a community that does not cohere in the ways that should matter for health care delivery, there *is* a dimension of identity which
 375 places African Americans into a discernible category. It does not, however, extend from an eliding of difference, but from an outside-of-group response to phenotype. Black Americans do share similar experiential patterns because of the way they are
 380 treated by people who are not African Americans, a matter made dramatically clear for medical professionals in well circulated studies of physician biases (Schulman 1999).

Cultural memory—the persistence of story—is
 385 one way to notice the resonance of the experience of color. In the United States, the recollection of medical histories like the Tuskegee Syphilis Study has become the paradigmatic illustration of the failure of medical ethics to make a difference in the medical
 390 treatment of African Americans—especially those enrolled in clinical trials. The fact that narratives like this one persist indicates an understanding of the potential for a similar vulnerability to be experienced by any person whom others judge based on
 395 the color of their skin. The memory for Tuskegee then, need not be a memory of direct experience, but one of direct vulnerability that is culturally constructed and culturally passed on. Although it may seem contradictory to argue both for the specificity
 400 of individual identity as well as for the generalizations of cultural memory—it is important to understand that the source of each of these is distinct. Race is not content neutral language as indicated in the cultural memories of pre-hospital emergency
 405 care in the black community and their stories of denied or diminished access. Maltheus Avery's story is illustrative.

In the last month of 1950, Avery, a young college student enrolled in what was then North
 410 Carolina A&T College, was denied admission to Duke Hospital in Durham, North Carolina because they had no "Negro" beds available. Avery had been involved in an automobile accident in nearby Burlington County. When he arrived by ambulance
 415 at Duke for treatment, he was turned away because Duke's quota of black beds had been achieved. He

was then transported to a black hospital in Durham, where he died of his injuries. Although Avery's story is one among many of black folk dying after being
 420 refused medical care in the south, his narrative has had a particular resonance because it was eventually confused with that of Dr. Charles Drew, the famous African American surgeon who developed a way for storing blood plasma. The stories that still circulate today rehearse a narrative of Drew's death asserting
 425 that he was denied entry to the nearest hospital (Holloway 2002). Another alleges that local doctors refused to give him a transfusion because they did not have any "black" blood on hand—an especial irony considering Drew's innovative discovery
 430 regarding plasma.

However, as Spencie Love's *One Blood* reveals, the incident of Drew's accident was actually confused with Avery's. Although Drew received heroic medical care at Alamance Hospital in Burlington, the
 435 legend survived that he too was one of the victims of denied admission and treatment (Love 1997).

This was an easy story to confuse in part because Avery's incident was a familiar event in the black south. Mid century, Ray Sprigle wrote:
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In Atlanta, [in] the Henry W. Grady Hospital for Negroes . . . many [Negroes] were convinced that Negro patients were used for experimentation by white surgeons and talented interns. . . . Pretty unreasonable, isn't it? But can you blame them when many of them
 445 have had personal experiences where presumably ethical and honorable white hospital administrators have let Negroes die in roaming ambulances because they couldn't find a bed in a Negro hospital and, no matter what the emergency, weren't permitted in a white
 450 man's hospital bed? (Sprigle 1949, X)

Famous and not so well known African Americans were victims of the Jim Crow politics of emergency medical care. The famous included Juliette Derri-
 455 cotte, renowned dean of women at Fisk University, and Elizabeth Price, the wife of W.C. Handy, composer of the St. Louis Blues. Blues singer Bessie Smith's death is tainted with a similar legend and prize fighter Jack Johnson, unable to use a better
 460 equipped white hospital following his auto accident in 1946, subsequently died. The renown of those individuals, coupled with the stories of neighborhood victims of lesser fame made this issue of
 465 biased emergency medical care a vigorous narrative in black neighborhoods. The stories were formed and nourished within the systems of institutionalized biases maintained in this nation's segregated hospital systems. The Institute Of Medicine (IOM)

report, *Unequal Treatment*, notes that “racial and ethnic disparities in healthcare emerge from an historic context in which healthcare has been differentially allocated on the basis of social class, race, and ethnicity” and that the contemporary result is that “racial and ethnic minority patients are far more likely than white patients to believe that discrimination is a problem in healthcare, and that they have personally experienced discriminatory treatment” (Smedley 1999). Although the information regarding segregated hospitals and disparate treatment seems historically situated, the report makes apparent how these experiences have contemporary saliency. The ways in which some of these stories revolve around emergency medical care are especially important when we consider contemporary health care policies and practices that, 1) disaggregate populations in racially specific ways; and 2) target these populations for what a lay person might label ‘experimentation.’ The proposed clinical trials for the blood substitute PolyHeme touches each of these issues.

