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NCI Advisors Criticize Plan To Fund R01s On ESA Research With Amgen, J&J Money

By Kirsten Boyd Goldberg and Paul Goldberg

A research program shot down by NCI scientific advisors earlier this week was unlike any other:

The institute proposed using $5 million in pharmaceutical industry money to pay for up to three R01 grants to study the tumor promotion potential of erythropoiesis-stimulating agents.

The money would be contributed by the sponsors of the controversial agents—Amgen Inc. and Johnson & Johnson—and floated through the Foundation for the National Institutes of Health, a non-profit created by Congress to raise private funds to help support biomedical research.

Confronted with the proposal for a Request for Applications at its

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European Agency Recommends Transfusions For Cancer Patients With Longer Life Expectancy

By Paul Goldberg

The European Medicines Agency has recommended that the labels for erythropoiesis-stimulating agents should warn that blood transfusions should be preferred in cancer patients with a reasonably long life expectancy.

The recommendation published by the London-based EMEA June 26 was developed by the agency's Committee for Medicinal Products for Human Use. The recommendations are based in part on expert advice obtained from the agency's oncology scientific advisory group, who stated that "in cancer patients with a reasonably long life-expectancy, the benefit of using epoetins to avoid blood transfusions does not balance the risks of tumor progression and shorter survival," the agency said.

The committee also recommended that the sponsors of ESAs conduct additional studies to clarify the risks and benefits of ESAs used in the treatment of cancer patients as currently recommended.

Last March, the FDA Oncologic Drugs Advisory Committee recommended that ESAs be avoided in the adjuvant and neo-adjuvant settings. Also, ODAC recommended excluding breast and head-and-neck cancers from the label and administering informed consent to every patient who considers taking the agents.

The EMEA documents don't mention specific diseases and appear to apply across the board, even to diseases where safety signals haven't been detected. Also, the document doesn't mention strengthening of informed

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NCI Sought Industry Funding Through Foundation For NIH

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meeting June 23, members of the NCI Board of Scientific Advisors were troubled both by the ethics of the funding arrangement and an overly broad research plan.

"However you say it—whatever way this money has been laundered—the fact is that the money has come from the company," said board member Robert Schreiber, professor of pathology at Washington University School of Medicine. "This is basically contract research."

After a contentious discussion, the advisory board voted to defer a decision on the proposal and appointed a committee to sort through the ethics and the science. A transcript of the discussion is posted at http://www.cancerletter.com/publications/special-reports.

At a time when NIH finds itself under scrutiny over conflicts of interest in its intramural and extramural programs, the ESA proposal points to a heretofore unexplored flavor of conflict—the role of the NIH Foundation in allowing drug sponsors to affect the institute's scientific priorities.

"It is a huge ethical no-no to try and cheapen the currency of the R01s either by undercutting the peer review process that gives them their prestige or simply by trying to target them from a particular funder," said Arthur Caplan, director of the University of Pennsylvania Center for Bioethics. "The whole point of the NIH R01s is that it is peers and peers alone who determine the value of the work. The reason the NIH R01s are so prestigious is that they kept us free from politics and influence from commercial interests as reasonably can be done. This undercuts that."

Sidney Wolfe, director of the Public Citizen Health Research Group, agrees. "This is a smoking-gun example of how industry buys influence," he said. "The people on the NIH Foundation and at NCI would swear on a stack of whatever that they are not influenced by money, and they are wrong. If they were not influenced by it, why do you think the industry is doing it?"

The fact that the proposal advanced as far as it did through the grant-making system demonstrates that the NIH Foundation can help bring commercial projects to the front of the line, in this case leading to the most sought-after and most prestigious grant in biomedical research—the NIH R01.

By proposing a Request for Applications, NCI officials were in effect stating that research on ESA tumor promotion is a high-priority topic that needs urgent attention. Grant applications submitted in response to RFAs go through special peer review committees set up by NCI, bypassing the normal NIH peer review system.

