DEPARTMENT OF JUSTICE

Antitrust Division

Proposed Final Judgment and Competitive Impact Statement; United States v. Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Associations, Inc.

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. section 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Southern District of West Virginia in *United States* v. *Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Association, Inc.*, Civil Case No. 1:05–0234. On March 21, 2005, the United States filed a Complaint alleging that, on January 30, 2003, Bluefield Regional Medical Center, Inc. (BRMC) and Princeton Community Hospital Association, Inc. (PCH) entered into two agreements in which BRMC agreed not to offer many cancer services and PCH agreed not to offer cardiac-surgery services. The BRMC–PCH agreements effectively allocated markets for cancer and cardiac-surgery services and restrained competition to the detriment of consumers in violation of section 1 of the Sherman Act.

The proposed Final Judgment filed with the Complaint will enjoin BRMC and PCH from enforcing the BRMC–PCH agreements. BRMC and PCH also will be enjoined from entering into, continuing, maintaining, or enforcing any agreement to allocate markets, territories, or customers concerning cancer services or cardiac surgery. In addition, BRMC and PCH will be enjoined from entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States. Finally, BRMC and PCH are enjoined from entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Documents Group, 325 Seventh Street, NW., Room 215 North, Washington, DC 20530 and at the Office of the Clerk of the United States District Court for the Southern District of West Virginia, 601 Federal Street, Room 2303, Bluefield, West Virgina 24701.

Public comment is invited within 60 days of the date of this notice. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Mark J. Botti, Chief, Litigation I Section, Antitrust Division, U.S. Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530 (Telephone (202) 307–0001).

Dorothy B. Fountain,

Deputy Director of Operations, Antitrust Division.

Final Judgment

Whereas, Plaintiff, the United States of America, filed its Complaint on March 21, 2005 alleging that Defendants, Bluefield Regional Medical Center, Inc. and Princeton Community Hospital Association, Inc., entered into agreements in violation of section 1 of the Sherman Act, 15 U.S.C. 1, and Plaintiff and Defendants, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against, or any admission by, any party regarding any such issue of fact or law;

And whereas, Defendants agree to be bound by the provisions of the Final Judgment pending its approval by this Court;

And whereas, the essence of this Final Judgment is to enjoin the Defendants from allocating markets for the provision of certain medical services and to restore lost competition as alleged in the Complaint;

And whereas, the United States requires Defendants to agree to certain procedures and prohibitions for the purpose of restoring the loss of competition alleged in the Complaint;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under section 1 of the Sherman Act, as amended (15 U.S.C. 1).

II. Definitions

As used in this Final Judgment:

A. ''Agreement'' means any kind of formal or informal agreement, arrangement, contract, understanding, memorandum of understanding, interim contract, contract appendix, addendum, attachment, amendment, waiver, or modification. Agreements that solely concern patient-treatment protocols or the transfer of patients necessary to render patient care that is unavailable at BRMC or PCH shall not be deemed an agreement within the scope of this Final Judgment. An agreement solely for the merger of BRMC and PCH, the acquisition by one of the other, or bringing all or substantially all of the operations or assets of BRMC and PCH under common control shall not be deemed an agreement within the scope of this Final Judgment if BRMC and PCH give at least thirty days advance notice of such merger, acquisition, or transaction to the United States.

B. ''BRMC'' means Defendant Bluefield Regional Medical Center, Inc. a non-profit corporation organized and existing under the laws of the State of West Virginia with its headquarters in Bluefield, West Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Cancer and Open-Heart Agreements'' means (1) the contract dated January 30, 2003 between BRMC and PCH concerning cancer services and all amendments and other agreements ancillary to that contract and (2) the contract dated January 30, 2003 among BRMC, PCH, and Charleston Area Medical Center, Inc. concerning cardiac surgery and all amendments and other agreements ancillary to that contract.

