

provisions of the Order within thirty (30) days following the date the Order becomes final, and every thirty (30) days thereafter until TRW has completed the required divestiture.

The purpose of this analysis is to facilitate the public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Donald S. Clark,
Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in TRW Inc./BDM, File No. 981 0081

I agree with my colleagues that the final decision and order that the Commission accepts today for public comment properly addresses the anticompetitive implications of the proposed transaction. I concur in the Commission's action except to the extent that Paragraph II.B. of the proposed order makes the Department of Defense a participant with the Commission in giving antitrust approval to any divestiture proposed under Paragraph II.A. of the order.

As I said in my concurring statement in *Litton Industries, Inc./PRC*, File No. C-3656 (decision and order, May 7, 1996), with due deference to the Department of Defense and in full recognition that it has the power to decide with which firms it will contract for the provision of goods and services vital to the national security, no persuasive argument has been presented to suggest that the Department has or should have a role in deciding the competitive implications of a particular divestiture. In addition, no showing has been made that this case is unique, that national security issues or concerns relating to the integrity of the Ballistic Missile Defense Organization's Lead Systems Integrator Program, to the extent they may be affected by this order, could not have been addressed, as they apparently have been in other defense-related transactions,¹ without inclusion of the Department of Defense as a necessary participant in a decision committed by statute to the Commission.

The need to obtain technical assistance in reviewing commercial transactions in sophisticated markets is not uncommon. Nor should the Commission forget that national security is the province of the country's defense agencies. The Commission might well find it necessary to consult with the

Department of Defense both to assess the viability of a proposed buyer of the BDM assets to be divested and to ensure that a proposed transaction is not inconsistent with national security. I would have preferred, however, to accommodate that need in this case by means other than making the Department of Defense a partner with the Commission in interpreting and applying a final order of the Commission.

[FR Doc. 98-709 Filed 1-9-98; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 931-0028]

Urological Stone Surgeons, Inc., et al.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 13, 1998.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th St. and Pa. Ave., N.W., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: William Baer or Robert Leibenluft, FTC/H-374, Washington, D.C. 20580. (202) 326-2932 or 326-3688.

C. Steven Baker, Federal Trade Commission, Chicago Regional Office, 55 East Monroe St., Suite 1437, Chicago, IL. 60603. (312) 353-8156.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement

package can be obtained from the FTC Home page (for January 6, 1998), on the World Wide Web, at "http://www.ftc.gov/os/actions/htm." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, Sixth Street and Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326-3627. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order settling charges that Urological Stone Surgeons, Inc. ("USS"), Stone Centers of America, L.L.C. ("SCA"), and Urological Services, Ltd. ("USL") (doing business as Parkside Kidney Stone Center ("Parkside")), and Marc A. Rubenstein, M.D., and Donald M. Norris, M.D. (individually, and as officers, directors, and shareholders of USS, as shareholders of SCA, and as owners and officers of USL), violated Section 5 of the Federal Trade Commission Act by agreeing on prices to be charged for the physician services provided by urologists as part of performing lithotripsy.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way.

The proposed consent order has been entered into for settlement purposes only, and does not constitute an admission by USS, SCA, USL, Dr. Rubenstein, or Dr. Norris that the law has been violated as alleged in the complaint.

The Complaint

Extracorporeal shock wave lithotripsy ("lithotripsy") is a non-surgical alternative for treating kidney stones. It

¹ See Lockheed Corporation, C-3576, decision and order (May 9, 1995); see also ARKLA, Inc., 112 F.T.C. 509 (1989).

requires the services of a urologist (a physician specializing in the diagnosis and treatment of diseases or medical conditions of the urogenital system) to operate a lithotripsy machine, which shatters the kidney stones into sand-like particles by means of high-energy pressure waves. The complaint charges that the five proposed respondents, and other unnamed urologists agreed to fix the price for their professional services in providing lithotripsy ("lithotripsy professional services") at Parkside.

Parkside is one of about eight providers of lithotripsy in the Chicago metropolitan area. Parkside operates two lithotripsy facilities: one in Park Ridge, Illinois; and a second in LaGrange, Illinois. The owners of USS and SCA, who constitute approximately 45 percent of the urologists in the Chicago metropolitan area, have jointly invested in the purchase and operation of the two lithotripsy machines that Parkside operates. USS, which is owned by 35 urologists, including Drs. Rubenstein and Norris, purchased and provides the lithotripsy machine for Parkside's Park Ridge facility. SCA, which is owned by USS and approximately 66 additional urologists, purchased and provides the lithotripsy machine for Parkside's LaGrange facility.

The complaint alleges that, beginning in 1985, the proposed respondents and unnamed urologists agreed to fix the price of lithotripsy professional services delivered at Parkside, and in furtherance of that agreement: (1) Agreed to use a common billing agent and to establish a uniform charge for lithotripsy professional services; (2) prepared and distributed fee schedules for lithotripsy professional services at Parkside; (3) billed a uniform amount, either the amount listed in the fee schedules or an amount negotiated on behalf of all urologists at Parkside.

