

estimated to be \$21,000, or \$2,100 per airplane.

The total cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Docket 94-NM-139-AD.

Applicability: Model ATP airplanes, constructor's numbers 2002 through 2063 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent migration of a shootbolt bush, which could jam the Type I passenger door, and subsequently could delay or impede the evacuation of passengers during an emergency, accomplish the following:

(a) Within 1,500 hours time-in-service after the effective date of this AD, or within 6 months after the effective date of this AD, whichever occurs first, modify the Type I passenger doors and aft baggage door, in accordance with Jetstream Service Bulletin ATP-52-26-10350B, dated June 29, 1994.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 30, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 95-13783 Filed 6-5-95; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 54

[Docket No. 93N-0445]

Financial Disclosure by Clinical Investigators; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing regarding a proposed regulation that would require disclosure of certain financial interests and arrangements by clinical investigators. The proposed regulation would require that sponsors submitting clinical studies in support of marketing applications for human drugs, biologics, and medical devices either certify to the absence of certain financial interests of clinical investigators or disclose those financial interests. The purpose of the public hearing is to obtain additional comments and information on specific issues for use in developing a final rule, and a proposed rule to extend these requirements to submissions for marketing approval related to human foods, animal foods, and animal drugs. The public hearing will address specific issues on which FDA seeks information and comment, and time will also be set aside after these issues have been addressed during which participants will have an opportunity to address other aspects of the proposed regulation.

DATES: The public hearing will be held on July 20, 1995, from 9 a.m. to 5:30 p.m. Submit written notices of participation, including a brief summary of the presentation and the approximate time requested, by June 30, 1995.

Written comments will be accepted until August 20, 1995.

ADDRESSES: The public hearing will be held in the Wilson Auditorium, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD. Submit written notices of participation and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. To expedite processing, written notices of participation may also be FAXED to 301-594-0113. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Transcripts of

the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT:
Mary Gross, Office of External Affairs,
Food and Drug Administration, 5600
Fishers Lane, Rockville, MD 20857,
301-443-3390, or FAX 301-594-0113.

SUPPLEMENTARY INFORMATION:

I. Background

FDA will sponsor a public hearing to solicit comments and views on specific aspects of a proposed regulation published in the **Federal Register** of September 22, 1994 (59 FR 48708) that would require disclosure of certain financial information by clinical investigators.

There has been a growing concern for some time, both at FDA and within the academic and scientific communities, that some financial arrangements between clinical investigators and product sponsors, as well as the personal financial interests of clinical investigators, are a potential source of bias in clinical trials. FDA currently has no mechanism to collect information concerning specific financial interests of clinical investigators who conduct studies in support of product marketing. FDA believes that institution of a system to collect and analyze this information will strengthen the product review process.

Under the proposed regulation, every sponsor filing an application for marketing approval would be required to make one of two alternative submissions as part of the application: (1) For any clinical study relied upon by the sponsor to establish that the product meets the regulatory requirements for approval, the sponsor may certify that: (a) The sponsor has not entered into any financial arrangement with any clinical investigator in which the value of financial compensation received by the clinical investigator for conducting the studies could be affected by the outcome of the research; (b) the investigator has not received significant payments of other sorts from the sponsor, such as a grant to fund ongoing research, compensation in the form of equipment, a retainer for ongoing consultation, or honoraria; (c) the clinical investigator has no proprietary interest, such as a patent or other direct financial interest in the clinically tested product; and (d) the clinical investigator holds no significant equity interest in the sponsor's company; or (2) if the sponsor does not provide certification, the sponsor must disclose the specific financial arrangements made with the clinical investigator, the investigator's

proprietary and equity interests in the tested product and the sponsor's company, and describe steps taken to minimize the potential for bias in data submitted in support of product applications. FDA would refuse to file any marketing application that does not include either certification or disclosure.

