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TO: NORMAN GOLDFARB
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RE: Model Agreement Group Initiative Antitrust Analysis

You have asked me to summarize the application of the antitrust laws to joint ventures and to identify any antitrust concerns raised by the Model Agreement Group Initiative (MAGI).

Facts

MAGI is a group that seeks to develop a flexible model clinical trial agreement (CTA) to streamline the process of negotiating clinical trial agreements. MAGI is not a legal entity, but rather is an informal group of individuals and organizations that participate in the clinical trial process. MAGI currently has over 100 members, and has no membership limitations of any kind. It is currently recruiting members from the community of trial sponsors, CROs, AROs, SMOs, investigative sites, and law firms, and related organizations.

The members and potential members of MAGI are drawn from the entire range of industries that are involved in clinical trial activity, and membership is not limited to U.S. organizations. This means that it is not possible to speak in general terms about "competition among MAGI members": a lawyer who drafts clinical trial agreements does not "compete" with a pharmaceutical company that sponsors trials, and neither of them "compete" with a hospital that seeks to conduct clinical trials. There is certainly competition or potential competition among distinct subgroups of MAGI members, however. To pick one example, one clinical trial site may compete with another in securing a specific trial from a specific sponsor. This competition is highly fragmented, however, because of the nature of clinical trials. Specifically, clinical trials generally require simultaneous use of many different sites in many diverse locations across the country or around the world, and discourage the use of multiple sites in the same city. They also often involve a mix of academic research centers and other types of facilities.

MAGI estimates that its current members comprise less than 1% of the “markets” for commercial investigative sites, CROs, trial sponsors, SMOs, and attorneys.¹ Even in the industry segment in which MAGI has its greatest concentration of participants – “prestigious” academic research sites – MAGI members comprise no more than 30%, and probably less, of the U.S. “market.” The percentage of clinical trial activity conducted at academic research sites has been steadily shrinking in recent years, however, so MAGI’s academic research site members face competition not only from each other but also from non-academic participants in the “market” for clinical trials.

At present, the lack of a widely used, easily understood model clinical trial agreement leads to considerable inefficiencies in commencing clinical trials: facilities seeking to host clinical trials must either spend time and effort negotiating contract language that could and should be standardized, or else they must accept contract terms proposed by trial sponsors that they may not understand or wish to accept. The premise of MAGI is that the existence of a flexible, widely used, model clinical trial agreement would expedite the process of bringing medical products to market. It will facilitate a healthier negotiation process, in which all parties understand the implications of alternative contract language.

In addition to wasted time and money spent in negotiating clinical trial agreement terms, every day that a new drug approval is delayed harms patients and costs an average of \$1.3 million in lost revenue, resulting in lower sponsor profits and higher consumer costs. MAGI intends to reduce trial start-up costs and aggravation for both sponsors and investigators by creating a flexible model agreement with broad industry acceptance. MAGI does not intend to exclude any industry participant from sharing in the efficiencies generated by its efforts: to the contrary, MAGI seeks to have its model agreement used by as many industry participants as possible, and ideally by everyone worldwide.

The model agreement that MAGI seeks to create and disseminate does not discuss pricing and contains no restrictions on the ability of users of the model agreement to negotiate prices. Nor will it

¹ It is doubtful, of course, that all (or any) of the listed categories of organizations comprise “relevant markets” in an antitrust sense. For example, a “trial sponsor” could be any person or organization that desires to conduct a clinical trial of a product, procedure, or course of treatment. In theory, just about any pharmaceutical company, government agency, academic research center, or foundation is a potential trial sponsor. That said, there may be discrete, definable sub-markets for certain kinds of activities related to clinical trials. Precise analysis of whether or not such sub-markets exist is beyond the scope of this memo, and in any event appears unnecessary in light of the very small percentage of participants therein who are members of MAGI.

limit the negotiability of other terms of clinical trial agreements that parties to such agreements have traditionally viewed as negotiable. The process of creating the model agreement will not require or encourage any MAGI participant to divulge non-public information about the clinical trial agreements they currently use.

MAGI does not plan to seek to persuade government regulatory entities to require the use of its model agreement, though informal endorsements from important entities such as the FDA or NIH would be welcome. MAGI is considering whether or not to copyright its model agreement, but doing so would be only for the purpose of controlling the development of the model, not to generate revenue. If it chooses to copyright its model agreement, MAGI anticipates charging at most a nominal licensing fee to cover costs of administration.

Applicable Legal Principles

Antitrust Guidelines Analysis. In April 2000, the Federal Trade Commission and U.S. Department of Justice (the “Agencies”) issued Antitrust Guidelines for Collaborations Among Competitors (“Guidelines”). The Guidelines explain how the Agencies analyze certain antitrust issues raised by collaborations among competitors or potential competitors. The Agencies use two alternative types of analysis to evaluate the lawfulness of an agreement among competitors: the per se rule and the rule of reason.

Per se rule. Certain types of agreements are so likely to harm competition and are so lacking in significant procompetitive benefit that they do not warrant the time and expense required for particularized inquiry into their effects. Once identified, such agreements are condemned as per se unlawful. These types of agreements include those designed to fix prices or reduce output, rig bids, or share or divide markets by allocating customers, suppliers, territories, or lines of commerce. All other agreements are analyzed under the rule of reason.

