

## The Ingelfinger rule, embargoes, and journal peer review—part 1

Lawrence K Altman

It is 27 years since Dr Franz Ingelfinger announced that a manuscript would be rejected by his journal, the *New England Journal of Medicine*, if it had been published elsewhere. Many other medical journals have since adopted this so-called Ingelfinger rule. The restrictions resulting from the rule have generated enormous controversy in medical journalism, as shown by the first of the two-part article *The Ingelfinger rule, embargoes, and journal peer review*. Critics say that the rule restricts the free flow of information, whereas proponents claim that information from a paper released early may be inaccurate because the paper has not been subjected to peer review. Yet peer review itself has also come under scrutiny, with its many limitations rarely being openly discussed.

Soon after becoming editor of the *New England Journal of Medicine* in 1967, Franz J Ingelfinger (figure) learned that two publications that were mailed free to doctors had reported details of a paper before its publication in his subscription-based, peer-reviewed journal. Ingelfinger believed that the earlier reports “demolished” their newsworthiness, which he viewed as a major element of the commercial profitability of his journal. Rather than conceding a scoop he retaliated. He announced that henceforth *NEJM*'s policy would be to reject a paper if it had been published elsewhere, in whole or substance. The Ingelfinger rule was born.<sup>1-3</sup>

Subsequently, many other medical journals, including *The Lancet*, have adopted the rule, although interpretations and applications have varied widely. Moreover, Ingelfinger's successors at his and other journals have expanded the scope of what they consider “prior publication”. To address advances in electronic communications, the *NEJM* recently announced that it will put much of its contents on the Internet. But the journal has also said that “posting a manuscript, including its figures and tables” on the Internet “will constitute prior publication”, making it ineligible for publication in the journal.<sup>4</sup> Ingelfinger exempted reports bearing on urgent public-health matters from the rule, but not until 1977.<sup>3</sup> Even today other journals have no stated exceptions to the rule pertaining to the public health.

It is important to distinguish between embargoes on journal content and embargoes on prior publication created by the Ingelfinger rule. The former applies to the news releases and advance copies of each issue that many journals send to subscribing news organisations or complimentary copies to seek publicity; the understanding is that the contents will not be reported until the date of publication. This embargo applies to the period from printing through distribution, and is intended to give all journalists simultaneous and equal opportunity to report on the journal's contents. With few exceptions, this embargo has created little controversy.

Major discord, however, surrounds the embargo and restrictions resulting from the Ingelfinger rule. It has generated controversy in medical journalism for all 27 years of its existence because of what many believe is its

unwarranted influence on the shaping of public-health policy. Because the rule restricts what authors may disclose long before publication in a journal, it helps determine not only what scientific information is disseminated but also how soon important information related to clinical care and public health is publicly disclosed. The rule has limited what scientists and doctors, eager to publish in journals, disclose at scientific meetings and in interviews, even long before submission. To ensure that a paper will remain eligible for consideration by journals, presenters have chosen not to disclose in part or in full findings at meetings where the data may become available to reporters. Thus, critics say the rule has had a chilling effect on the free flow of information.

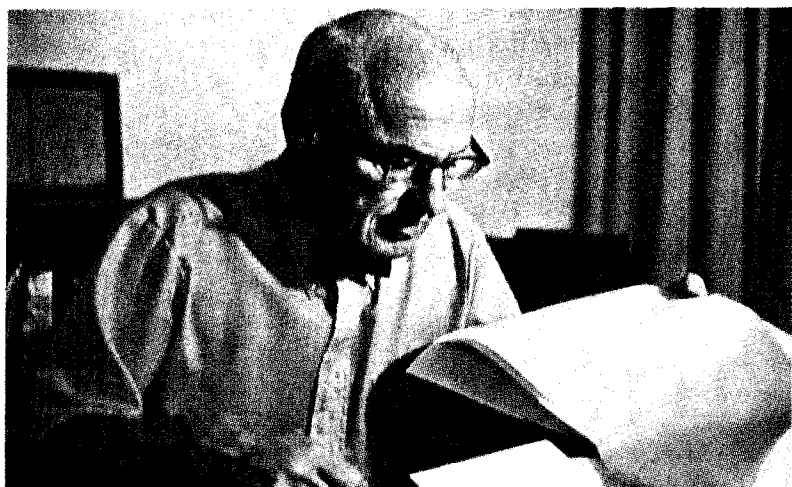
Dissemination of medical data is the hub of a complex web of sometimes competing interests that together wield enormous influence over public-health policies. First and foremost is the general public, which has invested increasingly large sums in medical care, research, and education. Because the rule strongly influences, if not controls, release of information resulting from publicly funded research (especially at open scientific meetings, many of which are publicly funded), it bears directly on how, when, and where findings resulting from taxpayer-supported research become public, and who profits.