In particular, in March 1985, USS informed its prospective investors, all of whom were urologists, that USS or its agent (USL) would bill and collect an estimated \$2,000 professional fee for each lithotripsy professional service provided at Parkside, and remit such fee to the provider urologist. In April 1985, in furtherance of this agreement, USS agreed to use its best efforts to establish a lithotripsy professional fee of \$2,000, subject to annual increases to reflect the changes in the cost of medical services in the Chicago metropolitan area. USL produced and disseminated to the urologists a fee schedule that included an initial lithotripsy professional fee of \$2,000. The urologists, in turn, agreed to accept the amount established by USL and to use USL as their common billing

agent for all services provided at Parkside. Each year thereafter, pursuant to the April 1986 agreement, USL increased the charges for lithotripsy professional services and distributed revised fee schedules.

The complaint further alleges that USL, acting in accordance with this series of agreements, uniformly billed the then-current fee schedule amount for lithotripsy professional services regardless of which urologist provided the service. In addition, USL, on behalf of all the urologists providing lithotripsy professional services at Parkside, negotiated contracts with purchasers of lithotripsy services. Pursuant to these contracts, each purchaser agreed to reimburse for such services on the basis of either a negotiated uniform percentage discount from charges, or a negotiated uniform bundled or "global" fee (which included the fee for use of the lithotripsy machine, the urologist's professional fee, and the fee for the anesthesiologist's services in the lithotripsy procedure). Through each such contract, the urologists effectively agreed collectively to offer their lithotripsy professional services to each purchaser at a fixed price or discount.

The "global fee" established at Parkside merely aggregates three uniformly necessary inputs to a single medical procedure—lithotripsy—where the usage, costs, and relative proportions of the inputs do not vary substantially from case to case.¹ Thus, the "global fee" used at Parkside is unlike arrangements in which health care providers, for a fixed, pre-determined "global fee" (sometimes called an "all-inclusive case rate"), agree to provide all needed services for a patient's complex or extended course of treatment, such as cardiac care or cancer treatment. This type of global fee arrangement, in contrast to the arrangement used by Parkside, may involve the sharing of substantial financial risk by the participants, and provide incentives for them to determine and use the most efficient combination of treatment inputs for each case. Under these circumstances, their collective setting of the global fee may be reasonably necessary for them to achieve significant efficiencies, and therefore judged under the rule of

¹ Anesthesia charges may vary somewhat, if a procedure takes slightly more or less time. However, even this variation is quite limited, since there are limits set on how much exposure to the shock waves generated by lithotripsy that patients may receive at any treatment.

reason rather than treated as unlawful price fixing.²

The complaint charges that, while the owners of USS and SCA have financially integrated by joint investing in the purchase and operation of the two lithotripsy machines that Parkside operates, collective setting of the price for their lithotripsy professional services, or for other non-investor urologists using Parkside, is not reasonably necessary (or "ancillary") to achieving any efficiencies that may be realized through their legitimate joint ownership and operation of the machines.³ Moreover, the complaint alleges that the urologists providing lithotripsy professional services at Parkside, which also includes urologists who are not investors in the machine joint venture, have not substantially integrated their professional practices so as to justify respondents' agreement to fix the price for urologists' lithotripsy professional services at Parkside.

About two-thirds of the lithotripsy procedures performed in the Chicago metropolitan area are, and for several years have been, performed at Parkside. The complaint charges that the agreement to fix the price of lithotripsy professional services at Parkside has injured consumers by restraining competition among urologists in the provision of lithotripsy professional services and fixing or increasing the prices for such services.

The Proposed Consent Order

Part II.A. of the proposed consent order would prohibit the five proposed respondents from engaging in any agreement with each other or with any other urologist: (1) To fix the price for lithotripsy professional services; and (2) concerning any other term of sale for lithotripsy professional services. In addition, under Part II.B. of the proposed consent order, USS, SCA, and USL would be required to terminate any agreement with any third-party payer for the provision of lithotripsy professional services that does not comply with Part II.A. of the order at the earlier of: (1) The termination or renewal date of the agreement; or (2) receipt of a written request from the third-party payer to terminate such agreement.

Despite these provisions, however, the proposed consent order would not prevent the five proposed respondents from providing lithotripsy professional services pursuant to any existing

² See U.S. Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care (Aug. 1996) at 68-69, 71-72; 107-110.

³ *Id.* at 18-19

agreement with any third-party payer until the earlier of (1) the termination or renewal date of the agreement, or (2) receipt of a written request from the third-party payer to terminate such agreement. In addition, the proposed consent order would not prevent either Dr. Rubenstein or Dr. Norris from entering into an agreement with any other physician with whom he practices in partnership or in a professional corporation, or who is employed by the same person as Dr. Rubenstein or Dr. Norris, to deal with any patient, purchaser, or their-party payer on collectively determined terms.