II. THE PROBLEM OF POLYHEME

A. Community Consultation

The idea of community has a particular resonance in clinical trials because it has been within these spaces that the language and practice of “community consultation” have emerged. But what exactly does “community consultation” mean? And how do we understand this term given its associations with diversity? Even if there were some way to bring together a population from a particular location into a discussion—in the fora used by political candidates for town meetings, for example—the relationship of these people to each other is based on the fact of location, not an intrinsic relationship. Although location certainly indicates that there is something shared within a population, the *idea of community* has been assigned a much wider valence in its potential identification of presumptively shared characteristics that authorize the group to be used as a proxy for the individuals within its boundaries.

It is important to acknowledge that in the cultures of medicine and ethics “community” has come to be associated with diversity—and this association cannot help but leak into this particular use by the FDA. The phrase does not remain insular within the medical profession—but is used publicly and extra-professionally. Its positioning in clinical research discourse effectively substitutes a group for the individual in an action consonant with the way

that the FDA, with detailed specificity, determines which family members might stand in for others.³

Community consultation is a practice that the Food and Drug Administration (FDA) and Department of Health and Human Services (DHHS) initiated in 1996 when they “enacted rules allowing a narrow exception to the requirement for prospective informed consent when enrolling critically ill patients in clinical research studies of emergency treatments” (Barren 1999). As the administration placed a community consultation into the mix of conversations encouraged when exceptions of consent might be necessary, the rules also called for IRBs to determine that the patient’s participation is in the subject’s “best interest,” and clarified the subgroups of family members that would be viable proxies in studies that did not require community consultation.

Such specificity stands in direct distinction to the obscurity of the community consultation category and the absence of any directive as to how the community might be consulted, or what operative standards should be applied in these situations. The distinction between ‘consultation’ and ‘consent’ is quite stark. The lack of clarity regarding the constituents of the group or the authority involved in consultation within the language of this protocol leaves a critically conflicted juxtaposition of subjects standing in narrative relationship to the other as if they are equal. The effect of the FDA’s revision of its protocols assigned a presumptive parallelism to individuals, families, and communities. And the effect of this waiver was to place urban and minority communities even farther away from the bedrock principles of autonomy and privacy.

As an exception to the rule, “community consultation,” a “means of advising the community from which the subjects are drawn about the plans for the study and the risks and benefits of the research”⁴

3. CFR 50.24 Section A (m) is quite specific as to family members indicating that this means “. . . any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.”

4. “The agency expects the IRB to provide an opportunity for the community from which research subjects may be drawn to understand the proposed clinical investigation and its risks and benefits and to discuss the investigation. The IRB should consider this community discussion in reviewing the investigation. Based on this community consultation, the IRB may decide, among other things, that it is appropriate to attempt to exclude

560 seems to stand as an alternative to proxy. But in
 practice it means only that the community shall
 be informed and asked for comment about a study
 that the IRB process has under consideration. Com-
 munity consultation is a performative process that
 takes on the character and conduct of proxy without
 565 its authority.

It is important to clarify that there are indeed
 significant reasons for devising policies to facilitate
 research in this critical area of medicine. These poli-
 cies make room for efficiencies that will ultimately
 570 benefit medical research—especially with regard to
 incapacitated patients, and it forwards advances in
 treatments that will significantly enhance medical
 treatment for all patient populations. Given the nature
 of emergency research in dealing with inca-
 575 pacitated patients in a timely manner, some accom-
 modation for the methodologies of research, and
 some distinction from the processes that ordinari-
 ly guide informed consent are necessary. But these
 kinds of fora must be created within familiar con-
 580 texts. I have noted earlier those used by political
 groups (town meetings) as one potential example.
 The need for medical institutions to find an expedi-
 ent means of making a clinical trial happen is not
 unrelated to the urge toward the efficiencies that an
 585 embrace of communities—rather than an empha-
 sis on individuals—might accomplish for “consent”
 procedures. As a consequence, and in the PolyHeme
 trial in particular, the category of community is situ-
 ated as the primary adjudicator of an individual’s
 590 health care, especially within certain populations.