D. ''Cancer Services'' means any health or other service relating to any service performed by cancer specialists such as radiation oncologists, medical oncologists, surgical oncologists, gynecological oncologists, and other oncologic physician specialists. This term includes any equipment, technology, or modality used in providing such services.

E. ''Cardiac Surgery'' means any health or other services relating to surgery on the heart or major blood vessels of the heart (including both open and closed heart surgery) and therapeutic cardiac catherization. This term includes any service, equipment, technology, or modality relating to the services of an open-heart surgeon, cardiovascular surgeon, cardiovascular anesthesiologist, interventional cardiologist, or perfusionist.

F. ''Certificate of Need'' means certificate of need as recognized by the

State of West Virginia (W. Va. Code § 16–2D–1 *et seq.*) and a certificate of public need as recognized in the Commonwealth of Virginia (Va. Code Ann. § 32.1–102.1 *et seq.*).

G. ''Health-Care Facility'' means any facility providing health-care services, including hospitals, hospital-owned or managed physician practices, ambulatory-care centers, clinics, urgent-care centers, free-standing emergency-care centers, and ambulatory-surgery centers.

H. ''PCH'' means Defendant Princeton Community Hospital Association, Inc., a non-profit corporation organized and existing under the laws of the State of West Virginia with its headquarters in Princeton, West Virginia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships and joint ventures, and their directors, officers, managers, agents, and employees.

I. The terms ''and'' and ''or'' have both conjunctive and disjunctive meanings.

III. Applicability

This Final Judgment applies to BRMC and PCH, as defined above, and all other persons in active concert or participation with any of them who receive actual notice of this Final Judgment by personal service or otherwise.

IV. Prohibited Conduct

A. BRMC and PCH are enjoined from enforcing all or any part of the Cancer and Open-Heart Agreements. BRMC's and PCH's obligations under this Final Judgment supersede their obligations under either of these agreements, and BRMC and PCH shall not object to the performance of their obligations under this Final Judgment on the grounds that those obligations would cause them to breach either agreement.

B. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement to allocate any cancer or cardiac-surgery service, market, territory, or customer.

C. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably.

D. BRMC and PCH are enjoined from, in any manner, directly or indirectly, entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States, which will not be withheld unreasonably.

V. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time duly authorized representatives of the United States Department of Justice, including consultants and other persons retained or designated thereby, shall, upon written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division and on reasonable notice to Defendants, be permitted:

1. Access during Defendants' office hours to inspect and copy, or at the United States' option, to require that Defendants provide copies of, all books, ledgers, accounts, records and documents in their possession, custody, or control relating to any matters contained in this Final Judgment; and

2. To interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of a duly authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants shall submit written reports, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested.

C. No information or documents obtained by the means provided in this section shall be divulged by Plaintiff to any person other than an authorized representative of the executive branch of the United States except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time Defendants furnish information or documents to the United States, they represent and identify in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure,'' then the United States shall give Defendants ten calendar days notice prior to divulging such material in any legal proceeding (other than a grand jury proceeding).

VI. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

VII. Expiration of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire ten years from the date of its entry.

VIII. Correspondence

BRMC and PCH shall provide notice and seek prior written approval as contemplated by this Final Judgment by sending correspondence to Chief, Litigation I, Antitrust Division, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530, or such other address as the United States shall designate.

IX. Public Interest Determination

Entry of this Final Judgment is in the public interest.

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. § 16.

United States District Judge.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and each of the parties hereto, and venue of this action is proper in this District.

2. The parties stipulate that a proposed Final Judgment in the form attached as Exhibit A may be entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the antitrust Procedures and Penalties Act, 15 U.S.C. 16, and without further notice to any party or other proceedings, provided that the United States has not withdrawn its consent, which it may do at any time before the entry of the proposed final

Judgment by serving notice thereof on defendants and by filing that notice with the Court.

