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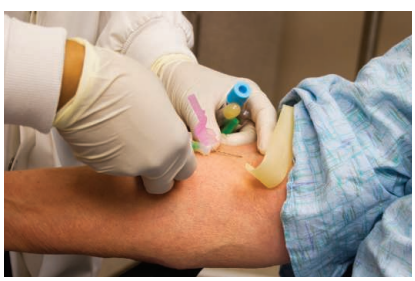
LETTERS

edited by Jennifer Sills

Paying for Tissue: The Case of WI-38

IN THEIR POLICY FORUM "PAYING PATIENTS FOR THEIR TISSUE: THE LEGACY OF HENRIETTA LACKS" (6 July, p. 37), R. D. Truog *et al.* overlook the L929 cell line, which, contrary to their statement about HeLa, was the first immortal cell line (*1*). Also overlooked are the commercial uses and questions of legal ownership first raised for normal human cell strains (*2*). WI-38, derived from the lung tissue of a surgically aborted fetus, has not only been used in research worldwide whenever a normal human cell is required, but has also been used as the substrate for the production of many of the world's human virus vaccines since the mid-1960s. About 2 billion people have directly benefitted from the use of WI-38 and similar strains (*3*). Although the commercial sales of vaccines produced in WI-38 cannot be accurately determined, it is certainly in the multiple billions of dollars. In the 1960s, I distributed WI-38 gratis to vaccine manufacturers and researchers worldwide because biological material could not be patented.



Truog *et al.* seem unaware that in 1975, the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Department of Health, Education, & Welfare (DHEW) argued that the WI-38 I used in my research was the sole property of the U.S. government. I and my colleagues had never received government support for the research or development of WI-38. In response to the government's claims of propriety, we sued. We believed that there are several stakeholders in the title to any human cell culture: the researchers who actually developed the culture, their institution, the individual from whom the tissue was derived, and the organization that supported the research.

During the 7 years of litigation, several decisive events torpedoed the government's position that it had sole title to WI-38. First, the Supreme Court decided that biological material could be patented (*4*). This decision established the principle that, even with federal research support, biological researchers have patentable intellectual property rights for their discoveries.

Second, the Bayh-Dole Act reversed the presumption of government title. Bayh-Dole permits a university, small business, or nonprofit institution to claim as its intellectual property the control of an invention in preference to the government and despite federal funding (*5*). The act further provides that royalties be shared with the inventor.

Third, in 1983, President Reagan instructed federal agency heads that all businesses should be able to retain patent rights on inventions made in the course of government-funded R&D work. His executive order explained that giving the private sector clear title to patents on inventions developed under federal contracts and grants would lead to more rapid commercialization of new products (*6*).

Fourth, the nascent biotechnology industry was then being formed by entrepreneurial biologists whose companies were founded by using biological materials discovered in federally funded university research laboratories. Thus, the NIH found itself in the untenable position of first claiming sole title to WI-38 by alleging that it was discovered using federal funds and later praising the use of federal funds to discover biological materials that were then used in the founding of new biotechnology companies.

The Justice Department, which defended the NIH, FDA, and DHEW, recognized their contradictory positions and accepted an out-of-court settlement. This is the first, and perhaps the only, instance where an individual scientist obtained federal legal title to a normal human cell strain, an event contradicted by subsequent state court decisions. The question of title to a self-duplicating human cell line or strain is still, after 50 years, a controversial issue.

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3. M. A. Fletcher *et al.*, *Dev. Biol. Stand*. **93**, 97 (1998).
4. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
5. Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980)35 U.S.C. § 200-212 (1980).
6. J. Walsh, *Science* **219**, 1408 (1983).

Paying for Tissue: Net Benefits

IN THEIR POLICY FORUM "PAYING PATIENTS for their tissue: The legacy of Henrietta Lacks" (6 July, p. 37), R. D. Truog *et al.* oppose sharing biomedical research revenues with the patients whose tissues enable that research. They argue that "reconceptualizing tissue acquisition as an economic exchange rather than as a gift relationship" might reduce tissue donation by "crowd[ing] out" altruistic motivations. We are skeptical of this argument.

The possibility of compensation might crowd out some individual donations, but other altruism-motivated donations would increase because of compensation, and nonaltruistic donations would also increase. It thus seems unlikely that net willingness to supply tissue would decline. Patients for whom compensation would truly decrease the enjoyment of donating tissues could pass on their compensation to nonprofits such as the American Cancer Society.

Truog *et al.* also argue that offering com-

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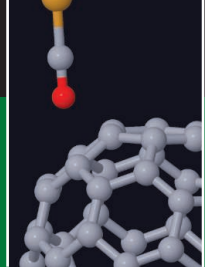

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pensation proportional to tissue value would be "unjust" because patients whose tissues yield "financial blockbusters" would be paid more than the vast majority of donors. This argument, too, is unconvincing. "Blockbuster" cell lines make some researchers very rich, whereas other researchers do not benefit at all; is that unjust? Moreover, it is standard to tie compensation to the value of personal characteristics such as intelligence or athletic ability. How could such a system, if applied to compensation for tissue donation, be less fair to patients than the current system, under which all revenues from tissue lines—"blockbuster" or otherwise—accrue to the medical community?

Offering value-based compensation to tissue donors would likely boost tissue supply. The great majority of patients would likely be willing to donate waste tissue in exchange for either a fixed fee or a chance to share in the rewards of financially successful research.