B. A Crisis in Confidence

PolyHeme is a blood substitute—a result of
 medicine’s search for an oxygen-carrying substitute
 for blood. Although scientific investigation for an
 595 effective and efficient substitute for whole blood be-
 came especially urgent during this nation’s wars, the
 search for a substitute has an ancient history and has
 included efforts to transfuse wine, nitric and sulfuric
 acids, milk, bovine and other animal bloods into hu-
 600 mans (Starr 1998). It was not until the last decades
 of the nineteenth century that saline was first used
 to replace volume after blood loss. For trauma vic-
 tims, oxygenated blood is critical in the minutes

certain groups from participation in the investigation,
 or that wider community consultation and discussion is
 needed. As described in the preamble to the proposed
 rule (60 FR 49086, September 21, 1995), IRBs should
 consider, for example, having a public meeting in the
 community to discuss the protocol. . . .” 21 CFR 50.24.

and hours following blood loss, but problems with
 typing and matching, as well as the short shelf- 605
 life of whole blood, have made carrying oxygenated
 blood impractical for ambulances and paramedics—
 where the first contact with trauma victims is often
 made.

Research into a suitable alternative—one 610
 that both carries oxygen and does not have the
 problems of matching has led to several medical
 trials of blood substitutes, including the one
 developed by Northfield Laboratories—Poly-SFH,
 or PolyHeme. The Northfield Laboratories website 615
 (<http://www.northfieldlabs.com/PolyHeme.html>)
 characterizes PolyHeme as “a unique human
 hemoglobin-based oxygen-carrying blood substi-
 tute in development for the treatment of urgent,
 large volume blood loss in trauma and surgical 620
 settings, with a particular focus on settings where
 blood is not immediately available.” Northfield’s
 product is made from outdated human blood (other
 contemporary trials have used bovine blood⁵),
 has an extended shelf life, and has the benefit of 625
 dispensing with the necessity for matching blood
 type. Its efficacy in emergency settings could
 significantly impact areas of medicine where blood
 loss is especially acute. The clinical trial protocol
 noted on the website calls for its use in injury 630
 related hemorrhage. Northfield Lab’s product is not
 the only of its kind currently under investigation,
 making successful trials and subsequent product
 marketing a high stakes competition. Success in
 the competition to develop a viable product and to 635
 secure the market has enormous financial potential.
 According to Robert Burtman, a reporter for the
Independent Weekly, “[Northfield] recently reaped
 a \$77 million bonanza in a stock sale based in
 part on speculation over the study results for 640
 PolyHeme, Northfield’s only product” (Burtman
 2004). PolyHeme is currently in “pivotal” Phase
 III prehospital trials following Northfield Labs’
 multiple clinical trials. The Phase III trial has been
 645 designed as a randomized application to ~720
 patients in Level I trauma centers across the United
 States.

When Duke University Medical Center in
 Durham, NC attempted to join the study, its re-
 searchers’ application to the university’s Institutional

5. Biopure’s “Hemopure” consists of “chemically sta-
 bilized bovine hemoglobin”; Baxter Pharmaceuticals has
 investigated a recombinant human hemoglobin; San-
 gart’s Hemospan, like Northfield’s PolyHeme, uses out-
 dated human blood.

650 Review Board was reviewed, and subsequently
 approved under the FDA exception for emergency
 research. Questions critical of the study's ethics had
 been raised in the press, and at a late fall Board
 of County Commissioners meeting. Minutes from
 655 that meeting include questions regarding approval
 of contracts allowing county EMS vehicles to partic-
 ipate in the study. The board was asked to vote
 against the PolyHeme study by a citizen who argu-
 ed that there had been insufficient community
 660 outreach and who questioned the necessity for the
 blood substitute's use for twelve hours after hospi-
 talization. After satisfying itself that the county
 would be indemnified from liability, the county ap-
 proved participation by its EMS vehicles and per-
 665 sonnel (Board 2004).