The Ingelfinger rule affects another key group: academics vying for credit for their work, faculty promotions, and grants. Application of the rule can be crucial to their careers; promotion committees (at least in US academia) assign more weight to papers published in certain journals, some of which happen to enforce the Ingelfinger rule. So the rule helps shape the composition of the faculties and staffs of many medical schools and health-care institutions as well as the outlook of younger generations of doctors. Because journals are a primary source of information on new therapies and advances in medicine, the rule ultimately influences the care given to millions of patients.

The rule also affects government officials whether they are in policy or research. Because publication in a well-known journal may help advance scientific careers, investigators may be tempted to withhold certain data at certain meetings for a certain period of time. At a recent meeting of clinicians and scientists, an investigator described a new molecule he had identified that he said might have value in a cancer vaccine. But in the discussion period, he refused to disclose the identity of

*Lancet* 1996; **347**: 1382-86

*New York Times*, 229 West 23rd Street, New York, NY 10024, USA  
(L K Altman MD, medical correspondent)



National Library of Medicine

Figure: Franz J Ingelfinger

the molecule because the paper documenting the work had not been accepted for publication.<sup>5</sup> When scientists withhold data at meetings, researchers and government officials may be inappropriately denied relevant information to make recommendations that could directly affect public-health policy.

Similarly, journalists will not be able to accurately report findings to the public—which may include officials responsible for public policies—if those who are presenting data at public meetings are less than forthcoming. And furtive retention of information to comply with the Ingelfinger rule, or leaking of information, may affect yet another important medical constituency—investors in biotechnology companies. Without timely and accurate information, investors may be misled about the merits of what they finance and may not support the most promising research.

Today, proponents justify the rule primarily on two grounds. The most common defence is that early release of scientific findings risks premature and inaccurate information reaching the profession and public unless details are first subjected to peer review.<sup>6</sup> Yet, peer review itself is contentious.<sup>7</sup> The Ingelfinger rule applies to disclosure of material at news conferences at scientific meetings, which generally are sponsored by organisations that have no connection with the journals. Nonetheless, journals encourage press conferences to coincide with the publication of a paper, which, if not a conflict of interest, surely reflects a vested interest. So when certain journals can extend their purview to put restrictions on the conduct of scientific meetings, critics say the rule gives those journals excessive power to control medical affairs.

Ingelfinger's justification for his rule, that a journal's newsworthiness will disappear if authors disclose findings before journal publication, is now the second most common defence for the rule. The newsworthiness that Ingelfinger described as "selfish" is now said to be "enlightened self-interest".<sup>6</sup> Newsworthiness is a form of scoop journalism and it helps contribute to the profitability of journals. Making profits is the American and western European way, but how profits are derived can be a public-policy issue if taxpayer funds are involved. Because the bulk of what is published in such journals is derived from publicly funded research, any rule that interferes with the free flow of information should be in the public interest. Any policy that can exert such enormous impact on medicine and society surely demands close scrutiny. Members of the general news media, including me, have strongly and frequently

criticised the rule for restricting the free flow of information. But physicians are generally unaware of the nature of this criticism. The scientific community has generally accepted the rule uncritically and without consideration of the broader issues involved. The overwhelming majority of what has been published in medical journals on the rule has come from its strongest defender, the journal that created it, and those articles have mostly been concerned with countering attacks on the rule. Probably no rule in medicine has been clarified more often. So, revisiting the writing of Ingelfinger is a necessary first step to the better understanding of the reasons for the confusion and controversy that buffet his rule long after his death.

## Ingelfinger

Ingelfinger, a distinguished gastroenterologist, researcher, medical educator, and newly appointed editor, originally promulgated his rule in a brief 1969 editorial:<sup>1</sup>

"The understanding is that material submitted to the *Journal* has not been offered to any book, journal or newspaper".

