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Attorney for Plaintiffs-Intervenors Peter A. Rasmussen, M.D., and David M. Hochhalter, RPh

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF OREGON

STATE OF OREGON,	)
Plaintiff,	(
&	(
PETER A. RASMUSSEN, M.D.; and DAVID MALCOM HOCHHALTER, RPh,	)
Plaintiffs-Intervenors,	(
&	Ź
KARL STANSEL; RICHARD HOLMES; JANE DOE #1; and JAMES ROMNEY (patients),	)
Plaintiffs-Intervenors,	
VS.	Ş
JOHN ASHCROFT, in his official capacity as United States Attorney General; ASA HUTCHINSON, in his official capacity as Administrator of the Drug Enforcement Administration; KENNETH W. MAGEE, in his official capacity as the Director of the Drug Enforcement Administration, Portland Office; THE UNITED STATES OF AMERICA; THE UNITED STATES	

DEPARTMENT OF JUSTICE; and THE

ENFORCEMENT ADMINISTRATION,

UNITED STATES DRUG

Defendants.

Case No. CV 01-1647-JE

FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A. RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh

(Declaratory and Injunctive Relief)

11,	Introduction
2	1.
3	This action challenges the United States Attorney General's directive that the
4	Controlled Substances Act (CSA) be interpreted and enforced against Oregon physicians
5	and pharmacists who prescribe and dispense federally controlled substances under the
6	Oregon Death With Dignity Act. This action seeks declaratory and injunctive relief against
7	the Drug Enforcement Administration (DEA) and Attorney General of the United States.
8	Jurisdiction and Venue
9	2.
10	This court has jurisdiction under 28 U.S.C. § 1331 (federal question) and 28 U.S.C.
11	§ 1346(a)(2) (civil action against the United States). Declaratory and injunctive relief is
12	proper pursuant to 28 U.S.C. § 2201 (declaratory judgment) and 5 U.S.C. § 702
13	(Administrative Procedures Act).
14	<b>3.</b> • • • • • • • • • • • • • • • • • • •
15	Venue is proper in this court pursuant to 28 U.S.C. § 1391(e), 28 U.S.C.
16	§ 1402(a)(1), and Local Rule 3.4. The defendants are all federal officials sued in their
17	official capacity. One or more plaintiffs reside within this judicial district. A substantial
18	part of the events giving rise to the claim occurred in this district.
19	The Oregon Death with Dignity Act
20	4.
21	The Oregon Death With Dignity Act was adopted by the people of Oregon at the
22	November 8, 1994 election. Three years later, on November 7, 1997, the people of
23	Oregon decisively rejected (by a margin of 60 percent to 40 percent) a proposal to repeal
24	the Oregon Death with Dignity Act. Two years later, on June 30, 1999, Governor John
25	Kitzhaber, M.D., signed into law SB 491, amending the Oregon Death with Dignity Act.
26	Accordingly, the Oregon Death With Dignity Act is a duly enacted state law, twice
Page 1	FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A.  RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh  ELI D. STUTSMAN Attorney At Law A Professional Corporation The American Bank Building Thirteenth Floor, 621 SW Morrison Portland, Oregon 97205 Telephone (503) 274-4048