In proposing an RFA, NCI staff must submit a justification to the advisory board. "Applications in this research area are sparse, and those received have not done well in peer review," stated the justification for the RFA, which was titled ESAs and Tumor Growth. "An RFA targeting this biologically and medically important research area is expected to stimulate the submission of high quality research applications, from outstanding applicants who may not have been previously motivated to enter this field. In addition, the NCI will be able to empanel a review panel with a specific understanding of the research needs of the field." The text of the RFA is posted at http://www.cancerletter.com/publications/special-reports.

R. Allan Mufson, program director in the NCI Division of Cancer Biology, who presented the proposal to the BSA, acknowledged that "this kind of research is not perhaps at the cutting edge of what is competing, but that doesn't mean the research is not important."

"Pretty Close" Connection to Amgen, J&J

At the BSA meeting, Robert Young, chairman of the advisory board, said the sponsors weren't sufficiently removed from the grant-making process.

In principle, the "money from the NIH Foundation donated by companies is fine," said Young, the

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chancellor of Fox Chase Cancer Center. However, "$5 million donated from Johnson & Johnson and Amgen for this RFA is not so fine. The question that I don't know the answer to is: What are we talking about here? Was this specific money from those companies saying, 'We'll give you the money if you do the research?'

"That's pretty close," Young said, characterizing the relationship between the sponsors and NCI.

The companies and NCI acknowledge that they have been working in unison. In December, when NCI conducted a workshop on ESA's potential for tumor promotion, institute officials acknowledged that the project was requested by the sponsors.

Now, senior NCI sources say that they, not the sponsors, had formally approached the NIH Foundation, asking it to channel the funds. Officials say that the industry funding obtained through the foundation would open a new source of funds for the cash-strapped institute.

"One of the functions of the foundation is to raise money, and what we are hoping is that, in fact, it will succeed in raising money from other sources," said Dinah Singer, director of the NCI Division of Cancer Biology, as she presented the RFA to the board. "I can only tell you now what has been committed.

"The hope is that it won't be just those two companies," said Singer, referring to Amgen and J&J.

For the ESA sponsors, the question of tumor promotion is anything but science for its own sake, said board member Jane Weeks, an oncologist and chief of the Division of Population Sciences at Dana-Farber Cancer Institute.

The proposal gave her a "queasy" feeling, she said.

"I tried to think about why I responded that way and I think context is crucial," Weeks said. "These are marginally effective supportive care drugs that don't cure anybody and cost an absolute fortune. The companies that make them have an enormous stake financially, but so do we as taxpayers. If we are ever going to look hard at something that's the sniff test question, this is the setting in which to look hard.

"What's bothering me about this is the argument about the impetus for this is helping patients," Weeks said. "If you really want to get fast the answer about whether these drugs are safe, you don't sidetrack off into basic biology. You do the relevant clinical studies, and mine existing databases, and look at what hemoglobin levels are saying, and what diseases are safe.

"If I were Amgen or J&J, I would want to do exactly this," Weeks said, referring to the proposed RFA. "I don't think scientifically that's the right answer, unless there is some reason apart from ESAs to understand more about the biology of these receptors.

"But that would call for a very different strategy than what's being proposed here," Weeks said. "This just looks like straight-over-the-plate what you'd want if you were a maker of one of these drugs, and not what you would want if you were a cancer patient or a taxpayer."

Under the RFA, NCI proposed to fund two to three R01 grants of up to $350,000 per year for five years.

The question of the role of EPO receptors in tumor promotion hasn't been exhaustively studied, and all recent efforts to restrict the uses of these agents have been triggered by safety signals from clinical trials.

The joint project between the sponsors and NCI was mentioned twice at the March 13 meeting of the FDA Oncologic Drugs Advisory Committee. Addressing ODAC, Tom Lillie, global development lead for Aranesp Oncology, Amgen, said that additional work needs to be done in studying EPO receptors. "And, indeed, the sponsors are supporting the NCI and the NIH in doing this," Lillie said at the time.

NCI Steps Into ESA Controversy

At the BSA meeting, NCI Director John Niederhuber said the institute was "under pressure from Congress to address this issue."

Indeed, late last year, Congress was considering vacating the decision by the Centers for Medicare and Medicaid Services to restrict coverage of ESAs. The pressure was caused in part by a massive lobbying campaign by Amgen and J&J.