Ingelfinger exempted publication of abstracts and "material that is not really submitted—eg, when a reporter notes what is said by a speaker at a public meeting". The following year, he expanded on his reasoning for the rule. Again, the focus was on the several-month publication process when the embargo was in effect.<sup>2</sup>

"The expression that I find most offensive is the publication in a medical news medium of an article that has already been accepted for publication in the *New England Journal of Medicine*."

Ingelfinger was keenly aware of the criticism that his rule hampered free dissemination of the news. He said he did not intend his rule to interfere with the news-gathering efforts of newspapers, magazines, and the general press. In a rebuttal of the critics, he wrote:

"If science writers had come and talked to me about it, I could have tried to reassure them that the meager paragraphs usually devoted to reporting a scientific observation in a lay news medium never come near qualifying as prior publication in my mind. If on that most rare occasion when a medical scientific report is so important that it is covered extensively by the *New York Times*, then probably the *Journal* is happy to publish the second or third report of that same event".<sup>2</sup>

This essay has been cited in medical published work only 14 times and never in direct response to criticism of the rule. (The 1969 editorial has been cited 23 times and the 1977 paper 11 times; Institute for Scientific Information research, personal communication).

Ingelfinger was one of my medical school professors and a man I admired. We did discuss the rule—several times—after we had both become involved in full-time medical writing. In these discussions, his focus was on the free medical newspapers and magazines, not the general news publications, because the medical giveaways were a journalistic threat, and were competing commercially for the same pharmaceutical-advertising dollar as his journal. Other science writers, including Barbara Culliton, now the editor of *Nature Medicine*, told me she had similar conversations with Ingelfinger that continued until his death.<sup>8</sup>

To Ingelfinger, his journal was "an educational institution".<sup>9</sup> To counter critics who said his journal

should not accept pharmaceutical advertising, he cited "hard-nosed business reasons" for the policy; it lowered the costs of subscriptions and helped the owner to use the profits to offset deficits incurred by other operations.<sup>10</sup> He did not specify what those operations were, but in the case of a politically active professional society, such operations could be important to public policy.

Several weeks later, in his 1969 editorial, Ingelfinger introduced considerable uncertainty into how much material a potential author could supply to any news reporter without jeopardising his or her chances of publication in the *NEJM*. "Suppose the speaker is interviewed after the talk and provides additional information", he wrote. "Here a decision may be difficult, but in the *Journal's* opinion the material has been contributed elsewhere if the speaker makes illustrations available to the interviewer, or if the published interview covers practically all the principal points contained in a subsequently submitted manuscript."<sup>2</sup>

In his 1970 essay, Ingelfinger was vague in commenting on application of the rule to meetings. "Reporters should not ask for, nor should authors offer, excerpts from the text or the specific figures that they eventually hope to submit to the medical literature", he said.<sup>2</sup> The statement left ambiguous the fate of an author who reported such data in a talk at a scientific meeting. But he was clear about his displeasure when the essence of an article to be published in his journal appeared in another standard journal, or in the news sections of *Science* and the *Journal of the American Medical Association*. One of his successors said that *JAMA* should dispense with its medical news section.<sup>11</sup> Ingelfinger also said that even a listener's transcription of an *NEJM* author's public speech leading to publication elsewhere "ignored" the journal's rights. Even now, editors squabble with each other when one journal publishes a report from an author's presentation at a meeting before a second publishes the author's original paper.

Shortly before his retirement in 1977, Ingelfinger again addressed the subject of news coverage of scientific findings before journal publication. "Accounts in the lay press may rarely be so extensive as to require invocation of the 'rule', but such accounts are usually too brief to infringe on the newsworthiness of articles subsequently published in the *Journal*", he wrote.<sup>3</sup>

The three Ingelfinger articles are noteworthy because they emphasise newsworthiness and competition with hardly a mention of peer review.

### Peer review

Ingelfinger's successor, Arnold S Relman, a distinguished nephrologist, turned the Ingelfinger rule into a gatekeeper function and used peer review as the rationale. "We believe medical research should be subjected to peer review and published in the scientific literature before it is touted to the public or the profession", he wrote.<sup>12</sup> He also campaigned to discourage news conferences at meetings because they could lead to violations of the rule.

"Work that has already been publicised, especially if its scientific substance has been presented in detail in the medical press or given full exposure by one or more major newspapers, has by our lights lost some of its interest. We consider that a kind of prior publication."