1	approved by Oregon voters, and subsequently amended by the Oregon legislature. The Act
2	is codified at ORS 127.800 through 127.995.
3	5.
4	The Oregon Death With Dignity Act is a duly enacted state law. ORS 127.800 to
5	127.897. The Oregon Death With Dignity Act establishes a statutory framework under
6	state law within which a competent, terminally ill adult resident of Oregon, may make a
7	voluntary and informed decision to obtain a prescription for controlled substances to hasten
8	an impending and unavoidable death. See, e.g., ORS 127.815(1)(a)-(c); ORS
9	127.815(1)(i). A physician may dispense drugs under the Oregon Death With Dignity Act,
10	but only if the physician is registered as a dispensing physician with the state Board of
11	Medical Examiners and further possesses a "Drug Enforcement Administration certificate."
12	ORS 127.815(1)(A). The Oregon Death With Dignity Act provides that no person shall be
13	subject to civil or criminal liability or professional disciplinary action for participating
14	under the Act. ORS 127.885.
15	6.
16	Under a new interpretation of the CSA narrowly tailored to nullify the Oregon
17	Death With Dignity Act, defendants threaten license revocation and criminal enforcement
18	actions against DEA registrants (physicians and pharmacists) who prescribe and dispense
19	controlled substances under the Act.
20	The Parties
21	<b>7</b> .
22	The United States of America is a sovereign nation, responsible for enacting and
23	enforcing the CSA and regulations purportedly adopted under the authority of that Act.
24	The United States Department of Justice and Drug Enforcement Administration are agencies
25	of the United States that have responsibility for enforcing provisions of the CSA.
26	Defendant John Ashcroft is the present Attorney General of the United States and is sued in
Page 2	FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A.

2	Enforcement Administration ("DEA") and is sued in his official capacity. Kenneth W.
3	Magee, is the Director of the Drug Enforcement Administration, Portland, Office and is
4	sued in his official capacity.
5	8.
6	Dr. Rasmussen is a medical oncologist licensed to practice medicine in the State of
7	Oregon. Dr. Rasmussen is also registered with the Drug Enforcement Administration
8	(DEA) and is authorized to prescribe and dispense controlled substances under state and
9	federal law.
10	<b>9.</b>
11	As a medical oncologist and DEA registrant, Dr. Rasmussen has treated terminally
12	ill patients for 21 years in Oregon. He estimates that he is currently treating hundreds of
13	patients facing a terminal disease. Due to the nature of his practice, at any given time,
14	many of his patients will be terminally ill, having less than six months to live. Since
15	passage of the Oregon Death With Dignity Act, Dr. Rasmussen has received many requests
16	from patients seeking information or assistance under the Act. As an attending physician
17	and DEA registrant, Dr. Rasmussen has participated under the Oregon Death With Dignity
18	Act several times and, when appropriate under the law, he has written prescriptions
19	approved by the Act several times. Dr. Rasmussen has provided copies of his dispensing
20	records to the Department of Human Services as required by the section 127.865(1)(b) of
21	the Oregon Death With Dignity Act.
22	10.
23	Currently, three of Dr. Rasmussen's patients have satisfied all of the requirements of
24	the Oregon Death With Dignity Act and are qualified to obtain prescriptions under the Act.
25	In order to preserve patient confidentiality, they are identified by profile:
26	
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his official capacity. Defendant Asa Hutchinson is the present Administrator of the Drug

