

SETTLEMENT AGREEMENT DATED SEPTEMBER 3, 1992

IN IN RE CLOZAPINE ANTITRUST LITIGATION

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SETTLEMENT AGREEMENT

This Settlement Agreement is made and entered into this 3rd day of September, 1992, by and between the States of Alabama, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Minnesota, Missouri, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin ("Plaintiff States"), Richard Newell, Victor Dauer, The Thresholds, and Dorothy Sabotka ("Private Plaintiffs"), Sandoz Pharmaceuticals Corporation ("Sandoz"), and Caremark, Inc. ("Caremark").

WHEREAS, the States of California, Colorado, Connecticut, Florida, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin filed their complaints in these proceedings on December 18, 1990; South Dakota filed its Complaint on January 10, 1991; Arizona filed its Complaint on February 7, 1991; Idaho filed its Complaint on February 13, 1991; Kansas filed its Complaint on February 19, 1991; Delaware and the District of Columbia filed their Complaints on February 20, 1991; Missouri filed its Complaint on February 26, 1991; Oklahoma filed its Complaint on March 11, 1991; Alabama and South Carolina filed their Complaints on March 15, 1991; Illinois filed its Complaint on June 26, 1991 (collectively referred to as "State Complaints"), seeking

Settlement Agreement

damages and injunctive relief against Defendants, asserting federal and state antitrust claims on their own behalf as purchasers and potential purchasers of Clozaril, and as parens patriae on behalf of natural persons residing in Plaintiff States who have purchased Clozaril during the period of the alleged conspiracy; and

WHEREAS, Private Plaintiffs filed their complaints on November 2, 1990, December 3, 1990, March 8, 1992, and by motion dated October 29, 1991 (the "Private Complaints"), seeking damages and injunctive relief, asserting federal antitrust claims on their own behalf as direct purchasers of Clozaril, and seeking to represent a class of direct purchasers of Clozaril; and

WHEREAS, Sandoz and Caremark deny the allegations set forth in the State Complaints and the Private Complaints; and

WHEREAS, the settlement of these actions will assist the parties to provide Clozaril treatment to additional patients; and

WHEREAS, Sandoz has in the past not terminated and has no present intention of terminating Clozaril treatment for patients to whom Clozaril has been or will be provided free of charge for whom Clozaril treatment is efficacious, regardless of the patient's ability to pay for such treatment.

NOW, THEREFORE, without any further adjudication of any issue of fact or law or admission of wrongdoing, and upon the consent of the parties, the parties enter into this Settlement Agreement ("Settlement" or "Agreement"):

I. DEFINITIONS

As used in this Settlement:

A. "Administration Account" means an account established and maintained by Defendants for the purpose of paying Administrative Costs. The principal of the Administration Account shall be funded as described in Paragraph VI below.

B. "Administration Costs" means all of the costs associated with administering this Settlement and paying valid claims including, but not limited to, notice by first class mail to all Eligible Clozaril Purchasers who can reasonably be identified, notice by publication, printing and copying, review and verification of claims, and postage and mailing costs as set forth in Paragraph VI.

C. "Caremark" means defendant Caremark, Inc., a California corporation, its predecessors, subsidiaries, divisions, groups, and affiliates controlled by Caremark, its successors and assigns, and their respective directors, officers, employees and representatives, and their respective successors and assigns.

D. "Case Management States" means the Offices of the Attorneys General of the States of California, Connecticut, Massachusetts, Minnesota, New Jersey, New York, Virginia, and Washington.

E. "Clozapine" is an antipsychotic prescription drug for the treatment of schizophrenia manufactured or sold by Sandoz under the trade name "Clozaril."

F. "Defendants" means Sandoz and Caremark collectively.

G. "Eligible Clozaril Purchasers" means all Purchasers who purchased Clozaril from Defendants under CPMS^R (Clozaril Patient

Management System) on or before May 31, 1991.

H. "Final Judgment" means the order entered by the Court after final approval of this Settlement in accordance with 15 U.S.C. § 15c and Rule 23 of the Federal Rules of Civil Procedure. The Final Judgment shall be in a form substantially similar to that attached as Exhibit A. The Judgment shall become final after entry is made and the time to appeal has expired or, if appealed, entry has been affirmed by the Court of last resort to which such an appeal has been taken and such affirmance is no longer subject to further appeal or review. In determining the time for appeal, further appeal, or review, the provisions of Rule 60 of the Federal Rules of Civil Procedure, and the All Writs Act, 28 U.S.C. § 1651, shall not apply.

I. "Joining States" means those States (other than the Plaintiff States) that choose to enter into the terms of this Settlement as provided in Paragraph IX.B., in their sovereign and proprietary capacities, on behalf of State bureaus, agencies, and departments, and as parens patriae on behalf of all natural persons residing in such States.

J. "Monitoring services" means pharmacy, distribution and delivery, blood drawing, record keeping, and clinical laboratory services, or other diagnostic techniques used to detect the medical condition known as agranulocytosis, either individually or in any combination of such services.

K. "NORD" means the National Organization for Rare Diseases.

L. "Patient" means a natural person to whom Clozapine is

administered under the supervision of a physician.

M. "Person" means any natural person, corporation, state, county, parish, municipality, other political subdivision of a state, government agency, government-sponsored program, partnership, other business entity, estate, trust, and any other entity recognized by law.

N. "Plaintiff States" means the States of Wisconsin, West Virginia, Washington, Virginia, Utah, Texas, Tennessee, South Dakota, South Carolina, Pennsylvania, Oregon, Oklahoma, Ohio, North Carolina, New York, New Jersey, New Hampshire, Missouri, Minnesota, Massachusetts, Maryland, Maine, Kansas, Iowa, Illinois, Idaho, Florida, Delaware, Connecticut, Colorado, California, Arizona, and Alabama, and the District of Columbia, in their sovereign and proprietary capacities, on behalf of State bureaus, agencies, and departments, and as parens patriae on behalf of all natural persons residing in such States. In addition, the State of Connecticut represents as parens patriae all Persons residing in the State of Connecticut.

O. "Private Plaintiffs" means Richard Newell, Victor Dauer, Dorothy Sabotka, and The Thresholds.

P. "Private Plaintiffs' Lead Counsel" means Perry Goldberg and Howard J. Sedran.

Q. "Provider" means a person who prescribes, dispenses, or orders Clozapine from Sandoz or from a wholesaler approved by Sandoz, including, but not limited to, providers such as federal, state, and local government agencies, community mental health

providers, managed health care providers, private agencies, pharmacies, and physicians.

R. "Purchaser" means:

1. any Person who buys Clozapine on his or her own behalf or for a Patient to the extent he or she is not reimbursed by a government agency; and
2. any state agency or any agency of a political subdivision of a state that pays for Clozapine provided to a patient.

S. "Sandoz" means Sandoz Pharmaceuticals Corporation, a Delaware corporation, its directors, officers, employees, agents, and representatives, its predecessors, subsidiaries, divisions, groups, and affiliates controlled by Sandoz, its successors and assigns, and their respective directors, officers, employees and representatives, and their respective successors and assigns.

T. "Settlement Account" means an account established and maintained by Defendants for the purpose of implementing this Settlement. The principal of the Settlement Account shall be funded as described in Paragraph VI below.

U. "State Mental Health Agencies" means those agencies or other parts of the Plaintiff States primarily responsible for the treatment of the mentally ill in State facilities.

V. "Washington" means the Office of the Attorney General for the State of Washington.

II. AGREEMENT

Subject to the approval of the Court, the parties agree to

settle their lawsuits on the terms and conditions described in this Settlement. The parties agree to use best efforts to secure the orders and other actions contemplated in this Settlement.

Private Plaintiffs and Defendants stipulate and agree for settlement purposes to certification of the following class:

All persons, firms or other entities in the United States who or which on or before May 31, 1991, have purchased or could have purchased Clozapine and/or blood testing monitoring services or to whom Clozaril was administered or could have been administered under the "Clozaril Patient Management System", excluding the defendants, their officers and immediate family members of such persons and the Plaintiff States and the Joining States that in their proprietary capacities have purchased Clozapine under CPMS.

Plaintiffs and Defendants stipulate and agree that the Plaintiff States as parens patriae or otherwise and counsel for the Private Plaintiffs as part of the stipulated class for settlement purposes intend to represent any and all Eligible Clozaril Purchasers.

III. INJUNCTION

A. For a period of ten (10) years from the date of entry of an order approving this Settlement, Sandoz in connection with the sale of Clozapine agrees forthwith to cease and desist from, directly or indirectly, or through any Person or other device:

1. Requiring any Patient, Provider, or Purchaser of Clozapine to purchase or obtain other goods or services from Sandoz or from any Person designated by Sandoz;

2. Provided, however, that nothing in this Settlement shall prevent Sandoz from requiring Providers to provide monitoring services for Patients or confirm that monitoring services are provided to Patients in order to obtain

Clozapine. Pursuant to this proviso, Sandoz may determine to cease supplying Clozaril to Providers who fail to agree to provide or confirm the provision of Patient monitoring services, but only if:

a. Sandoz determines: (a) within thirty (30) days of Sandoz's receipt of the Provider's request that Sandoz supply Clozapine, that the Provider has not undertaken to provide monitoring services or otherwise confirm that monitoring services are or shall be provided, or (b) that the Provider has, after having been supplied with Clozapine, failed to provide monitoring services or adequately confirm that monitoring services are provided;

b. Within seven (7) days of Sandoz's determination that it will not supply or will cease supplying Clozapine for the reasons set forth in Paragraph III.A.2.a., Sandoz shall: (a) notify the Provider in writing of its determination; (b) specifically identify for the Provider all bases for that determination; (c) provide a description of acceptable methods for providing Clozapine, and (d) provide a copy of the Final Judgment;

c. Sandoz's determination is based solely on criteria that are (a) publicly available or available on request from Sandoz, (b) objective, (c) medically reasonable, and (d) consistent with regulatory requirements current at the time Sandoz makes its determination;

d. Sandoz notifies, to the extent known to Sandoz, each Patient or Patient's guardian (if the Patient has a guardian), of the termination of the Patient's Provider as soon as practicable;

e. Sandoz notifies the Case Management States, Private Plaintiffs' Lead Counsel, and the Attorney General of the State in which the Clozaril is prescribed, dispensed, or ordered, in writing, within seven (7) days of any determination to refuse to supply or cease to supply services related to Clozaril to any Provider or prospective Provider for failure to meet the criteria referred to in Paragraph III.A.5.; and

3. Sandoz shall not seek an additional exclusive marketing period for Clozapine in its present form beyond September 16, 1994. This limitation shall not apply to any exclusivity that Sandoz may obtain under the patent or other laws of the United States by reason of any new, improved, or changed manufacturing process, means of delivery, or composition of Clozapine.

4. Sandoz shall notify Plaintiffs of its implementation of any changes in the criteria currently in effect. Sandoz shall give the Case Management States and Private Plaintiffs' Lead Counsel twenty (20) days advance notice of the implementation of such change. If such change is mandated by a regulatory agency, Sandoz shall give as much advance notice as is practicable under the circumstances.

5. A copy of the criteria in effect on the date the Final Judgment is entered shall be filed by Sandoz with the Court and served upon the Case Management States and Private Plaintiffs' Lead Counsel within twenty (20) days of entry of the Final Judgment. In addition, a copy of the criteria in effect on the date of this Settlement shall be provided by Sandoz to Plaintiff States and Private Plaintiffs' Lead Counsel before execution of this Settlement.