Although Duke's IRB initially approved the
 involvement of its researchers, the IRB approval
 was withdrawn when it became clear that North
 Carolina Patient's Bill of Rights requirement of
 670 prior consent as a requisite to enrollment of par-
 ticipants for medical trials had not been updated
 to correspond with the FDA exceptions for emer-
 gency research. This oversight made the study, as
 proposed, illegal in North Carolina and the subse-
 675 quent halt to the trial's implementation prompted
 additional media interest in the ethical questions
 the trial raised, and in the processes Duke had de-
 signed to satisfy the community consultation. Other
 states had had similar issues raised. Boston Hospi-
 680 tal's IRB, for example, denied its researchers a go-
 ahead for the trial on ethical grounds. Reporter Scott
 Allen explained their decision in *The Boston Globe*,
 writing that although

685 Boston Medical Center trauma doctors wanted to
 join the experiment, arguing that PolyHeme works
 as well as real blood by some measures and Poly-
 Heme would do more to help trauma patients than
 the saline solution that EMTs normally infuse. . . the
 690 hospital's institutional review board turned down the
 research. . . both because of consent concerns and be-
 cause Northfield Labs, the Illinois-based maker of
 PolyHeme, wanted them to continue giving patients
 the artificial blood for 12 hours after reach the hospi-
 tal. Ethicists such as Boston University's George
 695 Annas argued that would be unethical since the pa-
 tients would otherwise have ready access to natural
 blood (Allen 2004, E2).

Duke (and the University of North Carolina at
 Chapel Hill and Wake Forest University) petitioned
 700 state medical board authorities to amend the state
 document and to bring it into correspondence with
 the FDA waiver of prior, informed consent under

the special circumstances of emergency research.
 In March 2005, the state Medical Care Commis-
 sion made a temporary rules change to support the
 705 amendment, eliminating the obstacle to Duke's par-
 ticipation.

There was certainly federal authority that sup-
 ported Duke's request for the amendment to North
 Carolina's Patient Bill of Rights. Northfield Lab's
 710 own website links those who might need this in-
 formation directly to the FDA website explaining
 the exception that allows a trial like PolyHeme to
 proceed. Duke Hospital's request and subsequent
 authorization was legally and procedurally correct
 715 in its advance through state and federal regulatory
 bodies. But the opportunity to consider the cultural
 politics of its decision was not evident.

At this juncture of public review and IRB focus,
 the historical narratives about care at Duke in the
 720 black community of Durham are certainly relevant.
 Given its history of segregated medical care, and the
 distrust and misunderstanding that have extended
 from those days, there seemed a missed opportu-
 nity for Duke to develop a community consultation
 725 process that engaged more rigorously with urban
 Durham. Instead, Duke's efforts to "consult" the
 community regarding the trial's protocols seemed
 perfunctory: four (reportedly poorly attended) infor-
 mation sessions, a slot on a Rotary Club's meeting
 730 agenda, and three other sessions: at a mall (twice),
 and a 4th of July baseball game (Burtman 2004).
 Some indication of its standing within the black
 community is evident in the rebuff it received when
 735 requesting to speak to the congregations of two
 black churches in Durham regarding the proposed
 trial. The trial and the request to emend the guide-
 lines for informed consent intersect with the narra-
 tive histories of emergency medical care of African
 740 American citizens.

Because the FDA guidelines give no parameters
 for a standard of consultation there was no baseline
 to apply to any procedure that an IRB might adopt.
 Neither did state officials who gave their approval
 745 to a temporary rules change in the state guidelines
 specify the form that this consultation might take.
 Leaving the form of consultation open to the med-
 ical center IRB attenuates its visible responsibility
 to the community.

Protocols developed for the PolyHeme trials do
 750 not seem attentive to the cultural histories within
 communities. This absence of a cultural, narra-
 tive space of clinical trial protocol mirrors a busi-
 ness trend towards the corporatization of clinical
 research where interest in a business-like climate of
 755

growth and development distances the subject of these trials and shapes the process and the constitution of IRBs (Rettig, 2000).

760 The result of the process at Duke leaves questions for ethicists not unlike those raised by Annas at Boston Hospital regarding the ethics of continuing of the study after the patient arrives at the hospital as well as the most basic questions regarding proxies. The FDA directive that a trial should serve the patient's "best interest" seems to argue against the particular dimension of the study that continues the administration of a substitute when whole blood would ordinarily be available and arguably in the individual patient's best interest. 775 There is little evidence that citizen inquiry regarding this specific issue has received a straightforward explanation.