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Response

KOMINERS AND BECKER ARGUE THAT COMpensating patients for their tissue will increase the supply of tissue for research. But there is no evidence that lack of compensation, the current standard, is an impediment to procurement of tissue. This is tissue that will be discarded if it is not used for research, and we doubt that very many patients refuse to give permission for the use of such tissue or that those who do refuse would reconsider if offered compensation.

Kominers and Becker propose compensation mechanisms that would be complex and difficult to implement. Compensation to the patient could not be linked to the actual value of the tissue at the time of donation, because it is impossible to know the value of waste tissue at that point. It could be many years before it is known whether a sample has value. An alternative reimbursement scheme based on a future royalty interest would lead to substantial transaction costs and would favor patients whose identity, location, and relatives could be easily tracked over time, thereby unfairly disadvantaging those with less social stability and family integrity.

Even the suggestion to consider a compensation scheme based on a fixed fee for all samples is problematic. If we are correct that the number of tissue samples that have little or no value dwarfs the number of those that do (an empirically testable question), the actual amount of the fixed fee would likely be quite small. While it is difficult to predict the effect that a small amount of compensation would have on the willingness of patients to donate, some empirical evidence does suggest that small payments can decrease altruistic behavior in comparison with no payments at all (*1*). The complexity and costs to the research enterprise of any of these mechanisms would need to be justified by a positive argument about why those who donate waste tissue deserve financial compensation, an argument that Kominers and Becker do not provide.

Finally, on the question of fairness, we disagree with the authors that there is anything unfair about rewarding medical researchers for their ingenuity, talents, hard work, and willingness to take risks and to absorb opportunity costs in transforming medical waste into products that have scientific value.

We want to be clear that our Policy Forum only analyzed whether donors of waste tissue should receive financial compensation. Other forms of compensation, such as recognition or commitments to use a portion of the proceeds for other worthwhile purposes, are commendable and entirely appropriate. Indeed, when the research is federally funded, all proceeds retained by the academic institution, net of expenses such as the costs of protecting intellectual property, must be used for research and educational purposes, both important public goods. The question we addressed, however, focused only on the propriety of payments to the individual and family for the use of the original discarded specimen.

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Readers' Poll

Paying for Tissue

The family of Henrietta Lacks never received any financial compensation for the HeLa cell line, which was derived from the tissue that researchers obtained during her treatment for cervical cancer. Her story has raised the question of whether patients should be compensated for such tissue. In their Policy Forum (6 July, p. 37), R. D. Truog *et al*. argue against payment. They explain that the tissue only becomes valuable once research has been done by investigators. Once the prospect of money has been introduced, insufficient payments might provide a disincentive for donation. Payments would open the door to researcher biases affecting distribution, and patients would inevitably be compensated unequally, given that some cell lines lead to far more revenue than others. In their Letter (this issue, p. 1292), Kominers and Becker disagree with Truog *et al*. They argue that financially compensating patients would likely lead to a net increase in donations. They then suggest that unequal distribution of revenue does not make the system unethical; investigators currently reap unequal rewards for their work with the tissues in question. Truog *et al*.'s Letter Response (this issue, p. 1293) highlights the logistical challenges of implementing a fair payment system. What do you think?

When medical procedures result in tissue that would otherwise be discarded, should researchers be required to pay patients for its use?

❒ Yes
❒ No

Vote online at http://scim.ag/tissuepoll

Polling results reflect the votes of those who choose to participate; they do not represent a random sample of the population.

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CORRECTIONS AND CLARIFICATIONS

Editorial: "Iceberg alert for NIH" by H. R. Bourne and M. O. Lively (27 July, p. 390). The Editorial mistakenly indicated that 150 research faculty were laid off by the University of Miami's Miller School of Medicine. This sentence should have said that "researchers" were laid off (not "110 researchers" as indicated in the original correction). The text has been corrected in both the HTML and PDF versions online.

News & Analysis: "Stability at last for Australian Synchrotron?" by E. Finkel (20 July, p. 278). In the third paragraph, the story incorrectly stated that " seven of nine members of the synchrotron's International Scientific Advisory Committee resigned." In fact, five of nine members resigned.

TECHNICAL COMMENT ABSTRACTS

Comment on "Climate Sensitivity Estimated from Temperature Reconstructions of the Last Glacial Maximum"

J. Fyke and M. Eby

Schmittner *et al*. (Reports, 9 December 2011, p. 1385) report a new, low estimate of equilibrium climate sensitivity based on a comparison of Last Glacial Maximum climate model simulations and paleoproxy data. Here, we show that exclusion of questionable comparison points and constructive changes to model design are both likely capable of altering the most probable value of equilibrium climate sensitivity suggested in Schmittner *et al*.

Full text at www.sciencemag.org/cgi/content/full/337/6100/1294-b

Response to Comment on "Climate Sensitivity Estimated from Temperature Reconstructions of the Last Glacial Maximum"

Andreas Schmittner, Nathan M. Urban, Jeremy D. Shakun, Natalie M. Mahowald, Peter U. Clark, Patrick J. Bartlein, Alan C. Mix, Antoni Rosell-Melé

The removal of data by Fyke and Eby is mostly unjustified, and their statistics are oversimplified, but the suggestion that structural model uncertainty—in particular, the atmospheric heat flux formulation—may have led to underestimation of equilibrium climate sensitivity for a doubling of atmospheric carbon dioxide concentrations in our 2011 paper may have merit and should be quantified in future studies.

Full text at www.sciencemag.org/cgi/content/full/337/6100/1294-c

Letters to the Editor

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