6. Sandoz shall make available to manufacturers of Clozapine and Providers the information it collects and maintains regarding Clozapine Patients who have suffered adverse reactions to Clozapine, by advising such manufacturers and Providers whether specific Patients are authorized to receive Clozapine. Sandoz shall make this information available at cost. For purposes of this Paragraph III.A.6., cost shall be presumed to be ten dollars (\$10) or less per Patient. Sandoz may require manufacturers of Clozapine and Providers for such manufacturers to whom it provides adverse reaction information to reciprocate by providing to Sandoz the information such manufacturers and Providers collect and maintain regarding Clozapine patients who have suffered adverse reactions to Clozapine.

In addition, Sandoz shall make available to researchers, at not more than cost, all relevant data maintained by Sandoz pertaining to the occurrence of adverse reactions to Clozapine, including, but not limited to, data on dosage,

blood characteristics, statistics concerning the on-set of agranulocytosis or other adverse reactions. Such data shall be made available by Sandoz on such terms and conditions and subject to such restrictions on use and disclosure as Sandoz generally establishes for the release of product data to researchers. Within ten (10) days of Sandoz's refusal to provide data to any Person who claims to be a researcher who would be entitled to data under this subparagraph, Sandoz shall provide notice to the Case Management States and Private Plaintiffs' Lead Counsel of such refusal, explaining the basis for Sandoz's refusal.

B. Upon entry of a Final Judgment, Sandoz shall provide a fifteen percent (15%) rebate of Sandoz's wholesale price for Clozaril to Patients on SSDI (Social Security Disability Income) for the period beginning with the earlier of the Final Judgment becoming Final under Paragraph I(A) of this Agreement or October 1, 1992 through Sandoz's remaining exclusive marketing period for Clozaril (September 16, 1994). Sandoz, through NORD, shall provide this rebate to Patients that provide proof acceptable to NORD that (1) they are on SSDI, (2) they are not eligible for any other public assistance to pay for Clozaril, and (3) Clozaril has been purchased by them or on their behalf. The obligation of Sandoz to provide this rebate shall be subject to the following conditions: (1) making such rebates shall not be determined by any State or federal governmental entity to require Sandoz to reduce the price of Clozaril to Medicaid; and (2) in its sole discretion, Sandoz

shall have the right to limit the number of Patients receiving such rebates to two thousand (2,000).

C. For a period of ten (10) years from the date of entry of an order approving this Settlement, Caremark in connection with the sale of Clozapine agrees forthwith, upon the written request of the Case Management States, to take any reasonable action to ensure that the injunctive provisions of Paragraph III. are implemented, including but not limited to the obligations imposed on Sandoz under Paragraph III.A. This obligation shall include (1) notifying, to the extent known to Caremark, each Patient or Patient's guardian (if the Patient has a guardian), of the termination of the Patient's Provider under Paragraph III.A.2. as soon as practicable, and (2) making available, with the approval and authorization of Sandoz, that information that Caremark provides to Sandoz to those Persons to whom Sandoz is obligated to provide the information under Paragraph III.A.6. In addition, Caremark shall cease and desist from, directly or indirectly, or through any Person or other device to facilitate or otherwise assist Sandoz to evade or avoid the injunctive provisions of Paragraph III.A.

D. Nothing in this Settlement shall require Sandoz or Caremark to disclose information that is protected by any requirements of patient confidentiality unless the Person requesting disclosure is acting as a Provider of Clozapine to the Patient about whom the information is requested.

IV. NOTICE PROVISIONS

For the purpose of securing compliance with the Final Judgment and this Settlement defendants Sandoz and Caremark shall provide copies of the statement substantially in the form attached to this Settlement as Exhibit B, describing this Settlement and the Final Judgment to: (1) all officers and employees of defendants Sandoz and Caremark with supervisory authority over the manufacture or marketing of Clozaril or Clozaril-related services within fourteen (14) days of entry of the Final Judgment and (2) all Eligible Clozaril Purchasers within forty five (45) days of the Final Judgment.

V. INSPECTION

Upon providing reasonable notice, State Plaintiffs shall be permitted access during normal business hours to Defendants' books, ledgers, records, correspondence, and memoranda for the purpose of determining or securing compliance with the Final Judgment and this Settlement. Upon providing reasonable notice and with cause to believe that the Final Judgment or the Settlement have not been complied with, State Plaintiffs may also take statements under oath of any of the employees of defendants Sandoz and Caremark for the purpose of determining or securing compliance with the Final Judgment and this Settlement. In addition, nothing in this Settlement shall limit the investigative authority of any State Attorney General arising under state law. Nothing herein shall limit the right of Private Plaintiffs' Lead Counsel to enforce the injunctive provisions set forth in Paragraph III of this Settlement

Agreement.

VI. MONETARY AND OTHER DISTRIBUTIONS

A. Administration Account. By no later than September 13, 1992, Defendants shall make available to the Settlement Administrator an Administration Account established, maintained, and funded by the Defendants that contains the sum of two hundred thousand dollars (\$200,000) which, along with interest accrued, the parties anticipate and expect will be sufficient to pay the costs of administering this Settlement, including, without limitation, the costs associated with providing notice under 15 U.S.C. § 15c(b) or Rule 23(e) of the Federal Rules of Civil Procedure to Eligible Clozaril Purchasers and distributing the payments contemplated by this Settlement. The parties agree to use their best efforts to insure that the funds in the Administration Account will be sufficient to pay the costs of administration, consistent with providing fair and adequate notice to all Persons represented by State Plaintiffs as parens patriae or by Private Plaintiffs as class members and complying fully with all notice and settlement administration procedures agreed to in this Settlement or as required by the court. If, notwithstanding the expectation and best efforts of the parties, the costs of administering this Settlement exceed the funds available in the Administrative Account, Defendants shall pay into the Administration Account an additional sum sufficient to pay for administration of this Settlement.

Sandoz shall be solely responsible for the filing of all tax

returns, if any, required by any federal, state, or any other governmental entity with respect to the Administration Account.

B. Cash Distribution. Each and every Eligible Clozaril Purchaser, identified by the claims process described below, shall be entitled to receive a cash payment. The distribution of cash payments to Purchasers who: (1) are identified by Sandoz as Eligible Clozaril Purchasers, (2) present valid claims, or (3) who are otherwise eligible to receive cash payments, shall be accomplished by first class mail by the Settlement Administrator appointed pursuant to Paragraph VI.G. The amount of the cash payment shall equal \$38.92 multiplied by the number of weeks for which such Purchasers were Eligible Clozaril Purchasers. An Eligible Clozaril Purchaser that is a governmental entity shall receive the cash payment in the form of a credit on its purchases from Sandoz, with the option to take all or part of the cash payment as a check. The parties agree that Defendants may reduce any Eligible Clozaril Purchaser's debt for CPMS by \$38.92 per week in lieu of a cash payment or credit to that Eligible Clozaril Purchaser. The Settlement Administrator shall maintain records of all disbursements or other transactions.

Defendants have estimated to Plaintiffs that if all Eligible Clozaril Purchasers who paid in full for Clozaril during the period of their eligibility receive cash payments or credits in the amount specified above, Eligible Clozaril Purchasers would receive cash payments or credits worth approximately ten million dollars (\$10,000,000). Defendants shall honor any and all cash payments

for six (6) months and any and all credits for two (2) years, even if cash payments and credits to Eligible Clozaril Purchasers are in excess of ten million dollars (\$10,000,000).

State Mental Health Agencies in the Plaintiff States shall be entitled to receive credits in addition to any distribution they receive as Eligible Clozaril Purchasers. The credits distributed to State Mental Health Agencies shall be allocated to the Plaintiff States in the percentages set forth in Exhibit C. The face value of that credit in the aggregate shall total three million dollars (\$3,000,000). Plaintiff States shall in good faith endeavor to use the additional credit distributed to State Mental Health Agencies under this subparagraph to treat Patients who are not otherwise qualified for Medicaid benefits for clozapine therapy under any state or federal program.

Sandoz shall make payments to NORD in addition to any payment or distribution it otherwise is committed to make to NORD in the amount of three million dollars (\$3,000,000). Sandoz shall pay this additional \$3,000,000 to NORD on the condition that NORD shall use the additional payment under this subparagraph to treat new Patients with Clozaril who do not otherwise qualify for Medicaid reimbursement under any applicable state or federal program.

C. Settlement Account. No later than ten (10) days after the Court's final approval of this Settlement, Defendants shall make available to the Settlement Administrator a Settlement Account established, maintained, and funded by the Defendants containing the sum of ten million dollars (\$10,000,000), less the amount that

governmental Eligible Clozaril Purchasers take credits in lieu of cash payments and the cash payments to which Eligible Clozaril Purchasers would have been entitled except that such Purchasers chose to opt out of the Settlement. The parties anticipate and expect that this sum will be sufficient to pay those Persons entitled to cash payments.

In the event that valid claims for payment exceed the Settlement Account amount, plus accrued interest, Defendants shall make such additional payments to the Settlement Account as are necessary to pay such claims for the cash payments less the cash payments to which Eligible Clozaril Purchasers would have been entitled except that such Purchasers chose to opt out of the Settlement. The cash payment shall be provided by a negotiable instrument (check) governed by the applicable provisions of the Uniform Commercial Code and shall be valid for and the underlying obligation shall terminate six (6) months from the date of the instrument.

Sandoz shall be solely responsible for the filing of all tax returns, if any, required by any federal, state, or any other governmental entity with respect to the Settlement Account.

D. State Costs and Fees. No later than ten (10) days after the Court's preliminary approval of this Settlement, Defendants shall pay two million eighty thousand dollars (\$2,080,000) to Washington as reimbursement for the litigation costs and attorneys' fees incurred by Plaintiff States. The payment shall be held in escrow by Washington pending the Court's final approval of this

Settlement. The distribution of this payment and any interest accrued shall be determined by the Attorneys General of the Plaintiff States at their exclusive option and discretion limited only as set forth in this Paragraph VI.D. The Attorney General for each Plaintiff State shall determine the use and disposition of the payment to his or her State under this Paragraph VI.D. The payment shall be used by Plaintiff States solely for one or more of the following six (6) purposes, as determined by the Attorney General of each Plaintiff State, at her or his exclusive option and as otherwise consistent with law:

1. Payments to reimburse the costs and expenses of the litigation incurred by Plaintiff States or their agencies;
2. Increased or supplemental payments to Eligible Clozaril Purchasers, on a proportional or per capita basis, and/or the first class postage costs for each such Purchaser;
3. Antitrust enforcement by the Attorney General of such State;
4. Payment into a state antitrust revolving fund;
5. Payment into the treasury of such State; and/or
6. Payment into a fund exclusively dedicated to assisting State Attorneys General defray the costs of experts, economists, and consultants in multistate antitrust investigations and litigation.

E. Private Plaintiff Costs and Fees. No later than ten (10)

days after the Court's preliminary approval of this agreement, Defendants shall pay one million nine hundred twenty thousand dollars (\$1,920,000) to Private Plaintiffs' Lead Counsel, which payment represents (1) incentive fees totalling ninety thousand dollars (\$90,000), consisting of three payments of twenty-five thousand dollars (\$25,000) to Richard Newell, the Victor Dauer Trust dated 1992, and the Thresholds, and a payment of fifteen thousand dollars (\$15,000) to Dorothy Sabotka, and (2) one million eight hundred thirty thousand dollars (\$1,830,000) as reimbursement for the litigation costs and attorneys' fees incurred by counsel for Private Plaintiffs. The payment shall be held in escrow in an interest bearing account by Private Plaintiffs' Lead Counsel pending the Court's final approval of this Settlement.