According to the Center for Public Integrity, last year Amgen spent $22.7 million on lobbying, more than any other pharmaceutical company. J&J's spending of $7.7 million put it in sixth place.

Congressional pressure wasn't entirely generated on behalf of the companies. The oversight committees in the House and Sen. Chuck Grassley (R-Iowa) were critical of the system that created overtreatment with ESAs in oncology and nephrology.

"We chose to address this issue by a mechanism that we have commonly used, getting the best minds together for a workshop," Niederhuber said at the BSA meeting. "The whole purpose of that workshop was to look at the science. What do we know, what don't we know, what do we need to know about this particular class of agents in order to better manage patients. That was the driving force.

NCI stepped into the controversy last fall as it

started to organize an invitation-only workshop on tumor promotion. Though the meeting was technically open, those who expressed an interest in attending were initially told that the seating was limited.

An early list of invited participants included two patient advocates: Nancy Davenport-Ennis, of the Patient Advocate Foundation, a supporter of continued unrestricted coverage of ESAs, and Ellen Sigal, head of Friends of Cancer Research and a member of both the NIH Foundation board and the BSA.

As the word of the NCI workshop spread, other advocates demanded to be added to the list of participants, and a seat had to be found for a staff member of the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce. NCI's detailed summary of the workshop is posted at http://www.cancerletter.com/publications/special-reports.

"We had a great deal of difficulty managing the politics for that meeting," Niederhuber acknowledged to BSA. "We were under a lot of pressure from all kinds of organizations that wanted to participate in that meeting. We had to work very hard to keep this a scientific workshop and not have it criticized. Dinah [Singer] did an admirable job keeping this focused on the science. We tried to have the scientific community drive the research questions that would be asked in the RFA."

Many participants of the workshop understood that NCI got involved on request from the drug sponsors, said Robert Erwin, president of the Marti Nelson Cancer Foundation, who took part in the workshop.

"My recollection is that the only discussion of any sort of financial contribution from either Amgen or J&J was that they would provide biological materials, and protocols, and data, sort of in-kind contributions, as opposed to direct financial contributions," Erwin said.

Had the question of direct support been brought up, Erwin would have objected, he said. "I would have said that research should be NCI-funded," Erwin said. "There have been so many abuses of disclosure, conflict of interest rules, that people are becoming suspicious of medical research funded by specific companies with products that are the subject of that research.

"The second thing that's more serious is the possibility of very real conflicts of interest. I would worry that the fact that the money came from just two companies with these products would influence the nature of the scientists' inquiry, and the kind of questions they ask, and the rigor they apply to the task," Erwin said. "The origin of the money will always be a subtle influence."

Spokesmen for the companies acknowledged having committed to support the NCI studies, which they refer to as the "EPO-R" study.

"In terms of all of the EPO-R discussions with NCI, they have been initiated by NCI," said Kassy McGorty, a spokesman for Ortho Biotech, a division of J&J. "We have participated at their request. They initiated the discussions with us and we expressed interest in helping to answer some of these questions."

"In December of last year, the NCI held a workshop on the EPO receptor which Amgen participated in," said Ashleigh Koss, a spokeswoman for Amgen. "As part of our participation, and part of our ongoing efforts to address some of the concerns around the ESAs, we had said to NCI that Amgen would voluntarily provide funding to NIH for additional translational studies for the EPO receptor. But the NCI has their own processes put in place for how researchers apply for the grant money, and Amgen would really have no role in that."

NIH Foundation: "No Rigid Template" on Conflicts

The NIH Foundation doesn't have a uniform policy for handling conflicts of interest, said Charles Pucie Jr., director of public affairs for the foundation. The foundation's Board of Directors has to approve any new program, he said.

"In each of our projects, these issues are addressed according to the logic of the situation, rather than having a rigid template for every program," Pucie said. "The guidelines are based on our experience in the past. The principles and the background in which one eye is kept peeled, is the notion of equal access to all scientific research, no special advantage to a funder for providing funds. There is every attempt to be certain that the findings don't become the subject of a narrow, proprietary interest."