1

1	Patient A Patient A is a woman approximately 64 years old who is dying
2	from ovarian cancer. She has satisfied all of the requirements necessary under Oregon law
3	to obtain controlled substances to hasten her death.
4	Patient B is a man approximately 72 years old who is dying
5	from lung cancer. He has satisfied all of the requirements necessary under Oregon law to
6	obtain controlled substances to hasten his death.
7	Patient C is a woman approximately 52 years old who is also
8	dying from ovarian cancer. She has satisfied all of the requirements necessary under
9	Oregon law to obtain controlled substances to hasten her death.
10	11.
11	Dr. Rasmussen cannot predict whether any of these patients will choose to hasten
12	their impending deaths, but all three are qualified under the law to do so and Dr.
13	Rasmussen is currently attending to their needs, which is an ongoing process.
14	12.
15	Patients A and C both are both aware of Dr. Rasmussen's role in this litigation.
16	Both Patients A and C have expressed their support and appreciation to Dr. Rasmussen for
17	his willingness to represent their interests. Dr. Rasmussen is representing Patient A and
18	C's interests in this litigation, and the interests of his other patients similarly situated at any
19	given time.
20	<b>13.</b>
21	Due to the nature of Dr. Rasmussen's practice as a medical oncologist, at any given
22	time, many of his patients will be terminally ill and he will continue to receive requests
23	from patients for prescriptions and information under the Oregon Death With Dignity Act.
24	14.
25	As a physician practicing under the Oregon Death With Dignity Act Dr. Rasmussen
26	is practicing legitimate medicine in the normal course of his professional practice.
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1	<b>15</b> .
2	If the DEA enforcement directive in not enjoined, Dr. Rasmussen will need to
3	inform his patients that he cannot risk participation under the Oregon Death With Dignity
4	Act. Dr. Rasmussen cannot risk DEA registration revocation proceedings or other
5	sanctions, criminal and financial. Dr. Rasmussen cannot risk his ability to practice as a
6	medical oncologist, which has provided him his livelihood for 21 years. Dr. Rasmussen
7	cannot risk his family's security, or his ability to provide for his family.
8	16.
9	Three of Dr. Rasmussen's patients face particularly dire circumstances. Because
10	they are qualified to receive a prescription under the Oregon Death With Dignity Act they
11	are by definition "terminally ill." Consequently, they have only a short period of time
12	before they lose their competency, ability to self-administer, or die from their underlying
13	disease.
14	<b>17.</b>
15	Plaintiff David M. Hochhalter, RPh, is a pharmacist with 23 years experience and is
16	licensed to practice by the State of Oregon. Mr. Hochhalter owns a pharmacy that is
17	registered with the DEA and is authorized to dispense controlled substances under state and
18	federal law.
19	18.
20	As a licensed Oregon pharmacist and DEA registrant, Mr. Hochhalter has
21	previously filled prescriptions written under the Oregon Death With Dignity Act working in
22	conjunction with Dr. Peter Rasmussen, and has done so as recently as last week. Mr.
23	Hochhalter is willing to fill future prescriptions written by Dr. Rasmussen under the
24	Oregon Death With Dignity Act, a legitimate medical purposes in the normal course of his
25	professional practice.
26	///
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1	19.
2	In the absence of injunctive relief against Attorney General John Ashcroft's directive
3	to the DEA to enforce the CSA against DEA registrants practicing in accord with Oregon
4	law and the community standard of care, Mr. Hochhalter can no longer participate under
5	the Oregon Death With Dignity Act. In the absence of injunctive relief, Mr. Hochhalter
6	will inform Dr. Rasmussen and his patients that he cannot risk DEA registration revocation
7	proceedings or other sanctions, criminal and financial. Mr. Hochhalter cannot risk his
8	livelihood, or his family's security.
9	The Controlled Substances Act
10	<b>20</b> .
11	Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub
12	L 91-513, codified at 21 U.S.C. § 800, et seq., is known as the Controlled Substances Act
13	("CSA"). The CSA establishes a registration scheme for manufacturers, distributors, and
14	dispensers of certain enumerated substances. 21 U.S.C. § 822. The Attorney General, or
15	his designee, the DEA, administers this registration scheme. Under certain limited
16	circumstances, the DEA may deny or revoke a physician or pharmacy's DEA registration
17	and, with it, the right to prescribe or dispense controlled substances. 21 U.S.C. §§ 823-24
18	Any person distributing a controlled substance, except as authorized by the CSA, is subject
19	to criminal penalties. 21 U.S.C. §§ 841 through 846.
20	21.
21	All of the medications commonly prescribed and dispensed pursuant to the Oregon
22	Death With Dignity Act are controlled substances subject to the CSA, but not Schedule I
23	substances. Other substances are not suitable.
24	22.
25	One rule giving effect to the CSA is 21 C.F.R. §1306.04:
26	///
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1	"A prescription for a controlled substance to be effective must
2	be issued for a legitimate medical purpose by an individual
3	practitioner acting in the usual course of his professional practice
4	. An order purporting to be a prescription issued not in the usual
5	course of professional treatment is not a prescription within the
6	meaning and intent of section 309 of the Act (21 U.S.C. 829) and the
7	person knowingly filling such a purported prescription, as well as the
8	person issuing it, shall be subject to the penalties provided for
9	violations of the provisions of law related to controlled substances."
10	23.
11	Traditionally, the determination of what constitutes a legitimate medical purpose in
12	the usual course of professional practice has been left to the States.
13	The DEA's Opposition to the Oregon Death with Dignity Act
14	24.
15	On November 5, 1997, the day after the second Oregon election approving the
16	Oregon Death With Dignity Act, then DEA Administrator Thomas Constantine announced
17	by letter that the DEA would regard the issuance of a prescription, pursuant to the Oregon
18	Death with Dignity Act, as a violation of the CSA and its enabling regulations. Any person
19	issuing or filling such a prescription would be subject to criminal prosecution and
20	revocation of his or her DEA registration. Federal drug agents, working in Oregon,
21	quickly made clear that they would give effect to the Mr. Constantine's interpretation of the
2,2	CSA.
23	25.
24	In a letter dated June 5, 1998, the Department of Justice overruled Constantine's
25	position, concluding that:
26	///
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1 "adverse action against a physician who has assisted in a suicide in full 2 compliance with the Oregon Act would not be authorized by the CSA . . . . 3 The state of Oregon has reached the considered judgment that physician-4 [hastened death] should be authorized under narrow conditions and in compliance with certain detailed procedures. Under these circumstances, we 5 6 have concluded that the CSA does not authorize the DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in 7 compliance with Oregon law [emphasis added]." 8 9 26. The new Administration, led by President George W. Bush and Attorney General 10 John Ashcroft repudiated the prior Attorney General's interpretation of the CSA. In an 11 undated memorandum received by plaintiffs on November 6, 2001, Attorney General 12 Ashcroft directs the DEA Administrator Asa Hutchinson "to enforce and apply" the new 13 interpretation regardless of the prior, June 5, 1998 Attorney General's opinion quoted in 14 paragraph 15 above. 15 27. 16 In the undated memorandum received by plaintiffs on November 6, 2001, Attorney 17 General Ashcroft orders: 18 "\* \* \* I hereby determine that assisting suicide is not a 'legitimate medical purpose' 19 within the meaning of 21 C.F.R. §1306.04 (2001) and that prescribing, dispensing, 20 or administering federally controlled substances to assist suicide violates the CSA. 21 Such conduct by a physician registered to dispense controlled substances may 22 'render his registration . . . inconsistent with the public interest' and therefore 23 subject to possible suspension or revocation under 21 U.S.C. § 834(a)(4). This 24 conclusion applies regardless of whether state law authorizes or permits such 25 conduct by practitioners or others and regardless of the condition of the person 26 FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A. Page 8 -ELI D. STUTSMAN RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh Attorney At Law A Professional Corporation