F. Residue. One hundred ninety (190) days after all checks to Eligible Clozaril Purchasers are mailed (including checks that constitute final resolution of disputed claims under paragraph VII.E.), Defendants shall be entitled to close the Administration Account and the Settlement Account. Contemporaneously with closing the Administration Account and Settlement Account, the Defendants shall make available to the Settlement Administrator another account established, maintained, and funded by the Defendants that contains the sum of at least \$100,000 (the "Combined Account"), which shall remain in that account for a period of four months after the account is made available to enable the Settlement Administrator to pay late claims and Administration Costs that may arise. At the end of that four month period, the Defendants may

close the Combined Account.

Sandoz shall be solely responsible for the filing of all tax returns, if any, required by any federal, state, or any other governmental entity with respect to the Combined Account.

The Defendants shall honor additional credits distributed by the Settlement Administrator to the extent all Eligible Clozaril Purchasers are not otherwise compensated (the "Residue Credit"). The Residue Credit shall be calculated by the Settlement Administrator and shall equal the amount that would have been distributed if all Eligible Clozaril Purchasers had received cash payments less (1) the credits taken by governmental purchasers to the extent such credits are for purchases as Eligible Clozaril Purchasers (2) the cash payments or credits to which Eligible Clozaril Purchasers would have been entitled except that such Purchasers chose to opt out of the Settlement, and (3) the aggregate amount of the instruments (checks) distributed from the Settlement Account and cashed within six (6) months of the date of the instrument. The Defendants estimate and Plaintiffs have the right to confirm pursuant to the right of inspection under Paragraph VII.A., that the total value of cash payments and credits could be sixteen million dollars (\$16,000,000), which includes the distributions under Paragraph VI.B. to Eligible Clozaril Purchasers, State Mental Health Agencies, and NORD. The Settlement Administrator shall distribute such Residue Credit to NORD, upon the condition that NORD shall use the Residue Credit to treat new Patients with Clozaril who do not otherwise qualify for Medicaid

reimbursement under any applicable state or federal program.

G. Settlement Administrator. The Administration, Settlement, and Combined Accounts shall be administered by a Settlement Administrator jointly appointed by the Case Management States, Private Plaintiffs' Lead Counsel, and Defendants. The Settlement Administrator shall not act in a manner contrary to the terms of this Settlement.

To the extent there is no dispute concerning a claim pursuant to Paragraph VII.E., within forty-five (45) days after final approval of this Settlement and entry of a Final Judgment by the Court, the Settlement Administrator shall mail cash payments, notices of credit, or notice of offset to a debt for Clozaril to every Eligible Clozaril Purchaser and/or State Mental Health Agency. The Settlement Administrator shall contemporaneously mail copies of the notices of credits and offsets to Sandoz. Ninety (90) days after such cash payments are mailed, the Settlement Administrator shall send an additional notice by first class mail to all Eligible Clozaril Purchasers who were sent a check that has not yet been cashed.

VII. CLAIMS PROCEDURE

A. Defendants agree to undertake all reasonably necessary efforts to identify preliminarily every Eligible Clozaril Purchaser and the amounts of cash payments or credits that such Purchaser is or might be entitled to under the terms of this Settlement no later than thirty (30) days after the date of this Settlement. Further, Defendants shall make available to counsel for plaintiffs at a

mutually agreeable time and place their employees, agents, and records within their custody, possession, or control as may be required by plaintiffs' counsel to verify the completeness and accuracy of Defendants' preliminary identification. Plaintiffs shall be entitled to review during the course of such examination any information in the custody, possession, or control of Defendants as will show the identity of retail purchasers during the period between February 1, 1990 and July 31, 1991. In conducting such examination, plaintiffs agree to use their best efforts to limit their requests for access to only those documents and persons as may be necessary to insure the completeness and accuracy of defendants' preliminary identification.

B. Within thirty (30) days following preliminary approval of this Settlement by the Court, notice of this Settlement, in the form attached as Exhibit D or whatever form of notice is approved by the Court, will be given by first class mail to all Eligible Clozaril Purchasers preliminarily identified in Defendants' records as entitled to a distribution of cash payments, credits, or offsets to debt. Included with the notice shall be a notice to the Eligible Clozaril Purchaser of the total amount of the cash payment, credit, or offset to debt to which that Eligible Clozaril Purchaser would be entitled under this Settlement.

C. Subject to Court approval, notice of this Settlement will also be given by publication in trade journals. The notice shall be a full page and shall be published in one issue of: (1) the Journal of the American Medical Association; (2) the American

Journal of Psychiatry; (3) Psychiatric News; and (4) Hospital & Community Psychiatry. The notice shall give the name, address, and telephone number of the Settlement Administrator, summarize the Settlement, and provide instructions for making or contesting a claim.

D. Eligible Clozaril Purchasers identified pursuant to Paragraph VII.A. or in response to the publication notice of Paragraph VII.C. shall receive Notice in the form of Exhibit D by first-class mail of their eligibility to participate in this Settlement. The Notice shall describe this Settlement and the Final Judgment and shall indicate that each Person identified as an Eligible Clozaril Purchaser (1) will receive a cash payment if that Person, other than a governmental entity, takes no further action, (2) may opt out of the Settlement, (3) within seventy five (75) days of the date of the Notice referred to in Paragraph VII.B., may contest the amount of the cash payment, credit, or debt offset, and (4) will receive a credit if the Eligible Clozaril Purchaser is a governmental entity and takes no further action, and may file a claim for a cash payment in lieu of a credit if such Purchaser is a governmental entity.

E. The following schedule and procedure shall be followed to receive, review, approve, reject, notify, and reconsider claims or disputes concerning claims (a "claim"):

1. On or before ninety (90) days after notice of preliminary approval of this Settlement is mailed or ten (10) days after final approval of this Settlement, whichever is

later, the parties will determine the validity of each claim. A claim objected to by the Case Management States, Private Plaintiffs' Lead Counsel, or Defendants on reasonable grounds shall be deemed to be rejected.

2. On or before ninety-five (95) days after notice of preliminary approval of this Settlement is mailed or fifteen (15) days after final approval of this Settlement, whichever is later, the Settlement Administrator shall notify by first class mail any Person whose claim has been rejected. The notification shall state the reasons for the rejection and describe the person's right to reconsideration and appeal.

3. On or before one hundred fifteen (115) days after notice of preliminary approval of this Settlement is mailed or thirty-five (35) days after final approval of this Settlement, whichever is later, any Person whose claim has been rejected may request reconsideration and may present further evidence to support the claim.

4. On or before one hundred thirty-five (135) days after notice of preliminary approval of this Settlement is mailed or fifty-five (55) days after final approval of this Settlement, whichever is later, the parties shall notify such Persons of the results of the reconsideration.

5. On or before one hundred fifty-five (155) days after notice of preliminary approval of this Settlement is mailed or seventy-five (75) days after final approval of this Settlement, whichever is later, any Person whose claim remains

rejected may petition the Court for a final determination of the validity of the request.

VIII. COOPERATION AND IMPLEMENTATION

A. The parties shall apply to the Court for preliminary and final approval of this Settlement as soon as practicable after the execution of this Settlement. The parties to this Settlement believe it to be fair, reasonable, and adequate and intend to assert that position to all courts reviewing the fairness, reasonableness, and adequacy of this Settlement.

B. The parties agree to cooperate fully to implement the terms and conditions of this Settlement, and specifically to make every reasonable cooperative effort to identify Purchasers entitled to benefits pursuant to this Settlement. Defendants shall require any third parties over whom they have control to provide any records maintained by those third parties and called for under this Settlement.

C. The parties may extend the time periods set forth in this Agreement.

D. Except as otherwise provided in this Settlement, the parties waive any further claims for costs and attorneys' fees, except as may be incurred by Plaintiffs to monitor or enforce the Final Judgment or this Settlement.

E. The parties agree that a Final Judgment, in a form substantially similar to that attached as Exhibit A, may be entered by the Court following final approval of this Settlement in accordance with 15 U.S.C. § 15c and Rule 23 of the Federal Rules

of Civil Procedure.

F. This Settlement shall not be used or construed by any person as an admission of liability by either Defendant to any party or person.

G. If for any reason this Settlement is not approved by the Court, the Administration and Settlement Accounts may be closed by Defendants after payment of out-of-pocket costs and expenses incurred in the administration of this Settlement prior to the date of Court disapproval. In any event, Plaintiffs shall retain full rights to assert any and all causes of action against Defendants.

IX. BENEFIT AND BINDING EFFECT

A. The terms of this Settlement shall be binding on, and shall inure to the benefit of, the parties and their successors. The parties expressly disclaim any intention to create rights under this Settlement that may be enforced by any other person under any circumstances whatsoever, except as specified by this Paragraph IX.

B. The terms of this Settlement may be entered into by the Attorney General of any State (other than a Plaintiff State) who within 60 days after the date of this Settlement takes the following action (the "Joining Attorneys General"):

1. a. Signs a settlement agreement, in the form of Exhibit E ("Joining Settlement"), and
- b. Files the executed Joining Settlement and a Complaint against Defendants, substantially in the form of Exhibit F in the United States District Court for the Northern District of Illinois as a

related case, or

2. Designates the Attorney General of any or all of the Case Management States to represent such State pursuant to § 4G of the Clayton Act, 15 U.S.C. § 15g, and to file a Complaint and sign a Joining Settlement on behalf of such State; and serves notice, substantially in the form of Exhibit G by first class mail upon Defendants, the Case Management States, and Private Plaintiffs' Lead Counsel expressly notifying them of its intent to participate in the terms of this Settlement.

C. Defendants shall sign each Joining Settlement with a Joining Attorney General in the form of Exhibit E within five (5) business days after receipt.

X. TERM

This Settlement shall become effective as of the day and year first written above, and shall terminate ten years after the date of this Settlement or the date of the last payment or distribution of a cash payment, whichever is later.

XI. MISCELLANEOUS

A. This Settlement and the Exhibits contain the entire agreement and understanding of the parties. There are no additional promises or terms of this Settlement other than those contained in this Settlement. This Settlement shall not be modified except in writing signed by each of the parties hereto or by their authorized representative.

B. The remedies and rights pursuant to this Settlement shall be in addition to any other right or remedy that may be available

to Plaintiff States. This Settlement shall in no way limit or restrict those other rights or remedies.

C. This Settlement may be executed by counsel for the parties and shall become effective when executed by all of the parties. This Settlement may be executed on separate signature pages or in counterparts with the same effect as if all parties had signed the same instrument.

AGREED AND CONSENTED TO:

The State of Minnesota

By: _____
Honorable Hubert H. Humphrey III

The State of California

By: _____
Honorable Dan Lungren

The State of Connecticut

By: _____
Honorable Richard Blumenthal

The Commonwealth of Massachusetts

By: _____
Honorable Scott Harshbarger

The State of New Jersey

By: _____
Honorable Robert J. Del Tufo

The State of New York

By: _____
Honorable Robert Abrams

Sandoz Pharmaceuticals Corporation

By: _____

Caremark, Inc.

By: _____

Levin, Fishbein, Sedran & Berman

By: _____
Howard J. Sedran

Kathleen Mullen

By: _____
Kathleen Mullen

Cohen, Milstein, Hausfeld & Toll

By: _____
Michael D. Hausfeld

Kaplan & Kilsheimer

By: _____
Robert N. Kaplan

Commonwealth of Virginia

By: _____
Honorable Mary Sue Terry

The State of Washington

By: _____
Honorable Ken Eikenberry

The State of Alabama

By: _____
Honorable James H. Evans

The State of Arizona

By: _____
Honorable Grant Woods

The State of Colorado

By: _____
Honorable Gale Norton

The State of Delaware

By: _____
Honorable Charles M. Oberly III

The District of Columbia

By: _____
Honorable John Payton

The State of Florida

By: _____
Honorable Robert A. Butterworth

Specks & Goldberg

By: _____
Perry Goldberg

Alzheimer & Gray

By: _____
Gary L. Specks

Much, Shelist, Freed, Denenberg,
Ament & Eiger, P.C.

