

EXHIBIT A

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Frequently Asked Questions

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What will the program do?

Oregon's Prescription Drug Monitoring Program (PDMP) is a program developed to promote public health and welfare and help improve patient care. The information will aid healthcare providers and pharmacists to better manage patients' prescriptions to improve quality of care. It will also support the appropriate use of prescription drugs.

When will the Oregon PDMP system start?

Data upload procedures began on June 1, 2011. This is when pharmacies were able to create accounts and begin submitting data. Healthcare providers and pharmacists can apply for accounts to access patient information from the PDMP Website.

Why is my prescription data being collected?

The data is being collected so that your provider can give you better health care.

Why was this program started?

The number of deaths related to poisoning in Oregon has increased five-fold since 1990. This increase is mainly due to deaths associated with controlled substance prescription drugs. From 1999 - 2008, more than 1,300 Oregonians died from prescription drug poisonings. For these reasons, Oregon Senate Bill 355 established a PDMP in Oregon when the governor signed the bill into law in July, 2009.

What prescription information is collected?

The information includes: the patient's name, address, and date of birth, pharmacy and prescriber information, and specific prescription information including the drug name and dosage, when it was prescribed, and when it was dispensed. This is only for prescriptions that are classified as controlled substances (Schedules II, III and IV).

Which drugs does the Oregon PDMP monitor?

The Oregon PDMP collects data on Schedules II, III and IV controlled substances. For a list of these medications and more information, go to <http://www.deadiversion.usdoj.gov/schedules/>.

Will the program limit access to prescription drugs?

No. The program is not intended to prevent people from obtaining needed drugs nor is it intended to prevent healthcare providers from prescribing needed drugs to their patients.

Who is required to report data to the Oregon PDMP?

Pharmacies licensed with the Oregon Board of Pharmacy that dispense controlled substances in the state of Oregon, or to an address in the state, are required to electronically report prescription data. Neither hospital inpatient dispensing data nor data from veterinarians is collected.

Who can access information in the system?

Healthcare providers can access the system, but only for information regarding their own patients. Pharmacists can access the system, but only for information regarding their own customers.

Are providers or pharmacists required to access the database?

No. Prescribers and pharmacists are not required to use the system.

Will law enforcement be looking up my information?

Law enforcement agencies will not have direct access to the system, but law enforcement officials may request information from the Oregon Health Authority if they have a valid court order based on probable cause for an authorized drug-related investigation of an individual.

Will the system be used to monitor my prescribing practices?

No. Licensing boards may request information from the system, but only related to an investigation of a licensee related to licensure, renewal or disciplinary action.

Will my PDMP information be safe?

The information being gathered is health information protected by Oregon law and is safeguarded in both its collection and distribution. Access to the database is limited to authenticated users who agree to terms and conditions to assure the confidentiality of patient data. Reasonable efforts are made to keep your information private and secure.

Are providers permitted to share information?

Yes. However, this is limited to a healthcare provider sharing information with another healthcare provider who is engaged in an individual patient's care.

What if I suspect system information is accessed or used inappropriately?

Improper access or disclosure of information should be reported in writing to the Oregon Health Authority (OHA). The notification should include what information you suspect was inappropriately accessed or used, when and by whom, and why the action is considered inappropriate. OHA's Information Security Office will investigate the matter.

Can I get a copy of my own prescription information?

Yes. To request a free copy of their report, a patient needs to fill out a record request form and mail it to the program along with a copy of a government-issued photo ID.

What if I find an error in a patient record?

Errors should be reported to the program in writing. The notification should identify the error and any other relevant information. Staff will check to make sure it is not a system error. If it is a system error, the record will be corrected. If it is not a system error, the record will be flagged to indicate the error. Patients or healthcare providers then will need to request from the pharmacy that submitted the data to correct the error since the information was originated by the pharmacy.

Do other states have a similar program?

Currently 42 states have laws that authorize the establishment and operation of a PDMP, and 34 of these states' programs are up and running.

Who is paying for the system?

Healthcare providers and pharmacists are the ones paying for the system. Licensees pay a \$25 annual fee along with all of their other licensing fees. No general state funds are used. The rationale is that this will be a tool used by health care providers and pharmacists to help provide better patient care.

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EXHIBIT B

Oregon Public Health Division

2012

Oregon Prescription Drug Monitoring Program

<http://public.health.oregon.gov/DiseasesConditions/InjuryFatalityData/Pages/index.aspx>



Oregon Injury and Violence Prevention Program Fact Sheet

BASIC FACTS*

- The PDMP system became operational in September 2011.
- Approximately 7,000,000 prescription records are uploaded into the system annually.
- More than 98 percent of pharmacies required to participate are reporting.
- More than 5,000 practitioners and pharmacists have PDMP accounts.
- In 2012, an estimated 275,000 queries were made by practitioners and pharmacists.
- 60 percent of the prescriptions in the PDMP are prescribed by 2,000 practitioners; more than 60 percent of these top prescribers have PDMP accounts.
- Opioids account for more than 55 percent of the prescriptions in the PDMP data system.
- Opioids are the class of medications that has the highest potential for overdose, misuse, dependence, and abuse.
- Benzodiazepines are the second-most-often-prescribed class of medication in the PDMP data system.
- Opioids combined with benzodiazepines increase the risk of overdose.

What is the PDMP?

The Oregon Prescription Drug Monitoring Program (PDMP) is a Web-based data system that contains information on controlled prescription medications dispensed by Oregon-licensed retail pharmacies. Pharmacies are required by law to submit data weekly for all Schedule II – IV controlled substances dispensed. Controlled substances reported include opioids, sedative hypnotics, benzodiazepines, stimulants, and other drugs. Legislation for the PDMP was passed in 2009.

How does it work?

Authorized system users can logon to the PDMP Web-based system and request a report of the controlled substance medications dispensed to their patients. The patient report is a line list of prescriptions dispensed. Prescription records include information on the dispenser, prescriber and name and quantity of drug.

What is its purpose?

The primary purpose of the PDMP is to provide practitioners and pharmacists a tool to improve health care. These medications place patients at risk for overdose, side effects, increased effect when combined with alcohol and/or other drugs, risk for physical dependence, and risk for developing patterns of drug abuse. The PDMP provides practitioners and pharmacists a means to identify and address these problems.

Who can access PDMP information?

Access to PDMP information is regulated by law—ORS 431.966. Prescribing health care practitioners and pharmacists are encouraged to apply for an account. Ap-

proved applicants have 24-hour, seven-day-a-week online access to the PDMP. All others – including patients – may submit request forms to obtain a patient report. A patient report includes a list of anyone who queried the patient’s information to ensure proper access. Law enforcement requests must be pursuant to a valid court order. Health care regulatory board requests must be certified by the executive director.

Is patient privacy protected?

PDMP patient information is protected by law—ORS 431.966.

For more information:

Go to www.orpdmp.com.

Top 12 Prescriptions, JAN 2012—OCT 2012 *		
Drug	Number of Rx	Percent of all Rx
Hydrocodone	1,585,386	28.4%
Oxycodone	937,151	16.8%
Zolpidem	442,216	7.9%
Lorazepam	347,476	6.2%
Alprazolam	312,276	5.6%
Clonazepam	273,536	4.9%
Amphet ASP/AMPHET/D-AMPHET	199,241	3.6%
Morphine	196,401	3.5%
Methylphenidate	185,409	3.3%
Diazepam	153,936	2.8%
Methadone	103,191	1.8%
Pseudoephedrine	103,162	1.8%

*Data content source: Oregon PDMP Data System

EXHIBIT C

75th OREGON LEGISLATIVE ASSEMBLY--2009 Regular Session

A-Engrossed Senate Bill 355

Ordered by the Senate April 16
Including Senate Amendments dated April 16

Sponsored by Senators MORRISETTE, KRUSE, BATES

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Requires State Board of Pharmacy to establish electronic prescription monitoring program for information reported by **certain** pharmacies regarding dispensing of certain prescription drugs. Restricts access to and limits use of reported information. Provides certain immunities from civil liability relating to reporting or use of information.

Authorizes board to impose on individual violator of program and related provisions maximum penalty of \$250 and on drug outlet violator maximum penalty of \$1,000.

Requires licensees of certain boards to pay \$25 annual fee for prescribing and dispensing controlled substances. Establishes Electronic Prescription Monitoring Fund consisting of portion of fees. Appropriates moneys in fund to State Board of Pharmacy for purpose of administering program.

Creates Prescription Monitoring Program Advisory Commission.
Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to an electronic prescription monitoring program; appropriating money; and declaring an
3 emergency.

4 Whereas the ability to identify and inhibit the diversion of prescription drugs must be improved;
5 and

6 Whereas the appropriate use of prescription drugs for legitimate medical purposes must be pro-
7 tected; and

8 Whereas the goal of this 2009 Act is to improve the ability to identify and inhibit the diversion
9 of prescription drugs, while promoting appropriate utilization of prescription drugs for legitimate
10 medical purposes; and

11 Whereas the creation and operation of an electronic system to track prescriptions of controlled
12 substances would improve the ability to identify and inhibit the diversion of prescription drugs but
13 would not adversely effect prescriptions issued for legitimate medical purposes; and

14 Whereas the purpose of this 2009 Act is to authorize the development, implementation, operation
15 and evaluation of an electronic system for the monitoring of prescription drugs to accomplish the
16 goal of this 2009 Act; now, therefore,

17 **Be It Enacted by the People of the State of Oregon:**

18 **SECTION 1. Sections 2 to 10 of this 2009 Act are added to and made a part of ORS**
19 **chapter 689.**

20 **SECTION 2. As used in sections 2 to 10 of this 2009 Act:**

21 (1) **"Health professional regulatory board" has the meaning given that term in ORS**
22 **676.160.**

NOTE: Matter in **boldfaced** type in an amended section is new; matter *[italic and bracketed]* is existing law to be omitted. New sections are in **boldfaced** type.

1 (2) "Prescription" has the meaning given that term in ORS 475.005.

2 **SECTION 3.** (1)(a) The State Board of Pharmacy, in consultation with the Prescription
3 Monitoring Program Advisory Commission, shall establish and maintain a prescription mon-
4 itoring program for monitoring and reporting prescription drugs dispensed by pharmacies in
5 Oregon that are classified in schedules II through IV under the federal Controlled Sub-
6 stances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.

7 (b)(A) To fulfill the requirements of this subsection, the board shall establish, maintain
8 and operate an electronic system to monitor and report drugs described in paragraph (a) of
9 this subsection that are dispensed by prescription.

10 (B) The system must operate and be accessible by practitioners and pharmacies 24 hours
11 a day, seven days a week.

12 (C) The board may contract with a state agency or private entity to ensure the effective
13 operation of the electronic system.

14 (2) In consultation with the commission, the board shall adopt rules for the operation of
15 the electronic prescription monitoring program established under subsection (1) of this sec-
16 tion, including but not limited to standards for:

17 (a) Reporting data;

18 (b) Providing maintenance, security and disclosure of data;

19 (c) Ensuring accuracy and completeness of data;

20 (d) Complying with the federal Health Insurance Portability and Accountability Act of
21 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164,
22 federal alcohol and drug treatment confidentiality laws and regulations adopted under those
23 laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, in-
24 cluding ORS 179.505, 192.517 and 192.518 to 192.529;

25 (e) Ensuring accurate identification of persons or entities requesting information from
26 the database;

27 (f) Assessing civil penalties for failing to report or for intentional wrongful disclosure of
28 data; and

29 (g) Accepting printed or nonelectronic reports from pharmacies that do not have the
30 capability to provide electronic reports.

31 (3) The board shall submit an annual report to the commission regarding the prescription
32 monitoring program established under this section.

33 **SECTION 4.** (1) Not later than one week after dispensing a prescription drug subject to
34 the prescription monitoring program established under section 3 of this 2009 Act, a pharmacy
35 shall electronically report to the State Board of Pharmacy the:

36 (a) Name, address and date of birth of the patient;

37 (b) Identification of the pharmacy dispensing the prescription drug;

38 (c) Identification of the practitioner who prescribed the drug;

39 (d) Identification of the prescription drug by a national drug code number;

40 (e) Date of origin of the prescription;

41 (f) Date the drug was dispensed;

42 (g) Quantity of drug dispensed; and

43 (h) Other relevant information as required by rules adopted by the board.

44 (2) Notwithstanding subsection (1) of this section, the board may not:

45 (a) Require the reporting of prescription drugs administered directly to a patient or dis-

1 **pensed pursuant to ORS 127.800 to 127.897; or**

2 **(b) Collect or use Social Security numbers in the prescription monitoring program.**

3 **(3) Upon receipt of the data reported pursuant to subsection (1) of this section, the board**
4 **shall record the data in the electronic system operated pursuant to the prescription moni-**
5 **toring program.**

6 **(4)(a) The board may grant a pharmacy a waiver of the electronic submission require-**
7 **ment of subsection (1) of this section for good cause as determined by the board. The waiver**
8 **shall state the format, method and frequency of the alternate nonelectronic submissions**
9 **from the pharmacy and the duration of the waiver.**

10 **(b) As used in this subsection, “good cause” includes financial hardship.**

11 **(5) This section does not apply to pharmacies in institutions as defined in ORS 179.010.**

12 **SECTION 5. (1)(a) Except as provided under subsection (2) of this section, prescription**
13 **monitoring information submitted under section 4 of this 2009 Act to the prescription moni-**
14 **toring program established in section 3 of this 2009 Act:**

15 **(A) Is protected health information under ORS 192.518 to 192.529.**

16 **(B) Is not subject to disclosure pursuant to ORS 192.410 to 192.505.**

17 **(b) Except as provided under subsection (2)(a)(D) of this section, prescription monitoring**
18 **information submitted under section 4 of this 2009 Act to the prescription monitoring pro-**
19 **gram may not be used to evaluate a practitioner’s professional practice.**

20 **(2)(a) If prescription monitoring information disclosures comply with the federal Health**
21 **Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted**
22 **under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment**
23 **confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and**
24 **state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.518**
25 **to 192.529, the State Board of Pharmacy shall disclose the information:**

26 **(A) To a practitioner or pharmacist who certifies that the requested information is for**
27 **the purpose of evaluating the need for or providing medical or pharmaceutical treatment for**
28 **a patient to whom the practitioner or pharmacist anticipates providing, is providing or has**
29 **provided care.**

30 **(B) To designated representatives of the board or any vendor or contractor with whom**
31 **the board has contracted to establish or maintain the electronic system of the prescription**
32 **monitoring program.**

33 **(C) Pursuant to a valid court order based on probable cause and issued at the request**
34 **of a federal, state or local law enforcement agency engaged in an authorized drug-related**
35 **investigation involving a person to whom the requested information pertains.**

36 **(D) To a health professional regulatory board that certifies in writing that the requested**
37 **information is necessary for an investigation related to licensure, renewal or disciplinary**
38 **action involving the applicant, licensee or registrant to whom the requested information**
39 **pertains.**

40 **(E) To a prescription monitoring program of another state if the confidentiality, security**
41 **and privacy standards of the requesting state are determined by the State Board of Phar-**
42 **macy to be equivalent to those of the board.**

43 **(b) The board may disclose information from the prescription monitoring program that**
44 **does not identify a patient, practitioner or drug outlet:**

45 **(A) For educational, research or public health purposes; and**

1 (B) To officials of the Department of Human Services who are conducting special
2 epidemiologic morbidity and mortality studies in accordance with ORS 432.060 and rules
3 adopted under ORS 431.110.