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1	whose suicide is assisted.
2	"I hereby direct the DEA, effective upon publication of this
3	memorandum in the Federal Register, to enforce and apply this determination,
4	notwithstanding anything to the contrary in the June 5, 1998, Attorney General's
5	letter."
6	28.
7	The effect of this new interpretation, if it is allowed to stand, is that dispensing
8	controlled substances in compliance with the Oregon Death with Dignity Act is not an
9	"authorized" use of a controlled substance, or a "legitimate medical purpose by an
10	individual practitioner acting in the usual course of his professional practice." Rather, a
11	physician writing such a prescription, and the pharmacist who fills it, are both regarded as
12	common pushers peddling drugs on the street corner and subject to arrest and
13	imprisonment. 21 U.S.C. § 841(a); 21 C.F.R. § 1306.04(a). The maximum penalty is as
14	high as twenty years to life in prison without the possibility of parole, and a five million
15	dollar fine, depending upon which medication was prescribed (i.e., whether the particular
16	drug is classified on Schedule II, III, or IV) and whether the patient actually used the
17	prescription to end his or her life. 21 U.S.C. § 841(a)(2)(C), (D), and (b)(2).
18	29.
19	Additionally, revocation of a DEA registration has far reaching consequences for a
20	physician or pharmacist, since it precludes that person from prescribing, dispensing, or
21	possessing a wide variety of medications routinely used in medical practice.
22	The Present Controversy
23	30.
24	Dr. Rasmussen's patients have requested his participation under the Oregon Death
25	With Dignity Act. Dr. Rasmussen wishes to honor his patient's wishes and abide by the
26	conditions, limitations and restrictions established by the Oregon Death with Dignity Act.
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1	However, Dr. Rasmussen reasonably fears that as a result of the Department of Justice's
2	new interpretation and threatened enforcement of the CSA, such actions will now expose
3	him to criminal prosecution and loss of his DEA registration.
4	31.
5	As a pharmacist, Mr. Hochhalter wants to honor a valid prescription, issued by Dr.
6	Rasmussen in compliance with the Oregon Death with Dignity Act. However, he
7	reasonably fears that as a result of the Department of Justice's new interpretation and
8	threatened enforcement of the CSA, such actions will now expose him to criminal
9	prosecution and loss of his DEA registration.
10	<b>32.</b>
11	Because the potential sanctions criminal, professional, and administrative are so
12	severe, it is unreasonable to require a physician, pharmacist, or other person to expose
13	himself or herself to these sanctions in order to obtain a ruling on the constitutionality of
14	the Department of Justice's new interpretation and threatened enforcement of the CSA.
15	First Claim for Relief
16	(Declaratory Judgment)
17	33.
18	Paragraphs 1 through 32 are incorporated herein.
19	34.
20	There is a genuine controversy between the parties as to whether certain activity
21	under Oregon law (the Oregon Death With Dignity Act) is permissible under federal law
22	(the Controlled Substances Act).
23	35.
24	Plaintiffs contend that the Oregon Death with Dignity Act is a permissible state law
25	under the Controlled Substances Act.
26	<i>III</i>
Page 10	FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A.