3. Defendants shall abide by and comply with the provisions of the proposed Final Judgment, pending the Judgment's entry by the Court, or until expiration of time for all appeals of any Court ruling declining entry of the proposed Final Judgment, and shall, from the date of the signing of this Stipulation by the parties, comply with all the terms and provisions of the proposed Final Judgment as though the same were in full force and effect as an order of the Court.

4. This Stipulation shall apply with equal force and effect to any amended proposed Final Judgment agreed upon in writing by the parties and submitted to the Court.

5. In the event (a) the United States has withdrawn its consent, as provided in section 2 above, or (b) the proposed Final Judgment is not entered pursuant to this Stipulation, the time has expired for all appeals of any Court ruling declining entry of the proposed Final Judgment, and the Court has not otherwise ordered continued compliance with the terms and provisions of the proposed Final Judgment, then the parties are released from all further obligations under this Stipulation, and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

For Plaintiff United States of America:

Dated: March 21, 2005.

Peter J. Mucchetti, Esq.,
Litigation I Section, Antitrust Division, United States Department of Justice.

For Defendant Bluefield Regional Medical Center, Inc.:

Dated: March 18, 2005.

Arthur N. Lerner, Esq.,
Crowell & Moring LLP, Counsel for Defendant Bluefield Regional Medical Center, Inc.

For Defendant Princeton Community Hospital Association, Inc.

March 14, 2005.

Kevin E. Grady, Esq.,
Alston & Bird LLP, Counsel for Defendant Princeton Community Hospital Association, Inc.

Competitive Impact Statement

The United States of America, pursuant to section 2(b) of the Antitrust Procedures and Penalties Act, (''APPA''), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On March 21, 2005, the United States filed a civil antitrust Complaint alleging that Bluefield Regional Medical Center, Inc. (BRMC) and Princeton Community Hospital Association, Inc. (PCH) had violated Section 1 of the Sherman Act, 15 U.S.C. 1. BRMC owns and operates a 265-bed, general acute-care hospital in Bluefield, West Virginia. PCH owns and operates a 211-bed general acute-care hospital in Princeton, West Virginia. PCH also owns and operates St. Luke's Hospital, LLC (St. Luke's), a 79-bed, general acute-care hospital in Bluefield, West Virginia.

The Complaint alleges that, on January 30, 2003, BRMC and PCH entered into two agreements (the ''cancer and open-heart agreements'') in which BRMC agreed not to offer certain cancer services and PCH agreed not to offer certain cardiac-surgery services. The cancer and open-heart agreements effectively allocated markets for cancer and cardiac-surgery services and restrained competition to the detriment of consumers. With the Complaint, the United States, BRMC, and PCH filed an agreed-upon proposed Final Judgment that annuls the cancer and open-heart agreements and prohibits BRMC and PCH from taking actions that would reduce competition between the two hospitals for patients needing cancer and cardiac-surgery services.

The United States, BRMC, and PCH have agreed that the proposed Final Judgment may be entered after compliance with the APPA, provided that the United States has not withdrawn its consent. Entry of the Final Judgment would terminate the action, except that the Court would retain jurisdiction to construe, modify, or enforce the Final Judgment's provisions and to punish violations thereof.

II. Description of Practices and Events Giving Rise to the Alleged Violations of the Antitrust Laws

A. Services Provided by the Defendants and Events Preceding the Parties' Cancer and Open-Heart Agreements

At all times relevant to the matters alleged in the Complaint, BRMC and PCH have been significant competitors in general acute-care hospital services and in cancer services. PCH is located about fifteen miles from BRMC. PCH's St. Luke's Hospital is located about two miles from BRMC. BRMC, PCH, and St. Luke's are the only general acute-care hospitals in Mercer County, West Virginia.

BRMC and PCH also have been potential competitors in cardiac-surgery services. BRMC sought to develop cardiac-surgery services since at least 1999. Similarly, from at least 1999 until PCH agreed not to compete with BRMC in cardiac-surgery services, PCH sought to develop cardiac-surgery services by working with other hospitals in southern West Virginia.