Is this an ethical research design? At the very least, communities who have participated in the research should have an opportunity to review and to fully understand this important facet of the study. Further, IRB review of the twelve-hour rule should be transparent for communities whose individual citizens have lost the protection of informed consent through the emergency research waiver. In situations where a proxy has effectively been distributed to an aggregate of persons unknown becomes credible enough to displace the principle of consent, a more rigorous standard for review, discussion, and consultation seem minimally reasonable. 780 As the Boston Hospital IRB concluded, this is the most ethically problematic dimension of the trial. It was the question left unanswered at the Durham County Board of Commissioners meeting, and the one most frequently raised in media criticism of the study. 785

The consequence of a trial like PolyHeme is that it reveals that a principled focus on individual autonomy and informed consent inherently conflicts with the ways in which a community is constructed for medical expediency. The idea of community is historically situated, and this research trial's formulation does not acknowledge the effects of a cultural history where differential, lesser quality, and sometimes biased care have not been unusual. PolyHeme's exception from informed consent; its minimal involvement of trial participants; and the fact that the trial calls for participants to remain linked to the product despite the availability of the standard treatment of infusion of whole blood are facets of the study that join its protocols to those histories. 790 800 805

III. CONCLUSION

Early in 2005, Larry Green, a young African American man, was hit by a car and left lying on the roadside of rural Franklin County in North Carolina. When paramedics arrived at the scene, they found Green lying in a pool of blood. What happened next placed this event into the histories of stories told about black bodies and emergency medicine. 810 815

The first paramedic to arrive, Randy Kearney, reportedly took only three minutes to check Mr. Green's vital signs and make his determination that he was dead. When his colleagues arrived, Kearney reported to them that Green was dead. They did not connect him to the available electrocardiogram. The county medical examiner, J.B. Perdue, who was also called to the scene, accepted the determination of the paramedics even though firefighters on the scene overheard the paramedics noting the movement of Green's chest and asking the medical examiner if he was certain of death. The examiner confirmed the judgment without further examination, and directed that his body be transported to the morgue. Mr. Green remained in a refrigerated unit for almost two hours before Perdue removed him to begin an examination for the cause of death. At that point, the examiner noticed signs of breathing, and realized the ghastly error that had been made. He immediately called 911, summoning the same paramedics who had earlier pronounced him dead, and called for them to transport him immediately to Duke University's Medical Center (Brevorka 2005). 820 825 830 835 840

Although appropriate medical and professional authorities are investigating this catastrophic error, there is a discomfiting cultural space for this event that makes it feel all too familiar in African America. It is a narrative that anticipates black bodies are not as valued as white ones, that the medical attention shown to black Americans is less intense, less interested, and less professional than that shown to other citizens, and one where mistake, carelessness, and disregard are not infrequent. What happened to Mr. Green was surely a grievous error—but the fact that his story has a readily available narrative space to occupy is an additional tragedy. 845 850 855

The paramedics who made the decision regarding Mr. Green are not much different from those who will administer PolyHeme at the scene of similar accidents. Black urban victims of accident or injury in Durham who might be unwittingly enrolled

860 in the PolyHeme trials have inherited the cultural
stories that circulate around problematic histories
of medicine and black bodies. Mr. Green's horror
joins those others, interrupting medicine's goal of
865 earning the confidence of its "communities" to carry
out patient care and research with a respect for the
bodies it might encounter.

The Institute of Medicine report concludes its
chapter on "Racial and Ethnic Disparities in Health-
care: A Background and History" with the assess-
870 ment that "[t]he future health of America's health
system, and indeed its population, may hinge on
attaining a satisfactory resolution of its racial, class,
and ethnic disparities. . . problems that linger from
the nation's health past" (Smedley 1999). It would
875 seem important, given this warning, that the poli-
cies and practices of medicine and research in the
twenty-first century assiduously avoid the traps of
disparity that make this history so difficult to es-
cape. Understanding the evolution and use of its
880 own language may be one critical space of inter-
rogation for medicine. Proceeding cautiously with
the development and authority of institutions like
IRBs, and subjecting their processes and categorical
assumptions about patient populations to probing
885 and substantive ethical inquiry seems a necessary
step. Making a determination to share the basic op-
erations of research protocols in a forthright man-
ner, and to assess ways in which a population might
have more authoritative and knowledgeable partic-
890 ipation in the deliberative processes of emergency
medical research seem similarly critical. The epi-
graph that begins this essay indicates the ease with
which the biases of the past uncritically join the
present. These biases need not, however, be the
895 narrative of medicine's future. A commitment to
a twenty-first century practice of ethics, that rein-
stantiates a commitment to the idea of autonomy
for all patient populations seems an appropriate be-
ginning. ■

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