By: _____
Michael J. Freed

Meredith & Cohen

By: _____
Steven J. Greenfogel

Weschler, Skirnick, Hardwood,
Haleblian & Feffer

By: _____
Robert Skirnick

Saveri & Saveri

By: _____
Guido Saveri

State of Idaho

By: _____
Honorable Larry EchoHawk

The State of Illinois

By: _____
Honorable Roland W. Burris

The State of Iowa

By: _____
Honorable Bonnie Campbell

The State of Kansas

By: _____
Honorable Robert T. Stephan

The State of Maine

By: _____
Honorable Michael E. Carpenter

The State of Maryland

By: _____
Honorable J. Joseph Curran, Jr.

The State of Missouri

By: _____
Honorable William L. Webster

The State of New Hampshire

By: _____
Honorable John P. Arnold

The State of North Carolina

By: _____
Honorable Lacy H. Thornburg

The State of Ohio

By: _____
Honorable Lee Fisher

The State of Oklahoma

By: _____
Honorable Susan B. Loving

The State of Oregon

By: _____
Honorable Charles Crookham

The Commonwealth of Pennsylvania

By: _____
Honorable Ernest D. Preate, Jr.

The State of South Carolina

By: _____
Honorable T. Travis Medlock

The State of South Dakota

By: _____
Honorable Mark Barnett

The State of Tennessee

By: _____
Honorable Charles W. Burson

7 The State of Texas

By: _____
Honorable Dan Morales

The State of Utah

By: _____
Honorable Paul Van Dam

The State of West Virginia

By: _____
Honorable Mario Palumbo

The State of Wisconsin

By: _____
Honorable James E. Doyle

SO ORDERED: _____
(Preliminary Approval)

SO ORDERED: _____
(Final Approval)

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LIST OF EXHIBITS

Exhibit letter	Substance of Exhibit
Exhibit A	Final Judgment
Exhibit B	Notice of Final Approval of Settlement
Exhibit C	Allocation of Credits to State Mental Health Agencies
Exhibit D	Notice of Preliminary Approval of Settlement
Exhibit E	Joining Settlement
Exhibit F	Joining Complaint
Exhibit G	Designation to Join

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: CLOZAPINE ANTITRUST
LITIGATION

) MDL 874
) Consolidated Case No.: 91-C-2431
)
) Honorable Harry D. Leinenweber
)

This Document Relates To:
All Actions

)
) FINAL JUDGMENT
)
)

WHEREAS, the States of California, Colorado, Connecticut, Florida, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin filed their complaints in these proceedings on December 18, 1990; South Dakota filed its Complaint on January 10, 1991; Arizona filed its Complaint on February 7, 1991; Idaho filed its Complaint on February 13, 1991; Kansas filed its Complaint on February 19, 1991; Delaware and the District of Columbia filed their Complaints on February 20, 1991; Missouri filed its Complaint on February 26, 1991; Oklahoma filed its Complaint on March 11, 1991; Alabama and South Carolina filed their Complaints on March 15, 1991; Illinois filed its Complaint on June 26, 1991; Joining States filed their Complaints on _____ (collectively referred to as "State Complaints"), seeking damages and injunctive relief against Defendants, asserting federal and state antitrust claims on their own behalf as purchasers and potential purchasers of Clozaril, and as parens patriae on behalf

of natural persons residing in Plaintiff States who have purchased Clozaril during the period of the alleged conspiracy; and

WHEREAS, Richard Newell, Victor Dauer, Dorothy Sabotka, and The Thresholds filed their complaints on November 2, 1990, December 3, 1990, April 1992, and by motion dated October 29, 1991 (the "Private Complaints"), seeking damages and injunctive relief, asserting federal antitrust claims on their own behalf as direct purchasers of Clozaril, and seeking to represent a class of direct purchasers of Clozaril; and

WHEREAS, Sandoz and Caremark deny the allegations set forth in the State Complaints and the Private Complaints (collectively the "Complaints"); and

WHEREAS, Plaintiffs and defendants Sandoz and Caremark, through 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 evidence or admission by any party with respect to any issue of fact or law; and

WHEREAS, notice of the Settlement was given pursuant to Court Order in accordance with 15 U.S.C. § 15c and Rule 23 of the Federal Rules of Civil Procedure. The Court reviewed the terms of the Settlement Agreement, the submissions of parties in support of it, and the comments received in response to the notices. After a hearing held on _____, the Court approved the Settlement Agreement on _____.

NOW, THEREFORE, without any further adjudication of any issue

of fact or law or admission of wrongdoing, and upon the motion of all parties, it is hereby

ORDERED, ADJUDGED AND DECREED as follows:

I. JURISDICTION

This Court has jurisdiction over the subject matter of and parties to this action. The Complaints state claims against defendants Sandoz and Caremark under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. The State Complaints also state claims against defendants Sandoz and Caremark under state antitrust and consumer protection law. The Court has jurisdiction over the state antitrust and consumer protection law claims pursuant to the doctrine of pendent jurisdiction.

II. DEFINITIONS

As used in this Final Judgment, the following definitions shall apply:

A. "Caremark" means defendant Caremark, Inc., a California corporation, its predecessors, subsidiaries, divisions, groups, and affiliates controlled by Caremark, its successors and assigns, and their respective directors, officers, employees and representatives, and their respective successors and assigns.

B. "Case Management States" means the Offices of the Attorneys General of the States of California, Connecticut, Massachusetts, Minnesota, New Jersey, New York, Virginia, and Washington.

C. "Clozapine" is an antipsychotic prescription drug for the treatment of schizophrenia manufactured or sold by Sandoz under the

trade name "Clozaril."

D. "Defendants" means Sandoz and Caremark collectively.

E. "Eligible Clozaril Purchasers" means all Purchasers who purchased Clozaril from Defendants under CPMS^R (Clozaril Patient Management System) on or before May 31, 1991.

F. "Joining States" means the States of _____.

G. "Monitoring services" means pharmacy, distribution and delivery, blood drawing, record keeping, and clinical laboratory services, or other diagnostic techniques used to detect the medical condition known as agranulocytosis, either individually or in any combination of such services.

H. "NORD" means the National Organization for Rare Diseases.

I. "Patient" means a natural person to whom Clozapine is administered under the supervision of a physician.

J. "Person" means any natural person, corporation, state, county, parish, municipality, other political subdivision of a state, government agency, government-sponsored program, partnership, other business entity, estate, trust, and any other entity recognized by law.

K. "Plaintiff States" means the States of Wisconsin, West Virginia, Washington, Virginia, Utah, Texas, Tennessee, South Dakota, South Carolina, Pennsylvania, Oregon, Oklahoma, Ohio, North Carolina, New York, New Jersey, New Hampshire, Missouri, Minnesota, Massachusetts, Maryland, Maine, Kansas, Iowa, Illinois, Idaho, Florida, Delaware, Connecticut, Colorado, California, Arizona, and Alabama, and the District of Columbia, in their sovereign and

proprietary capacities, on behalf of State bureaus, agencies, and departments, and as parens patriae on behalf of all natural persons residing in such States. In addition, the State of Connecticut represents as parens patriae all Persons residing in the State of Connecticut.

L. "Private Plaintiffs" means Richard Newell, Victor Dauer, Dorothy Sabotka, and The Thresholds.

M. "Private Plaintiffs Lead Counsel" means Perry Goldberg and Howard J. Sedran.

N. "Provider" means a person who prescribes, dispenses, or orders Clozapine from Sandoz or from a wholesaler approved by Sandoz, including, but not limited to, providers such as federal, state, and local government agencies, community mental health providers, managed health care providers, private agencies, pharmacies, and physicians.

O. "Purchaser" means:

1. any Person who buys Clozapine on his or her own behalf or for a Patient to the extent he or she is not reimbursed by a government agency; and
2. any state agency or any agency of a political subdivision of a state that pays for Clozapine provided to a patient.

P. "Sandoz" means Sandoz Pharmaceuticals Corporation, a Delaware corporation, its directors, officers, employees, agents, and representatives, its predecessors, subsidiaries, divisions, groups, and affiliates controlled by Sandoz, its successors and

assigns, and their respective directors, officers, employees and representatives, and their respective successors and assigns.

Q. "Settlement Agreement" means the settlement agreement between Plaintiffs and Defendants presented to the Court by motion for Preliminary Approval on or about August 13, 1992.

III. PUBLIC INTEREST

Given the complex nature of this litigation, the costs previously incurred and likely to be incurred in prosecuting this action to resolution, the uncertainties inherent in this litigation, the agreement to halt certain conduct alleged to be contrary to the public interest and to make payments to Eligible Clozaril Purchasers or other claimants under the Settlement, and the settlement between Plaintiffs and Defendants Sandoz and Caremark, as evidenced by the Settlement Agreement filed in this action, the Settlement Agreement is adjudged to be fair, reasonable, adequate, and in the best interests of the parties and the public.

IV. APPLICABILITY

A. The provisions of this Final Judgment shall apply to defendants Sandoz and Caremark, their officers, directors, agents, employees, successors, and assigns, and to all other persons, partners, joint venturers, affiliates and any persons in active concert or participation with any of them, who receive actual notice of this Final Judgment by personal service or otherwise.

B. For settlement purposes, the following class is certified:

All persons, firms or other entities in the United States who or which on or before May 31, 1991, have

purchased or could have purchased Clozapine and blood testing monitoring services or for whom Clozaril was prescribed or could have been prescribed under the "Clozaril Patient Management System", excluding the defendants, their officers and immediate family members of such persons and the Plaintiff States and the Joining States that in their proprietary capacities have purchased Clozapine under CPMS.

V. INJUNCTION

A. For a period of ten (10) years from the date of entry of this order, Sandoz in connection with the sale of Clozapine, is ordered forthwith to cease and desist from, directly or indirectly, or through any Person or other device:

1. Requiring any Patient, Provider, or Purchaser of Clozapine to purchase or obtain other goods or services from Sandoz or from any Person designated by Sandoz;

2. Provided, however, that nothing in this Judgment shall prevent Sandoz from requiring Providers to provide monitoring services for Patients or confirm that monitoring services are provided to Patients in order to obtain Clozapine. Pursuant to this proviso, Sandoz may determine to cease supplying Clozaril to Providers who fail to agree to provide or confirm the provision of Patient monitoring services, but only if:

- a. Sandoz determines: (a) within thirty (30) days of Sandoz's receipt of the Provider's request that Sandoz supply Clozapine, that the Provider has not undertaken to provide monitoring services or otherwise confirm that monitoring services are or shall be provided, or (b) that

the Provider has, after having been supplied with Clozapine, failed to provide monitoring services or adequately confirm that monitoring services are provided;

b. Within seven (7) days of Sandoz's determination that it will not supply or will stop supplying Clozapine for the reasons listed in Paragraph V.A.2.a., Sandoz shall: (a) notify the Provider in writing of its determination; (b) specifically identify for the Provider all bases for that determination; (c) provide a description of acceptable methods for providing Clozapine, and (d) provide a copy of the Final Judgment;

c. Sandoz's determination is based solely on criteria that are (a) publicly available or available on request from Sandoz, (b) objective, (c) medically reasonable, and (d) consistent with regulatory requirements current at the time Sandoz makes its determination;

d. Sandoz notifies, to the extent known to Sandoz, each Patient or guardian (if the Patient has a guardian), of the termination of the Patient's Provider as soon as practicable;

e. Sandoz notifies the Case Management States, Private Plaintiffs Lead Counsel, and the Attorney General of the State in which the Clozaril is prescribed, dispensed, or ordered, in writing, within seven (7) days of any determination to refuse to supply or cease to

supply services related to Clozaril to any Provider or prospective Provider for failure to meet the criteria referred to in Paragraph V.A.5.; and

3. Sandoz shall not seek an additional exclusive marketing period for Clozaril in its present form beyond September 16, 1994. This limitation shall not apply to any exclusivity that Sandoz may obtain under the patent or other laws of the United States by reason of any new, improved, or changed manufacturing process, means of delivery, or composition of Clozaril.