The State of West Virginia and the Commonwealth of Virginia require that a hospital obtain a certificate of need or a certificate of public need (collectively, ''CON'') from a state agency before a hospital may provide either cardiac-surgery services or radiation-therapy services (using a linear accelerator) for treating patients with cancer. The West Virginia Health Care Authority (WVHCA) administers the CON program in West Virginia. The Virginia Department of Health's Certificate of Public Need Division and regional health planning agencies administer the CON program in Virginia.

In January 1999, BRMC submitted a CON application to the WVHCA to develop a cardiac-surgery program in Mercer County, West Virginia. At that time, neither BRMC, PCH, nor St. Luke's had a CON to operate a cardiac-surgery program. PCH, St. Luke's, and other hospitals opposed BRMC's application. PCH and St. Luke's argued, in part, that BRMC's application should be denied because it did not provide a role for PCH and St. Luke's in the provision of cardiac-surgery services in southern West Virginia.

In February 2000, the WVHCA issued a written decision that denied BRMC's application for a CON to develop a cardiac-surgery program because BRMC was unable to show that, without working with other hospitals, it would be able to attract a sufficient number of patients. In its decision, the WVHCA wrote that PCH, St. Luke's and other hospitals had:

> failed to successfully negotiate with [BRMC] to reach a shared goal. The goal being to provide advanced cardiology services to the citizens of southern West Virginia and southwestern Virginia * * *. [The WVHCA] would have preferred that the parties work together to present a project that could have been approved under the existing law. Instead, the parties fought among themselves, failed to resolve their differences, and in return, the citizens of southern West Virginia will be inconvenienced and suffer by not having a regional open-heart service provider.

On one or more occasions during 2002, BRMC and PCH representatives met with WVHCA officials. The WVHCA officials encouraged BRMC and PCH to reach an understanding that would enable the parties to submit an application for an open-heart surgery

CON that the WVHCA would be able to approve. The WVHCA officials, however, neither instructed nor encouraged BRMC and PCH to allocate markets.

B. The Cancer and Open-Heart Agreements

On January 30, 2003, BRMC and PCH entered into the cancer and open-heart agreements. The cancer agreement concerned PCH's provision of certain cancer services, including radiation-therapy services, and the open-heart agreement concerned BRMC's plan to develop cardiac-surgery services (open-heart surgery and therapeutic cardiac-catheterization services). The agreements applied to McDowell, Mercer, Monroe, Raleigh, Summers, and Wyoming counties in southern West Virginia and Bland, Giles, and Tazewell counties in western Virginia. In the agreements, BRMC agreed to submit a joint CON application with PCH to transfer BRMC's CON to operate radiation-therapy equipment to PCH. PCH agreed to submit a joint CON application with BRMC for BRMC to receive a cardiac-surgery CON.

As part of the cancer and open-heart agreements, BRMC agreed to refrain from competing with PCH in various ways, none of which was related to a procompetitive purpose. BRMC agreed, among other things:

- Not to apply for, finance, encourage, or participate in a CON to provide cancer services by itself or with any entity other than PCH;
- That, in the event that the State of West Virginia or the Commonwealth of Virginia no longer requires a CON to provide cancer services, BRMC would not develop, finance, encourage, participants in, or support the development or provision of cancer services by BRMC or any entity other than PCH;
- Not to engage in, support, finance, encourage, or participate in the recruitment of any physician cancer specialists to BRMC's medical staff or for any other entity or individual, other than PCH;
- To provide to PCH information relating to cancer services provided by BRMC;
- Not to market or advertise that BRMC has a cancer center;
- Not to provide outpatient chemotherapy services (except for those services ordered or performed by either of two physicians currently practicing at BRMC);
- Not to lease space in its existing or future medical office buildings to any cancer specialists, except for those cancer specialists leasing space as of the date of the agreement; and
- That, in the event that any new technology or modality for the diagnosis or treatment of cancer becomes available that is not offered generally at hospitals similar to PCH and BRMC, BRMC would not acquire, develop, offer or provide such technology or modality, and BRMC would not finance, encourage, participate in, or support the development or offering of such technology or modality by any entity other than PCH.