FDA received 47 comments on the proposed regulation. Many comments supported the proposed regulation with relatively minor modifications, while others questioned the substantive provisions of the rule. In view of the complexity of some of the issues that were raised, and the diversity of views expressed on these issues, FDA believes that it would be useful to convene a public meeting to provide interested parties with an opportunity to present further comment. At this time, the agency also wishes to provide an opportunity to interested persons to comment on FDA's intention to propose extending financial disclosure requirements to submissions for marketing approval related to human foods, animal foods, and animal drugs.

II. Public Hearing

Consistent with FDA regulations at 21 CFR 10.40(f)(2), the agency is holding a hearing under part 15 (21 CFR part 15) to discuss the proposed rule. Presentations submitted and comments received at the hearing will be included in the administrative record for that regulation. In addition, written comments submitted to the Dockets Management Branch (address above) by August 20, 1995, will also be part of the administrative record.

The format of the hearing is one in which specific issues, as listed below, are dealt with one at a time in the order listed. A block of time will be allotted to discussion of additional issues by participants once the listed issues have been addressed. Issues to be addressed are as follows:

(1) In the proposed regulation, FDA specified four specific financial arrangements or interests of a clinical investigator that would be required to be disclosed, including any significant equity interest in the applicant held by a clinical investigator. For purposes of the regulation, a significant equity interest was defined as any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest in a publicly traded corporation that exceeds 5 percent of total equity. With respect to an equity interest in a publicly traded corporation, a number of comments

requested clarification as to whether "5 percent" refers to 5 percent of the investigator's equity, or 5 percent of the equity of the corporation. Other comments argued that a dollar threshold should be set for disclosure of an equity interest in a publicly traded corporation. These comments suggested threshold amounts ranging from \$5,000 to \$50,000. In specifying an equity interest that exceeds 5 percent of total equity, FDA was referring to equity of a corporation. FDA initially considered specific dollar amounts that might be used to trigger disclosure, but wanted to avoid setting an amount that would be so small as to trigger excessive and not particularly meaningful disclosure. On the other hand, the agency acknowledges that the value of 5 percent of equity in publicly traded companies could vary widely. FDA is interested in further discussion as to what would constitute a reasonable threshold for disclosure of an equity interest in a publicly traded corporation.

(2) The proposed regulation would require disclosure of "significant payments of other sorts," which were defined for purposes of the regulation as payments that exceed \$5,000 (e.g., grants to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) or that exceed 5 percent of the total equity in a publicly held or widely traded company. Comments were divided as to the need to require disclosure of arrangements that would fall under this definition. Some comments held that only payments directly related to the conduct of covered studies should be required to be disclosed. It should also be noted that a number of comments stated that the regulation was intrusive and burdensome, particularly with respect to the need to obtain extensive information from investigators, adding that much of the need to query investigators would be associated with accessing "significant payments of other sorts." FDA seeks additional discussion and views on whether such arrangements should be disclosed, and the value of such disclosure to the intent of the regulation.

(3) In proposed § 54.2(e), FDA defined a clinical study as:

Any study involving human subjects, including a study to establish bioavailability or bioequivalence, submitted in a marketing application subject to this part, that either: (1) The sponsor identifies as one that the sponsor relies on to establish that the product meets the regulatory requirements for marketing, or (2) FDA identifies as one that it intends to rely on to support its decision to permit the marketing of the product * *

*

Comments suggested that the definition of a covered study be narrowed by exempting, for example, phase 1 safety studies, because they are not as important to evaluation for marketing as phase 2 and 3 studies, and bioavailability and pharmacokinetic studies, because they generally result in quantitative, objective results based on tangible data that are not especially vulnerable to bias. It was also suggested that covered studies be limited to open label (unblinded) studies of a nonpharmacokinetic nature, study designs with subjective endpoints, and single investigator studies. FDA is interested in further discussion as to what should constitute a covered study and whether the scope of the proposed definition might be narrowed.