1	36.
2	Defendants' new interpretation and mandated enforcement of the CSA exceeds the
3	statutory authority delegated to the defendants under the CSA.
4	<b>37</b> .
5	Alternatively, defendants' interpretation and threatened enforcement of the CSA, as
6	applied to the Oregon Death With Dignity Act, exceeds Congresses' enumerated powers
7	under the United States Constitution, specifically the Commerce Clause set out in Article I,
8	section 8.
9	38.
10	Alternatively, the Attorney General's reinterpretation of 28 C.F.R. § 1306.04 is
11	invalid because it represents an improper attempt to promulgate or amend a substantive rule
12	without complying with the notice and comment requirements of the APA.
13	<b>39</b> ,
14	Alternatively, the Attorney General's reinterpretation of 28 C.F.R. § 1306.04 is
15	invalid because the Attorney General violated the notice requirements of Executive Order
16	No. 13132, 64 F.R. 43255 (Federalism, August 4 1999).
17	40.
18	Alternatively, defendants' interpretation and threatened enforcement of the CSA, as
19	applied to the Oregon Death With Dignity Act:
20	(a) violates the Tenth Amendment of the United States Constitution by usurping
21	powers that the Constitution denies to Congress or reserves to the states or the people;
22	(b) intrudes into areas that have traditionally been matters of state concern where
23	states have historically been sovereign; and
24	(c) is contrary to principles of federalism evidenced by the design and structure of
25	the United States Constitution, as interpreted by the United States Supreme Court.
26	<i>III</i>
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1	41.
2	Plaintiffs have an immediate need to know whether, as a result of the latest
3	interpretation and threatened enforcement of the CSA, they will face criminal, professional,
4	or administrative sanctions, including denial or revocation of DEA registration, if they act
5	in compliance with the Oregon Death with Dignity Act.
6	42.
7	There is a present justiciable controversy between the parties as to whether the new
8	interpretation and threatened enforcement of the CSA is valid. Declaratory relief is
9	appropriate to resolve this controversy.
10	43.
11	Plaintiffs ask this court to declare that the Oregon Death With Dignity Act is
12	permitted under the Controlled Substances Act and to permanently enjoin defendants from
13	enforcing or otherwise giving effect to the new interpretation because it:
14	a. is wrong as a matter of law;
15	b. exceeds the enumerated powers of Congress;
16	c. violates the Tenth Amendment of the United States Constitution by usurping
17	powers that the Constitution denies to Congress or reserves to the States or the people;
18	d. intrudes into areas of traditional state concern, where states historically have
19	been sovereign;
20	e. is contrary to principles of federalism evidenced by the design and structure of
21	the United States Constitution, the plan of the Constitutional Convention, and the text and
22	penumbra of the Ninth, Tenth, and Eleventh Amendments to the United States Constitution,
23	as each has been interpreted by the United States Supreme Court; and
24	44.
25	Pursuant to 28 U.S.C. §§ 1920 and 2412(a)(1), plaintiffs are entitled to recover their
26	costs of suit. Pursuant to 28 U.S.C. § 2412(b) and (d)(1)(A), plaintiffs are entitled to
Page 12	FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A. RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh  ELI D. STUTSMAN Attorney At Law