Relman defended his journal's policy of objecting to speakers being interviewed or providing copies of the text

of what they had said at a meeting to reporters (especially when they might enhance the accuracy of a story) simply because he believed that medical information should be published before release to the public.<sup>13</sup>

Relman was so concerned about the Ingelfinger rule that he invited representatives of key news organisations and editors of major journals to his office to discuss it. Commenting on the rule, Edward Huth, then editor of the *Annals of Internal Medicine*, said he believed "Franz was wrong".<sup>14,15</sup> In reference to Relman's concern about misinformation reaching doctors and the public, Huth said that intelligent doctors would not leap to erroneous conclusions from newspaper articles. If they do, he said, "it's a difficulty for the medical profession, not the press, the problem lying with the medical schools' not teaching doctors to sift out bad information". Summing up the meeting, a reporter wrote, "When the day was over, the only editor or reporter who agreed with Dr Relman was Dr Relman".<sup>14</sup>

Although peer review is described as a lynchpin of science, little is known about it except that it is not a scientific process. It is a tool of editing, which rightfully is a subjective process. Peer review is an amorphous, and perhaps intentionally mysterious, phrase that begs for definition. It is not applied in a standard way from journal to journal and sometimes not even within the same journal. Although journals regard their method of peer review as the gold standard, they are not the sole source of peer review. Other equally respectable medical organisations, both public and private (eg, the National Institutes of Health and the American Heart Association) often tap the same experts for their criticisms of a study, and many clinical trials are assessed by various reviewers from planning to completion. It is doubtful that peers limit their criticisms when reviewing for certain organisations yet reserve their best critiques for journals. So in terms of criticisms from referees, why do journal editors regard their method of peer review as the gold standard?

Most scientists equate journal peer review with outside review—ie, by experts who do not work for the journal to which a paper is submitted. It is an assumption because journal policy statements usually do not specify that the reviewers will be independent of the publication, and the assumption does not always hold. For instance, an editor of *JAMA* said in depositions for a law suit against his journal that the peer review for articles<sup>16,17</sup> about the pathologists who carried out the necropsy on President John F Kennedy was conducted by the journal's own staff (deposition testimony in Crenshaw, et al v *JAMA*, et al: George Lundberg, Dec 21, 1993; Richard M Glass, Dec 2, 1993; and Dennis L Breo, Sept 15 and 22, 1993, unpublished). Because the identity of the reviewers is usually kept secret, there is no way for readers to know how often *JAMA* and other journals publish papers without external peer review. (A spot check of the information pages that journals provide for authors indicates that the practice may be more common than many readers believe because the statements about the process by which journals carry out peer review are vague.)

Intentionally or not, journals that impose the Ingelfinger rule and prepublication embargoes have created a misimpression that publication in a peer-reviewed journal is equivalent to the *Good Housekeeping* seal of approval. George Lundberg, editor of *JAMA*, has

repeatedly said, as he shows a slide, "We like it when the *Chicago Tribune* says, 'All of this is true because it was reported in the *Journal of the American Medical Association*'" (Lundberg G, personal communication). The misimpression has been nurtured by a promotional advertisement in another journal saying its peer review system "insures accuracy and technical integrity".<sup>18</sup>

By using peer review to justify the Ingelfinger rule, journals assume an enormous responsibility for assuring the validity of the data they publish. But editors say they cannot provide such a guarantee. Their acknowledgments that peer review cannot detect fraud have been made grudgingly only after peer-reviewed journals have published fraudulent papers. The reason is clear: editors and reviewers deal with what investigators and authors report; they examine primary data, only when a question arises about its validity, and perhaps not even then. Those occasions are rare. All

too often, editors avoid even raising a question about fraud with authors. "A request from an editor for primary data to support the honesty of an author's findings in a manuscript under review would probably poison the air and make civil discourse between authors and editors even more difficult than it is now", Relman said in defence of his journal's role in publishing fraudulent papers by John R Darsee.<sup>19</sup> Darsee had fabricated findings in a number of published papers—from his college days, to his medical house staff training at Emory, and during fellowship at Harvard. And when important clues to fraud appear in manuscripts, editors do not aggressively follow them up. For example, authors of an important study on breast cancer said that they excluded 24 cases from one hospital because of difficulty with the quality of the data. Yet editors were not suspicious of the problem, did not question the data, and published the paper without demanding an explanation.<sup>20</sup> In another example, in 1995, a woman in upstate New York was convicted of smothering her five children 25 years earlier.<sup>21</sup> Two of the deaths in that case had been cited in an article in *Pediatrics* in 1972 as compelling evidence that sudden infant death syndrome was familial. The journal article did not mention the possibility of foul play.