(4) In proposed § 54.2(d), FDA defined "clinical investigator" as any investigator who is: "(i) Directly involved in the treatment or evaluation of research subjects, or (ii) Could otherwise influence the outcome of the research; * * *." Some comments stated that this definition was overly broad. It was suggested that FDA use for the purposes of this regulation the definition of "clinical investigator" relied on by the agency's investigational drug application regulations at 21 CFR 312.3(b), as follows:

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team. FDA notes that the term "clinical investigator," was defined in a Public Health Service (PHS) proposed rule on objectivity in research that published in the **Federal Register** of June 28, 1994 (59 FR 33242), as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research. Both FDA's proposed rule and the PHS final rule defined "investigator" as including the spouse and dependent children of the investigator. FDA is interested in obtaining additional views on the definition of "clinical investigator" for purposes of financial disclosure.

(5) In the preamble to the proposed regulation, FDA stated its expectation that disclosed financial interests and steps taken to minimize bias would vary with different applications, and explained that the agency would therefore evaluate and act on these applications on a case-by-case basis. As to what actions the agency might take in response to disclosure of problematic interests, FDA stated that, if a study

design is sufficiently robust as a result of factors such as independent data monitoring, multiple investigators, blinding, and independent endpoint assessment, the agency could determine that the financial interest would not likely introduce bias and the data could be accepted. In other situations, there might be sufficient replication of critical results to render questionable data less important, or it might be possible to carry out further analyses or observations (such as reexamination of hospital records or patients) that would provide assurance as to the quality of the data. In still others, intensified scrutiny by FDA's bioresearch monitoring staff might be sufficient to permit FDA to accept the data in support of product marketing applications. In some cases, however, if adequate steps were not taken to minimize potential bias, FDA stated that it might not be able to conclude that the data were reliable and might find it necessary to require sponsors to conduct further studies. This range of actions was listed in proposed § 54.5(c). A number of comments criticized the proposed process as subjective. One comment argued that FDA must develop specific criteria for evaluating the potential impact of financial interests to avoid ad hoc decisionmaking by reviewers. FDA is interested in further discussion of how these evaluations might be conducted, especially with respect to specific criteria that might be applied.

(6) In the preamble to the proposed rule, FDA stated its intention to propose the extension of this rulemaking on financial disclosure to additional products for which sponsors submit data from clinical investigators, or investigators who conduct the equivalent of clinical studies in animals, in support of marketing. Examples of these products include food and color additives, infant formulas, human foods labeled with health claims, animal foods, and animal drugs. FDA is interested in hearing comments on this extension from the industries that would be affected, as well as other interested persons.

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The presiding officer will be Sharon Smith Holston, Deputy Commissioner for External Affairs. Ms. Holston will be joined by other FDA officials.

Persons who wish to participate must file a written notice of participation

with the Dockets Management Branch (address above) on or before June 30, 1995. All notices submitted should be identified with the docket number found in brackets in the heading of this document and should contain the person's name, address, telephone number, FAX number, business affiliation, if any, a brief summary of the presentation, and the approximate time requested for the presentation.

The agency requests that individuals or groups having similar interests consolidate their comments and present them through a single representative. FDA may request joint presentations by persons with common interests. FDA will allocate the time available for the hearing among persons who properly file a notice of participation.

After reviewing the notices of participation and accompanying information, FDA will schedule each appearance and notify each participant by mail, telephone, or FAX, of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The schedule of the public hearing will be available at the hearing and then placed on file in the Dockets Management Branch (address above) after the hearing under docket number 93N-0445.

Under § 15.30, the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of their presentation.

Public hearings, including hearings under part 15, are subject to FDA's guideline (21 CFR part 10, subpart C) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings. Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). Orders for copies of the transcript can be placed at the meeting or through the Dockets Management Branch (address above).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

The administrative record of the proposed rule will remain open until August 20, 1995 to allow comments on matters raised at the hearing. Persons

who wish to provide additional materials for consideration should file these materials with the Dockets Management Branch (address above) by August 20, 1995.