4 (c) The board shall disclose information relating to a patient to that patient if requested
5 in accordance with procedures established by the board. The information shall be disclosed
6 to the patient within 10 business days of the request being received by the board, and the
7 patient may make a request to the board up to once every six months. A patient may request
8 the board to correct any information about the patient that is erroneous.

9 (d) In accordance with ORS 192.518 to 192.529 and federal privacy regulations, any person
10 authorized to prescribe or dispense a prescription drug and who is entitled to access a pa-
11 tient's prescription monitoring information may discuss or release the information to other
12 health care providers involved with the patient's care, in order to provide safe and appro-
13 priate care coordination.

14 (3)(a) The board shall maintain records of the information disclosed through the pre-
15 scription monitoring program including, but not limited to:

16 (A) The identification of each person who requests or receives information from the
17 program and the organization, if any, the person represents;

18 (B) The information released to each person or organization; and

19 (C) The date and time the information was requested and the date and time the infor-
20 mation was provided.

21 (b) Records maintained as required by this subsection may be reviewed by the Pre-
22 scription Monitoring Program Advisory Commission.

23 (4) Information in the prescription monitoring program that identifies an individual pa-
24 tient must be removed no later than three years from the date the information is entered
25 into the program.

26 (5) A pharmacy required to report information to the board, or a person authorized under
27 this section to obtain or use information from the prescription monitoring program, is im-
28 mune from civil liability arising out of the reporting or release of the information if the
29 pharmacy or person reports, obtains or uses the data in good faith.

30 (6) The board and the commission are immune from civil liability arising from the inac-
31 curacy of any information submitted under section 4 of this 2009 Act to the prescription
32 monitoring program.

33 (7) Nothing in sections 2 to 10 of this 2009 Act requires a practitioner or pharmacist who
34 prescribes or dispenses a prescription drug to obtain information about a patient from the
35 prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses
36 a prescription drug may not be held liable for damages in any civil action on the basis that
37 the practitioner or pharmacist did or did not request or obtain information from the pre-
38 scription monitoring program.

39 **SECTION 6.** A pharmacist may not refuse to fill a valid prescription solely because the
40 pharmacist cannot receive patient information from the prescription monitoring program
41 established under section 3 of this 2009 Act at the time the patient requests that the pre-
42 scription be filled.

43 **SECTION 7.** (1) In addition to any other penalty provided by law, the State Board of
44 Pharmacy may impose a civil penalty for any violation of sections 4 to 6 of this 2009 Act. A
45 civil penalty imposed under this section may not exceed \$250 for each violation by an indi-

1 **vidual and \$1,000 for each violation by a drug outlet.**

2 **(2) Civil penalties recovered under this section shall be deposited in the State Board of**
3 **Pharmacy Account established in ORS 689.139.**

4 **(3) Civil penalties under this section shall be imposed as provided in ORS 183.745.**

5 **(4) Notwithstanding ORS 183.745, the person to whom the notice is addressed has 10 days**
6 **from the date of service of the notice to make written application for a hearing before the**
7 **board.**

8 **SECTION 8. (1) As used in this section, “board” means:**

9 **(a) The Oregon Medical Board;**

10 **(b) The Oregon Board of Dentistry;**

11 **(c) The Board of Naturopathic Examiners;**

12 **(d) The Oregon State Board of Nursing;**

13 **(e) The Oregon Board of Optometry; and**

14 **(f) The State Board of Pharmacy.**

15 **(2) The State Board of Pharmacy may accept grants, donations, gifts or moneys from any**
16 **source for expenditures consistent with the purposes of sections 2 to 10 of this 2009 Act.**

17 **(3)(a) In addition to other licensing fees imposed by a board on licensees, a board shall**
18 **adopt rules imposing a fee of \$25 per year on each person licensed by the board who is au-**
19 **thorized to prescribe or dispense controlled substances. A board shall collect the fee at the**
20 **same time the board collects other licensing fees imposed on licensees.**

21 **(b) A board shall retain 10 percent of the fees collected under paragraph (a) of this sub-**
22 **section to cover the costs of accounting and collection of the fees.**

23 **(c) On the first day of each calendar quarter, a board shall transmit 90 percent of the**
24 **fees collected under paragraph (a) of this subsection during the preceding calendar quarter**
25 **to the Electronic Prescription Monitoring Fund established in section 11 of this 2009 Act.**

26 **SECTION 9. (1) The Prescription Monitoring Program Advisory Commission is created**
27 **for the purposes of:**

28 **(a) Studying issues related to the prescription monitoring program established under**
29 **section 3 of this 2009 Act;**

30 **(b) Reviewing the program’s annual report and making recommendations to the State**
31 **Board of Pharmacy regarding the operation of the program; and**

32 **(c) Developing criteria that should be used to evaluate program data.**

33 **(2) The commission shall consist of 15 members appointed by the board as follows:**

34 **(a) A person nominated by the Pain Management Commission;**

35 **(b) A person nominated by the Oregon State Pharmacy Association;**

36 **(c) A person nominated by the Oregon Dental Association;**

37 **(d) A physician nominated by the Oregon Medical Association;**

38 **(e) A doctor of osteopathy nominated by the Osteopathic Physicians and Surgeons of**
39 **Oregon;**

40 **(f) A person nominated by the Oregon Nurses Association;**

41 **(g) A person nominated by the Oregon Association of Naturopathic Physicians;**

42 **(h) A person nominated by the Oregon Board of Dentistry;**

43 **(i) A physician nominated by the Oregon Medical Board;**

44 **(j) A person nominated by the Board of Naturopathic Examiners;**

45 **(k) A person nominated by the Oregon State Board of Nursing;**

1 (L) A person nominated by the State Board of Pharmacy;

2 (m) A member of the public nominated by the State Board of Pharmacy;

3 (n) A person nominated by a health professional licensing board that regulates addiction
4 counselors; and

5 (o) A person nominated by the Department of Human Services from a division of the
6 department responsible for administering addiction services.

7 **SECTION 10.** (1) The term of office of each member of the Prescription Monitoring Pro-
8 gram Advisory Commission is four years, but a member serves at the pleasure of the State
9 Board of Pharmacy. Before the expiration of the term of a member, the board shall appoint
10 a successor whose term begins on July 1 next following. A member is eligible for reappoint-
11 ment. If there is a vacancy for any cause, the board shall make an appointment to become
12 immediately effective.

13 (2) The commission shall elect one of its members to serve as chairperson.

14 (3) The commission shall meet at least once annually at a time and place specified by the
15 chairperson of the commission. The commission may meet at other times and places speci-
16 fied by the call of the chairperson or of a majority of the members of the commission.

17 (4) The commission may adopt rules necessary for the operation of the commission.

18 (5) A majority of the members of the commission constitutes a quorum for the trans-
19 action of business.

20 (6) Official action by the commission requires the approval of a majority of the members
21 of the commission.

22 (7) The board shall provide staff support to the commission.

23 (8) Members of the commission are not entitled to compensation, but may be reimbursed
24 for actual and necessary travel and other expenses incurred by them in the performance of
25 their official duties in the manner and amounts provided for in ORS 292.495. Claims for ex-
26 penses incurred in performing functions of the commission shall be paid out of funds appro-
27 priated to the board for that purpose.

28 (9) All agencies of state government, as defined in ORS 174.111, are directed to assist the
29 commission in the performance of its duties and, to the extent permitted by laws relating
30 to confidentiality, to furnish such information and advice as the members of the commission
31 consider necessary to perform their duties.

32 **SECTION 11.** The Electronic Prescription Monitoring Fund is established in the State
33 Treasury, separate and distinct from the General Fund. The Electronic Prescription Moni-
34 toring Fund consists of moneys transmitted to the fund under section 8 of this 2009 Act.
35 Interest earned by the fund shall be credited to the fund. Moneys in the fund are contin-
36 uously appropriated to the State Board of Pharmacy for the purpose of carrying out the
37 provisions of sections 2 to 10 of this 2009 Act.

38 **SECTION 12.** Notwithstanding the term of office specified by section 10 of this 2009 Act,
39 the members first appointed to the Prescription Monitoring Program Advisory Commission
40 shall determine by lot at the first meeting of the commission the initial terms of office for
41 commission members as follows:

42 (1) Five shall serve for a term ending July 1, 2010.

43 (2) Five shall serve for a term ending on July 1, 2011.

44 (3) Five shall serve for a term ending on July 1, 2012.

45 **SECTION 13.** (1) Sections 4 to 6 of this 2009 Act become operative on July 1, 2010.

1 **(2) The State Board of Pharmacy may take any action before the operative date in sub-**
2 **section (1) of this section that is necessary to enable the board to exercise on or after the**
3 **operative date in subsection (1) of this section, all of the duties, functions and powers con-**
4 **ferred on the board by sections 4 to 6 of this 2009 Act.**

5 **SECTION 14. This 2009 Act being necessary for the immediate preservation of the public**
6 **peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect**
7 **on its passage.**

8

EXHIBIT D

Controlled Substances

- by CSA Schedule -

SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
1-(1-Phenylcyclohexyl)pyrrolidine	7458	I	N	PCPy, PHP, rolicyclidine
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	9663	I	Y	PEPAP, synthetic heroin
1-[1-(2-Thienyl)cyclohexyl]piperidine	7470	I	N	TCP, tenocyclidine
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	7473	I	N	TCPy
1-Methyl-4-phenyl-4-propionoxypiperidine	9661	I	Y	MPPP, synthetic heroin
2,5-Dimethoxy-4-ethylamphetamine	7399	I	N	DOET
2,5-Dimethoxyamphetamine	7396	I	N	DMA, 2,5-DMA
2C-C (2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine)	7519	I	N	2C-C
2C-D (2-(2,5-Dimethoxy-4-methylphenyl) ethanamine)	7508	I	N	2C-D
2C-E (2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine)	7509	I	N	2C-E
2C-H (2-(2,5-Dimethoxyphenyl) ethanamine)	7517	I	N	2C-H
2C-I (2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine)	7518	I	N	2C-I
2C-N (2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine)	7521	I	N	2C-N
2C-P (2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine)	7524	I	N	2C-P
2C-T-2 (2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine)	7385	I	N	2C-T-2
2C-T-4 (2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine)	7532	I	N	2C-T-4
2C-T-7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine)	7348	I	N	2C-T-7
3,4,5-Trimethoxyamphetamine	7390	I	N	TMA
3,4-Methylenedioxyamphetamine	7400	I	N	MDA, Love Drug
3,4-Methylenedioxymethamphetamine	7405	I	N	MDMA, Ecstasy, XTC
3,4-Methylenedioxy-N-ethylamphetamine	7404	I	N	N-ethyl MDA, MDE, MDEA
3-Methylfentanyl	9813	I	Y	China White, fentanyl
3-Methylthiofentanyl	9833	I	Y	Chine White, fentanyl
4-Bromo-2,5-dimethoxyamphetamine	7391	I	N	DOB, 4-bromo-DMA
4-Bromo-2,5-dimethoxyphenethylamine	7392	I	N	2C-B, Nexus, has been sold as Ecstasy, i.e. MDMA
4-Methoxyamphetamine	7411	I	N	PMA
4-Methyl-2,5-dimethoxyamphetamine	7395	I	N	DOM, STP
4-Methylaminorex (cis isomer)	1590	I	N	U4Euh, McN-422
5-Flouro-UR-144 and XLR11 [1-(5-Flouro-pentyl)1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	7011	I	N	5-Flouro-UR-144 and XLR11
5-Methoxy-3,4-methylenedioxyamphetamine	7401	I	N	MMDA
5-Methoxy-N,N-diisopropyltryptamine	7439	I	N	5-MeO-DIPT
5-Methoxy-N,N-dimethyltryptamine	7431	I	N	5-MeO-DMT