As part of the cancer and open-heart agreements, PCH also agreed to refrain from competing with BRMC is various ways, none of which was related to a procompetitive purpose. PCH agreed, among other things:

- Not to apply for, finance, encourage, or participate in a CON to provide cardiac-surgery services by itself or with any entity other than BRMC;
- That, in the event that the State of West Virginia or the Commonwealth of Virginia no longer requires a CON to provide cardiac-surgery services, PCH would not develop, finance, encourage, participate in, or support the development or provision of cardiac-surgery services by PCH or any entity other than BRMC;
- Not to engage in, support, finance, encourage, or participate in the recruitment of any cardiac-surgery specialists to PCH's medical staff or for any other entity or individual, other than BRMC;
- To provide to BRMC information relating services provided by PCH;
- Not to solicit, entertain, finance, aid, support, or participate in any competing proposal from any entity or physician to develop cardiac-surgery services;
- Not to lease space in its existing or future medical office buildings to any open-heart surgery specialist; and
- That, in the event that any new technology or modality for the diagnosis or treatment or cardiovascular disease becomes available that is not offered generally at hospitals similar to PCH and BRMC, PCH would not acquire, develop, offer or provide such technology or modality, and PCH would not finance, encourage, participate in, or support the development or offering of such technology or modality by any entity other than BRMC.

The term of the cancer and open-heart agreements commend on January 30, 2003 and terminates five years after the first open-heart surgery is performed at BRMC or the first cancer patient is treated at a PCH comprehensive cancer center, whichever is later. Neither agreement can last longer than eight years. Each agreement automatically terminates if, within three years from commencement, either party has not received all government approvals needed to provide its services.

PCH and BRMC structured the agreements such that PCH would independently own its cancer-treatment facilities and provide its cancer services independently of BRMC, BRMC would independently own its cardiac-surgery facilities and provide its cardiac-surgery services independently of PCH, and BRMC and PCH would not provide these services as part of a joint venture.

On January 23, 2003, BRMC submitted to the WVHCA a CON application, with PCH as a joint applicant, to develop a cardiac-surgery program at BRMC. On July 30, 2003, PCH submitted to the WVHCA an application, with BRMC as a joint applicant, to transfer BRMC's CON to operate radiation-therapy equipment to PCH. The WVHCA approved BRMC's cardiac-surgery CON application on August 1, 2003. PCH's application to transfer BRMC's radiation-therapy equipment CON to PCH remains pending with the WVHCA.

Because of the cancer and open-heart agreements, BRMC and PCH have refrained and, if not enjoined, likely would continue to refrain from competing to serve patients that need cancer and cardiac-surgery services. The cancer and open-heart agreements have had and, unless enjoined, likely would have the following harmful effects:

- Managed-care purchasers, their enrollees and employees, and other patients in southern West Virginia and western Virginia have been denied and would be denied the benefits of price competition between PCH and BRMC;
- The quality of services has decreased and likely would decrease in the absence of competition between PCH and BRMC to provide cancer and cardiac-surgery services;
- Patients have lost and would lose the ability to choose between PCH and BRMC when selecting a hospital to provide cancer services;
- Patients have lost and would lose the benefit of potential competition between PCH and BRMC in cardiac-surgery services; and
- PCH's and BRMC's incentives to innovate or offer new cancer and cardiac-surgery services have been and would be decreased.

C. The Cancer and Open-Heart Agreements Are Not Entitled to Federal Antitrust Immunity Under the State-Action Doctrine

The state-action doctrine provides immunity from Federal antitrust liability where a party can satisfy a two-part test. First, the party must show that the challenged restraint is one clearly articulated and affirmatively expressed as state policy. *California Retail Liquor Dealers Association* v. *Midcal Aluminum*, 445 U.S. 97, 105 (1980). To satisfy the clear-articulation requirement, a defendant must show only that ''the legislature contemplated the kind of action complained of.'' *Town of Hallie* v. *City of Eau Claire*, 471 U.S. 34, 44 (1985). Second, the state must actively supervise the challenged conduct. *Midcal*, 445 U.S. at 105.

