Vera Sharav

Personal tragedy motivates Vera Sharav in her campaign to protect the human rights of research subjects in clinical trials.

Industry critic Vera Sharav's vitriolic blog is read by thousands of people. Key to her writings is the belief that biomedical research is a profit-driven, corporate enterprise that perpetuates "a big lie" on healthcare consumers, tricking them into trial participation under the guise of medical treatment.

That belief has led her to target, in the biotech realm, such companies as Evanston, Illinois–based Northfield Laboratories, and Biopure in Cambridge, Massachusetts—both developers of artificial blood substitutes for emergency trauma care. These companies have relied on "waivers of informed consent" from the US Food and Drug Administration to test their products on human subjects, who might be trauma victims and unconscious at the time of enrollment. Sharav says the FDA's consent waiver rule, which permits institutional review boards to approve drug testing on individuals without consent under specific conditions (e.g., unconsciousness or incapacitation), violates "fundamental principles of medical research within a civilized society."

Sharav was born in Romania during World War II. A child survivor of the Holocaust, which claimed her father's life, she left a Ukrainian detention camp at the age of 3 and was cared for by relatives while her mother settled in the United States. When she was 8, Sharav and her mother were reunited in New York City, where she lives today.

She went to the City College of New York during the 1950s, and majored in art history. After marrying, she had two sons and returned to school for a master's degree in library science at the Pratt Institute in New York, graduating in 1971.

Her stance on biomedicine was sparked by a life-altering tragedy. In the 1980s, her teenage son was diagnosed with schizo-affective disorder. Sharav and her husband pushed hard for access to clozapine, one of the first atypical antipsychotics then available. In 1994, after her son had been on clozapine (Clozaril, Fazaclo) for several years, he suddenly suffered a fatal reaction to the drug—a condition called neuroleptic malignant syndrome.

Grieving and feeling betrayed, Sharav battled with New York state's mental health office, which, she says, denied that clozapine was the cause. "I tried to find the best treatment and I wound up bumping against the obscenity of the mental health system," she says. "At that point, I became an outspoken critic of modern medicine; a watchdog. And to my surprise, I had no competition and I still have no competition."

Today, among other activities, Sharav has become particularly interested in campaigning against clinical studies in which patient consent is at issue. That's where her crusade against Northfield comes in. Working through the nonprofit organization she founded in 2001—the Alliance for Human Research Protection (AHRP)—Sharav tried to block Northfield's 2006 clinical trial with its lead product, PolyHeme (human hemoglobin modified by pyridoxylation and glutaraldehyde polymerization), claiming that it is toxic and inferior to real blood. She filed complaints with the Office for Human Research Protections in the Department of Health and Human Services, spoke out against PolyHeme in the media, and sent thousands of 'infomails' blasting both the FDA's consent waiver practices and artificial blood substitutes in general, to doctors, lawyers and congressional staff. Her campaign attracted the attention of *The Wall Street Journal*, which reported that enrolled communities hadn't been adequately warned of PolyHeme's risks. That in turn got the attention of Senator Chuck Grassley (R-Iowa), who chaired the US Senate's finance committee.

Grassley took issue with Northfield's trial, prodding the FDA to justify its authorization. The company was forced into a defensive posture and spent months trying to regain public favor. Today, with its human testing completed, Northfield is seeking FDA approval. Sharav, meanwhile, would like all waived consent trials banned, and suggests blood substitutes should be tested in other scenarios, such as surgery, on patients who consciously agree to participate.

Marcia Angell, a senior lecturer at Cambridge, Massachusetts–based Harvard Medical School, describes Sharav as an extraordinarily observant and valuable critic. "I see her as someone the research establishment badly needs," says Angell, a past editor of the *New England Journal of Medicine* and author of *The Truth About Drug Companies: How They Deceive Us and What To Do About It*, who herself is not an avid industry fan.

In contrast, Arthur Caplan, chair of the department of medical ethics at the University of Pennsylvania in Philadelphia, views Sharav as a dangerous gadfly. "She's best on the subjects she knows something about, like psychiatry, which she hates," he says. "But when she attacks efforts to find better therapies for emergency situations [e.g., blood substitutes], she causes real harm and she risks killing people. She doesn't understand that sometimes injured people come to the hospital without friends or relatives, and that if they could, they'd authorize the use of novel treatments that could save them. It's crazy to say you won't do the research if you can't get good informed consent when the alternative could be death."

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Angell concedes Sharav is sometimes "hyperbolic," but also claims her facts are by and large correct. "Even if she sometimes gets on a detour, she always supplies the evidence for her views," Angell adds. "She'll get her stories from the media, but then she'll find and attach the relevant documents."

Sharav claims she's particularly motivated to protect children from "nontherapeutic experimentation," and she is adamantly opposed to the six-month extension of exclusive marketing rights for companies that sponsor drug trials recruiting children.

Caplan agrees that Sharav's efforts to block trials using children to merely extend market rights are warranted. "She's right about that," he says, but adds that Sharav's opposition to the role of business in research is naive. "The challenge is to manage the reality of what we're dealing with," he says. "She simply points to the problems, and that's a straightforward job. The bigger challenge is coming up with answers realizing that the medical industrial complex isn't going away."

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