4. Sandoz shall notify Plaintiffs of its implementation of any changes in the criteria currently in effect. Sandoz shall give the Case Management States and Private Plaintiffs Lead Counsel twenty (20) days prior notice of the implementation of such change. If such change is mandated by a regulatory agency, Sandoz shall give as much advance notice as is practicable under the circumstances.

5. A copy of the criteria in effect on the date the Final Judgment is entered shall be filed by Sandoz with the Court and served upon the Case Management States and Private Plaintiffs Lead Counsel within twenty (20) days of entry of the Final Judgment.

6. Sandoz shall make available to manufacturers of Clozapine and Providers the information it collects and maintains regarding Clozapine Patients who have suffered adverse reactions to Clozapine, by advising such manufacturers

and Providers whether specific Patients are authorized to receive Clozapine. Sandoz shall make this information available at cost. For purposes of this Paragraph V.A.6., cost shall be presumed to be ten dollars (\$10) or less per Patient. Sandoz may require manufacturers of Clozapine and Providers for such manufacturers to whom it provides adverse reaction information to reciprocate by providing to Sandoz the information such manufacturers and Providers collect and maintain regarding Clozapine Patients who have suffered adverse reactions to Clozapine.

In addition, Sandoz shall make available to researchers, at not more than cost, all relevant data maintained by Sandoz pertaining to the occurrence of adverse reactions to Clozapine, including, but not limited to, data on dosage, blood characteristics, statistics concerning the on-set of agranulocytosis or other adverse reactions. Such data shall be made available by Sandoz on such terms and conditions and subject to such restrictions on use and disclosure as Sandoz generally establishes for the release of product data to researchers. Within ten (10) days of Sandoz's refusal to provide data to any Person who claims to be a researcher who would be entitled to data under this subparagraph, Sandoz shall provide notice to the Case Management States and Private Plaintiffs Lead Counsel of such refusal, explaining the basis for Sandoz's refusal.

B. Upon entry of a Final Judgment, Sandoz shall provide a

fifteen percent (15%) rebate of the wholesale price for Clozaril to Patients on SSDI (Social Security Disability Income) for the period beginning with the earlier of the Final Judgement becoming Final under Paragraph I(A) of the Settlement Agreement or October 1, 1992 through Sandoz's remaining exclusive marketing period for Clozaril (September 16, 1994). Sandoz, through NORD, shall provide this rebate to Patients that provide proof acceptable to NORD that (1) they are on SSDI, (2) they are not eligible for any other public assistance to pay for Clozaril, and (3) the Clozaril has been purchased on their behalf. The obligation of Sandoz to provide this rebate shall be subject to the following conditions: (1) making such rebates shall not be determined by any State or federal governmental entity to require Sandoz to reduce the price of Clozaril to Medicaid; and (2) in its sole discretion, Sandoz shall have the right to limit the number of Patients receiving rebates to two thousand (2,000).

C. For a period of ten (10) years from the date of entry of this Final Judgment, Caremark, in connection with the sale of Clozapine, is hereby ordered, upon the written request of the Case Management States, to take any reasonable action to ensure that the injunctive provisions of Paragraph V. are implemented, including but not limited to the obligations imposed on Sandoz under Paragraph V.A. This obligation shall include (1) notifying, to the extent known to Caremark, each Patient or guardian (if the Patient has a guardian), of the termination of the Patient's Provider under Paragraph V.A.2. as soon as practicable, and (2) making available,

with the approval and authorization of Sandoz, that information that Caremark provides to Sandoz to those Persons to whom Sandoz is obligated to provide the information under Paragraph V.A.6. In addition, Caremark shall cease and desist from, directly or indirectly, or through any Person or other device to facilitate or otherwise assist Sandoz to evade or avoid the injunctive provisions of Paragraph V.A.

D. Nothing in this Final Judgment shall require Sandoz or Caremark to disclose information that is protected by any requirements of patient confidentiality unless the Person requesting disclosure is acting as a Provider of Clozapine to the Patient about whom the information is requested.

VI. NOTICE PROVISIONS

For the purpose of securing compliance with this Final Judgment, defendants Sandoz and Caremark shall provide copies of the statement substantially in the form attached to the Settlement Agreement as Exhibit B, describing this Settlement and the Final Judgment to: (1) all officers and employees of defendants Sandoz and Caremark with supervisory authority over the manufacture or marketing of Clozaril or Clozaril-related services within fourteen (14) days of entry of the Final Judgment and (2) all Eligible Clozaril Purchasers within forty five (45) days of the Final Judgment. The mailing to Eligible Clozaril Purchasers shall include the letters referred to paragraph VI.G of the Settlement Agreement.

VII. INSPECTION

Upon providing reasonable notice, State Plaintiffs shall be permitted access during normal business hours to Defendants' books, ledgers, records, correspondence, and memoranda for the purpose of determining or securing compliance with this Final Judgment and the Settlement Agreement. Upon providing reasonable notice and with cause to believe that the Final Judgment or the Settlement have not been complied with, State Plaintiffs may also take statements under oath of any of the employees of defendants Sandoz and Caremark for the purpose of determining or securing compliance with the Final Judgment and this Settlement. In addition, nothing in this Final Judgment shall limit the investigative authority of any State Attorney General arising under state law. Nothing herein shall limit the right of Private Plaintiffs Lead Counsel to enforce the injunctive provisions set forth in Paragraph V of this Final Judgment.

VIII. TERM

This Final Judgment shall expire ten (10) years from the date of entry.

IX. ENTRY

The Court directs that this Final Judgment be entered in this case in accordance with Federal Rule of Civil Procedure 54(b). There is no just reason for delay in the entry of final judgment.

X. INCORPORATION OF SETTLEMENT AGREEMENT; ORDER; FEES

The Settlement Agreement is approved in its entirety and is incorporated by reference and made an Order of this Court. In full and final settlement of the monetary claims, including attorney

fees and costs, set forth in the Complaints, defendants Sandoz and Caremark are ordered to make the payments and/or provide the credits as set forth in the Settlement Agreement.

Attorneys' fees and costs payable to Plaintiff States shall be apportioned among the states as determined by the Attorneys General of the Plaintiff States at their exclusive option and discretion, limited as provided in the Settlement Agreement. The payment of attorneys' fees and costs to the Private Plaintiffs' Counsel as set forth in the Settlement Agreement is approved. The incentive award payments to Richard Newell (\$25,000), the Victor Dauer Trust dated 1992 (\$25,000), the Thresholds (\$25,000), and Dorothy Sabotka (\$15,000) are approved.

XI. CONTINUING JURISDICTION

Jurisdiction of this case is retained for the purpose of enabling any party to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this Final Judgment, for the modification or termination of any of its provisions, for its enforcement or compliance, and for the punishment of violations of any of its provisions.

Dated:

UNITED STATES DISTRICT JUDGE

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LETTER TO ELIGIBLE CLOZARIL PURCHASERS AFTER FINAL APPROVAL

Dear Clozaril and CPMS Purchaser:

I am pleased to inform you that the federal court in Chicago has approved the settlement of the antitrust lawsuit brought by the Attorneys General of 34 states and private plaintiffs against Sandoz Pharmaceuticals Corp. and Caremark, Inc. Those lawsuits claimed that Sandoz and Caremark illegally tied the sale of Clozaril to the sale of CPMS. Sandoz and Caremark denied the allegations. In approving the settlement, the court found that the settlement was fair and provided adequate compensation to eligible purchasers. I enclose a check or a credit notice, which represents the court-approved recovery for the Clozaril/CPMS treatment that you purchased, along with a summary of the Final Judgment entered by the court.

Very truly yours,

NOTICE TO DEFENDANTS' EMPLOYEES OF FINAL APPROVAL

The federal court in Chicago has approved the settlement of the antitrust lawsuit brought by the Attorneys General of 34 states and private plaintiffs against Sandoz Pharmaceuticals Corp. and Caremark, Inc. Those lawsuits claimed that Sandoz and Caremark illegally tied the sale of Clozaril to the sale of CPMS. Sandoz and Caremark denied the allegations.

The court-approved settlement provides a final resolution of all claims that were, or could have been, asserted in the lawsuits or that are based on the facts alleged in the complaints in these actions. A copy of the Final Judgment entered by the Court is attached. You may have obligations and responsibilities under the settlement and final judgment. Please read the judgment carefully.

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<u>State</u>	<u>Percentage</u>
Alabama	2.04%
Arizona	1.83%
California	14.18%
Colorado	1.67%
Connecticut	1.60%
Delaware	0.32%
District of Columbia	0.30%
Florida	6.24%
Idaho	0.50%
Illinois	5.65%
Iowa	1.34%
Kansas	1.21%
Maine	0.59%
Maryland	2.30%
Massachusetts	2.86%
Minnesota	2.10%
Missouri	2.53%
New Hampshire	0.56%
New Jersey	3.84%
New York	8.65%
North Carolina	3.26%
Ohio	5.25%
Oklahoma	1.60%
Oregon	1.35%
Pennsylvania	5.76%

South Carolina	1.73%
South Dakota	0.34%
Tennessee	2.42%
Texas	8.62%
Utah	0.86%
Virginia	3.00%
Washington	2.27%
West Virginia	0.90%
Wisconsin	2.34%

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: CLOZAPINE
ANTITRUST LITIGATION

CASE NO. MDL 874

This Document Applies To:
All Cases

Hon. Harry D. Leinenweber

MAILED NOTICE OF PROPOSED SETTLEMENT

TO: ALL PERSONS, WHO PURCHASED OR COULD HAVE
PURCHASED CLOZARIL OR FOR WHOM CLOZARIL WAS
ADMINISTERED OR COULD HAVE BEEN ADMINISTERED
UNDER THE CLOZARIL PATIENT MANAGEMENT SYSTEM
BETWEEN FEBRUARY 1, 1990 AND MAY 31, 1991.

PLEASE READ THIS NOTICE CAREFULLY AND IN ITS
ENTIRETY. YOUR RIGHTS WILL BE AFFECTED BY
LEGAL PROCEEDINGS IN THIS LITIGATION. IF YOU
ARE A CLOZARIL CLAIMANT (DESCRIBED BELOW) YOU
MAY BE ENTITLED TO RECEIVE BENEFITS UNDER THE
PROPOSED SETTLEMENT DESCRIBED IN THIS NOTICE.

I.

THE LAWSUITS

There are now pending in the United States District Court for
the Northern District of Illinois lawsuits filed by 34 state
attorneys general and four class action lawsuits.

The lawsuits allege that defendants, Sandoz Pharmaceuticals,
Inc. and Caremark, Inc., violated the antitrust laws by refusing
to sell Clozapine unless the purchaser also purchased Clozaril
Patient Management System ("CPMS"), which were blood monitoring and
other services provided by the defendants only. The lawsuits also
allege that as a result of defendants' violations of the antitrust
laws, those persons who purchased Clozapine under CPMS paid higher

prices than they would otherwise have paid.

The defendants deny those claims. To avoid the further expense, inconvenience, and burden of protracted litigation, Sandoz and Caremark have agreed to settle those lawsuits.