As discussed below, no state action in either West Virginia or Virginia shields the cancer and open-heart agreements from federal antitrust review. The West Virginia legislature has not enpowered the WVHCA to authorize hospitals to enter into market-allocation agreements. Furthermore, the WVHCA is not empowered to exercise, and has not exercised, active supervision over the cancer and open-heart agreements. Indeed, the WVHCA did not purport to authorize the parties to enter into the agreements. Similarly, in Virginia, no state agency or official encouraged or authorized BRMC and PCH to reach an understanding or agreement concerning cardiac-surgery or cancer services.

1. The West Virginia Legislature Did Not Empower the WVHCA To Authorize Private Market-allocation Agreements

The West Virginia legislature empowered the WVHCA to administer West Virginia's CON program according to legislatively established criteria. W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*. Although the West Virginia legislature granted the WVHCA significant regulatory powers over competition in West Virginia health-care markets, it limited the means by which the WCHCA can regulate competition among health-care providers principally to granting or denying CONs to firms wishing to compete. W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*.

In administering the CON program, the WVHCA is called upon to review and, if appropriate, to grant or deny CON applications for certain medical services. W. Va. Code § 16–29–11. The statutory framework grants third parties the right to intervene to protect their interests; affords adversely affected parties the right of judicial review; requires written findings as to whether approval of a CON would further legislatively established criteria; and establishes other procedural safeguards. W. Va. Code §§ 16–29B–12(f), 16–29B–13, and 16–2D–9. When reviewing CON applications, the WVHCA must follow established procedures and act within the CON process. *See* W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq*. The statutes and regulations delineating the responsibilities of the WVHCA do not explicitly empower it to consider, or to issue opinions concerning, private market-allocation agreements. *See, e.g.*, W. Va. Code § 16–2D–1 *et seq.*, W. Va. Code St. R. § 65–7–1 *et seq.*, W. Va. Code § 16–29B–1 *et seq.*, W. Va. Code St. R. § 65–5–1 *et seq.*, W. Va. Code St. R. § 65–26–1 *et seq*.

Nor does the WVHCA have implicit authority to approve private agreements as a means of regulating competition. In light of the rights and procedural safeguards afforded in the statutory framework to affected parties, to conclude that WVHCA has implied authority to authorize private market-allocation agreements would be inconsistent with that framework and effectively would give to the WVHCA unreviewable discretion to regulate health-care markets. To the contrary, the legislature generally has left West Virginia health-care providers free to make market decisions on how to compete as long as they are not (1) adding or expanding health-care services; (2) incurring a capital expenditure of $2 million or more; (3) obtaining major medical equipment valued at $2 million or more; or (4) developing or acquiring new health-care facilities. W. Va. Code § 16–2D–3.

Because the West Virginia legislature has not granted to the WVHCA the explicit authority to approve private market-allocation agreements such as the cancer and open-heart agreements, because any implicit authority of the WVHCA to approve such agreements would be inconsistent with the statutory framework that the legislature did create, and because the legislature clearly contemplated that West Virginia hospitals would compete in the free market for many of the activities covered by the cancer and open-heart agreements, these agreements cannot be considered part of a ''clearly articulated and affirmatively expressed state policy.'' *Midcal*, 445 U.S. at 105.

2. The WVHCA Is Not Empowered To Exercise, and Has Not Exercised, Active Supervision Over the Cancer and Open-Heart Agreements

The active-supervision requirement of the state-action doctrine requires that the State actively supervise and exercise ultimate control over the challenged anticompetitive conduct. *Midcal*, 445 U.S. at 105, *Patrick* v. *Burget*, 486 U.S. 94, 100–101 (1988). ''The requirement is designed to ensure that the state-action doctrine will shelter only the particular anticompetitive acts of private parties that, in the judgment of the State, actually further state regulatory policies.'' *Patrick*, 486 U.S. at 100–101.