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Acetorphine	9319	I	Y	
Acetyl-alpha-methylfentanyl	9815	I	Y	
Acetyldihydrocodeine	9051	I	Y	Acetylcodone
Acetylmethadol	9601	I	Y	Methadyl acetate
Allylprodine	9602	I	Y	
Alphacetylmethadol except levo-alphacetylmethadol	9603	I	Y	
Alpha-ethyltryptamine	7249	I	N	ET, Trip
Alphameprodine	9604	I	Y	
Alphamethadol	9605	I	Y	
Alpha-methylfentanyl	9814	I	Y	China White, fentanyl
Alpha-methylthiofentanyl	9832	I	Y	China White, fentanyl
Alpha-methyltryptamine	7432	I	N	AMT
AM-2201 (1-(5-Fluoropentyl)-3-(1-naphthoyl) indole)	7201	I	N	AM-2201
AM-694 (1-(5-Fluoropentyl)-3-(2-iodobenzoyl) indole)	7694	I	N	AM-694
Aminorex	1585	I	N	has been sold as methamphetamine
APINACA and AKB48 N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide	7048	I	N	APINACA and AKB48
Benzethidine	9606	I	Y	
Benzylmorphine	9052	I	Y	
Betacetylmethadol	9607	I	Y	
Beta-hydroxy-3-methylfentanyl	9831	I	Y	China White, fentanyl
Beta-hydroxyfentanyl	9830	I	Y	China White, fentanyl
Betameprodine	9608	I	Y	
Betamethadol	9609	I	Y	
Betaprodine	9611	I	Y	
Bufotenine	7433	I	N	Mappine, N,N-dimethylserotonin
Cathinone	1235	I	N	Constituent of "Khat" plant
Clonitazene	9612	I	Y	
Codeine methylbromide	9070	I	Y	
Codeine-N-oxide	9053	I	Y	
CP-47497 (5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol)	7297	I	N	CP-47497
CP-47497 C8 Homologue (5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol)	7298	I	N	CP-47497 C8 Homologue
Cyprenorphine	9054	I	Y	
Desomorphine	9055	I	Y	
Dextromoramide	9613	I	Y	Palfium, Jetrium, Narcolo
Diampromide	9615	I	Y	
Diethylthiambutene	9616	I	Y	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Diethyltryptamine	7434	I	N	DET
Difenoxin	9168	I	Y	Lyspafen
Dihydromorphine	9145	I	Y	
Dimenoxadol	9617	I	Y	
Dimepheptanol	9618	I	Y	
Dimethylthiambutene	9619	I	Y	
Dimethyltryptamine	7435	I	N	DMT
Dioxaphetyl butyrate	9621	I	Y	
Dipipanone	9622	I	Y	Dipipan, phenylpiperone HCl, Diconal, Wellconal
Drotebanol	9335	I	Y	Metebanyl, oxymethebanol
Ethylmethylthiambutene	9623	I	Y	
Etonitazene	9624	I	Y	
Etorphine (except HCl)	9056	I	Y	
Etoxidine	9625	I	Y	
Fenethylamine	1503	I	N	Captagon, amfetamine, ethyltheophylline amphetamine
Furethidine	9626	I	Y	
Gamma Hydroxybutyric Acid	2010	I	N	GHB, gamma hydroxybutyrate, sodium oxybate
Heroin	9200	I	Y	Diacetylmorphine, diamorphine
Hydromorphanol	9301	I	Y	
Hydroxypethidine	9627	I	Y	
Ibogaine	7260	I	N	Constituent of "Tabernanthe iboga" plant
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I	N	JWH-018 and AM-678
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	7019	I	N	JWH-019
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	7173	I	N	JWH-073
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I	N	JWH-081
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I	N	JWH-122
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	7200	I	N	JWH-200
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I	N	JWH-203
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I	N	JWH-250
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I	N	JWH-398
Ketobemidone	9628	I	Y	Cliradon
Levomoramide	9629	I	Y	
Levophenacymorphan	9631	I	Y	
Lysergic acid diethylamide	7315	I	N	LSD, lysergide
Marihuana	7360	I	N	Cannabis, marijuana
MDPV (3,4-Methylenedioxypropylvalerone)	7535	I	N	MDPV
Mecloqualone	2572	I	N	Nubarene

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Mephedrone (4-Methyl-N-methylcathinone)	1248	I	N	Mephedrone
Mescaline	7381	I	N	Constituent of "Peyote" cacti
Methaqualone	2565	I	N	Quaalude, Parest, Somnafac, Opitimil, Mandrax
Methcathinone	1237	I	N	N-Methylcathinone, "cat"
Methyldesorphine	9302	I	Y	
Methyldihydromorphine	9304	I	Y	
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I	N	Methylone
Morpheridine	9632	I	Y	
Morphine methylbromide	9305	I	Y	
Morphine methylsulfonate	9306	I	Y	
Morphine-N-oxide	9307	I	Y	
Myrophine	9308	I	Y	
N,N-Dimethylamphetamine	1480	I	N	
N-Benzylpiperazine	7493	I	N	BZP, 1-benzylpiperazine
N-Ethyl-1-phenylcyclohexylamine	7455	I	N	PCE
N-Ethyl-3-piperidyl benzilate	7482	I	N	JB 323
N-Ethylamphetamine	1475	I	N	NEA
N-Hydroxy-3,4-methylenedioxyamphetamine	7402	I	N	N-hydroxy MDA
Nicocodeine	9309	I	Y	
Nicomorphine	9312	I	Y	Vilan
N-Methyl-3-piperidyl benzilate	7484	I	N	JB 336
Noracymethadol	9633	I	Y	
Norlevorphanol	9634	I	Y	
Normethadone	9635	I	Y	Phenyldimazone
Normorphine	9313	I	Y	
Norpipanone	9636	I	Y	
Para-Fluorofentanyl	9812	I	Y	China White, fentanyl
Parahexyl	7374	I	N	Synhexyl,
Peyote	7415	I	N	Cactus which contains mescaline
Phenadoxone	9637	I	Y	
Phenamipromide	9638	I	Y	
Phenomorphin	9647	I	Y	
Phenoperidine	9641	I	Y	Operidine, Lealgin
Pholcodine	9314	I	Y	Copholco, Adaphol, Codisol, Lantuss, Pholcolin
Piritramide	9642	I	Y	Piridolan
Proheptazine	9643	I	Y	
Properidine	9644	I	Y	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Propiram	9649	I	Y	Algeril
Psilocybin	7437	I	N	Constituent of "Magic mushrooms"
Psilocyn	7438	I	N	Psilocin, constituent of "Magic mushrooms"
Racemoramide	9645	I	Y	
SR-18 (Also known as RCS-8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I	N	SR-18 and RCS-8
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole)	7104	I	N	SR-19 and RCS-4
Tetrahydrocannabinols	7370	I	N	THC, Delta-8 THC, Delta-9 THC, dronabinol and others
Thebacon	9315	I	Y	Acetylhydrocodone, Acedicon, Thebacetyl
Thiofentanyl	9835	I	Y	Chine white, fentanyl
Tilidine	9750	I	Y	Tilidate, Valoron, Kitadol, Lak, Tilsa
Trimeperidine	9646	I	Y	Promedolum
UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I	N	UR-144
1-Phenylcyclohexylamine	7460	II	N	PCP precursor
1-Piperidinocyclohexanecarbonitrile	8603	II	N	PCC, PCP precursor
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II	N	ANPP
Alfentanil	9737	II	Y	Alfenta
Alphaprodine	9010	II	Y	Nisentil
Amobarbital	2125	II	N	Amytal, Tuinal
Amphetamine	1100	II	N	Dexedrine, Adderall, Obetrol
Anileridine	9020	II	Y	Leritine
Bezitramide	9800	II	Y	Burgodin
Carfentanil	9743	II	Y	Wildnil
Coca Leaves	9040	II	Y	
Cocaine	9041	II	Y	Methyl benzoylecgonine, Crack
Codeine	9050	II	Y	Morphine methyl ester, methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	9273	II	Y	Propoxyphene
Dihydrocodeine	9120	II	Y	Didrate, Parzone
Dihydroetorphine	9334	II	Y	DHE
Diphenoxylate	9170	II	Y	
Ecgonine	9180	II	Y	Cocaine precursor, in Coca leaves
Ethylmorphine	9190	II	Y	Dionin
Etorphine HCl	9059	II	Y	M 99
Fentanyl	9801	II	Y	Duragesic, Oralet, Actiq, Sublimaze, Innovar
Glutethimide	2550	II	N	Doriden, Dorimide
Hydrocodone	9193	II	Y	dihydrocodeinone
Hydromorphone	9150	II	Y	Dilaudid, dihydromorphinone

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Isomethadone	9226	II	Y	Isoamidone
Levo-alphaacetylmethadol	9648	II	Y	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	9210	II	Y	
Levorphanol	9220	II	Y	Levo-Dromoran
Lisdexamfetamine	1205	II	N	Vyvanse
Meperidine	9230	II	Y	Demerol, Mepergan, pethidine
Meperidine intermediate-A	9232	II	Y	Meperidine precursor
Meperidine intermediate-B	9233	II	Y	Meperidine precursor, normeperidine
Meperidine intermediate-C	9234	II	Y	Meperidine precursor
Metazocine	9240	II	Y	
Methadone	9250	II	Y	Dolophine, Methadose, Amidone
Methadone intermediate	9254	II	Y	Methadone precursor
Methamphetamine	1105	II	N	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	1724	II	N	Concerta, Ritalin, Methylin
Metopon	9260	II	Y	
Moramide-intermediate	9802	II	Y	
Morphine	9300	II	Y	MS Contin, Roxanol, Oramorph, RMS, MSIR
Nabilone	7379	II	N	Cesamet
Opium extracts	9610	II	Y	
Opium fluid extract	9620	II	Y	
Opium poppy	9650	II	Y	Papaver somniferum
Opium tincture	9630	II	Y	Laudanum
Opium, granulated	9640	II	Y	Granulated opium
Opium, powdered	9639	II	Y	Powdered opium
Opium, raw	9600	II	Y	Raw opium, gum opium
Oripavine	9330	II	Y	
Oxycodone	9143	II	Y	OxyContin, Percocet, Endocet, Roxicodone, Roxicet,
Oxymorphone	9652	II	Y	Numorphan
Pentobarbital	2270	II	N	Nembutal
Phenazocine	9715	II	Y	Narphen, Prinadol
Phencyclidine	7471	II	N	PCP, Sernylan
Phenmetrazine	1631	II	N	Preludin
Phenylacetone	8501	II	N	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	9730	II	Y	
Poppy Straw	9650	II	Y	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	9670	II	Y	Concentrate of Poppy Straw, CPS
Racemethorphan	9732	II	Y	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Racemorphan	9733	II	Y	Dromoran
Remifentanil	9739	II	Y	Ultiva
Secobarbital	2315	II	N	Seconal, Tuinal
Sufentanil	9740	II	Y	Sufenta
Tapentadol	9780	II	Y	
Thebaine	9333	II	Y	Precursor of many narcotics
13Beta-ethyl-17beta-hydroxygon-4-en-3-one	4000	III	N	
17Alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane	4000	III	N	
17Alpha-methyl-3beta,17beta-dihydroxy-5alpha-androstane	4000	III	N	
17Alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene	4000	III	N	
17Alpha-methyl-4-hydroxynandrolone (17alpha-methyl-4-hydroxy-17beta-hydroxyestr-4-en-3-one)	4000	III	N	
17Alpha-methyl-delta1-dihydrotestosterone (17beta-hydroxy-17alpha-methyl-5alpha-androst-1-en-3-one)	4000	III	N	17-Alpha-methyl-1-testosterone
19-Nor-4,9(10)-androstadienedione	4000	III	N	
19-Nor-4-androstenediol (3beta,17beta-dihydroxyestr-4-ene; 3alpha,17beta-dihydroxyestr-4-ene)	4000	III	N	
19-Nor-4-androstenedione (estr-4-en-3,17-dione)	4000	III	N	
19-Nor-5-androstenediol (3beta,17beta-dihydroxyestr-5-ene; 3alpha,17beta-dihydroxyestr-5-ene)	4000	III	N	
19-Nor-5-androstenedione (estr-5-en-3,17-dione)	4000	III	N	
1-Androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene; 3alpha,17beta-dihydroxy-5alpha-androst-1-ene)	4000	III	N	
1-Androstenedione (5alpha-androst-1-en-3,17-dione)	4000	III	N	
3Alpha,17beta-dihydroxy-5alpha-androstane	4000	III	N	
3Beta,17beta-dihydroxy-5alpha-androstane	4000	III	N	
4-Androstenediol (3beta,17beta-dihydroxy-androst-4-ene)	4000	III	N	4-AD
4-Androstenedione (androst-4-en-3,17-dione)	4000	III	N	
4-Dihydrotestosterone (17beta-hydroxyandrost-3-one)	4000	III	N	Anabolex, Andractim, Pesomax, Stanolone
4-Hydroxy-19-nortestosterone (4,17beta-dihydroxyestr-4-en-3-one)	4000	III	N	
4-Hydroxytestosterone (4,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	
5-Androstenediol (3beta,17beta-dihydroxy-androst-5-ene)	4000	III	N	
5-Androstenedione (androst-5-en-3,17-dione)	4000	III	N	
Amobarbital & noncontrolled active ingred.	2126	III	N	
Amobarbital suppository dosage form	2126	III	N	
Anabolic steroids	4000	III	N	"Body Building" drugs
Androstanedione (5alpha-androst-3,17-dione)	4000	III	N	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Aprobarbital	2100	III	N	Alurate
Barbituric acid derivative	2100	III	N	Barbiturates not specifically listed
Benzphetamine	1228	III	N	Didrex, Inapetyl
Bolasterone (7alpha,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	
Boldenone (17beta-hydroxyandrost-1,4-diene-3-one)	4000	III	N	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Boldione	4000	III	N	
Buprenorphine	9064	III	Y	Buprenex, Temgesic, Subutex, Suboxone
Butabarbital (secbutabarbital)	2100	III	N	Butisol, Butibel
Butalbital	2100	III	N	Fiorinal, Butalbital with aspirin
Butobarbital (butethal)	2100	III	N	Soneryl (UK)
Calusterone (7beta,17alpha-dimethyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Methosarb
Chlorhexadol	2510	III	N	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorphentermine	1645	III	N	Pre-Sate, Lucofen, Apsedon, Desopimon
Clortermine	1647	III	N	Voranil
Clostebol (4-chloro-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Codeine & isoquinoline alkaloid 90 mg/du	9803	III	Y	Codeine with papaverine or noscapine
Codeine combination product 90 mg/du	9804	III	Y	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dehydrochloromethyltestosterone (4-chloro-17beta-hydroxy-17alpha-methylandrost-1,4-dien-3-one)	4000	III	N	Oral-Turinabol
Delta1-dihydrotestosterone (17beta-hydroxy-5alpha-androst-1-en-3-one)	4000	III	N	1-Testosterone
Desoxymethyltestosterone	4000	III	N	
Dihydrocodeine combination product 90 mg/du	9807	III	Y	Synalgos-DC, Compal
Dronabinol (synthetic) in sesame oil in soft gelatin capsule as approved by FDA	7369	III	N	Marinol, synthetic THC in sesame oil/soft gelatin as approved by FDA
Drostanolone (17beta-hydroxy-2alpha-methyl-5alpha-androstan-3-one)	4000	III	N	Drolban, Masterid, Permastril
Embutramide	2020	III	N	Tributane
Ethylestrenol (17alpha-ethyl-17beta-hydroxyestr-4-ene)	4000	III	N	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmorphine combination product 15 mg/du	9808	III	Y	
Fluoxymesterone (9-fluoro-17alpha-methyl-11beta,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	Anadroid-F, Halotestin, Ora-Testryl
Formebolone (2-formyl-17alpha-methyl-11alpha,17beta-dihydroxyandrost-1,4-dien-3-one)	4000	III	N	Esiclene, Hubernol
Furazabol (17alpha-methyl-17beta-hydroxyandrostano[2,3-c]-furazan)	4000	III	N	Frazalon, Miotolon, Qu Zhi Shu
Gamma Hydroxybutyric Acid preparations	2012	III	N	Xyrem
Hydrocodone & isoquinoline alkaloid <15 mg/du	9805	III	Y	Dihydrocodeinone+papaverine or noscapine
Hydrocodone combination product <15 mg/du	9806	III	Y	Lorcet, Lortab, Vicodin, Vicoprofen, Tussionex, Norco
Ketamine	7285	III	N	Ketaset, Ketalar, Special K, K