II.

SUMMARY OF THE SETTLEMENT

A proposed settlement, subject to Court approval, has been reached by the plaintiffs with the defendants and is summarized below.

Those who will be bound by the Settlement, if the Settlement is approved by the Court, are the following persons:

All persons, firms, or other entities in the United States who purchased or could have purchased Clozaril or to whom Clozaril was administered or could have been administered under the Clozaril Patient Management System between February 1, 1990 and May 31, 1991 and all other persons who may have a cause of action based upon the claims set forth or that could have been set forth in the complaints in these actions ("Clozaril Claimants").

The settlement provides a final resolution of all claims that were, or could have been, asserted in the lawsuits or that are based on the facts alleged in the complaints in these actions. Under the terms of the settlement, payments to purchasers of Clozaril under CPMS will total approximately \$10 million. Each purchaser will receive a payment of \$38.92 for each week of purchases of the Clozaril/CPMS package during the period February 1, 1990 to May 31, 1991. Purchasers that are governmental

agencies will receive the payment as a credit toward purchases from Sandoz, with the option to receive a check instead of the credit.

Defendants have also agreed to injunctive relief requiring them to cease and desist from requiring that purchasers of Clozaril obtain blood monitoring and other services through Sandoz or companies selected by Sandoz. Sandoz may require that providers of Clozaril (such as hospitals or druggists) perform blood monitoring or confirm that this service has been performed, but may not establish unreasonable requirements for Clozaril providers. If Sandoz refuses to supply Clozaril to a provider, Sandoz must give notice to the provider, the patient, and certain government agencies. Sandoz has also agreed to make portions of its database available to researchers and other clozapine manufacturers.

Sandoz has also agreed not to seek an additional exclusive marketing period for Clozaril in its present form beyond September 16, 1994.

Defendants have agreed to distribute, through state mental health agencies of the 34 original litigating states, credits with a value of \$3 million. The state mental health agencies will in good faith endeavor to use the credits to treat patients who do not otherwise qualify for Medicaid benefits for clozapine therapy under any state or federal program.

For non-purchaser claims for other Clozaril Claimants who did not purchase Clozaril under CPMS between February 1, 1990 and May

31, 1991, defendants have agreed to provide \$3 million to the National Organization for Rare Diseases ("NORD") on the condition that NORD uses the payment to treat new Clozaril patients who do not otherwise qualify for Medicaid reimbursement under any applicable state or federal program.

In addition, from October 1, 1992 through Sandoz's remaining exclusive marketing period for Clozaril (September 16, 1994), Sandoz agrees to provide a 15% rebate for purchases of Clozaril (based on Sandoz's wholesale price for Clozaril) to patients on Social Security Disability Income ("SSDI"). The rebate will be distributed through NORD to persons who demonstrate to NORD that (1) they are on SSDI; (2) they are not eligible for any other public assistance to pay for Clozaril and (3) the Clozaril has been purchased by them or on their behalf. The obligation of Sandoz to provide this rebate is subject to the condition that: (1) the rebates are not determined by any state or federal government entity to require Sandoz to reduce the price of Clozaril to Medicaid and (2) Sandoz may limit the number of persons receiving the rebates to 2,000 SSDI patients.

The Settlement provides for the payment of attorneys' fees and expenses to counsel for the states and private plaintiffs in the amounts of \$2,080,000 and \$1,830,000 respectively. In addition, the Settlement provides for the payment of incentive awards to the private plaintiffs totalling \$90,000.

This is only a summary of the Settlement Agreement. A complete copy of the Settlement Agreement is on file with the

Office of the Clerk of the United States District Court for the Northern District of Illinois, 219 South Dearborn Street, Chicago, Illinois, which can be examined or copied during regular office hours. Information regarding the process for applying for the 15% rebate for SSDI recipients or the \$3 million fund to be administered by NORD to provide Clozaril to patients who do not qualify for Medicaid can be secured by writing to NORD Clozaril Assistance Program, P.O. Box 8923, New Fairfield, CT 06812-1783 or by calling 1-800-937-NORD.

III.

HOW TO PROTECT YOUR RIGHTS

PLEASE TAKE NOTICE THAT:

A. If you are a Clozaril Claimant, you will be entitled to participate in this settlement.

B. As a Clozaril Claimant, you will be represented in this litigation by counsel for plaintiffs. If you wish to enter an individual appearance in this litigation, you may do so by filing a Notice of Appearance with the Clerk of the Court of the United States District Court for the Northern District of Illinois, 219 South Dearborn Street, Chicago, Illinois, in MDL No. 874, together with proof of service on counsel for plaintiffs and defendants, whose names and addresses appear below. If you retain an attorney, you will be responsible for the fees and costs of the attorney.

C. You may elect to be excluded from the settlement. Any election must be made in writing and postmarked no later than

November 6, 1992. If you exclude yourself, you will not be permitted to share in the settlement, but will remain free to pursue, on your own behalf, whatever legal rights you may have. If you wish to exclude yourself, send your notice of exclusion to:

Clozapine Settlement Administrator
P.O. Box

D. Because the records provided by the defendants to plaintiffs indicate that you purchased Clozaril under CPMS on or before May 31, 1991, included with this Notice is a determination of your share of the settlement proceeds according to those records. This amount is determined by multiplying \$38.92 by the number of weeks you purchased Clozaril under CPMS from February 1, 1990 through May 31, 1991. If you wish to be a Clozaril Claimant and receive the amount listed on the package insert that also has your address, you do not need to take any action. Your share of the settlement proceeds will be sent to you following final approval of this settlement by the Court. If you contest the enclosed determination of your share, you may send notice of your claim by midnight _____, 1992 to the Clozapine Settlement Administrator at the address listed above, along with an explanation of your claim and any supporting documentation. The Court will finally decide (with no right of appeal) the amount to which you are entitled.

E. If you do not elect to be excluded from the settlement, you will be bound by the terms of the Settlement and any judgment entered, if final approval is granted by the Court.

IV.

SETTLEMENT HEARING

The Court will hold a hearing on November ___, 1992 at 10:00 a.m. before the Honorable Harry D. Leinenweber, United States District Judge, United States Courthouse, 219 South Dearborn Street, Chicago, Illinois for the purpose of determining whether the proposed settlement is fair, reasonable, and adequate and whether the settlement, the request for attorneys' fees and expenses and incentive awards should be approved by the Court. The hearing may be rescheduled without further notice.

You do not need to appear at the settlement hearing or to take any other action to participate in the settlement. At the hearing, any Clozaril Claimant who has not requested exclusion from the settlement may file objections to the settlement and the request for attorneys' fees and expenses and the request for incentive awards. No person will be heard and no paper or brief will be accepted or considered by the Court unless on or before November 6, 1992, that person files with the Clerk of the Court a statement of the person's position and the reasons for that position, notice of whether the person intends to appear at the hearing, and copies of any supporting papers or briefs. Papers filed with the Court must also be mailed to each of the following:

For State Plaintiffs: James Spencer
 Special Assistant Attorney
 General
 NCL Tower, Suite 1400
 445 Minnesota Street
 St. Paul, Minnesota 55101

 Robert L. Hubbard
 Assistant Attorney General
 Antitrust Bureau

120 Broadway, Suite 2601
New York, New York 10271

For Sandoz:

Daniel R. Shulman
Gray, Plant, Mooty, Mooty,
& Bennett, P.A.
3400 City Center
33 South Sixth Street
Minneapolis, MN 55402

For Caremark:

Michael Sennett
Bell, Boyd & Lloyd
70 West Madison, Suite 3200
Chicago, IL 60602

For Private Plaintiffs:

Perry Goldberg
Specks & Goldberg
Suite 3500
10 South Wacker Drive
Chicago, IL 60606

Howard J. Sedran
Levin, Fishbein, Sedran & Berman
320 Walnut Street
Suite 600
Philadelphia, PA 19106

(A complete list of the attorneys who have appeared in this litigation is available in the Court file.)

V.

EFFECT OF FINAL COURT APPROVAL

If the Settlement Agreement is approved, the Court will enter an order and judgment dismissing the lawsuits on the merits and discharging defendants from all claims of Clozaril Claimants which were, or could have been asserted in the lawsuits or based on the facts alleged in the complaints in these proceedings.

VI.

INQUIRIES

Any inquiries by Clozaril Claimants concerning this Notice or Settlement should be addressed to:

Exhibit D to Settlement Agreement

page 8

Clozapine Settlement Administrator
P.O. Box
Telephone #

Inquiries should not be directed to the Court.

Dated: September __, 1992 /s/ _____
Clerk of the United States
District Court for the
Northern District of Illinois

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SETTLEMENT AGREEMENT

This Settlement Agreement is made and entered into this ____ day of ____, 1992, by and between the State of ____, Sandoz Pharmaceuticals Corporation ("Sandoz"), and Caremark, Inc. ("Caremark").

WHEREAS, the State of ____ filed its complaint in this proceeding on ____, asserting antitrust claims on its own behalf and as parens patriae on behalf of natural persons residing in the State; and

WHEREAS, Sandoz and Caremark deny the allegations set forth in the Complaint; and

WHEREAS, the parties confirm that they have read the Settlement Agreement dated August 13, 1992, in In re Clozapine Antitrust Litigation, MDL 874 (N.D. Ill.) (HDL) (the "Settlement").

NOW, THEREFORE, upon the consent of the parties, the State of ____ elects to participate in the Settlement and accept the terms stated in the Settlement on behalf of the State of ____ and the natural persons citizens of that state as parens patriae.

AGREED AND CONSENTED TO:

The State of [] Sandoz Pharmaceuticals Corporation

By: _____ By: _____

Caremark, Inc.

By: _____

SO ORDERED: _____
(Preliminary Approval)

SO ORDERED: _____
(Final Approval)

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

-----X
THE STATE OF
BY ITS ATTORNEY GENERAL,

Plaintiff,

-against-

SANDOZ PHARMACEUTICALS CORPORATION
AND CAREMARK INC.,

Defendants.
-----X

:
:
: COMPLAINT
:
: MDL 874
: JURY DEMAND
:

Plaintiff, The State of [], by its Attorney General [], brings this antitrust tying action to remedy injuries caused by Sandoz Pharmaceuticals Corporation ("Sandoz") and others. Sandoz holds the exclusive right in the United States to market clozapine, a drug for the treatment of schizophrenia. At least until April 1, 1991, Sandoz refused to sell clozapine unless the buyer also agreed to purchase non-drug medical services from Sandoz or its designee. No other drug manufacturer in the United States ties the sale of its drugs to non-drug services; clozapine is not tied to non-drug services in Europe. Sandoz uses a clozapine side effect, agranulocytosis, to attempt to justify these anticompetitive acts. If it were not illegally tied to these non-drug services, clozapine would be more widely available at a much lower cost. Plaintiff seeks to eliminate the tie, remedy the harm caused by the tie, and make the drug available to thousands of schizophrenia patients. Plaintiff seeks injunctive relief, damages, and civil penalties,

and complains and alleges as follows:

JURISDICTION AND VENUE

1. This complaint is brought under §§ 4, 4c, and 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, and 26, to prevent and restrain violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. Pendent state claims are also stated.

2. This Court has jurisdiction of this action under 28 U.S.C. §§ 1331, 1337 and the principles of pendent jurisdiction.

3. At all times relevant to the bringing of this action, each corporation named as a defendant transacted business, did business, was found, or resided in the Southern District of New York.