Asked by a reporter to look into the specifics of the ESA case, Pucie failed to respond by deadline.

A conflict of interest policy that is not spelled out is not a conflict of interest policy, Caplan said. "No one needs a rigid template, but I think the way to administer things done in the name of the public is to have a template that's understood and available for public discussion and comment," he said. "Then you can start to exercise judgment, discretion, exemptions, and waivers."

Since it began operations in 1996, the foundation has raised over $410 million and "facilitated over 50 projects," according to the organization's 2007 annual report. "A flexible infrastructure, combined with disciplined scientific, administrative, and program-management capabilities, allows the foundation to

create innovative, successful partnerships that benefit all parties," the report said.

NCI conducts several projects through the foundation, including:

—Avon-NCI Progress for Patients Awards Program, which provides $33 million for breast cancer research.

—Genentech Inc. supports a program called Targeted Cancer Therapies Tutorials, which funds the creation of animated tools for physicians to use to explain to patients how therapies work.

—A study on FDG-PET through the Biomarkers Consortium established by the foundation in 2006, with $6.43 million from nine private-sector donors and $3.75 million from NCI.

In 2006, Bristol-Myers Squibb Co. gave $8 million to the foundation to support a clinical trial with 300 patients with schizophrenia to determine the effect of the company's drug aripiprazole (Abilify) vs. continued treatment with three other medications. The study was designed by researchers at the University of North Carolina at Chapel Hill in collaboration with the National Institute of Mental Health.

It's unclear whether the $5 million for the ESA project has been transferred to the NIH Foundation.

"I doubt if the money is in the bank," Niederhuber said at the BSA meeting. "It probably wouldn't come" if the concept didn't get approved.

If the transfer of funds to the NIH Foundation was, in fact, contingent on approval of the RFA, this would suggest that the sponsors are playing a role in the research, critics say.

"That doesn't sound unrestricted to me," Erwin said. "It sounds like a payment for a very specific task."

BSA member Stuart Schreiber, chairman of chemical biology at the Broad Institute of Harvard and MIT, suggested that NCI consider using the Request for Proposals mechanism to fund the research through contracts.

"I think that's a good suggestion," Niederhuber said. "I'm not sure that I can *not* do something in this area. Politically, I'm going to be asked that question down the road."

During the discussion at BSA, Niederhuber said the objections from the board members didn't surprise him and even offered to withdraw the proposal before the vote.

"I understand all of the things you are concerned about," he said to the board. "There's nothing that you said that we haven't said around the table as well."

But as Niederhuber offered to withdraw the concept, Young made a counterproposal: "Is it easier for you to withdraw it and come back to us, or for us to defer it and create and subcommittee to work directly with you, and if the subcommittee approves, we could do it on an email ballot, or something like that?"

The motion to defer the concept passed unanimously, and Young appointed a four-member committee to work with Singer to put together a more acceptable strategy. Members of the committee are Paul Allen, Robert Schreiber, Michael Caligiuri, CEO and director of the Ohio State University Comprehensive Cancer Center, and Richard Schilsky, chairman of Cancer and Leukemia Group B and professor of medicine and associate dean for clinical research at University of Chicago.

"If they are satisfied with the restructured proposal, they [would] embrace it with enthusiasm and send a message to us and we by email will vote," Young said. "That at least enables the NCI to get a reasonably rapid answer to an important political problem."

European Agency Prefers Transfusions Over ESAs

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consent procedures.

The European agency's review was triggered by new information indicating that in the oncology setting ESAs may be associated with an increased risk of venothrombolic events, an increased risk of tumor progression, and shorter overall survival times, the agency said.

According to EMEA, the new information included:

—A meta-analysis published in the Journal of the American Medical Association in February 2008;

—A study in women with cervical cancer published in the journal Gynecologic Oncology in February 2008. The study was stopped early because of concerns over the number of VTEs seen in patients receiving ESAs;

—The interim results of an unpublished study carried out with Aranesp (darbepoetin alfa) in women with breast cancer. In this neoadjuvant trial, a small increase in the death rate was observed in the patients receiving darbepoetin alfa.