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Lysergic acid	7300	III	N	LSD precursor
Lysergic acid amide	7310	III	N	LSD precursor
Mestanolone (17alpha-methyl-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Assimil, Ermalone, Methybol, Tantarone
Mesterolone (1alpha-methyl-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Androviron, Proviron, Testiwop
Methandienone (17alpha-methyl-17beta-hydroxyandrost-1,4-diene-3-one)	4000	III	N	Dianabol, Metabolina, Nerobol, Perbolin
Methandriol (17alpha-methyl-3beta,17beta-dihydroxyandrost-5-ene)	4000	III	N	Sinesex, Stenediol, Troformone
Methasterone (2alpha,17alpha-dimethyl-5alpha-androstan-17beta-ol-3-one)	4000	III	N	Methasterone
Methenolone (1-methyl-17beta-hydroxy-5alpha-androst-1-en-3-one)	4000	III	N	Primobolan, Primobolan Depot, Primobolan S
Methyldienolone (17alpha-methyl-17beta-hydroxyestr-4,9(10)-dien-3-one)	4000	III	N	
Methyltestosterone (17alpha-methyl-17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Android, Oreton, Testred, Virilon
Methyltrienolone (17alpha-methyl-17beta-hydroxyestr-4,9,11-trien-3-one)	4000	III	N	Metribolone
Methypylon	2575	III	N	Noludar
Mibolerone (7alpha,17alpha-dimethyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Cheque, Matenon
Morphine combination product/50 mg/(100 ml or 100 gm)	9810	III	Y	
Nalorphine	9400	III	Y	Nalline
Nandrolone (17beta-hydroxyestr-4-en-3-one)	4000	III	N	Deca-Durabolin, Durabolin, Durabolin-50
Norbolethone (13beta,17alpha-diethyl-17beta-hydroxygon-4-en-3-one)	4000	III	N	Genabol
Norclostebol (4-chloro-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Anabol-4-19, Lentabol
Norethandrolone (17alpha-ethyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Nilevar, Pronabol, Solevar
Normethandrolone (17alpha-methyl-17beta-hydroxyestr-4-en-3-one)	4000	III	N	Lutenin, Matronal, Orgasteron
Opium combination product 25 mg/du	9809	III	Y	Paregoric, other combination products
Oxandrolone (17alpha-methyl-17beta-hydroxy-2-oxa-5alpha-androstan-3-one)	4000	III	N	Anavar, Lonavar, Oxandrin, Provitarn, Vasorome
Oxymesterone (17alpha-methyl-4,17beta-dihydroxyandrost-4-en-3-one)	4000	III	N	Anamidol, Balnimax, Oranabol, Oranabol 10
Oxymetholone (17alpha-methyl-2-hydroxymethylene-17beta-hydroxy-5alpha-androstan-3-one)	4000	III	N	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Pentobarbital & noncontrolled active ingred.	2271	III	N	FP-3
Pentobarbital suppository dosage form	2271	III	N	WANS
Phendimetrazine	1615	III	N	Plegine, Prelu-2, Bontril, Melfiat, Statobex
Prostanozol (17beta-hydroxy-5alpha-androstano[3,2-c]pyrazole)	4000	III	N	Prostanozol
Secobarbital & noncontrolled active ingred	2316	III	N	

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Secobarbital suppository dosage form	2316	III	N	
Stanozolol (17alpha-methyl-17beta-hydroxy-5alpha-androst-2-eno[3,2-c]-pyrazole)	4000	III	N	Winstrol, Winstrol-V
Stenbolone (17beta-hydroxy-2-methyl--5alpha-androst-1-en-3-one)	4000	III	N	
Stimulant compounds previously excepted	1405	III	N	Mediatric
Sulfondiethylmethane	2600	III	N	
Sulfonethylmethane	2605	III	N	
Sulfonmethane	2610	III	N	
Talbutal	2100	III	N	Lotusate
Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)	4000	III	N	Teolit, Teslac
Testosterone (17beta-hydroxyandrost-4-en-3-one)	4000	III	N	Android-T, Androlan, Depotest, Delatestryl
Tetrahydrogestrinone (13beta,17alpha-diethyl-17beta-hydroxygon-4,9,11-trien-3-one)	4000	III	N	THG
Thiamylal	2100	III	N	Surital
Thiopental	2100	III	N	Pentothal
Tiletamine & Zolazepam Combination Product	7295	III	N	Telazol
Trenbolone (17beta-hydroxyestr-4,9,11-trien-3-one)	4000	III	N	Finaplix-S, Finajet, Parabolan
Vinbarbital	2100	III	N	Delvinal, vinbarbitone
Alprazolam	2882	IV	N	Xanax
Barbital	2145	IV	N	Veronal, Plexonal, barbitone
Bromazepam	2748	IV	N	Lexotan, Lexatin, Lexotamil
Butorphanol	9720	IV	N	Stadol, Stadol NS, Torbugesic, Torbutrol
Camazepam	2749	IV	N	Albego, Limpidon, Paxor
Carisoprodol	8192	IV	N	Soma
Cathine	1230	IV	N	Constituent of "Khat" plant, (+)-norpseudoephedrine
Chloral betaine	2460	IV	N	Beta Chlor
Chloral hydrate	2465	IV	N	Noctec
Chlordiazepoxide	2744	IV	N	Librium, Libritabs, Limbitrol, SK-Lygen
Clobazam	2751	IV	N	Urbadan, Urbanyl
Clonazepam	2737	IV	N	Klonopin, Clonopin
Clorazepate	2768	IV	N	Tranxene
Clotiazepam	2752	IV	N	Trecalmo, Rize, Clozan, Veratran
Cloxazolam	2753	IV	N	Akton, Lubalix, Olcadil, Sepazon
Delorazepam	2754	IV	N	
Dexfenfluramine	1670	IV	N	Redux
Dextropropoxyphene dosage forms	9278	IV	Y	Darvon, propoxyphene, Darvocet, Propacet
Diazepam	2765	IV	N	Valium, Diastat
Dichloralphenazone	2467	IV	N	Midrin, dichloralantipyrene

Controlled Substances - by CSA Schedule

SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Diethylpropion	1610	IV	N	Tenuate, Tepanil
Difenoxin 1 mg/25 ug AtSO4/du	9167	IV	Y	Motofen
Estazolam	2756	IV	N	ProSom, Domnamid, Eurodin, Nuctalon
Ethchlorvynol	2540	IV	N	Placidyl
Ethinamate	2545	IV	N	Valmid, Valamin
Ethyl loflazepate	2758	IV	N	
Fencamfamin	1760	IV	N	Reactivan
Fenfluramine	1670	IV	N	Pondimin, Ponderal
Fenproporex	1575	IV	N	Gacilin, Solvolip
Fludiazepam	2759	IV	N	
Flunitrazepam	2763	IV	N	Rohypnol, Narcozep, Darkene, Roipnol
Flurazepam	2767	IV	N	Dalmane
Fospropofol	2138	IV	N	Lusedra
Halazepam	2762	IV	N	Paxipam
Haloxazolam	2771	IV	N	
Ketazolam	2772	IV	N	Anxon, Loftran, Solatran, Contamex
Loprazolam	2773	IV	N	
Lorazepam	2885	IV	N	Ativan
Lorcaserin	1625	IV	N	Belviq
Lormetazepam	2774	IV	N	Noctamid
Mazindol	1605	IV	N	Sanorex, Mazanor
Mebutamate	2800	IV	N	Capla
Medazepam	2836	IV	N	Nobrium
Mefenorex	1580	IV	N	Anorexic, Amexate, Doracil, Pondinil
Meprobamate	2820	IV	N	Miltown, Equanil, Micrainin, Equagesic, Meprospan
Methohexital	2264	IV	N	Brevital
Methylphenobarbital (mephobarbital)	2250	IV	N	Mebaral, mephobarbital
Midazolam	2884	IV	N	Versed
Modafinil	1680	IV	N	Provigil
Nimetazepam	2837	IV	N	Erimin
Nitrazepam	2834	IV	N	Mogadon
Nordiazepam	2838	IV	N	Nordazepam, Demadar, Madar
Oxazepam	2835	IV	N	Serax, Serenid-D
Oxazolam	2839	IV	N	Serenal, Convertal
Paraldehyde	2585	IV	N	Paral
Pemoline	1530	IV	N	Cylert
Pentazocine	9709	IV	N	Talwin, Talwin NX, Talacen, Talwin Compound

Controlled Substances - by CSA Schedule

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SUBSTANCE	DEA NUMBER	CSA SCH	NARC	OTHER NAMES
Petrichloral	2591	IV	N	Pentaerythritol chloral, Periclor
Phenobarbital	2285	IV	N	Luminal, Donnatal, Bellergal-S
Phentermine	1640	IV	N	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Pinazepam	2883	IV	N	Domar
Pipradrol	1750	IV	N	Detaril, Stimolag Fortis
Prazepam	2764	IV	N	Centrax
Quazepam	2881	IV	N	Doral
Sibutramine	1675	IV	N	Meridia
SPA	1635	IV	N	1-dimethylamino-1,2-diphenylethane, Lefetamine
Temazepam	2925	IV	N	Restoril
Tetrazepam	2886	IV	N	Myolastan, Musaril
Triazolam	2887	IV	N	Halcion
Zaleplon	2781	IV	N	Sonata
Zolpidem	2783	IV	N	Ambien, Ivadal, Stilnoct, Stilnox
Zopiclone	2784	IV	N	Lunesta
Codeine preparations - 200 mg/(100 ml or 100 gm)		V	Y	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du		V	Y	Motofen
Dihydrocodeine preparations 10 mg/(100 ml or 100 gm)		V	Y	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4		V	Y	Lomotil, Logen
Ethylmorphine preparations 100 mg/(100 ml or 100 gm)		V	Y	
Ezogabine	2779	V	N	Potiga
Lacosamide	2746	V	N	Vimpat
Opium preparations - 100 mg/(100 ml or 100 gm)		V	Y	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pregabalin	2782	V	N	Lyrica
Pyrovalerone	1485	V	N	Centroton, Thymergix

EXHIBIT E



Adderall

(amphetamine salt combo) - Shire

BOXED WARNING

High potential for abuse; avoid prolonged use. Misuse of amphetamine may cause sudden death and serious cardiovascular (CV) adverse events.

THERAPEUTIC CLASS

Sympathomimetic amine

INDICATIONS

Treatment of attention-deficit disorder with hyperactivity (ADHD) and narcolepsy.

ADULT DOSAGE

Adults: Narcolepsy: Initial: 10mg/day. Titrate: May increase by 10mg/day every week. Usual: 5-60mg/day. Give 1st dose upon awakening, and additional doses q4-6h.

PEDIATRIC DOSAGE

Pediatrics: ADHD: ≥6 Yrs: 5mg qd-bid. Titrate: May increase by 5mg weekly. Max (usual): 40mg/day. 3-5 Yrs: Initial: 2.5mg qd. Titrate: May increase by 2.5mg weekly. Narcolepsy: ≥12 Yrs: Initial: 10mg/day. Titrate: May increase by 10mg/day every week. 6-12 Yrs: Initial: 5mg/day. Titrate: May increase by 5mg weekly. Usual: 5-60mg/day. Give 1st dose upon awakening, and additional doses q4-6h.

HOW SUPPLIED

Tab: 5mg*, 7.5mg*, 10mg*, 12.5mg*, 15mg*, 20mg*, 30mg* *scored

CONTRAINDICATIONS

Advanced arteriosclerosis, symptomatic CV disease, moderate to severe HTN, hyperthyroidism, glaucoma, agitated states, history of drug abuse, during or within 14 days of MAOI use.

WARNINGS/PRECAUTIONS

May exacerbate symptoms of behavior disturbance and thought disorder in psychotic patients. Caution when using stimulants to treat patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episode in such patients. Stimulants at usual doses can cause treatment emergent psychotic or manic symptoms (eg, hallucinations, delusional thinking, mania) in children and adolescents without prior history of psychotic illness. Aggressive behavior or hostility reported. Monitor growth in children. May lower convulsive threshold; d/c in presence of seizures. Visual disturbances reported with stimulant treatment. May exacerbate Tourette's syndrome and phonic or motor tics. Caution with HTN and monitor BP. Interrupt occasionally to determine if patient requires continued therapy. Sudden death reported in children with structural cardiac abnormalities; avoid with known structural cardiac abnormalities or other serious cardiac problems.

ADVERSE REACTIONS

HTN, tachycardia, palpitations, CNS overstimulation, dry mouth, GI disorders, anorexia, impotence, urticaria, rash, angioedema, anaphylaxis, Stevens-Johnson syndrome.

DRUG INTERACTIONS

See contraindications. GI acidifying agents (eg, guanethidine, reserpine, glutamic acid, etc.) and urinary acidifying agents (eg, ammonium chloride, etc.) decrease efficacy. Potentiated by GI and urinary alkalizers, propoxyphene overdose. Avoid coadministration with GI alkalizing agents (eg, antacids). Potentiated effects of both agents with TCAs. May delay absorption of phenytoin, ethosuximide, phenobarbital. Potentiates meperidine, norepinephrine, phenobarbital, phenytoin. Antagonized by haloperidol, chlorpromazine, lithium. Antagonizes adrenergic blockers, antihistamines, antihypertensives, veratrum alkaloids (antihypertensive).

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

CNS stimulant; thought to block reuptake of norepinephrine and dopamine into presynaptic neuron and increase release of these monoamines into extraneuronal space.

PHARMACOKINETICS

Absorption: T_{max}≈approximately 3 hrs (fasted). **Metabolism:** CYP2D6 (oxidation): 4-hydroxy-amphetamine and norephedrine. **Elimination:** Urine, T_{1/2}=9.77-11 hrs (d-amphetamine), 11.5-13.8 hrs (l-amphetamine).