DEFINITIONS

4. As used in this complaint:

a. "Agranulocytosis" means a medical condition resulting from acute suppression of the bone marrow's ability to produce white blood cells. Mild or non-acute suppression of white blood cell production is called "leukopenia."

b. "Blood drawing services" means those medical services that consist of taking a blood sample from a patient under controlled conditions for subsequent analysis. Blood drawing services are generally provided by a phlebotomist or nurse.

c. "Case administration services" means those services designed to generate and maintain records that track blood drawing, drug dispensing, and other medical services or treatments. Case administration services are generally

provided by medical personnel as part of medical treatment.

d. "Clozapine" is an atypical antipsychotic neuroleptic drug that is a tricyclic dibenzodiazepine derivative used for the treatment of schizophrenia.

e. "Clozaril" means Sandoz's trade name for clozapine.

f. "CPMS" means Sandoz's program for monitoring patients for agranulocytosis before, during, and after administration of Clozaril. CPMS includes the sale of Clozaril. Sandoz has referred to CPMS as an acronym for "Clozaril Patient Management System," "Clozaril Patient Monitoring System," or "Clozaril Postmarket Surveillance."

g. "Data base services" mean computer services designed to collect and analyze patient medical history to track the incidence of therapeutic side effects of medical treatment.

h. "Dispensing services" means the services involved in filling a prescription for a drug. Dispensing services are generally provided by licensed pharmacists.

i. "FDA" means the Food and Drug Administration of the United States Department of Health and Human Services.

j. "Laboratory services" means those services that consist of analyzing the composition of blood samples.

PLAINTIFF

5. Plaintiff brings this action on its own behalf, on behalf of its institutions, agencies, departments, divisions, and political subdivisions that purchase health care goods and services, as parens patriae on behalf of schizophrenia patients and

other natural persons for whom plaintiff may act, and as parens patriae on behalf of plaintiff's economy and general welfare. The violations of federal and state law alleged herein have caused loss and damage and threaten further loss and damage:

a. To plaintiff and parties represented by plaintiff as purchasers of health care goods and services, including drugs to treat schizophrenia;

b. To schizophrenia patients and other natural persons who purchase or who could benefit from clozapine; and

c. To plaintiff's general welfare and economy.

DEFENDANTS AND CO-CONSPIRATORS

6. Defendant Sandoz Pharmaceuticals Corporation ("Sandoz") is a Delaware corporation with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Sandoz transacts business in the State of [], the Southern District of New York, and the Northern District of Illinois.

7. Defendant Caremark Inc. ("Caremark") is a California corporation with its principal place of business at 455 Kingsbridge Parkway, Lincolnshire, Illinois 60069. Caremark transacts business in the State of [], the Southern District of New York, and the Northern District of Illinois.

8. Various other corporations, partnerships, business entities, and individuals not named as defendants, unknown and known to plaintiff, have participated as co-conspirators in the violations of federal and state law alleged in this action and have performed acts and made statements in furtherance of those

violations.

TRADE AND COMMERCE

9. The activities of defendants and the co-conspirators that are the subject of this complaint are within the flow of and substantially affect interstate commerce. A not insubstantial volume of trade and commerce is involved and affected by the violations alleged in this complaint.

10. Substantial quantities of clozapine and blood samples are shipped in interstate commerce.

11. The manufacture, marketing, and/or distribution of clozapine, blood drawing services, case administration services, data base services, and laboratory services in the United States occurs, at least in part, through use of various channels of interstate transportation and communication.

PRODUCT AND GEOGRAPHIC MARKETS

12. Clozapine provides treating physicians and schizophrenia patients with a unique product for which other drugs, including other neuroleptics, are not suitable substitutes. Clozapine constitutes a relevant product market for which a geographic market is the United States.

13. Blood drawing services provide treating physicians and schizophrenia patients with a unique service for collecting blood for analyzing the effects of medical treatment for which no other services are suitable substitutes. Blood drawing services constitute a relevant product market for which the geographic market is normally the locality of the patient or treating

physician.

14. Case administration services provide treating physicians and schizophrenia patients with a unique service for gathering information about medical treatment for which no other services are suitable substitutes. Case administration services constitute a relevant product market for which geographic market is normally the locality of the patient or treating physician.

15. Data base services provide treating physicians and schizophrenia patients with a unique service for analyzing or researching the effects of medical treatment for which no other services are suitable substitutes. Data base services constitute a relevant product market for which a geographic market is the United States.

16. Dispensing services provide treating physicians and schizophrenia patients with a unique service for use of drugs as part of medical treatment for which no other services are suitable substitutes. Dispensing services constitute a relevant product market for which the geographic market is normally the locality of the patient or dispensing pharmacist.

17. Laboratory services provide treating physicians and schizophrenia patients with a unique service for laboratory analysis of blood to test the effects of medical treatment for which no other services are suitable substitutes. Laboratory services constitute a relevant product market for which geographic market is normally the locality of the patient or treating physician.

THE MARKET FOR CLOZAPINE

18. Schizophrenia is a psychosis marked by withdrawn, bizarre, and sometimes delusional behavior. The disease is characterized by intellectual and emotional deterioration, which is both expensive to treat and economically debilitating to its victims. As a result, many schizophrenia patients depend in part on governmental entities for medical services.

19. About 1% of the United States population, 2,400,000 people, suffer from the disease. 200,000 of these schizophrenia patients do not respond adequately to conventional treatment. An estimated 1,700,000 schizophrenia patients have been hospitalized for schizophrenia. About 25% of all the beds used for any medical treatment in the United States are used by schizophrenia patients.

20. The estimated medical cost in the United States for treatment of schizophrenia runs as high as \$40 billion a year.

21. At least 80% of the institutionalized patients identified by Sandoz as suitable candidates for Clozaril treatment are treated at public expense.

22. Most in-patient treatment of schizophrenia occurs in state funded and operated institutions.

CONVENTIONAL DRUG THERAPY

23. Since the mid-1960s haldol, thorazine, chlorprozamine, and other drugs ("standard neuroleptics") have been used to treat schizophrenia. Standard neuroleptics relieve some symptoms of the disease, such as violent behavior and delusions, without treating others (schizophrenia patients treated with standard neuroleptics

generally remain withdrawn and apathetic).

24. One major adverse side effect of standard neuroleptics is tardive dyskinesia, an often irreversible syndrome consisting of involuntary movement or rigidity of the muscles. Standard neuroleptics cause tardive dyskinesia at an estimated rate of 4 cases per 100 patient years of treatment. Standard neuroleptics also mask tardive dyskinesia, with the result that the full scope of the side effect is evident only after treatment with a standard neuroleptic is discontinued.

CLOZAPINE AND AGRANULOCYTOSIS

25. Clozapine treatment is vastly superior to treatment with standard neuroleptics for many schizophrenia patients. Clozapine relieves symptoms of schizophrenia that are not relieved with any other treatment. In one study, 45% of formerly treatment resistant patients had improved enough within two years of commencing treatment with Clozaril to have obtained employment.

26. After 460 patient years of Clozaril treatment in the United States, no Clozaril patient had developed tardive dyskinesia.

27. Sandoz claims that clozapine causes agranulocytosis in 1% to 2% of the patients treated with clozapine. Undetected agranulocytosis may lead to death from infection.

28. Other recent studies of clozapine patients have found a risk of leukopenia of .2%, with no incidence of agranulocytosis.

29. If blood tests are performed, the risk of leukopenia or agranulocytosis from clozapine is estimated to be comparable to the

risk associated with standard neuroleptics.

30. Agranulocytosis (and leukopenia) have been identified as side effects of other drugs, including standard neuroleptics, penicillin, ibuprofen, and many other commonly used drugs. For example, a high incidence of agranulocytosis -- between 2% and 8% -- is associated with treatment with methicillin, a form of penicillin.

31. Access to these drugs, unlike Clozaril, is not conditioned on the purchase on non-drug services.

32. Monitoring a patient for the side effects of medical treatment, including the risk of agranulocytosis, is done primarily by the treating physician.

CLOZAPINE AS THE TYING PRODUCT

33. Unlike the manufacturer of any other drug, Sandoz, at least until April 1, 1991, distributed clozapine only through its proprietary CPMS system. If a patient wanted to purchase clozapine, that patient was required to also purchase the non-drug services of CPMS.

34. CPMS addresses only one aspect of the medical services that must be provided to schizophrenia patients. Even though schizophrenia patients receive a variety of treatments, including treatments with more than one drug, CPMS focuses on only one drug (Clozaril). CPMS also focuses solely on one potentially fatal side effect (leukopenia-agranulocytosis) associated with that drug. Clozaril is also associated with tachycardia (increased heart rate), myocarditis (infection of the heart lining), and other

cardiac problems. In addition, about 3% of the patients receiving Clozaril experience seizures. Hyperthermia (increased body temperature) and hypotension (low blood pressure) are also associated with Clozaril treatment.

35. Because none of these other potentially fatal side effects are monitored by CPMS, schizophrenia patients receiving Clozaril must still be monitored by their primary care physicians.

TYING CLOZAPINE TO CPMS

36. In Germany, where the sale of clozapine is not tied to the sale of non-drug services, clozapine is available at approximately 2,500 DM (\$1,666) per year for out-patient treatment and 1,300 DM (\$866) per year for in-patient treatment.

37. Sandoz has set the price of the tied Clozaril/CPMS package in the United States at \$172 per week per patient or \$8,944 annually. Sandoz refuses, or at least until April 1, 1991, refused to sell Clozaril to anyone unless that person agreed also to purchase the blood drawing services, case administration services, data base services, dispensing services, and laboratory services of CPMS.

38. The purchasers of Clozaril, including plaintiff and persons represented by plaintiff, are, or at least until April 1, 1991, were always charged the same price regardless of the treatment setting, dosage, or location. The cost for a patient who does not want or need to purchase anything other than the drug is the same as the cost for a patient who wants to purchase the entire CPMS package.

39. The extraordinary expense of the Clozaril/CPMS package limits access to Clozaril therapy.

40. By exclusive contract dated October 2, 1989 with Sandoz (the "Caremark Contract"), defendant Caremark provides the blood drawing, case administration, data base, and dispensing services required for CPMS. Caremark provides phlebotomists, nurses, computer personnel, and pharmacists for those services. The Caremark Contract defines the relationship between Caremark and Sandoz as that of independent contractors, not agents or partners. Caremark takes title to all Clozaril upon delivery from Sandoz.

41. Sandoz sets, or at least until April 1, 1991, did set the resale price for the Clozaril/CPMS package and Caremark receives a fee from Sandoz for its services under CPMS at a rate in excess of the competitive price for its services.

42. Sandoz's documents demonstrate Sandoz intends to use the Caremark Contract to extend Sandoz's control over clozapine into profit from the non-drug services of CPMS. The "CPMS Partnership Evaluation" states that "Clozaril drug cost [is] \$500/year [per patient]" and that "100% of drug revenue [will go] to Sandoz." A separate line states "50% of CPMS revenue to Sandoz." The Clozaril Business Plan also states that among the "Key Issues For 1991 and 1992" are to "Maintain or increase Sandoz profitability under CPMS."

43. For the full fifteen years of the Caremark Contract, Caremark foreclosed actual and potential competition to Sandoz by agreeing not to sell or distribute any product containing clozapine.

other than Clozaril. For seven and a half years, Caremark has agreed not to perform any services in connection with the sale of any neuroleptic that could compete with Clozaril.

44. Sandoz has an exclusive contract with a laboratory to perform the laboratory services for CPMS. Sandoz requires the laboratory to foreclose actual and potential competition to Sandoz by agreeing not to provide laboratory services for any non-Sandoz form of clozapine and by agreeing with the laboratory not to provide any CPMS services to anyone other than the "CPMS participating partners" designated by Sandoz. In exchange, Sandoz has agreed to pay a fee in excess of the competitive price for laboratory services.