"Amgen continues to be constructively engaged with EMEA, FDA and other regulatory authorities on ESA label issues," said Ashleigh Koss, the company spokesman. "We're looking forward to final label language later this year."

"The company will be working with the health

authorities in Europe to amend the label to reflect recent CHMP recommendations," said Mark Wolfe, a J&J spokesman. "The company also remains committed to working with Health Authorities and the scientific community to further define the benefit/risk [ratio] of EPREX/ERYPO within its labeled indications."

In an earlier review, completed in September 2007, EMEA changed the label to state that ESAs should be prescribed only to symptomatic patients and that the hemoglobin target should be set between 10 and 12 g/dL.

In the U.S., FDA and the sponsors of the ESAs marketed in the U.S. are similarly negotiating the label changes.

In the Cancer Centers:

RPCI Appoints Walker EVP, Johnson Deputy Director

ROSWELL PARK Cancer Institute announced leadership positions. **Jeff Walker** was named executive vice president. He had been associate institute director for administration since April 2007. Walker, who will continue as advisor to **Donald Trump**, president and CEO of RPCI, is responsible for the development, direction and operation of the institute including administrative, scientific and clinical departments, all mission area programs and oversight of strategic planning initiatives. He also provides leadership and direction to clinical and nursing administration, corporate projects and initiatives, fiscal and corporate counsel operations. **Candace Johnson** was appointed deputy director. She will continue as chairman of the Department of Pharmacology and Therapeutics. Johnson has been a senior faculty member in the department and senior vice president, translational research, since 2002, and was endowed as the Robert, Lew, and Ann Wallace Chair in Translational Research in 2005. Also at Roswell Park, the Research Participation Program in Science for Young Scholars will provide a summer learning experience to young scientists and medical students, for the 56th consecutive year. Eighty students from colleges and high schools in 10 states, China, Canada, Argentina, and Russia are working on research projects from the basic science of cancer to studies on cancer prevention, detection and treatment, and are under the supervision of RPCI scientists and clinicians. The program, established in 1953, is supported by grants from NCI. . . . **OHIO STATE** University Comprehensive Cancer Center researchers were awarded a five-year, $11.9 million grant from NCI to study thyroid cancer. The program project grant was awarded to a team led by principal investigator **Matthew Ringel**, professor of internal medicine and co-director of Ohio State's Thyroid Cancer Unit. The study, "Genetic and Signaling Pathways in Epithelial Thyroid Cancer," encompasses four projects including studies to identify genes that predispose patients to develop thyroid cancer, clarify differences between benign and malignant thyroid nodules to enhance diagnostic accuracy, define the molecular pathways that alter sensitivity to current treatments, and define new therapeutic targets for patients with progressive thyroid cancer. The grant includes faculty members in endocrinology, oncology, molecular virology, immunology, medical genetics, biostatistics, pathology, genetics, the College of Veterinary Medicine, cellular and molecular biochemistry, and the College of Pharmacy, as well as faculty with the Cleveland Clinic Foundation. . . . **PATRICIA AULT**, nurse practitioner, Department of Leukemia, M. D. Anderson Cancer Center, received the 2008 Ethel Fleming Arceneaux Outstanding Nurse-Oncologist Award. Funded by The Brown Foundation Inc., the Arceneaux Award recognizes nurses at M. D. Anderson who are selected by a committee representing the M. D. Anderson clinical faculty, patient care administration and nursing staff. Ault said she plans to use the $15,000 prize money to establish a cancer prevention clinic to encourage weight loss and health goals.

FDA News:

FDA Warns Firms To Stop Selling Fake Cancer "Cures"

FDA officials said the agency sent warning letters to 23 U.S. companies and two foreign individuals marketing a wide range of products fraudulently claiming to prevent and cure cancer.

The agency advised consumers not to use or buy the products, which include tablets, teas, tonics, black salves, and creams, and are sold under various names on the Internet.

Those companies and individuals warned, the complete list of products and their manufacturers are available at http://www.fda.gov/cder/news/fakecancercures.htm.