Nothing in the proposed order would prevent USS, SCA, or USL from offering a bundled or "global" fee that included the lithotripsy machine fee and the anesthesia fee, without the lithotripsy professional service fee, since such an arrangement would not involve any agreement on fees of lithotripsy professional services. Likewise, the proposed order would not prohibit them from contracting with purchasers of payers using a "messenger model" arrangement that did not involve any explicit or implicit agreement among urologist regarding the prices, discounts, or other terms of sale or reimbursement of their services.

The proposed consent order also would not prohibit any of the respondents from dealing through an integrated joint venture with any purchaser on collectively determined terms regarding lithotripsy professional services, provided that the respondent first notifies the Federal Trade Commission of any such joint venture activity in writing at least forty-five (45) days prior to the activity.

Part III of the proposed consent order would require USS, SCA, and USL to distribute copies of the proposed order and accompanying complaint to (a) persons whose activities are affected by the order, or who have responsibilities with respect to the subject matter of the order, and (b) each urologist who provides lithotripsy professional services at Parkside. In addition, the proposed consent order would require USS, SCA, and USL to distribute copies of the proposed order and accompanying complaint, together with the NOTICE attached to the order, to each third-party payer with whom they have an agreement that does not comply with Part II.A. of the order.

Parts IV, V, and VI of the proposed order impose certain reporting requirements in order to assist the Commission in monitoring compliance with the order.

The proposed consent order would terminate 20 years after the date it is issued.

Donald S. Clark,
Secretary.

Separate Statement of Commissioner Mary L. Azcuenaga Concurring in Part and Dissenting in Part in Parkside Kidney Stone Center, File No. 391-0028

I agree that an order requiring the respondents to cease and desist from fixing the price of professional lithotripsy services is warranted, but the requirement that the respondents, for ten years, give the Commission 45 days notice before "forming or participating in an integrated joint venture" that deals on collectively determined terms for lithotripsy services is unjustified and unnecessary.¹ The prior notice requirement departs from the Commission's policy adopting a presumption against prior approval and prior notice provisions in merger and joint venture orders.² An exception to the policy may be appropriate, if these is a credible risk that prior notice is necessary to prevent repetition of the unlawful conduct. Given the express prohibition in the proposed order of the allegedly unlawful conduct, the potential liability for civil penalties for a violation, and the periodic reports of compliance that may be required under the order, no such necessity appears. I dissent from the prior notice requirement.

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¹ The prior notice requirement is inconsistent with the weight of Commission precedent. Similar cases in the health care field typically have not imposed any notice requirements or have required notice within 30 days after certain joint venture activity. See e.g., *Physicians Group, Inc.*, Docket C-3620 (Aug. 11, 1995); *Trauma Associates of North Broward, Inc.*, Docket C-3541 (Nov. 1, 1994); *Southbank IPA, Inc.*, 114 F.T.C. 783 (1991); *Preferred Physicians, Inc.*, 110 F.T.C. 157 (1988); *Medical Staff of Doctors' Hospital of Prince George's County*, 100 F.T.C. 476 (1988). But see *Montana Associated Physicians, Inc.*, Docket C-3704 (Jan 13, 1997) (20-year prior approval); *College of Physicians-Surgeons of Puerto Rico*, File No. 971-0011 (filed D. Puerto Rico Oct. 2, 1997) (Commissioner Azcuenaga concurring in part and dissenting from perpetual prior approval requirement).

² Prior Approval Policy Statement (June 1955), *Reprinted in 4 Trade Reg. Rept. Rep.* (CCH) ¶13,241.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC) and Subcommittee on Genetic Testing: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meetings.

Name: Subcommittee on Genetic Testing, Clinical Laboratory Improvement Advisory Committee (CLIAC).

Times and Dates: 8:30 a.m.-4:30 p.m., January 27, 1998; 8:30 a.m.-4:30 p.m., January 28, 1998.

Place: CDC, Auditorium B, Building 2, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: This subcommittee advises CLIAC on issues related to Genetic Testing.

Matters To Be Discussed: Agenda items include a discussion on the definition of Genetic Testing under the Clinical Laboratory Improvement Amendments (CLIA) regulations; and the use of general versus specific CLIA requirements for pre-analytic, analytic, and post-analytic components of genetic testing.

Agenda items are subject to change as priorities dictate.

Name: Clinical Laboratory Improvement Advisory Committee.

Times and Dates: 8:30 a.m.-4:30 p.m., January 29, 1998; 8 a.m.-4:30 p.m., January 30, 1998.

Place: CDC, Auditorium B, Building 2, 1600 Clifton Road, E, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards; and the modification of the standards to accommodate the technological advances.

Matters To Be Discussed: Agenda items include an update on CLIA implementation; CLIA requirements for the pre-analytic, analytic, and post-analytic components of Genetic Testing; International Guidelines for Proficiency Testing (PT) programs; and criteria for adding analytes to CLIA PT requirements.

Agenda items are subject to change as priorities dictate.

Contact Person: John C. Ridderhof, Dr. P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, M/S G-25, Atlanta, Georgia 30341-3724, telephone 770/488-4674.