ASSESSMENT

Assess for agitation, glaucoma, tics, family history of Tourette's syndrome, CV conditions (eg, severe HTN, angina pectoris, cardiac abnormalities, arrhythmias, heart failure, recent MI), hyperthyroidism or thyrotoxicosis, bipolar illness, history of drug dependence or alcoholism.

MONITORING

Monitor for cardiac abnormalities, exacerbations of behavior disturbances and thought disorder, bipolar illness, aggression, seizures, and visual disturbances. Periodically monitor CBC, differential and platelet count, LFTs. Monitor height and weight in children.

PATIENT COUNSELING

Inform about risks of treatment, appropriate use, drug abuse/dependence. Advise caution while operating machinery/driving.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT F



Ambien

(zolpidem tartrate) - Sanofi-Aventis

THERAPEUTIC CLASS

Imidazopyridine hypnotic

INDICATIONS

Short-term treatment of insomnia characterized by difficulties with sleep initiation.

ADULT DOSAGE

Adults: Individualize dose. Usual: 10mg qhs. Max: 10mg/day. Elderly/Debilitated/Hepatic Insufficiency: 5mg qhs. Use with CNS Depressants: Adjust dose.

HOW SUPPLIED

Tab: 5mg, 10mg

WARNINGS/PRECAUTIONS

Initiate only after careful evaluation; failure of insomnia to remit after 7-10 days of treatment may indicate presence of primary psychiatric and/or medical illness. Severe anaphylactic/anaphylactoid reactions reported; do not rechallenge if angioedema develops. Abnormal thinking, behavioral changes, visual/auditory hallucinations, and complex behaviors (eg, sleep-driving) reported. Worsening of depression, including suicidal thoughts and actions, reported in primarily depressed patients. Withdrawal symptoms may occur with rapid dose reduction or abrupt d/c. May impair mental/physical abilities. Closely monitor elderly and debilitated patients for impaired motor and/or cognitive performance and for unusual sensitivity. Respiratory insufficiency reported mostly in patients with preexisting respiratory impairment. Caution with compromised respiratory function, sleep apnea syndrome, myasthenia gravis, depression, and diseases/conditions that could affect metabolism or hemodynamic responses. Closely monitor patients with renal/hepatic impairment or history of drug/alcohol addiction or abuse.

ADVERSE REACTIONS

Drowsiness, dizziness, headache, diarrhea, drugged feeling, lethargy, dry mouth, back pain, pharyngitis, sinusitis, allergic reactions.

DRUG INTERACTIONS

Caution with CNS-active drugs. CNS depressants may potentially enhance effects. Avoid use with alcohol. Additive effect of decreased alertness reported with imipramine or chlorpromazine. Additive effect on psychomotor performance reported with chlorpromazine or alcohol. May decrease levels of imipramine. Fluoxetine may increase $T_{1/2}$. Increased C_{max} and decreased T_{max} reported with sertraline in females. CYP3A inhibitors (eg, itraconazole, ketoconazole) may increase exposure; use caution and consider lower dose with ketoconazole. Rifampin may decrease levels.

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Imidazopyridine, nonbenzodiazepine hypnotic; interacts with a gamma-aminobutyric acid-BZ receptor complex and binds the BZ₁ receptor preferentially with a high affinity ratio of the α_1/α_5 subunits.

PHARMACOKINETICS

Absorption: Rapid. C_{max} =59ng/mL (5mg), 121ng/mL (10mg). T_{max} =1.6 hrs (5mg, 10mg). **Distribution:** Plasma protein binding (92.5%); found in breast milk. **Elimination:** Renal; $T_{1/2}$ =2.6 hrs (5mg), 2.5 hrs (10mg).

ASSESSMENT

Assess for primary psychiatric and/or medical illness, myasthenia gravis, compromised respiratory function, sleep apnea syndrome, diseases/conditions that could affect metabolism or hemodynamic responses, depression, hypersensitivity to the drug, hepatic/renal impairment, history of drug/alcohol addiction or abuse, pregnancy/nursing status, possible drug interactions.

MONITORING

Monitor for anaphylactic/anaphylactoid reactions, withdrawal effects, motor/cognitive impairment, abnormal thinking, behavioral changes, complex behaviors, visual/auditory hallucinations, and other adverse reactions. Monitor patients with hepatic/renal impairment or with history of drug/alcohol addiction or abuse.

PATIENT COUNSELING

Inform about risks, benefits, and appropriate use of therapy. Advise to seek medical attention immediately if any anaphylactic/anaphylactoid reactions occur. Counsel to take drug just before hs and only when able to stay in bed a full night (7-8 hrs) before being active again. Advise not to take drug with or immediately after a meal, and when drinking alcohol. Instruct to immediately report events such as sleep-driving and other complex behaviors. Advise to report all concomitant medications to the prescriber.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT G



Android

(methyltestosterone) - Valeant

THERAPEUTIC CLASS

Androgen

INDICATIONS

Testosterone replacement therapy in males with primary hypogonadism or hypogonadotropic hypogonadism. To stimulate puberty in males with delayed puberty. May be used secondarily in females with advancing inoperable metastatic (skeletal) mammary cancer who are 1-5 yrs postmenopausal. Treatment in premenopausal females with breast cancer who have benefitted from oophorectomy and have a hormone-responsive tumor.

ADULT DOSAGE

Adults: Individualize dose (based on age, sex, and diagnosis). Adjust according to response and appearance of adverse reactions. Replacement Therapy in Androgen-Deficient Males: 10-50mg/day. Breast Carcinoma in Females: 50-200mg/day.

PEDIATRIC DOSAGE

Pediatrics: Individualize dose (based on age, sex, and diagnosis). Adjust according to response and appearance of adverse reactions. Replacement Therapy in Androgen-Deficient Males: 10-50mg/day. Delayed Puberty in Males: Use lower range of 10-50mg/day for limited duration (eg, 4-6 months). May start on lower dose then gradually increase as puberty progresses with/without a decrease to maint levels, or may start on higher dose then use a lower maint dose after puberty.

HOW SUPPLIED

Cap: 10mg

CONTRAINDICATIONS

Males with carcinomas of the breast or with known/suspected carcinomas of the prostate. Females who are or may become pregnant.

WARNINGS/PRECAUTIONS

May cause hypercalcemia in patients with breast cancer; d/c if this occurs. Peliosis hepatis and hepatic neoplasms, including hepatocellular carcinoma, reported with prolonged use of high doses. D/C if cholestatic hepatitis, jaundice, or abnormal LFTs occur. May increase risk of prostatic hypertrophy and prostatic carcinoma in elderly. Edema with or without congestive heart failure (CHF) may develop with preexisting cardiac, renal, or hepatic disease; d/c and consider diuretic therapy. Gynecomastia may develop. Caution in healthy males with delayed puberty; monitor bone maturation by assessing bone age of wrist and hand every 6 months. May accelerate bone maturation without producing compensatory gain in linear growth in children; may result in compromised adult stature. Should not be used for enhancement of athletic performance. Monitor for signs of virilization in females; d/c therapy at evidence of mild virilism.

ADVERSE REACTIONS

Amenorrhea, menstrual irregularities, inhibition of gonadotropin secretion, virilization in females, gynecomastia, excessive frequency and duration of penile erections, hirsutism, male pattern baldness, acne, fluid and electrolyte disturbances, nausea, cholestatic jaundice, alterations in LFTs, headache, anxiety, increased/decreased libido.

DRUG INTERACTIONS

May decrease oral anticoagulant requirement. May increase oxyphenbutazone levels. May decrease blood glucose and insulin requirements in diabetics.

PREGNANCY

Category X, not for use in nursing.

MECHANISM OF ACTION

Androgen; responsible for normal growth and development of male sex organs and for maintenance of secondary sex characteristics.

PHARMACOKINETICS

Metabolism: Liver (less extensive compared to testosterone). **Elimination:** $T_{1/2}$ =Longer compared to testosterone.

ASSESSMENT

Assess for breast/prostate carcinoma in males, cardiac/renal/hepatic disease, pregnancy/nursing status, other conditions where treatment is contraindicated/cautioned, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hypercalcemia, liver dysfunction, edema with/without CHF, prostatic hypertrophy/carcinoma in elderly, virilization in females, and other adverse reactions. Periodically monitor urine and serum calcium in breast cancer patients, Hgb, Hct, and LFTs. Assess bone age

of the wrist and hand every 6 months in males with delayed puberty.

PATIENT COUNSELING

Instruct to report to physician any of the following: too frequent or persistent erections of the penis (adult/adolescent males); hoarseness, acne, changes in menstrual period, more hair on the face (females); and N/V, changes in skin color or ankle swelling (all patients).

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT H



Lorazepam

(lorazepam) - Various

OTHER BRAND NAMES

Ativan (Biovail)

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Management of anxiety disorders or for short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms.

ADULT DOSAGE

Adults: Individualize dose, frequency, and duration. Anxiety: Initial: 2-3mg/day given bid or tid. Usual: 2-6mg/day in divided doses; take largest dose before hs. Increase dose gradually PRN; when higher dosage is indicated, increase pm dose before daytime doses. Dosage Range: 1-10mg/day. Insomnia: 2-4mg as a single dose qhs. Elderly/Debililitated: Initial: 1-2mg/day in divided doses; adjust PRN and as tolerated.

PEDIATRIC DOSAGE

Pediatrics: ≥12 yrs: Individualize dose, frequency, and duration. Anxiety: Initial: 2-3mg/day given bid or tid. Usual Range: 2-6mg/day in divided doses; take largest dose before hs. Increase dose gradually PRN; when higher dosage is indicated, increase pm dose before daytime doses. Dosage Range: 1-10mg/day. Insomnia: 2-4mg as a single dose qhs.

HOW SUPPLIED

Sol: 2mg/mL; Tab: (Ativan) 0.5mg, 1mg*, 2mg* *scored

CONTRAINDICATIONS

Acute narrow-angle glaucoma.

WARNINGS/PRECAUTIONS

Effectiveness in long-term use (>4 months) has not been assessed; prescribe for short periods only (eg, 2-4 weeks) and periodically reassess usefulness of drug. Continuous long-term use is not recommended. Preexisting depression may emerge or worsen; not for use with primary depressive disorder or psychosis. May lead to potentially fatal respiratory depression. May impair mental/physical abilities. Use may lead to physical and psychological dependence; increased risk with higher doses, longer term use, and in patients with history of alcoholism/drug abuse, or with significant personality disorders. Withdrawal symptoms reported; avoid abrupt d/c and follow a gradual dosage-tapering schedule after extended therapy. May develop tolerance to sedative effects. Paradoxical reactions reported; d/c if occur. May have abuse potential, especially with a history of drug and/or alcohol abuse. Possible suicide in patients with depression; do not use in such patients without adequate antidepressant therapy. Caution with compromised respiratory function (eg, chronic obstructive pulmonary disease, sleep apnea syndrome), impaired renal/hepatic function, hepatic encephalopathy, in elderly, and in debilitated patients. May worsen hepatic encephalopathy. Adjust dose with severe hepatic insufficiency; lower doses may be sufficient. Monitor frequently for symptoms of upper GI disease. Leukopenia and elevations of lactate dehydrogenase reported; perform periodic blood counts and LFTs with long-term therapy.

ADVERSE REACTIONS

Sedation, dizziness, weakness, unsteadiness.

DRUG INTERACTIONS

Increased CNS-depressant effects with other CNS depressants (eg, alcohol, barbiturates, antipsychotics, sedative/hypnotics, anxiolytics, antidepressants, narcotic analgesics, sedative antihistamines, anticonvulsants, anesthetics); may lead to potentially fatal respiratory depression. Concomitant use with clozapine may produce marked sedation, excessive salivation, hypotension, ataxia, delirium, and respiratory arrest. Increased plasma concentrations with valproate and more rapid onset or prolonged effect with probenecid; reduce dose by 50%. Decreased sedative effects with theophylline or aminophylline.

PREGNANCY

Not for use in pregnancy/nursing.

MECHANISM OF ACTION

Benzodiazepine; has a tranquilizing action on the CNS with no appreciable effect on the respiratory or cardiovascular systems.

PHARMACOKINETICS

Absorption: Readily absorbed. Absolute bioavailability (90%); (2mg) C_{max} =20ng/mL; T_{max} =2 hrs. **Distribution:** Plasma protein binding (85%); found in breast milk. **Metabolism:** Glucuronidation. **Elimination:** Urine; $T_{1/2}$ =12 hrs.

ASSESSMENT

Assess for acute narrow-angle glaucoma, primary depressive disorder, psychosis, personality disorders, compromised respiratory function, impaired renal/hepatic function, hepatic encephalopathy, history of alcohol/drug abuse, previous hypersensitivity to the drug, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for respiratory depression, physical/psychological dependence, withdrawal symptoms, tolerance, abuse, suicidal thinking, paradoxical reactions, symptoms of upper GI disease, and emergence/worsening of depression. Reassess usefulness of drug periodically. Monitor elderly/debilitated frequently and addiction-prone individuals carefully. Perform periodic blood counts and LFTs with long-term therapy.

PATIENT COUNSELING

Inform that psychological/physical dependence may occur; instruct to consult physician before increasing dose or abruptly d/c drug. Warn not to operate dangerous machinery or motor vehicles and that tolerance for alcohol and other CNS depressants will be diminished. Advise to consult physician if become pregnant.

ADMINISTRATION/STORAGE

Administration: Oral route. (Sol) Dispense only in the bottle and only with the calibrated dropper provided. Mix with liquid or semi-solid food. Refer to PI for further instructions. **Storage:** (Sol) 2-8°C (36-46°F). Protect from light. Discard opened bottle after 90 days. (Tab) 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT I



Cesamet

(nabilone) - Meda

THERAPEUTIC CLASS

Cannabinoid

INDICATIONS

Treatment of N/V associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

ADULT DOSAGE

Adults: Night Before Chemotherapy: May give 1 or 2 mg. Day of Chemotherapy: Start with a lower dose 1-3 hrs before the chemotherapy agent. Titrate: Increase PRN; may be given bid or tid during the entire course of each chemotherapy cycle and, PRN, for 48 hrs after the last dose of each cycle. Usual: 1 or 2mg bid. Max: 6mg/day in divided doses tid. Elderly: Start at the low end of dosing range.