Moreover, peer-reviewed journals do not subject all their contents to the peer-review process and do not identify the peer-reviewed articles in their pages. Letters to the Editor, which often report new data, for example, are covered by the Ingelfinger rule even in journals that do not peer review such material.<sup>22</sup> By holding information hostage if it appears in the form of a non-peer-reviewed letter, journals undermine the basis of their rationale for the rule. Because peer review is cited as an important justification for the rule, its application to non-peer-reviewed material supports the charge of scoop journalism, with concomitant commercial motivations.

Editors contend that peer review has led to changes in, and even reversal of, conclusions of a study before publication. But editors have provided little data on how often peer review influences publication, or even how often it leads to important changes in a paper. Relman has justified peer review as a critical scientific step in helping to screen out shoddy work, improving a paper's quality by weeding out errors and inaccurate data, and blunting possible biases by investigators.<sup>23</sup> However, following

---

**“. . . editors have provided little data on how often peer review influences publication, or even how often it leads to important changes in a paper.”**

---

criticism of peer review, the same editor shifted the blame to others:<sup>24</sup> "*Contrary to popular opinion, [my italics] the peer-review process does not eliminate the mediocre, the inferior, or even all the fallacious papers. Eighty five or ninety percent of what is submitted is going to be published somewhere. There are so many journals hungry for material that you can get a paper published somewhere if you try hard enough*". Indeed, since there are more than 25 000 biomedical journals world wide (news release from American College of Physicians, Sept 7, 1995), few people disagree that almost every paper will get published if the author persists. About 3500 journals are included in *Index Medicus*, which is the basis of most electronic data banks for citations in the biomedical literature. The head of the National Library of Medicine, which publishes the index, says that some of the finest indexed journals are not peer reviewed. More than once, the authors

of a paper rejected by journal A and published in journal B have won a Nobel Prize. Two examples are the development of the radioimmunoassay and the discovery of the hepatitis B antigen, then known as the Australia antigen.

No-one knows the overall monetary costs of reviewing to journals and to the public that pays for a scientist's time to review another scientist's paper. American journals do not pay reviewers, though some European journals do. The *NEJM* has said that costs of peer review exceeded \$1 million a year in the late 1980s.<sup>25</sup> Peer review costs the *Annals of Internal Medicine* more than \$100 per submitted article.<sup>26</sup> However, since most papers submitted for publication eventually get published, the peer-review process does not seem overall to be cost-effective.

Scientists have impressed on the public the benefits of peer review. But they have talked much less openly about its limitations. Indeed, the first meeting ever to examine the journal peer-review process in 1989<sup>27</sup> was provoked largely by criticism of the Ingelfinger rule and peer review. Despite the weaknesses of peer review, many editors defend the Ingelfinger rule as the firewall between questionable medical data and the naïve public. However, that view is not universally accepted. Richard Smith, editor of the *British Medical Journal*, pierced the veneer by saying that only 5% of what peer-reviewed journals publish is credible, the rest being "rubbish".<sup>28,29</sup> The criticism supports the view of Jeffrey Harris, professor at the Massachusetts Institute of Technology; he told a conference on the changing relationship between medicine and the media, that "the press has no obligation to withhold coverage of any scientific finding just because it's tentative or unproven".<sup>30</sup>

Another point of disagreement over both the embargo and the Ingelfinger rule is the need to withhold information from the public until publication to allow subscribers a chance to study the data for themselves.<sup>31</sup> The *NEJM* has said that a poll of its readers provided evidence for "a mandate" to maintain its embargo.<sup>32</sup> However, a study of authors' experiences contradicted editors' statements that doctors need all the information in hand to deal with patients' inquiries; it found no "strong support for delaying dissemination to the public to allow community physicians to first review the findings".<sup>33</sup>