Dated: June 1, 1995.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 95-13886 Filed 6-5-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD13-94-039]

RIN 2115-AE47

Drawbridge Operation Regulations; Lake Washington, Seattle, WA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to amend the regulations governing the operation of the Evergreen Point, State Route 520, floating drawbridge across Lake Washington at Seattle, Washington. The proposed rule would modify five different aspects of the existing operation regulations for the bridge including the notice period for requesting an opening; the length of weekday closed periods; the exemptions from weekday closed periods for Federal holidays and vessels greater than 2000 gross tons; and the requirement that non-self propelled vessels be towed through the draw. Through this action, the Coast Guard seeks to alleviate commuter traffic congestion on the bridge while continuing to meet the reasonable needs of navigation on Lake Washington.

DATES: Comments must be received on or before August 7, 1995.

ADDRESSES: Comments may be mailed to Commander (OAN), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174-1067. The comments and other materials referenced in this notice will be available for inspection and copying at 915 Second Avenue, Room 3410, Seattle, Washington. Normal office hours are between 7:45 a.m. and 4:15 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: John E. Mikesell, Chief, Plans and Programs Section, Aids to Navigation and Waterways Management Branch, (Telephone: (206) 220-7270).

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD13-94-039) and the specific section of this proposal to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments received.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the address listed under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If the Coast Guard determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Drafting Information

The principal persons involved in drafting this document are Austin Pratt, Project Officer, Aids to Navigation Branch, Thirteenth Coast Guard District, and Lieutenant Commander John C. Odell, Project Counsel, Thirteenth Coast Guard District Legal Office.

Background and Purpose

At the request of the Washington State Department of Transportation (WDOT), the Coast Guard is proposing to amend the drawbridge operation regulations for the Evergreen Point, State Route 520, floating bridge across Lake Washington at Seattle, Washington. The chief purpose of the proposed amendment is to alleviate commuter traffic congestion on the bridge while continuing to meet the reasonable needs of navigation.

In recent years vehicular traffic volumes on the bridge have increased dramatically while requests for openings of the drawspan have declined. State Route 520 is a major four-lane arterial in the Seattle area and is heavily traveled during daily commuting hours. Any opening of the drawspan during commuting hours would cause severe traffic congestion and back ups.

Most of the vessels on Lake Washington are able to pass under the bridge at its two fixed transition spans at either end of the floating segment. With the exception of a few tall-masted sailing vessels, floating construction equipment is the chief user of the drawspan. The predominant navigational use of Lake Washington is recreational.

In recent years, the drawspan has been under extensive repair and refurbishment. This work has required temporary changes to bridge operations. Since September 21, 1992, temporary regulations allowed WDOT to keep the drawspan closed except from 11 p.m. to 2 a.m. during the week and from 11 p.m. to 5 a.m. on weekends. From April 1, 1994, to October 1, 1994, the Coast Guard authorized WDOT to keep the drawspan closed at all times during the final phase of the repair project. Despite the highly restrictive nature of these temporary bridge operation regulations, no objections were received from entities representing commercial or recreational navigation on Lake Washington.

In order to alleviate roadway traffic congestion while continuing to meet the reasonable needs of navigation, the proposed amendment would modify five different aspects of the existing regulations:

First, the proposed amendment would increase the notice period for requesting openings from one hour to two hours. The bridge does not currently have continuous attendance by drawtenders, and in recent years, drawtenders have had difficulty getting to the bridge in time to make requested openings. This difficulty is the result of increased roadway traffic in the Seattle metropolitan area. The proposed increase in the notice period would give drawtenders sufficient time to arrive at the bridge for openings. This proposal would not seriously inconvenience navigation because vessel transits of the drawspan are infrequent and can be planned in advance by vessel operators.

Second, the proposed amendment would increase the period during which the drawspan may remain closed on weekdays. The existing drawbridge operation regulations at 33 CFR 117.1049(c) allow the bridge to remain closed from 6 a.m. to 10 a.m. and from 2 p.m. to 7 p.m. Monday through Friday. The proposed amendment would establish a single, yet substantially increased, closed period from 5 a.m. to 9 p.m. Monday through Friday. The proposed increase in the length of the weekday closed period is necessary to prevent the interruption of commuter traffic on the bridge. A bridge