HOW SUPPLIED

Cap: 1mg

WARNINGS/PRECAUTIONS

Not intended for use on PRN basis or as 1st antiemetic product prescribed. High potential for abuse. Adverse psychiatric reactions can persist for 48-72 hrs following d/c of treatment. May cause dizziness, drowsiness, euphoria, ataxia, anxiety, disorientation, depression, hallucinations, psychosis, tachycardia, and orthostatic hypotension. May alter mental states; keep patients under adult supervision, especially during initial use and dose adjustments. May impair mental/physical abilities. May elevate supine and standing HR and may cause postural hypotension. Caution with HTN, heart disease, elderly, current or previous psychiatric disorders (eg, manic depressive illness, depression, schizophrenia) and history of substance abuse. Caution in pregnant/nursing patients and pediatrics.

ADVERSE REACTIONS

Drowsiness, vertigo, dizziness, dry mouth, euphoria, ataxia, headache, concentration difficulties, dysphoria, sleep/visual disturbance, asthenia, anorexia, depression, hypotension.

DRUG INTERACTIONS

Avoid with alcohol, sedatives, hypnotics, or other psychoactive drugs. Additive HTN, tachycardia, and possible cardiotoxicity with sympathomimetics (eg, amphetamines, cocaine). Additive or super-additive tachycardia, and drowsiness with anticholinergics (eg, atropine, scopolamine, antihistamines). Additive tachycardia, HTN, and drowsiness with TCAs (eg, amitriptyline, amoxapine, desipramine). Additive drowsiness and CNS depression with CNS depressants (eg, barbiturates, benzodiazepines, ethanol, lithium, opioids, buspirone, antihistamines, muscle relaxants). May result in hypomanic reaction with disulfiram and fluoxetine in patients who smoked marijuana. May decrease clearance of antipyrine and barbiturates. May increase theophylline metabolism in patients who smoked marijuana/tobacco. Cross-tolerance and mutual potentiation with opioids. Enhanced tetrahydrocannabinol effects with naltrexone. Increase in the positive subjective mood effects of smoked marijuana with alcohol. Impaired psychomotor function with diazepam. May displace highly protein-bound drugs; monitor for dose requirement changes.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Cannabinoid; interacts with the cannabinoid receptor system, CB (1) receptor, which has been discovered in neural tissues.

PHARMACOKINETICS

Absorption: Complete, $C_{max}=2\text{ng/mL}$, $T_{max}=2$ hrs. **Distribution:** $V_d=12.5\text{L/kg}$. **Metabolism:** Liver (extensive) via reduction and oxidation; CYP450. **Elimination:** Feces (60%), urine (24%); $T_{1/2}=2$ hrs (identified metabolites), 35 hrs (unidentified metabolites).

ASSESSMENT

Assess for history of hypersensitivity to cannabinoids, heart disease, HTN, previous/current psychiatric disorders, history of substance abuse (eg, alcohol abuse/dependence, marijuana use), pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for adverse psychiatric reactions or unmasking of symptoms of psychiatric disorders, signs/symptoms of CNS effects (eg, dizziness, drowsiness, euphoria, ataxia, anxiety, disorientation, depression, hallucinations, and psychosis), postural hypotension. Monitor BP and HR. Monitor for signs of excessive use, abuse, and misuse. Monitor for signs and symptoms of hypersensitivity and other adverse reactions.

PATIENT COUNSELING

Inform about additive CNS depression effect if taken concomitantly with alcohol or other CNS depressants (eg, benzodiazepines, barbiturates); advise to avoid this combination. Advise not to engage in hazardous activity (eg, operating machinery/driving). Inform of possible mood changes and other adverse behavioral effects that may occur during therapy. Instruct to remain under supervision of responsible adult during treatment.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT J



Clonazepam

(clonazepam) - Various

OTHER BRAND NAMES

Klonopin (Genentech)

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Adjunct or monotherapy in the treatment of Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. May be useful in patients with absence seizures (petit mal) who have failed to respond to succinimides. Treatment of panic disorder with or without agoraphobia.

ADULT DOSAGE

Adults: Seizure Disorders: Initial: Not to exceed 1.5mg/day divided into three doses. Titrate: May increase in increments of 0.5-1mg every 3 days until seizures are controlled or until side effects preclude any further increase. Maint: Individualize dose. Max: 20mg/day. Panic Disorder: Initial: 0.25mg bid. Titrate: May increase to target dose of 1mg/day after 3 days; for some, may increase in increments of 0.125-0.25mg bid every 3 days until panic disorder is controlled or until side effects make further increases undesired. Max: 4mg/day. D/C: Decrease by 0.125mg bid every 3 days. Elderly: Start at low end of dosing range.

PEDIATRIC DOSAGE

Pediatrics: Seizure Disorders: ≤ 10 yrs or ≤ 30 kg: Initial: 0.01-0.03mg/kg/day up to 0.05mg/kg/day given in two or three divided doses. Titrate: May increase by no more than 0.25-0.5mg every 3 days until maintenance dose is reached, unless seizures are controlled or until side effects preclude further increase. Maint: 0.1-0.2mg/kg/day divided into three doses.

HOW SUPPLIED

Tab: (Klonopin) 0.5mg*, 1mg, 2mg; Tab, Disintegrating (ODT): 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg *scored

CONTRAINDICATIONS

Significant liver disease, untreated open-angle glaucoma, acute narrow-angle glaucoma.

WARNINGS/PRECAUTIONS

May impair mental/physical abilities. May increase risk of suicidal thoughts or behavior; monitor for the emergence of worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Caution with use in pregnancy and women of childbearing potential; may increase risk of congenital malformations. Avoid use during the 1st trimester of pregnancy. May increase incidence or precipitate the onset of generalized tonic-clonic seizures in patients in whom several different types of seizure disorders coexist; addition of appropriate anticonvulsants or increase in their dosages may be required. Withdrawal symptoms reported after d/c of therapy. Avoid abrupt withdrawal; may precipitate status epilepticus. Caution with renal impairment. May produce an increase in salivation; caution with chronic respiratory diseases. Caution with addiction-prone individuals and elderly. (ODT) Contains phenylalanine.

ADVERSE REACTIONS

CNS depression, ataxia, drowsiness, abnormal coordination, depression, behavior problems, dizziness, upper respiratory tract infection, memory disturbance, dysmenorrhea, fatigue, influenza, nervousness, sinusitis.

DRUG INTERACTIONS

Decreased serum levels with CYP450 inducers (eg, phenytoin, carbamazepine, phenobarbital), and propantheline. Caution with CYP3A inhibitors (eg, oral antifungals). Alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, phenothiazines, thioxanthene and butyrophenone antipsychotics, MAOIs, TCAs, other anticonvulsant drugs, and other CNS depressant drugs may potentiate CNS-depressant effects. May produce absence status with valproic acid.

PREGNANCY

Category D, not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; has not been established. Suspected to be related to its ability to enhance activity of gamma-aminobutyric acid, the major inhibitory neurotransmitter in the CNS.

PHARMACOKINETICS

Absorption: Rapid and complete. Absolute bioavailability (90%); T_{max} =1-4 hrs. **Distribution:** Plasma protein binding (85%). **Metabolism:** Liver via CYP450 (including CYP3A), acetylation, hydroxylation, and glucuronidation. **Elimination:** Urine (<2% unchanged); $T_{1/2}$ =30-40 hrs.

ASSESSMENT

Assess for history of sensitivity to benzodiazepines, acute narrow-angle glaucoma, untreated open-angle glaucoma, liver/renal impairment, mental depression, history of drug or alcohol addiction, chronic respiratory diseases, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for CNS depression, emergence or worsening of depression, suicidal thoughts/behavior, unusual changes in mood or behavior, and worsening of seizures. Periodically monitor blood counts and LFTs during prolonged therapy. Upon withdrawal, monitor for withdrawal symptoms.

PATIENT COUNSELING

Instruct to take medication as prescribed. Inform that therapy may produce physical and psychological dependence; instruct to consult physician before either increasing the dose or abruptly discontinuing the drug. Caution about operating hazardous machinery, including automobiles. Counsel that drug may increase risk of suicidal thoughts/behavior and advise of need to be alert for the emergence/worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm. Advise to notify physician if patient becomes pregnant or intends to become pregnant during therapy. Advise not to breastfeed while on therapy. Advise to inform physician if taking, or planning to take any prescription or OTC drugs and to avoid alcohol while on therapy. (ODT) Inform that drug contains phenylalanine.

ADMINISTRATION/STORAGE

Administration: Oral route. ODT: 1) Peel back foil on blister. Do not push tablet through foil. 2) Using dry hands, remove tab and place it in mouth. Tab: Swallow whole with water. **Storage:** 20-25°C (68-77°F). (Klonopin) 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT K



Codeine Sulfate

(codeine sulfate) - Various

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Management of mild to moderately severe pain where the use of an opioid analgesic is appropriate.

ADULT DOSAGE

Adults: Individualize dose. Refer to PI for factors to consider when selecting an initial dose. Usual: 15-60mg (2.5-10mL) repeated up to q4h PRN. Max: 360mg/24 hrs. Titrate based upon the individual patient's response to the initial dose. Continue to reevaluate with special attention to the maintenance of pain control and side effects. Reassess the continued need for opioid analgesic use during chronic therapy, especially for non-cancer-related pain. Taper dose gradually. Specific CYP2D6 Ultra-Rapid Metabolizers/Nursing Mothers: Give the lowest effective dose for the shortest period of time. Renal/Hepatic Impairment: Start at lower dose or with longer dosing intervals and titrate slowly while monitoring for side effects. Elderly: Start at lower end of dosing range.

HOW SUPPLIED

Sol: 30mg/5mL [500mL]; Tab: 15mg*, 30mg*, 60mg* *scored

CONTRAINDICATIONS

Respiratory depression in the absence of resuscitative equipment, acute or severe bronchial asthma or hypercarbia, known or suspected paralytic ileus.

WARNINGS/PRECAUTIONS

Respiratory depression may occur; increased risk in elderly or debilitated patients and in those with conditions accompanied by hypoxia, hypercapnia, or upper airway obstruction. Caution when used postoperatively in patients with pulmonary disease or SOB, or with depressed ventilatory function. Use with extreme caution and consider alternative nonopioid analgesics with chronic obstructive pulmonary disease (COPD) or cor pulmonale, substantially decreased respiratory reserve (eg, severe kyphoscoliosis), hypoxia, hypercapnia, or preexisting respiratory depression. Contains codeine sulfate, an opioid agonist and Schedule II controlled substance, that is subject to misuse, abuse, or diversion. Respiratory depressant effects and the capacity to elevate CSF pressure may be markedly exaggerated in the presence of head injury, intracranial lesions, or preexisting increase in intracranial pressure; may obscure clinical course of patients head injuries. May cause severe hypotension when ability to maintain BP has been compromised by a depleted blood volume. May produce orthostatic hypotension and syncope in ambulatory patients. Caution with circulatory shock. Avoid with GI obstruction, especially paralytic ileus; may obscure diagnosis or clinical course with acute abdominal conditions. Chronic use may result in obstructive bowel disease, especially with intestinal motility disorder. May cause/aggravate constipation. Caution with biliary tract disease (eg, acute pancreatitis); may cause spasm of the sphincter of Oddi and diminish biliary and pancreatic secretions. Caution in patients with severe renal or hepatic impairment, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture, CNS depression, acute alcoholism, delirium tremens, and in elderly or debilitated. May aggravate convulsions in patients with convulsive disorders and may induce or aggravate seizures. Ultra-rapid metabolizers due to specific CYP2D6*2 x 2 genotype may experience overdose symptoms (eg, extreme sleepiness, confusion, shallow breathing). May impair mental/physical abilities. May elevate plasma amylase and lipase. Not recommended for use in women during and immediately prior to labor.

ADVERSE REACTIONS

Respiratory/circulatory depression, respiratory arrest, shock, cardiac arrest, drowsiness, lightheadedness, dizziness, sedation, SOB, N/V, sweating, constipation.

DRUG INTERACTIONS

May result in additive CNS/respiratory depression, hypotension, profound sedation, or coma when used with other opioids, illicit drugs, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (eg, sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, other tranquilizers, alcohol); use with caution and reduce dose when taking these agents. Avoid use with mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol); may reduce analgesic effect and/or may precipitate withdrawal symptoms. Anticholinergics or other medications with anticholinergic activity may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus. MAOIs or TCAs may increase the effect of either antidepressant or codeine. MAOIs markedly potentiate morphine sulfate (major metabolite); avoid use or within 14 days of stopping MAOIs. CYP3A4 inhibitors (eg, macrolide antibiotics [eg, erythromycin], azole-antifungal agents [eg, ketoconazole], protease inhibitors [eg, ritonavir] or CYP2D6 inhibitors (eg, certain cardiovascular drugs [eg, amiodarone, quinidine, polycyclic antidepressants]) may increase plasma concentration. CYP450 inducers (eg, rifampin, carbamazepine, phenytoin) may decrease plasma concentrations and may cause lack of efficacy or, possibly, development of abstinence syndrome in a patient who had developed physical dependence to codeine. Caution when initiating therapy with, currently taking, or discontinuing CYP450 inhibitors or CYP3A4 inducers if coadministration is necessary; evaluate patients at frequent intervals and consider dose adjustments until stable drug effects are achieved.

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Opioid analgesic; precise mechanism unknown. Specific CNS opiate receptors and endogenous compounds with morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression and perception of analgesic effects. Causes respiratory

depression, in part by a direct effect on the brainstem respiratory centers, and depresses cough reflex by direct effect on the cough center in the medulla.

PHARMACOKINETICS

Absorption: GI tract; T_{max} =60 min. **Distribution:** V_d =3-6L/kg; plasma protein binding (7-25%); crosses placenta, found in breast milk. **Metabolism:** Via UGT2B7 and 2B4, CYP2D6 and 3A4; conjugation, O- and N-demethylation; morphine sulfate (major metabolite) further metabolized to morphine-6-glucuronide (M6G). **Elimination:** Kidney (90%, 10% unchanged); $T_{1/2}$ =3 hrs.

ASSESSMENT

Assess for risk factors for and/or history of abuse, addiction, or diversion, general condition and medical status, opioid experience/tolerance, pain severity/type, previous opioid daily dose, potency, and type of prior analgesics used, respiratory depression, COPD or other respiratory complications, GI obstruction, paralytic ileus, renal/hepatic impairment, pregnancy/nursing status, possible drug interactions, and any other conditions where treatment is contraindicated or cautioned.