Rule of Reason. Rule of reason analysis compares the state of competition with and without the relevant agreement. The central question is whether the agreement likely harms competition by increasing the competitors’ ability or incentive profitably to raise price above or reduce output, quality, service, or innovation below what likely would exist without the agreement. The analysis begins with an identification of the nature of the relevant agreement in order to determine the type of anticompetitive harm that might result. If the agreement falls into one of the per se categories, the Agencies would challenge it without further analysis. If, however, as is more likely, the agreement is not within the scope of any per se rule, the Agencies will proceed with the rule of reason analysis.

In this fact-intensive evaluation, the Agencies will define relevant markets, calculate market shares and evaluate concentration and market structure. The Agencies examine whether and to what extent the participants have the ability and incentive to compete independently, such as whether an agreement is exclusive or non-exclusive in its duration. The Agencies also evaluate whether new entry by additional competitors may deter any anticompetitive harms. In essence, the Agencies evaluate the procompetitive benefits the Parties expect from the agreement and examine whether the restrictions in the agreement are reasonably necessary to achieve these procompetitive benefits. Ultimately, the reasonableness, and therefore the legality of the agreement turns on whether, on balance, the procompetitive benefits will outweigh any anticompetitive effects.

Safety Zones. Because competitive collaborations are often procompetitive, the Guidelines contain “safety zones.” The safety zones are designed to provide participants in a competitor collaboration with a degree of certainty in those situations where anticompetitive effects are so unlikely that the Agencies presume the arrangements to be lawful without inquiring into particular circumstances.

The Agencies do not challenge competitor collaboration when the market shares of the collaboration and its participants collectively account for no more than twenty percent of each relevant market in which competition may be affected. Although we are presently unable to definitively assess the applicability of the safety zone with certainty due to a lack of specific information identifying the relevant markets and market shares of MAGI members, it appears quite likely that MAGI will qualify for the 20% safety zone.

Analysis of MAGI

MAGI is not the type of collaboration that likely would come within the per se rule. The draft Agreement does not appear to fix prices, reduce output, or divide markets by allocating customers, suppliers, territories, or lines of commerce. The Agencies, therefore, likely would analyze the Agreement under the rule of reason to determine its overall competitive effect. The determinative question is whether, on balance, the procompetitive benefits from the draft Agreement will outweigh any anticompetitive effects.

Market definition. As described above, definition of the relevant product, service, and geographic markets is not straightforward with respect to MAGI. For any particular MAGI member it is accurate to say that it does not now, nor will it ever, compete with most other members in any manner. Discrete subsets of MAGI’s membership group may be actual or potential competitors in various submarkets, however. As a hypothetical example, two investigative sites in a specific town may

compete for certain types of studies, but probably not for all types of studies. In addition, both sites may compete with other sites in the same state. We have not been given information sufficient to define any such markets, and indeed the information required to perform such an analysis for all of the possible permutations of members and markets would be impractical to gather.

Even in the absence of information sufficient to define all of the possible relevant markets, the following general points can be made. The Agencies are concerned when a joint venture either creates or maintains “market power,” that is, the ability of a competitor to raise prices or reduce output in a relevant market. While we do not have information to identify MAGI members’ individual shares of various possible relevant markets, the numerosity of the participants in most aspects of the clinical trial process renders it unlikely that any of these sub-markets are highly concentrated or that any participants therein have “market power.” We have no information indicating that any MAGI member has market power today. Equally important, MAGI does not create a joint operating entity that would aggregate the market shares of its members. Instead, the members will remain independent, viable competitors (to the extent they compete at all), each with their respective shares of the market. Accordingly, MAGI appears unlikely to result in the creation of market power.

Procompetitive benefits. As indicated above, MAGI is likely to create several significant procompetitive benefits by developing a flexible CTA template with “certified” “multiple-choice” language. First, MAGI expects to create significant cost savings for the entire clinical trial industry. In the present system, CTA negotiations can take months, and retaining contract specialists and attorneys for this process is expensive. It is a great waste for participants to spend their time and energy negotiating terms that could and should be standardized instead of getting started on their research. Medical research is usually time sensitive, and yet most industry participants agree that contract negotiations delay the average study. Specifically, Quintiles, Inc., has done a survey that calculated average negotiation-related delays of 35 days for agreements involving community-based sites, and 96 days for academic research sites. These delays are multiplied by the fact that multiple trials are required for the approval of each new drug.

MAGI believes it can reduce these delays and speed the average new drug’s time-to-market by at least a couple of months by reducing start up time. Shortening the average clinical trial process by a few weeks or months will, in the aggregate, result in millions of dollars of revenue increases for industry participants. MAGI’s leadership hopes that it can reduce the pecuniary cost of negotiating contracts by 80% for all parties.

Second, the benefits to consumers of new drugs and other medical products reaching the market sooner are incalculable. Though it is impossible to quantify this benefit, a general shortening of the time it takes to win approval for new drugs and medical devices would obviously be of tremendous, in some cases life-saving, value to patients. With lower costs of development, medical products companies will be under less pressure to charge consumers high prices.