The West Virginia legislature, however, has not empowered the WVHCA to require parties to private agreements to maintain, alter, or abandon their agreements. Thus, the WVHCA has no power to exercise active supervision or control over private agreements such as the cancer and open-heart agreements. Moreover, the WVHCA has not purported to actively supervise the cancer and open-heart agreements, as it did not (1) develop a factual record concerning the initial or ongoing nature and effect of the agreements; (2) issue a written decision approving the agreements; or (3) assess whether the agreements further criteria established by the West Virginia legislature. *See FTC* v. *Ticor Title Ins. Co.*, 504 U.S. 621, 637–639 (1992).

The WVHCA, in its February 2000 decision and in the actions of its officials during 2002, did not purport to authorize BRMC and PCH to enter into market-allocation agreements. In its February 2000 decision denying BRMC's cardiac-surgery CON application, the WVHCA simply stated a preference that BRMC and PCH work together to develop a cardiac-surgery project and encouraged the parties to submit a cardiac-surgery CON application that could be approved under the law. The decision did not encourage or instruct BRMC and PCH to allocate cardiac-surgery or cancer services. Similarly, during meetings in 2002 with representatives of BRMC and PCH, WVHCA officials neither instructed nor encouraged BRMC and PCH to allocate markets or to agree to anticompetitive conduct such as that later contained in the cancer and open-heart agreements.

Regulation by the WVHCA of the rates charged by BRMC and PCH, *see, e.g.*, W. Va. Code § 16–29B–1 *et seq.*, W. Va. Code St. § 65–5–1 *et seq.*, W. Va. Code St. R. § 65–26–1 *et seq.*, also does not satisfy the active-supervision requirement. In this case, the

anticompetitive conduct is not the prices charged by the hospitals; rather, it is the terms of the cancer and open-heart agreements. The WVHCA's regulation of rates does not directly address market-allocation issues or the potential anticompetitive effects of such allocations, as rate regulation may fail to ensure that the hospitals charge rates equal to those rates that would have prevailed in a competitive market and it fails to address decreases in quality of service, innovation, and consumer choice that result from an agreement not to compete.

3. No Virginia Official or Agency Encouraged or Authorized BRMC and PCH To Reach an Agreement Concerning Cardiac-Surgery or Cancer Services

Although the cancer and open-heart agreements allocate markets for cancer and cardiac surgery in three Virginia counties, no Virginia state action immunizes the agreements from federal antitrust review. An extensive discussion of why the state-action doctrine does not apply in Virginia is not necessary as BRMC and PCH has no contacts with any Virginia agency or official that might suggest a state-action defense. No Virginia agency or official encouraged or authorized BRMC and PCH to enter into the agreements or reach any understanding concerning cardiac-surgery or cancer services. BRMC and PCH also never sought or received approval for the agreements from any Virginia agency or official.

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment would enjoin BRMC and PCH from enforcing any part of the cancer and open-heart agreements. BRMC and PCH also would be enjoined from entering into, continuing, maintaining, or enforcing any agreement to allocate any cancer or cardiac-surgery service, market, territory, or customer. In addition, BRMC and PCH would be enjoined from entering into, continuing, maintaining, or enforcing any other agreement that (1) prohibits or restricts a health-care facility from obtaining a certificate of need relating to cancer services or cardiac surgery or (2) otherwise prohibits or restricts a health-care facility from taking actions related to providing cancer services or cardiac surgery without prior notice to and prior written approval of the United States. Finally, BRMC and PCH would be enjoined from entering into, continuing, maintaining, or enforcing any agreement with each other concerning cancer services or cardiac surgery without prior notice to and prior written approval of the United States. The effect of the proposed Final Judgment would be to restore competition between BRMC and PCH that the cancer and open-heart agreements eliminated, and would prevent BRMC and PCH from engaging in similar conduct in the future.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of such actions. Under the provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a) the Final Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against the Defendant.