MONITORING

Monitor for respiratory depression, CSF pressure elevation, hypotension, orthostatic hypotension, syncope, occurrence/aggravation of constipation, aggravation of convulsions/seizures, tolerance, physical dependence, renal/hepatic function, and other adverse reactions. Reassess the continued need of therapy.

PATIENT COUNSELING

Advise to take only as directed and not to adjust dose without consulting a physician. Caution against performing hazardous tasks (eg, operating machinery/driving). Advise not to combine with alcohol or CNS depressants during therapy except by the orders of the prescribing physician. Inform that drug has potential for abuse; instruct not to share drug with others and to protect from theft. Advise to store in secure place out of the reach of children. Inform of the potential for severe constipation and other most common adverse events that may occur while on therapy. Advise patients who have genetic variation that overdose symptoms (eg, extreme sleepiness, confusion, shallow breathing) may occur. Instruct nursing mothers to monitor their infants for signs of morphine toxicity (eg, increased sleepiness, breastfeeding/breathing difficulties, limpness). Counsel on the importance of safely tapering the dose and inform that abrupt d/c may precipitate withdrawal symptoms. Instruct to notify physician if pregnant/plan to become pregnant before initiating or continuing therapy. (Sol) Instruct on how to measure and take the correct dose of sol.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** (Tab) 15-30°C (59-86°F); (Sol) 20-25°C (68-77°F); excursion permitted between 15-30°C (59-86°F). Protect from moisture and light.

EXHIBIT L



Depo-Testosterone

(testosterone cypionate) - Pharmacia & Upjohn

THERAPEUTIC CLASS

Androgen

INDICATIONS

Testosterone replacement in males with congenital or acquired primary hypogonadism or hypogonadotropic hypogonadism.

ADULT DOSAGE

Adults: Individualize dose. Give 50-400mg IM deep in the gluteal muscle every 2-4 weeks. Consider chronological and skeletal ages in determining initial dose and titration. Adjust according to response and adverse reactions.

PEDIATRIC DOSAGE

Pediatrics: ≥12 Yrs: Individualize dose. Give 50-400mg IM deep in the gluteal muscle every 2-4 weeks. Consider chronological and skeletal ages in determining initial dose and titration. Adjust according to response and adverse reactions.

HOW SUPPLIED

Inj: 100mg/mL [10mL], 200mg/mL [1mL, 10mL]

CONTRAINDICATIONS

Serious cardiac, hepatic or renal disease. Males with carcinoma of the breast or known or suspected carcinoma of the prostate gland. Women who are or may become pregnant.

WARNINGS/PRECAUTIONS

May cause hypercalcemia in immobilized patients; d/c if this occurs. May develop hepatic adenomas, hepatocellular carcinoma, and peliosis hepatis with prolonged use of high doses. Caution in elderly; increased risk of prostatic hypertrophy and prostatic carcinoma. May develop gynecomastia. May accelerate bone maturation without linear growth. D/C with appearance of acute urethral obstruction, priapism, excessive sexual stimulation, or oligospermia; restart at lower doses. Caution with BPH and males with delayed puberty. Do not use interchangeably with testosterone propionate, for enhancement of athletic performance, or as IV. Contains benzyl alcohol.

ADVERSE REACTIONS

Gynecomastia, excessive frequency/duration of penile erections, male pattern baldness, increased/decreased libido, oligospermia, hirsutism, acne, nausea, hypercholesterolemia, clotting factor suppression, polycythemia, altered LFTs, priapism, anxiety, depression.

DRUG INTERACTIONS

May increase sensitivity to oral anticoagulants. Increased levels of oxyphenbutazone. May decrease insulin requirements in diabetic patients.

PREGNANCY

Category X, not for use in nursing.

MECHANISM OF ACTION

Endogenous androgen; responsible for normal growth and development of male sex organs and for maintenance of secondary sex characteristics.

PHARMACOKINETICS

Metabolism: Liver. **Elimination:** Urine (90%), feces (6%); T_{1/2}=8 days.

ASSESSMENT

Assess males for known drug hypersensitivity, carcinoma of the breast, known or suspected carcinoma of the prostate gland, cardiac/hepatic/renal disease, delayed puberty, BPH, and possible drug interactions.

MONITORING

Periodically monitor Hgb and Hct. Monitor for signs/symptoms of hypersensitivity reactions, edema with/without congestive heart failure, gynecomastia, and hypercalcemia. Assess bone development every 6 months in males with delayed puberty.

PATIENT COUNSELING

Instruct to report to physician if N/V, changes in skin color, ankle swelling, or too frequent or persistent penile erections occur.

ADMINISTRATION/STORAGE

Administration: IM route. **Storage:** 20-25°C (68-77°F). Protect from light.

EXHIBIT M



Didrex

(benzphetamine hcl) - Pharmacia & Upjohn

THERAPEUTIC CLASS

Anorectic sympathomimetic amine

INDICATIONS

Management of exogenous obesity as a short-term (a few weeks) adjunct in a regimen of weight-reduction based on caloric restriction in patients with an initial BMI of $\geq 30\text{kg/m}^2$ who have not responded to appropriate weight reducing regimen (diet/exercise) alone.

ADULT DOSAGE

Adults: Individualize dose. Initial: 25-50mg qd. Increase in according to response. Usual: 25-50mg qd-tid. Elderly: Start at the low end of dosing range.

PEDIATRIC DOSAGE

Pediatrics: ≥ 12 yrs: Individualize dose. Initial: 25-50mg qd. Increase according to response. Usual: 25-50mg qd-tid.

HOW SUPPLIED

Tab: 50mg* *scored

CONTRAINDICATIONS

Advanced arteriosclerosis, symptomatic cardiovascular (CV) disease, moderate to severe HTN, agitated states, hyperthyroidism, glaucoma, history of drug abuse, concomitant CNS stimulant use, MAOI use concomitantly or within 14 days, pregnancy.

WARNINGS/PRECAUTIONS

May increase the risk of pulmonary HTN if used >3 months; d/c and evaluate for possible pulmonary HTN if exertional dyspnea, or unexplained angina pectoris, syncope, or lower extremity edema occur. Prolonged use or higher than recommended doses may contribute to the development of valvular heart disease; perform ECG during and after therapy to detect valvular disorders. Consider baseline cardiac evaluation should to detect pre-existing valvular heart diseases or pulmonary HTN prior to therapy. To limit unwarranted exposure and risks, continue treatment only if satisfactory weight loss occurs within the 1st 4 weeks of treatment. D/C if tolerance develops. Psychological disturbances reported with restrictive dietary regimen. Not recommended with heart murmur/valvular heart disease, severe HTN, symptomatic CV disease including arrhythmias, and those who used any anorectic agents within the prior year. Caution with mild HTN and in elderly. Not recommended in children <12 yrs.

ADVERSE REACTIONS

Palpitation, tachycardia, BP elevation, restlessness, dizziness, insomnia, headache, tremor, sweating, dry mouth, nausea, diarrhea, unpleasant taste, urticaria, altered libido.

DRUG INTERACTIONS

See Contraindications. Hypertensive crisis risk if used concomitantly or within 14 days of MAOIs. May potentiate TCAs. Avoid with other CNS stimulants. May decrease hypotensive effects of antihypertensives. Increased blood levels and decreased excretion of amphetamines when taken with urinary alkalinizing agents. Decreased blood levels and increased excretion of amphetamines when taken with urinary acidifying agents. May alter insulin requirements in diabetes mellitus (DM). Avoid with other anorectic agents (including prescribed, OTC, and herbal products). Use in combination with other anorectic drugs such as fenfluramine and dexfenfluramine may lead to valvular heart disease.

PREGNANCY

Category X, not for use in nursing.

MECHANISM OF ACTION

Anorectic sympathomimetic amine; not established as appetite suppressor; CNS stimulant.

PHARMACOKINETICS

Distribution: Found in breast milk.

ASSESSMENT

Assess for DM, advanced arteriosclerosis, symptomatic CV disease including arrhythmias, HTN, glaucoma, hyperthyroidism, agitated states, history of drug abuse, hypersensitivity or idiosyncrasy to sympathomimetic amines, pre-existing valvular heart disease or pulmonary HTN, patients with known heart murmur, use of any anorectic agents within the prior year, pregnancy/nursing status, and possible drug interactions. Perform baseline cardiac evaluation prior to treatment. Assess risk of serious adverse effects (eg, valvular heart disease/pulmonary HTN) against potential weight loss benefit.

MONITORING

Obtain baseline vital signs and weight. Monitor for weight loss and continue treatment only if satisfactory weight loss occurs within the 1st 4 weeks.

Monitor for signs/symptoms of HTN, psychological disturbances, hypersensitivity reactions, and for tolerance. Monitor for valvular heart disease and pulmonary HTN (eg, exertional dyspnea, angina pectoris, syncope, lower extremity edema). Perform ECG during and after treatment.

PATIENT COUNSELING

Advise patients on possible impairment of physical abilities; caution should be used when engaging in potentially hazardous activities. Caution that tolerance may develop; do not exceed recommended dosage, rather d/c therapy. Advise to seek medical attention if symptoms of hypersensitivity reactions or HTN occur. Counsel to avoid if patient is pregnant or may become pregnant due to fetal harm. May be desirable to avoid late afternoon administration.

ADMINISTRATION/STORAGE

Administration: Oral route. If single daily dose, preferably give in midmorning or midafternoon according to eating habits. **Storage:** 20-25°C (68-77°F).

EXHIBIT N



Librium

(chlordiazepoxide hcl) - Valeant

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Management of anxiety disorders and short-term relief of anxiety symptoms, withdrawal symptoms of acute alcoholism, and preoperative apprehension and anxiety.

ADULT DOSAGE

Adults: Individualize dose. Mild-Moderate Anxiety: 5-10mg tid-qid. Severe Anxiety: 20-25mg tid-qid. Alcohol Withdrawal: 50-100mg; repeat until agitation controlled. Max: 300mg/day. Preoperative Anxiety: 5-10mg tid-qid on days prior to surgery. Elderly/Debililitated: 5mg bid-qid.

PEDIATRIC DOSAGE

Pediatrics: ≥6 yrs: Individualize dose. Usual: 5mg bid-qid. May increase to 10mg bid-tid.

HOW SUPPLIED

Cap: 5mg, 10mg, 25mg

WARNINGS/PRECAUTIONS

May impair mental/physical abilities, including mental alertness in children. Risk of congenital malformations during 1st trimester of pregnancy; avoid use. Paradoxical reactions (eg, excitement, stimulation, and acute rage) reported in psychiatric patients, and in hyperactive aggressive pediatric patients. Caution in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present. Caution with porphyria, renal or hepatic dysfunction. Use lowest effective dose in elderly and debilitated patients. Avoid abrupt withdrawal after extended therapy; withdrawal symptoms reported following d/c.

ADVERSE REACTIONS

Drowsiness, ataxia, confusion, skin eruptions, edema, nausea, constipation, extrapyramidal symptoms, libido changes, EEG changes.

DRUG INTERACTIONS

Additive effects with CNS depressants and alcohol. Coadministration with other psychotropic agents not recommended; caution with MAOIs and phenothiazines. Altered coagulation effects reported with oral anticoagulants.

PREGNANCY

Not for use in pregnancy, safety not known in nursing.

MECHANISM OF ACTION

Benzodiazepine; not established. Has antianxiety, sedative, appetite stimulating, and weak analgesic actions; blocks EEG arousal from stimulation of brain stem reticular formation.

PHARMACOKINETICS

Elimination: Urine (1-2% unchanged, 3-6% conjugates); $T_{1/2}$ =24-48 hrs.

ASSESSMENT

Assess for pregnancy status, hepatic/renal function, and possible drug interactions.

MONITORING

Monitor elderly/debililitated patients for ataxia and oversedation, drowsiness, confusion. Monitor for paradoxical reactions in psychiatric patients and in hyperactive aggressive pediatric patients. Periodic blood counts and LFTs are advisable when treatment is protracted. Monitor for signs of impending depression or any suicidal tendencies.

PATIENT COUNSELING

Inform that psychological/physical dependence may occur; consult physician before increasing dose or abruptly d/c. Advise to notify physician if become pregnant during therapy or plan to become pregnant. May impair mental/physical abilities; caution while operating machinery/driving. May impair mental alertness in children. Avoid alcohol and other CNS depressant drugs.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT O



Lunesta

(eszopiclone) - Sunovion

THERAPEUTIC CLASS

Nonbenzodiazepine hypnotic agent

INDICATIONS

Treatment of insomnia.

ADULT DOSAGE

Adults: Individualize dose. Initial: 2mg immediately before hs; may be initiated at 3mg if clinically indicated. Titrate: May be raised to 3mg if clinically indicated. Elderly: Difficulty Falling Asleep: Initial: 1mg immediately before hs. Titrate: May increase to 2mg if clinically indicated. Difficulty Staying Asleep: Usual: 2mg immediately before hs. Severe Hepatic Impairment: Initial: 1mg. Concomitant Potent CYP3A4 Inhibitors: Initial: Do not exceed 1mg. Titrate: May be raised to 2mg, if needed. Concomitant CNS Depressants: Dosage adjustment may be necessary.

HOW SUPPLIED

Tab: 1mg, 2mg, 3mg

WARNINGS/PRECAUTIONS

Initiate only after careful evaluation; failure of insomnia to remit after 7-10 days of treatment may indicate presence of a primary psychiatric and/or medical illness. Use lowest effective dose, especially in elderly. Severe anaphylactic/anaphylactoid reactions reported; do not rechallenge if angioedema develops. Abnormal thinking and behavioral changes (eg, bizarre behavior, agitation, hallucinations, depersonalization) reported. Amnesia and other neuropsychiatric symptoms may occur unpredictably. Worsening of depression, including suicidal thoughts and actions, reported in primarily depressed patients. Complex behaviors (eg, sleep-driving) reported; consider discontinuation if a sleep-driving episode occurs. Withdrawal signs/symptoms reported following rapid dose decrease or abrupt discontinuation. May impair mental/physical abilities. Should be taken immediately before hs; taking medications while still up and about may result in short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness. Caution with severe hepatic impairment, elderly/debilitated patients, patients with diseases/conditions that could affect metabolism/hemodynamic responses, compromised respiratory function, history of alcohol/drug abuse, history of psychiatric disorders, and in patients exhibiting signs and symptoms of depression.

ADVERSE REACTIONS

Headache, unpleasant taste, somnolence, dry mouth, dizziness, infection, rash, pain, N/V, diarrhea, hallucinations, dyspepsia, nervousness, depression, anxiety.