1	recover reasonable autorney rees incurred in connection with this nugation.
2	WHEREFORE, plaintiffs ask that this court:
3	1. declare that the Oregon Death With Dignity Act is permitted under the
4	Controlled Substances Act;
5	2. temporarily, preliminarily, and permanently enjoin defendants from enforcing or
6	otherwise giving effect to the new interpretation because it:
7	a. is wrong as a matter of law;
8	b. exceeds the enumerated powers of Congress;
9	c. violates the Tenth Amendment of the United States Constitution by usurping
10	powers that the Constitution denies to Congress or reserves to the States or the people;
11	d. intrudes into areas of traditional state concern, where states historically have
12	been sovereign;
13	e. is contrary to principles of federalism evidenced by the design and structure of
14	the United States Constitution, the plan of the Constitutional Convention, and the text and
15	penumbra of the Ninth, Tenth, and Eleventh Amendments to the United States Constitution,
16	as each has been interpreted by the United States Supreme Court; and
17	3. Award plaintiffs reasonable attorney fees and costs of suit; and
18	4. Award plaintiffs such other relief as the court deems just.
19	DATED this 22nd day of January, 2002.
20	
21	
22	By
23	Of Attorneys for Peter A. Rasmussen, M.D., and David M. Hochhalter, RPh, Plaintiffs-Intervenors
24	
25	
26	
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,1	CERTIFICATE OF SERVICE
2	I hereby certify that on the 22nd day of January, 2002, I served the
3	foregoing FIRST AMENDED COMPLAINT IN INTERVENTION FILED BY PETER A.
4	RASMUSSEN, M.D., AND DAVID M. HOCHHALTER, RPh on the following parties at
5	the following addresses:
6	Stephen K. Bushong, Esq.
7	Special Litigation Unit Department of Justice
8	1162 Court Street, NE Salem, Oregon 97301-4096 Of Attorneys for Plaintiff State of Oregon
9	
10	Craig J. Casey Assistant U.S. Attorney Office of the U.S. Attorney
11	1000 SW 3rd Avenue, Suite 600 Portland, Oregon 97204-2902
12	Of Attorneys for Defendants
13	Joseph W. LoBue Senior Trial Attorney
14	United States Department of Justice 901 E. Street, NW, Room 1060
15	Washington, D.C. 20530 Of Attorneys for Defendants
16	Nicholas van Aelstyn
17	Heller Ehrman White & McCauliffe LLP  333 Bush Street
18	San Francisco, CA 94104-2878 Of Attorneys for Patient Plaintiffs Intervenors
19	•
20	by mailing to them a true and correct copy thereof, placed in a sealed envelope addressed
21	to them at the addresses set forth above, and deposited in the U.S. Post Office at Portland,
22	Oregon on said day with postage prepaid.
23	
24	By Eli D. Stutsman, OSB No. 92136
25	Of Attorneys for Peter A. Rasmussen, M.D., & David Malcom Hochhalter, RPh, Plaintiffs-Intervenors
26	ivialcom frocumanci, Reii, Flaimmis-inici venois

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