DEPARTMENT OF JUSTICE
Antitrust Division

THOMAS O. BARNETT
Assistant Attorney General

Main Justice Building
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530-0001
(202) 514-2401 / (202) 616-2645 (Fax)
E-mail: antitrust@usdoj.gov
Web site: http://www.usdoj.gov/atr

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Robert F. Leibenluft, Esq.
Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, DC 20004

Dear Mr. Leibenluft:

This letter responds to your request for a business review letter pursuant to the Department of Justice's Business Review Procedure, 28 C.F.R. § 50.6. You have requested a statement of the Antitrust Division's current enforcement intention with respect to a proposal by your client, the CEO Roundtable on Cancer ("CRC"), to develop and publicize model clauses for use in agreements governing clinical trials of potential new cancer treatments.

The CRC is a 501(c)(3) non-profit organization whose goal is to make continual progress toward the elimination of cancer as a personal disease and public-health problem. Contributions from the CRC's member organizations, principally pharmaceutical and biotechnology companies, support the organization. Officials from the National Cancer Institute ("NCI" - part of the United States National Institutes of Health), the United States Food and Drug Administration, and the United States Senate are also members of the CRC.

You stated that the CRC is working in partnership with the NCI to develop model clauses for use in clinical-trial agreements to help increase efficiency in contract negotiations and reduce transactional costs for all parties. Clinical-trial agreements typically involve three parties: (1) a pharmaceutical or medical-device company known as a "sponsor," (2) a hospital, clinic, or university where the research is performed, known as the "research institution," and (3) the physician who is in charge of the trial, known as the "principal investigator." You represent that the lack of model language for clinical-trial agreements results in significant delays in the initiation of clinical trials and that model language will reduce inefficiencies with drafting and negotiating contracts and potentially reduce the time needed to bring medical therapies to patients.

The NCI and the CRC will jointly lead the project to develop model clinical-trial agreement clauses. The NCI has hired the Science and Technology Policy Institute ("STPI"), an independent, federally funded research and development center, to collect template clinical-trial agreements and redacted versions of final clinical-trial agreements for analysis and to review

these and other documents to identify which specific clinical-trial agreement clauses should be included in the model-clause project. To identify these clauses, STPI will work with a broad group involved in the research and treatment of cancer including sponsors, research institutions, cancer centers, and networks of researchers, physicians, and other healthcare professionals. STPI, with the assistance of outside legal counsel, will generate a list of key differences in the identified clinical-trial agreement clauses and possible language for these clauses. In some cases, STPI may identify two or more alternative options for model clauses.

The NCI and the CRC will then work together to develop a structured approach for achieving consensus on the language for model clauses. While the NCI and CRC have not yet determined the method of consensus-building, they anticipate that it will involve representatives from a broad range of sponsors, research institutions, cancer centers, researchers, physicians, other healthcare professionals, and other organizations concerned with cancer clinical trials. Once the NCI and CRC have achieved consensus on the model language, they will publicize the model clauses to sponsors, research institutions, and other interested parties.

You represent that the model clauses will be made publicly available for sponsors, research institutions, and principal investigators to use on a voluntary basis at their sole discretion. All parties will be free to choose whether to use any or all model clauses, negotiate changes to them, or reject the model clauses entirely. In publicizing the model clauses, the NCI and CRC will make clear that the use of these model clauses is completely voluntary.

You further represent that the project will not address price or price-related clauses and that the project will be implemented in a way so as not to cause or increase the possibility of sharing competitively significant information. Rather, the project will likely address terms dealing with intellectual property and licensing, publishing rights, confidentiality, ownership of data, risk and indemnification, and rights to bio-specimens, which terms you represent are not as competitively significant in negotiating clinical-trial agreements. You represent that outside legal counsel will review the model clauses to ensure that none of the clauses are related to price.

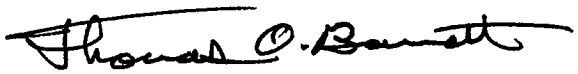
You contend that there is little, if any, likelihood that the model clauses would adversely affect competition. Instead, you claim that the creation of the model clauses will reduce the costs of negotiating contracts and decrease the time and efforts needed to begin a clinical trial.

Based upon the representations made in your request, the documents and information submitted in support of your request, and the information obtained during our own review, the Department has no present intention of challenging the proposal to develop and publicize model clauses for use in clinical-trial agreements. Making the model clauses available to sponsors, research institutions, and principal investigators, as proposed by CRC, is not likely to reduce competition. The model clauses will not contain any provisions specifying prices or rates. Whether to use the clauses or any of their provisions will be left to the determination of each party acting independently. Thus, sponsors, research institutions, and principal investigators will remain free to compete by offering their individually determined contract terms. Moreover, the proposed model clauses could have procompetitive effects by improving the efficiency of contract negotiations, potentially reducing costs and shortening the time needed to begin clinical trials.

This letter expresses the Department's current enforcement intention and is issued in reliance on the information and representations contained in the CRC's written submissions and oral statements. In accordance with our normal practices, the Department reserves the right to bring any enforcement action in the future should circulation of the model clauses prove to be anticompetitive in purpose or effect.

This statement is made in accordance with the Department's Business Review Procedure 28 C.F.R. § 50.6. Pursuant to its terms, your business-review request and this letter will be made publicly available immediately, and any supporting data will be made publicly available within 30 days of the date of this letter, unless you request that part of the material be withheld in accordance with Paragraph 10(c) of the Business Review Procedure.

Yours sincerely,



Thomas O. Barnett
Assistant Attorney General