"Although promotions of bogus cancer 'cures' have always been a problem, the Internet has provided a mechanism for them to flourish," said Margaret Glavin, FDA associate commissioner for regulatory affairs. "These warning letters are an important step to ensure that consumers do not become the victim of false 'cures'

that may cause greater harm to their health."

The products contain ingredients such as bloodroot, shark cartilage, coral calcium, cesium, ellagic acid, Cat's Claw, an herbal tea called Essiac, and mushroom varieties such as Agaricus Blazeii, Shitake, Maitake, and Reishi.

Reports on these products may be made to MedWatch, at www.fda.gov/medwatch/report.htm.

Funding Opportunities:

Lung Cancer Partnership Seeks Applicants For Awards

The National Lung Cancer Partnership announces the opening of the application period for two award programs:

National Lung Cancer Partnership/ LUNGevity Foundation Research Grants for the promotion of understanding lung cancer risk, biology, and response to treatment. This grant program, administered by the National Lung Cancer Partnership and co-funded with the LUNGevity Foundation, is designed to provide seed money for promising novel research in lung cancer for faculty members at any point in their careers, performing research at any institution world-wide.

Two grants are available: One is specifically for research in the area of sex differences in lung cancer. One is for research pertaining to any facet of lung cancer. Research Grants will be awarded for one or two years, for up to $50,000 per year ($100,000 maximum over two years).

National Lung Cancer Partnership Career Development Award for junior clinical and basic investigators involved in lung cancer etiology, prevention, and treatment at any U.S. or Canadian research institution. The National Lung Cancer Partnership's goal is to create a critical mass of lung cancer researchers to ensure that basic and behavioral research discoveries are effectively translated into patient therapies to reduce lung cancer incidence, morbidity and mortality. Applicants will be judged on the merits of their research proposal, career development plan, and research environment, among other factors. Applicants must be post-doctoral fellows, or within the first five years of a faculty appointment. Career Development Awards will be awarded for one or two years, for up to $50,000 per year ($100,000 maximum over 2 years).

Application instructions are available at www.NationalLungCancerPartnership.org. Application deadline is Sept. 2.

Lustgarten Foundation RFP

The Lustgarten Foundation for Pancreatic Cancer Research provides funding for research into the biology, diagnosis, treatment and prevention of adenocarcinoma of the pancreas. Grants on all areas related to adenocarcinoma of the pancreas are welcomed. This year the foundation is particularly interested in grants studying the Kras pathway.

Applications will be accepted from individual investigators and from collaborating institutions. Grants will be awarded for a one-year period for a maximum of $100,000, of which no more than 10% can be used for indirect costs. National and international applications will be considered. Mandatory Letters of Intent are due by July 31. The application deadline is August 18, 2008. Funding will commence January 2009.

Applications may be obtained from the web site at www.lustgarten.org or by contacting The Lustgarten Foundation, 1111 Stewart Ave., Bethpage, NY 11714, phone 516-803-2304, fax 516-803-2303.

NIH Funding Opportunities:

RFA-CA-08-022: Improving Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations. R01. Letters of Intent Receipt Date: Oct, 24. Application Due Date: Nov. 24. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-022.html. Inquiries: Erik Augustson, 301-435-7610; augustse@mail.nih.gov.

RFA-CA-08-023: Improving Effectiveness of Smoking Cessation Interventions and Programs in Low Income Adult Populations. R21. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-08-023.html.

PAR-08-183: Exploratory Collaborations with National Centers for Biomedical Computing. NIH Roadmap Initiatives. R21. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-08-183.html. Inquiries: Jennifer Couch, 301-435-5226; couchj@mail.nih.gov.

PAR-08-184: Collaborations with National Centers for Biomedical Computing. NIH Roadmap Initiatives. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-08-184.html. Inquiries: : Jennifer Couch, 301-435-5226; couchj@mail.nih.gov.

RFP N02PC85014-19: Informatics Support Center for Breast and Colon Cancer Family Registries. Full text: http://www.fbodaily.com/archive/2008/06-June/22-Jun-2008/FBO-01597815.htm. Inquiries: Diane Stalder, 301-435-3877; ds88b@nih.gov.

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