Third, the existence of a model agreement may expand the quantity and quality of clinical trials that are conducted. Reducing the cost of clinical trials may also enable more trials to take place during the clinical research phase of product testing. Moreover, it is reasonable to expect that trials will be of marginally higher quality if resources are directed away from contract negotiations and towards more productive activities. Faster-starting trials can translate into higher quality trials by relieving some of the enormous time pressures typical of clinical trials.

Fourth, by standardizing boilerplate contract terms, and by providing accompanying commentary to its model agreement, MAGI will enhance the understanding of contract terms by industry participants. Current CTAs are written by sponsors and clinical research organizations, and can be difficult to understand. Even where the language in existing CTAs is easy to understand, the simple fact that CTAs are all different forces clinical trial participants to waste time studying (or drafting) the varying “fine print” terms. MAGI’s “multiple choice” format and commentary will inform sites and sponsors of alternative language options and their significance. As a result, although this may result in less variability in terminology and phraseology, there will be more contract variability in substance.

Last, MAGI may expand the number of entities performing clinical trials by reducing barriers to entry in the industry. Over three-quarters of new investigators leave the clinical trial market after one trial because they did not understand the responsibilities, costs and liabilities they were accepting. A good model CTA would help prevent this.

Anticompetitive effects. MAGI does not appear to threaten the imposition of anticompetitive harm. MAGI’s agreement does not affect the freedom of industry participants to independently negotiate prices for each specific CTA, and the model CTA is designed to provide maximum flexibility to the parties to design pricing structures that meet their needs. The model CTA will also be designed to give trial participants maximum flexibility in negotiating non-pecuniary contract terms, such as those related to conduct of the study. No one will ever be required to use MAGI’s model CTA—it is simply an optional template to facilitate contract negotiations. Moreover, MAGI’s process of creating a model CTA will not involve any party disclosing heretofore confidential price or cost information to competitors or potential competitors.

Ancillary Restraints. The Agencies are especially sensitive to restrictions in joint venture agreements that are not reasonably related to the success of the venture and that affect the parties' incentives or abilities to compete vigorously. The Guidelines require that a restraint adopted in connection with a joint venture be reasonably related to the collaboration and reasonably necessary to achieve its procompetitive benefits. The Agencies are similarly watchful that the joint venture not be used as a vehicle for the sharing of competitively sensitive information that is unnecessary for the venture's successful operations. MAGI does not appear to involve any ancillary restraints on its members. In fact, since membership in MAGI is entirely voluntary, involves no contractual obligations, and may be terminated at any time, there do not appear to be any "restraints" on participants at all, ancillary or otherwise.

Conclusion

MAGI appears likely to create substantial procompetitive benefits for participants in the clinical trial process as well as for consumers. The risk of anticompetitive effects from MAGI's activities appears minimal. Furthermore, MAGI does not include any problematic ancillary restraints that affect MAGI members' continuing ability to compete with one another. Consequently, MAGI is likely to be viewed by regulators as reasonable and procompetitive, and therefore lawful under the antitrust laws.

Notes

Thomson CenterWatch provided the industry statistics in the foregoing memorandum.

About Reed Smith LLP

The antitrust lawyers of Reed Smith LLP have tried and won substantial antitrust cases for plaintiffs, defendants and the United States government. Eight of our lawyers are former federal antitrust prosecutors. We have tried cases involving price fixing, mergers, customer allocations, boycotts, monopolization and economic tying. In addition to their experience as prosecutors, our lawyers have represented many clients in connection with civil and criminal government antitrust investigations and prosecutions.

Reed Smith's antitrust attorneys represent companies and individuals in connection with grand jury investigations, premerger notifications and merger investigations, civil antitrust investigations, plea

agreements, penalty negotiations, damage claims by the government as purchaser and complaints to prosecutors by confidential informants. We counsel business clients and litigate in diverse commercial fields, including pharmaceuticals, health care, construction services and materials, transportation, industrial chemicals, real estate brokerage, soft drink bottling, steel and other metal products, solid waste disposal, computers and computer peripherals, plumbing fixtures, intellectual property, radio and telecommunications.

Additionally, Reed Smith's Health Care Group includes lawyers who specialize in the application of the antitrust laws to health care providers and other entities in the health care industry. Reed Smith attorneys have represented hospital and other provider clients in a range of antitrust matters, including hospital mergers, the creation of provider networks such as physician-hospital organizations and independent practice associations, the development of a variety of joint ventures, staff privileges cases, exclusive contracting, and the formation of and participation in PPOs and HMOs.

More than 170 of the Firm's nearly 1,000 attorneys practice health care law full time or include it as a portion of their practice. Our health care clients are located throughout the country, and over the years we have represented virtually every type of enterprise connected with the health care industry. Examples of our health industry clients include: HMOs and other managed care organizations; PPOs, physician-hospital organizations, independent practice associations, management service organizations and other provider alliances and networks; health insurance companies; pharmaceutical companies; biotechnology companies; manufacturers of medical equipment; and device and diagnostic companies.