45. In the United States, public and private hospitals, health maintenance organizations, and state case management systems are fully capable of performing blood drawing, case administration, data base, dispensing, and laboratory services. On an out-patient basis, family members or others might be able to facilitate the medical treatment of these patients.

46. The Clozaril/CPMS tie forecloses competition in the markets for blood drawing, case administration, data base, dispensing, or laboratory services.

47. Contrary to standard industry practices, Sandoz refuses to provide Clozaril to independent researchers except as part of CPMS. This limits the extent that independent testing can verify Sandoz's claims relating to agranulocytosis, develop new treatment strategies limiting the need for CPMS, or develop equally effective

safety standards to support competing marketing strategies for clozapines.

FDA APPROVAL

48. Clozapine was approved by the FDA on September 26, 1989. This date begins Sandoz's five year period of exclusivity to market clozapine in the United States. On February 5, 1990, Sandoz began to market clozapine under the trade name Clozaril in the United States.

49. Sandoz sought to further its scheme to foreclose competition by describing CPMS in the product labelling and otherwise to mislead the public into believing that CPMS enjoyed the FDA's imprimatur. Sandoz undertook this effort even though Sandoz understood that the FDA neither required, approved, nor even considered the proprietary CPMS system that Sandoz has imposed.

50. The proprietary CPMS system was never a condition or a requirement of the FDA's approval of Clozaril. Rather, as interpreted by the FDA, the approved labelling requires only that blood monitoring be reliably linked to the use of clozapine.

51. Sandoz intended the approved labelling to compel competing drug manufacturers to offer a similar distribution network for all clozapines.

52. Entry by many drug manufacturers into the clozapine market would be deterred if they were unwilling to provide blood drawing, case administration, data base, dispensing, and laboratory services as a condition to the sale of clozapine.

FIRST CLAIM FOR RELIEF - SHERMAN ACT SECTION 1 - ILLEGAL TIE

THE CLOZAPINE/CPMS TIE

53. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 - 52 with the same force and effect as if here set forth in full.

54. Beginning sometime in 1985, the exact date unknown to plaintiff, and continuing thereafter, to at least April 1, 1991, defendants Sandoz, Caremark, and their co-conspirators have illegally tied the sale of the drug clozapine (tying product) to blood drawing, case administration, data base, dispensing, and laboratory services (tied products) in violation of section 1 of the Sherman Act, 15 U.S.C. § 1.

55. The illegal tie consists of a continuing agreement, understanding and concert of action between defendants and their co-conspirators, the substantial elements of which are:

a. The tying product is a separate product from the tied products;

b. the purchasers of clozapine are forced to also purchase all the non-drug services of CPMS;

c. Sandoz possesses sufficient economic power over clozapine to force purchasers of clozapine to also purchase all the non-drug services of CPMS;

d. the tie results in anticompetitive effects in the markets for blood drawing, case administration, data base, dispensing, and laboratory services; and

e. the tie involves a not insubstantial amount of interstate commerce in the markets for blood drawing, case

administration, data base, dispensing, and laboratory services.

56. The anticompetitive effects of the illegal tie in violation of Sherman Act Section 1 in the markets for blood drawing services, case administration services, data base services, dispensing services, and laboratory services have been the following, among others:

a. actual and potential competition between Sandoz, Caremark, and others in each of these markets have been eliminated;

b. prices for CPMS have been fixed, raised, maintained, and stabilized;

c. actual and potential competitors of defendants in each of these markets have been injured in their business and property as a result of the Clozapine/CPMS tie;

d. hospitals, laboratories, and businesses that serve schizophrenia patients, doctors and nurses who treat schizophrenia patients, and other businesses have been denied the benefits of a free, open, and competitive market;

e. schizophrenia patients and other individuals for whom clozapine treatment is indicated have been denied the benefits of a free, open, and competitive market; and

f. the public and plaintiff's general welfare and economy have been injured.

57. This illegal tie and the effects thereof are continuing and will continue unless the injunctive relief requested below is

granted. Plaintiff and the persons represented by plaintiff have no adequate remedy at law.

58. As a result of the violations of law alleged in this claim, plaintiff and the persons represented by plaintiff have been injured in their business and property in an amount that will be established at the trial of this action.

**SECOND CLAIM FOR RELIEF - SHERMAN ACT SECTION 1 -
PRICE FIXING**

59. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 - 58 with the same force and effect as if here set forth in full.

60. Beginning sometime in 1985, the exact date unknown to plaintiff, and continuing thereafter, until at least April 1, 1991, defendants Sandoz, Caremark, and their co-conspirators have continually engaged in a vertical price fixing agreement relating to the sale of the drug Clozaril, blood drawing, case administration, data base, dispensing, and laboratory services in violation of section 1 of the Sherman Act, 15 U.S.C. § 1.

61. The price fixing agreement consists of a continuing agreement, understanding, and concert of action between defendants and their co-conspirators, the substantial terms of which have been:

a. Sandoz sets the resale price for Clozaril, blood drawing, case administration, data base, dispensing, and laboratory services constituting CPMS;

b. Caremark has agreed to Sandoz's resale price for Clozaril and for blood drawing, case administration, data

base, and dispensing services constituting CPMS; and

c. Caremark resells Clozaril and CPMS at the agreed upon price.

62. The anticompetitive effects of the vertical price fixing in violation of Sherman Act Section 1 in the markets for Clozaril, for blood drawing, case administration, data base, dispensing, and laboratory services have been the following, among others:

a. prices for CPMS have been fixed, raised, maintained, and stabilized;

b. hospitals, laboratories, and businesses that serve schizophrenia patients, doctors and nurses who treat schizophrenia patients, and other businesses have been denied the benefits of a free, open, and competitive market;

c. schizophrenia patients and other individuals for whom Clozaril treatment is indicated have been denied the benefits of a free, open, and competitive market; and

d. the public and plaintiff's general welfare and economy have been injured.

63. This vertical price fixing and the effects thereof are continuing and will continue unless the injunctive relief requested below is granted. Plaintiff has no adequate remedy at law.

64. As a result of the violations of law alleged in this claim, plaintiff and persons represented by plaintiff have been injured in their business and property in an amount that will be established at the trial of this action.

**THIRD CLAIM FOR RELIEF - SHERMAN ACT SECTION 2 -
MONOPOLIZING CLOZAPINE**

65. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 - 64 with the same force and effect as if here set forth in full.

66. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, defendant Sandoz and others acting in concert with it have knowingly and intentionally and with specific intent to do so monopolized the relevant market for the drug clozapine.

67. The monopolization of this market has been effected by the means and the overt acts described above. Sandoz's monopolization consists of (1) leveraging its monopoly power over clozapine to gain competitive advantage in the markets for blood drawing, case administration, data base, dispensing, and laboratory services, and (2) extending and maintaining its monopoly power over clozapine beyond its current five year exclusive marketing period.

68. Sandoz and others acting in concert with it intended by their actions to:

- a. control the supply and price of services in the relevant market;
- b. eliminate actual and potential competition in said market; and
- c. exclude and foreclose other persons from participating in or entering said market.

69. This monopolization has had, among other things, the following effects:

- a. actual and potential competing vendors in the relevant markets have been restrained, suppressed, and

eliminated;

b. purchasers in the relevant markets have had to pay artificially inflated prices;

c. actual and potential competing vendors have been injured in their business and property;

d. hospitals that care for schizophrenia patients, laboratories, doctors and nurses who treat schizophrenia, pharmacists who dispense drugs for schizophrenia patients, and other businesses that service schizophrenia patients have been denied the benefits of a free, open, and competitive market;

e. in place of a free, open, and competitive market, a monopoly in the relevant market has been established or maintained;

f. schizophrenia patients and other individuals for whom clozapine treatment is indicated have been denied the benefits of a free, open, and competitive market; and

g. the public and plaintiff's general welfare and economy have been injured.

70. The monopolization and the effects thereof are continuing and will continue unless the injunctive relief sought by plaintiff is granted. Plaintiff has no adequate remedy at law.

71. As a result of the violations of law alleged in this claim, plaintiff and the persons represented by plaintiff have been injured in their business and property in an amount that will be established at the trial of this action.

FOURTH CLAIM FOR RELIEF
GENERAL RESTRAINT OF TRADE

72. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 - 71 with the same force and effect as if here set forth in full.

73. In violation of section 1 of the Sherman Act, 15 U.S.C. § 1, defendants and their co-conspirators entered into a contract, combination, and conspiracy in unreasonable restraint of trade and commerce in the markets for clozapine and the non-drug services included within CPMS.

74. This unlawful contract, combination, and conspiracy and the effects thereof are continuing and will continue unless the injunctive relief requested below is granted. Plaintiff has no adequate remedy at law.

75. As a result of the violations of law alleged in this claim, plaintiff and the persons represented by plaintiff have been injured in their business and property in an amount that will be established at the trial of this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests:

A. That the Court adjudge and decree that the defendants have committed the violations of federal and state law alleged herein;

B. That the Court enjoin the defendants from tying the sale of clozapine to the purchase of blood drawing, case administration, data base, dispensing, and/or laboratory services;

C. That the defendants and their directors, officers, employees, agents, and successors be enjoined and restrained from, in any manner, directly or indirectly continuing or maintaining the

violations of Sections 1 and 2 of the Sherman Act in which they been alleged to have been engaged, or from committing any other violations of such statutes having a similar purpose or effect;

D. That the Court void the Caremark Contract dated October 2, 1989 between Caremark and Sandoz;

E. That the Court void Sandoz's laboratory contract dated April 2, 1990;

F. That the Court permanently enjoin the defendants and their directors, officers, employees, agents, and successors from jointly owning or operating a treatment program, whether such would be accomplished through merger, acquisition, joint-venture, joint operating agreement, or any other arrangement with a similar purpose or effect to the Caremark Contract or Sandoz's laboratory contract;

G. That the Court order Sandoz to divest itself of any interest in blood drawing, case administration, data base, dispensing, or laboratory services of CPMS;

H. That the Court order Caremark to divest itself of any interest in the marketing of Clozaril;

I. That the Court void the Caremark Contract and order Sandoz to divest itself of all interests in Caremark including Sandoz's option to prohibit Caremark from distributing drugs that compete with Clozaril and to take all other action required to restore the marketing of Clozaril to the competitive posture that existed prior to the Caremark Contract;

J. That the Court order Sandoz to license its right to

manufacture clozapine to third parties;

K. That pursuant to sections 4 and 4c of the Clayton Act, 15 U.S.C. §§ 15, 15c the Court enter judgment against defendants, jointly and severally, for three times the amount of damages suffered by plaintiff and the persons represented by plaintiff as a result of defendants' violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2; and

L. That the plaintiff be granted such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for each and every issue triable of right to a jury.

Dated:

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[A.G. Letterhead]

Re: In re Clozapine Antitrust Litigation, MDL 874 (90
C. 6412; 91 C. 2431) (N.D. Ill.) (HDL)

Dear General(s) [Abrams, Blumenthal, Del Tufo, Eikenberry,
Harshbarger, Humphrey, Lungren, and/or Terry]:

This is to notify you that I elect to participate in the
Settlement Agreement between 34 Plaintiff States, Private
Plaintiffs, Sandoz Pharmaceuticals Corp., and Caremark, Inc. as
parens patriae on behalf of the natural persons residing in this
state and on behalf of the State.

I hereby designate the Attorney General of [California,
Connecticut, Massachusetts, Minnesota, New Jersey, New York,
Virginia, and/or Washington] as our representative for the purpose
of bringing such action, and entering into the Settlement Agreement
with Caremark and Sandoz.

Very truly yours,

Attorney General
State of _____

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