**Part 2 will appear in the May 25 issue.**

## References

- 1 Ingelfinger FJ. Definition of "sole contribution". *N Engl J Med* 1969; **281**: 676-77.
- 2 Ingelfinger FJ. Medical literature: the campus without tumult. *Science* 1970; **169**: 831-37.
- 3 Ingelfinger FJ. Shattuck lecture. The general medical journal: for readers or repositories? *N Engl J Med* 1977; **296**: 1258-64.
- 4 Kassirer JP, Angell M. The Internet and the journal. *N Engl J Med* 1995; **332**: 1709-10.
- 5 Rosenberg SA. Secrecy in medical research. *N Engl J Med* 1996; **334**: 392-94.
- 6 Relman AS. An open letter to the news media. *N Engl J Med* 1979; **300**: 554-55.
- 7 Altman LK. The myth of passing peer review. In: Bailer J, ed. Bethesda: Council of Biology Editors, 1990.
- 8 Culliton B. Dual publication: "Ingelfinger rule" debated by scientists and press. *Science* 1972; **176**: 1403-05.
- 9 Ingelfinger FJ. The foggy poll. *N Engl J Med* 1969; **281**: 386.
- 10 Ingelfinger FJ. Annual discourse—swinging copy and sober science. *N Engl J Med* 1969; **281**: 526-32.
- 11 Elliott J. Relman of *NEJM* accused of restricting free news flow. *NASW Newsletter*. August, 1979: 5.
- 12 Relman AS. The Ingelfinger rule. *N Engl J Med* 1981; **305**: 824-26.
- 13 Relman AS. Medical meetings should be back-grounders, not news. *NASW Newsletter*. November 1979: 9.
- 14 Bloom M. Relman stands alone at meeting with reporters. *NASW Newsletter*. November 1979: 10.
- 15 Huth EJ. News media and the question of prior publication. *NASW Newsletter*. January 1980: 9.
- 16 Breo DL. JFK's death the plain truth from the MDs who did the autopsy. *JAMA* 1992; **267**: 2794-803.
- 17 Breo DL. JFK's death, part II—Dallas MDs recall their memories. *JAMA* 1992; **267**: 2804-07.
- 18 Hines W. False, fraudulent studies slip by publications' review system. *Chicago Sun-Times*. May 17, 1989.
- 19 Relman AS. Lessons from the Darsee affair. *N Engl J Med* 1983; **308**: 1415-17.
- 20 Altman LK. The NASBP Trials. *N Engl J Med* 1994; **331**: 810.
- 21 Judson G. Mother guilty in the killings of 5 babies. *New York Times*. April 22, 1995.
- 22 Relman AS. How reliable are letters? *N Engl J Med* 1983; **308**: 1219-20.
- 23 Relman AS. More on the Ingelfinger rule. *N Engl J Med* 1988; **318**: 1125-26.
- 24 Relman AS. Medical research, medical journals and the public interest. *J Soc Res Administrators* 1989; **21**.
- 25 Relman AS. Peer review in scientific journals: what good is it? *West J Med* 1990; **153**: 520-22.
- 26 Fletcher RH, Fletcher SW. Medical journals and society: threats and responsibilities. *Ann Intern Med* 1992; **232**: 215-21.
- 27 Guarding the guardians: Research on editorial peer review. *JAMA* 1990; **263**: 1309-1456.
- 28 Pini P. Media wars. *Lancet* 1995; **346**: 1681-83.
- 29 Smith R. Promoting research into peer review. *BMJ* 1994; **309**: 143-44.
- 30 Harris J. In: Medicine and the media: a changing relationship. Catigny conference series. Oct 13-14, 1994. Chicago: Robert R McCormick Tribune Foundation 1995: p 37.
- 31 Relman AS. Reporting the aspirin study. The journal and the media. *N Engl J Med* 1988; **318**: 918-20.
- 32 Relman AS. Our readers vote for the news embargo. *N Engl J Med* 1988; **318**: 1680.
- 33 Wilkes MS, Kravitz RL. Medical researchers and the media: attitudes toward public dissemination of research. *JAMA* 1992; **268**: 999-1003.

---

**Medicine and art**

## Exomphalos III

Amy Goodrich

---



Since the termination in 1994 of her first baby because of exomphalos, Amy Goodrich's work has centred around this loss. It can be seen at a touring exhibition called *Angels and Mechanics*, in which 40 contemporary artists explore the theme of fertility. Work in the exhibition (May 19 to July 7, Riverside Studios, London, and Watermans Arts Centre, Kew, Middlesex) includes painting, sculpture, installation, photography, printmaking, and live art by men and women.