V. Procedures Available for Modifications of the Proposed Final Judgment

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty days of the date of publication of this Competitive Impact Statement in the **Federal Register**. All comments received during this period will be considered by the Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to the Court's entry of judgment. The comments and the response of the United States will be filed with the Court and published in the **Federal Register**.

Written comments should be submitted to: Mark J. Botti, Chief, Litigation I Section, Antitrust Division, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

The United States considered, as an alternative to the proposed Final Judgment, a full trial on the merits against defendants BRMC and PCH. The United States is satisfied, however, that the Final Judgment, with its prohibition on anticompetitive conduct, will more quickly achieve the primary objectives of a trial on the merits—reestablishing competition in the relevant markets.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

The APPA requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court shall consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration or relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) and (B). As the United States Court of Appeals for the District of Columbia Circuit has held, the APPA permits a court to consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1458–62 (D.C. Cir. 1995).

''Nothing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2). Thus, in conducting this inquiry, ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the

benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney).[1] Rather:

> [a]bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should * * * carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

United States v. *Mid-America Dairymen, Inc.,* 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977).

Accordingly, with respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also* Microsoft, 56 F.3d at 1460–62. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is *''within the reaches of the public interest.''* More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[2]

The proposed Final Judgment, therefore, should not be reviewed under a standard of whether it is certain to eliminate every anticompetitive effect of a particular practice or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. ''[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.''' *United States* v. *AT&T,* 552 F. Supp. 131, (D.D.C. 1982) (citations omitted) (quoting Gillette, 406 F. Supp. at 716), aff'd sub nom. *Maryland* v. *United States,* 460 U.S. 1001 (1983); *see also United States* v. *Alcan Aluminum Ltd.,* 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint; the APPA does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' Microsoft, 56 F.3d at 1459. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecurtorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Id.* at 1459–60.

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: March 21, 2005.

Respectfully submitted,

Mark J. Botti,
Chief, Litigation I.

Kasey Warner,
United States Attorney.

Peter J. Mucchetti,
Joan S. Huggler,
Mitchell H. Glende,
Attorneys for the United States, United States Department of Justice, 1401 H Street, NW., Suite 4000, Washington, DC 20530. Telephone: (202) 353–4211. Facsimile: (202) 307–5802.

Stephen M. Horn,
Assistant United States Attorney.

[FR Doc. 05–6536 Filed 4–1–05; 8:45 am]

BILLING CODE 4410–11–M

[1] *See United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (recognizing it was not the court's duty to settle; rather, the court must only answer ''whether the settlement achieved [was] within the reaches of the public interest''). A ''public interest'' determination can be made properly on the basis of the Competitive Impact Statement and Response to Comments filed by the Department of Justice pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. *See* H.R. Rep. No. 93–1463, 93rd Cong 2d Sess. 8–9 (1974), reprinted in 1974 U.S.C.C.A.N. 6535, 6538.

[2] Cf. BNS, 858 F.2d at 464 (holding that the court's ''ultimate authority under the [APPA] is limited to approving or disapproving the consent decree''); Gillette, 406 F. Supp. at 716 (noting that, in this way, the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally* Microsoft, 56 F3.d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest'''

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(1), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(b) authorizing the importation of such substances, provide manufacturers holding registrations for the bulk manufacture of the substances an opportunity for a hearing.

Therefore, in accordance with Title 21 CFR 1301.34(a), this is notice that on July 26, 2004, Aveva Drug Delivery Systems Inc., 3250 Commerce Parkway, Miramar, Florida 33025–3907, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Fentanyl (9801), a basic class of controlled substance listed in Schedule II.

The company plans to import the listed controlled substance for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file written comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2004.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import the basic class of any controlled substance listed in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office