DRUG INTERACTIONS

Increased risk of complex behaviors with alcohol and other CNS depressants. May produce additive CNS-depressant effects with other psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs that produce CNS depression. Avoid with alcohol. Decreased exposure and effects with CYP3A4 inducers (eg, rifampicin). Increased exposure with ketoconazole and other strong CYP3A4 inhibitors (eg, itraconazole, clarithromycin, nefazodone, troleandomycin, ritonavir, nelfinavir); dose reduction of eszopiclone is needed. Decreased digit symbol substitution test scores with olanzapine.

PREGNANCY

Category C, safety not known in nursing.

MECHANISM OF ACTION

Nonbenzodiazepine hypnotic agent; not established. Believed to result from its interaction with GABA-receptor complexes at binding domains located close to or allosterically coupled to benzodiazepine receptors.

PHARMACOKINETICS

Absorption: Rapid. $T_{max}=1$ hr. **Distribution:** Plasma protein binding (52-59%). **Metabolism:** Liver (extensive) via oxidation and demethylation pathways by CYP3A4 and CYP2E1. (S)-zopiclone-N-oxide and (S)-N-desmethyl zopiclone (primary metabolites). **Elimination:** Urine (75% metabolites, <10% parent drug); $T_{1/2}=6$ hrs.

ASSESSMENT

Assess for psychiatric or physical illness, depression, severe hepatic impairment, diseases/conditions that could affect metabolism/hemodynamic responses, compromised respiratory function, history of alcohol/drug abuse, history of psychiatric disorders, drug hypersensitivity, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for complex behaviors, anaphylactic/anaphylactoid reactions, emergence of any new behavioral signs/symptoms, withdrawal symptoms, abnormal thinking, behavioral changes, and other adverse reactions.

PATIENT COUNSELING

Inform of the risks and benefits of therapy. Advise to seek medical attention immediately if any adverse reactions (eg, severe anaphylactic/anaphylactoid reactions, sleep-driving, and other complex behaviors) develop. Instruct to take immediately prior to hs and only if 8 hrs of sleep can be dedicated. Advise to consult with physician if patients have history of depression, mental illness, suicidal thoughts, history of drug/alcohol abuse, or have liver disease. Instruct to not take with alcohol or with other sedating medications. Advise to contact physician if pregnant, plan to become pregnant, or if nursing.

ADMINISTRATION/STORAGE

Administration: Oral route. Taking with or immediately after a heavy, high-fat meal results in slower absorption and reduced effect on sleep latency.
Storage: 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT P



Marinol

(dronabinol) - Abbott

THERAPEUTIC CLASS

Cannabinoid

INDICATIONS

Treatment of anorexia associated with weight loss in AIDS patients and N/V associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

ADULT DOSAGE

Adults: Individualize dose. Appetite Stimulation: Initial: 2.5mg bid before lunch and supper. Titrate: Reduce dose to 2.5mg qpm or qhs if 5mg/day dose is intolerable. Max: 20mg/day in divided doses. Antiemetic: Initial: 5mg/m² 1-3 hrs before chemotherapy, then q2-4h after chemotherapy, for a total of 4-6 doses/day. Titrate: May increase dose by 2.5mg/m² increments. Max: 15mg/m²/dose.

PEDIATRIC DOSAGE

Pediatrics: Antiemetic: Initial: 5mg/m² 1-3 hrs before chemotherapy, then q2-4h after chemotherapy, for a total of 4-6 doses/day. Titrate: May increase dose by 2.5mg/m² increments. Max: 15mg/m²/dose.

HOW SUPPLIED

Cap: 2.5mg, 5mg, 10mg

CONTRAINDICATIONS

Allergy to sesame oil.

WARNINGS/PRECAUTIONS

May impair mental/physical abilities. Seizure and seizure-like activity reported; d/c immediately if seizures develop. Caution with history of seizure disorders, substance abuse, and cardiac disorders due to occasional hypotension, possible HTN, syncope, or tachycardia. Caution in patients with mania, depression, or schizophrenia; exacerbation of these illnesses may occur. Caution in elderly (particularly those with dementia), pregnancy, nursing, and pediatrics.

ADVERSE REACTIONS

Abdominal pain, N/V, dizziness, euphoria, paranoid reaction, somnolence, abnormal thinking.

DRUG INTERACTIONS

May displace highly protein-bound drugs; dose requirement changes may be needed. Additive or synergistic CNS effects with sedatives, hypnotics, or other psychoactive drugs. Additive HTN, tachycardia, and possible cardiotoxicity with sympathomimetics (eg, amphetamines, cocaine). Additive or super-additive tachycardia, and drowsiness with anticholinergics (eg, atropine, scopolamine, antihistamines). Additive tachycardia, HTN, and drowsiness with TCAs (eg, amitriptyline, amoxapine, desipramine). Additive drowsiness and CNS depression with CNS depressants (eg, barbiturates, benzodiazepines, ethanol, lithium, opioids, buspirone, antihistamines, muscle relaxants). May result in hypomanic reaction with disulfiram and fluoxetine in patients who smoked marijuana. May decrease clearance of antipyrine and barbiturates. May increase theophylline metabolism in patients who smoked marijuana/tobacco.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Cannabinoid; has complex effects on the CNS, including central sympathomimetic activity.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different pharmacokinetic parameters. **Distribution:** V_d=10L/kg; plasma protein binding (97%); found in breast milk. **Metabolism:** Liver via microsomal hydroxylation; 11-OH-delta-9-THC (active metabolite). **Elimination:** Urine (10-15%), bile/feces (50%, <5% unchanged); T_{1/2}=25-36 hrs.

ASSESSMENT

Assess for history of hypersensitivity to the drug and sesame oil, history of seizure disorders, substance abuse (including alcohol abuse/dependence), cardiac disorders, mania, depression, schizophrenia, pregnancy/nursing status, hepatic/renal impairment, and possible drug interactions.

MONITORING

Monitor for psychiatric illness exacerbation, abdominal pain, N/V, dizziness, euphoria, paranoid reaction, somnolence, abnormal thinking, hypotension or HTN, syncope, tachycardia, for psychological and physiological dependence, and other adverse reactions.

PATIENT COUNSELING

Inform about additive CNS depression effect if taken concomitantly with alcohol or other CNS depressants (eg, benzodiazepines, barbiturates). Advise to use caution while performing hazardous tasks (eg, operating machinery/driving) until effect is well-tolerated. Inform of mood changes and other behavioral effects that may occur during therapy. Advise that patients must be under constant supervision of a responsible adult during initial use and following dosage adjustments. Instruct to immediately report to physician any adverse effects and notify if pregnant or breastfeeding.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 8-15°C (46-59°F). Protect from freezing.

EXHIBIT Q



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Meperidine

(meperidine hcl) - Roxane

OTHER BRAND NAMES

Demerol (Sanofi-Aventis)

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Relief of moderate to severe pain.

ADULT DOSAGE

Adults: Usual: 50-150mg q3-4h PRN. Concomitant Phenothiazines/Other Tranquilizers: Reduce dose by 25-50%.

PEDIATRIC DOSAGE

Pediatrics: Usual: 1.1-1.8mg/kg, up to the adult dose, q3-4h PRN. Concomitant Phenothiazines/Other Tranquilizers: Reduce dose by 25-50%.

HOW SUPPLIED

Sol: 50mg/5mL; Tab: 50mg*, 100mg*; (Demerol) Tab: 50mg*, 100mg *scored

CONTRAINDICATIONS

During or within 14 days of MAOI use. (Demerol) Severe respiratory insufficiency.

WARNINGS/PRECAUTIONS

May be habit forming. Not for chronic pain; may increase risk of toxicity (eg, seizures) with prolonged use. Respiratory depressant effects and elevation of CSF pressure may be exaggerated in the presence of head injury, other intracranial lesions, or preexisting increase in intracranial pressure. May obscure diagnosis or clinical course of head injuries or acute abdominal conditions. Extreme caution with acute asthmatic attack, chronic obstructive pulmonary disease or cor pulmonale, or other respiratory conditions. May cause severe hypotension in postoperative patients or individuals whose ability to maintain BP has been compromised by depleted blood volume. May impair mental/physical abilities. May produce orthostatic hypotension in ambulatory patients. Not recommended during labor. Caution in elderly, debilitated, patients with atrial flutter or other supraventricular tachycardias, and other special risk patients; refer to PI. May aggravate preexisting convulsions. Caution with alcoholism or other drug dependencies; may develop tolerance, dependence, addiction, or abuse. Avoid abrupt d/c.

ADVERSE REACTIONS

Lightheadedness, dizziness, sedation, N/V, sweating, respiratory/circulatory depression.

DRUG INTERACTIONS

See Contraindications. Additive effects with alcohol, other opioids, or illicit drugs that cause CNS depression. Caution and consider dose reduction with other CNS depressants (eg, sedatives or hypnotics, general anesthetics, phenothiazines, other tranquilizers, alcohol); may result in respiratory depression, hypotension, profound sedation, or coma. Caution with agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol, buprenorphine); may reduce the analgesic effect and/or precipitate withdrawal symptoms. Acyclovir may increase levels. Cimetidine may reduce clearance and V_d; caution with coadministration. Phenytoin may enhance hepatic metabolism; use caution. Avoid with ritonavir; may increase levels of active metabolite. May enhance neuromuscular-blocking action of skeletal muscle relaxants. May result in severe hypotension with phenothiazines or certain anesthetics.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Narcotic analgesic; produces actions similar to morphine most prominently involving the CNS and organs composed of smooth muscle. Produces analgesic and sedative effects.

PHARMACOKINETICS

Metabolism: Liver; normeperidine (metabolite). **Distribution:** Crosses placental barrier; found in breast milk.

ASSESSMENT

Assess for intensity/type of pain, patient's general condition and medical status, any other conditions where treatment is contraindicated or cautioned, renal/hepatic function, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of tolerance or dependence, misuse or abuse, increase in CSF pressure, hypotension, respiratory depression, convulsions, and toxicity.

PATIENT COUNSELING

Advise to report pain or adverse events occurring during treatment. Instruct not to adjust dose or abruptly d/c therapy without consulting physician. Counsel that drug may impair mental and/or physical ability required for driving, operating heavy machinery, or other potentially hazardous tasks. Instruct not to drink alcohol or take other CNS depressants (eg, sleep aids, tranquilizers). Advise women who become or are planning to become pregnant about the effects of the drug in pregnancy. Inform that medication has potential for drug abuse; counsel to protect from theft and use by anyone other than the prescribed patient. Instruct to keep medication in a secure place and flush unused tab if no longer needed.

ADMINISTRATION/STORAGE

Administration: Oral route. (Sol) Take each dose in 1/2 glass of water. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT R



Methadose

(methadone hcl) - Mallinckrodt

BOXED WARNING

Deaths due to cardiac and respiratory effects reported during initiation and conversion from other opioid agonists. Respiratory depression and QT prolongation observed. Only certified/approved opioid treatment programs can dispense oral methadone for treatment of narcotic addiction. Use as analgesic should be initiated only if benefits outweigh risks. (Powder) For oral administration only and must be used in the preparation of a liquid by dissolving powder in an appropriate vehicle. Preparation must not be injected.

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Detoxification and maintenance treatment of opioid addiction (heroin or other morphine-like drugs) in conjunction with appropriate social and medical services. (Tab) Treatment of moderate to severe pain not responsive to non-narcotic analgesics.

ADULT DOSAGE

Adults: Detoxification: Initial/Induction: 20-30mg/day. Titrate: Give 5-10mg 2-4 hrs later if needed. Max: 40mg on first day. Adjust dose to control withdrawal symptoms over first week. Short-Term Detoxification: Titrate to 40mg/day given in divided doses to achieve adequate stabilizing level. Stabilization can continue for 2-3 days, then decrease dose every 1-2 days depending on symptoms. Maint: Titrate to a dose at which symptoms are prevented for 24 hrs. Usual: 80-120mg/day. Medically Supervised Withdrawal After a Period of Maintenance Treatment: Dose reductions should be <10% of established tolerance or maintenance dose, and 10- to 14-day intervals should elapse between dose reductions. Pregnancy: May increase dose or decrease dosing interval. (Tab) Pain in Opioid Nontolerant: Initial: 2.5-10mg q8-12h, slowly titrated to effect. Conversion From Parenteral: Use a 1:2 dose ratio parenteral to oral. Switching From Other Chronic Opioids: Use caution; see PI for dosing details.

HOW SUPPLIED

Oral Concentrate: 10mg/mL; Powder (generic): 50g, 100g, 500g, 1kg; Tab: 5mg*, 10mg*; Tab, Dispersible: 40mg *scored

CONTRAINDICATIONS

In any situation where opioids are contraindicated, such as respiratory depression (in the absence of resuscitative equipment or in unmonitored settings), acute bronchial asthma or hypercarbia, and paralytic ileus.

WARNINGS/PRECAUTIONS

Can cause respiratory depression and elevate CSF pressure; caution with decreased respiratory reserve, hypoxia, hypercapnia, head injuries, other intracranial lesions or a preexisting increase in intracranial pressure (ICP). Cases of QT interval prolongation and serious arrhythmia observed; caution in patients with risk of prolonged QT interval and evaluate for risk factors. Caution in elderly. Caution in patients with severe hepatic/renal impairment, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture. Risk of tolerance, dependence, and abuse. May obscure the diagnosis or clinical course of acute abdominal conditions. May impair mental/physical abilities. Patients tolerant to other opioids may be incompletely tolerant to methadone. Infants born to opioid-dependent mothers may exhibit respiratory difficulties and withdrawal symptoms. May produce hypotension.

ADVERSE REACTIONS

Lightheadedness, dizziness, sedation, sweating, N/V.

DRUG INTERACTIONS

Inhibitors and inducers of CYP3A4, CYP2B6, CYP2C19, CYP2C9, and CYP2D6 may alter metabolism and effects. Opioid antagonists, mixed agonist/antagonists, and partial agonists may precipitate withdrawal symptoms. Concomitant use with other opioid analgesics, general anesthetics, phenothiazines, tranquilizers, sedative-hypnotics, or other CNS depressants may cause respiratory depression, hypotension, profound sedation, or coma. Deaths reported when abused in conjunction with benzodiazepines. Caution with drugs that may prolong QT interval. MAOIs may cause severe reactions. May increase levels of desipramine. Abacavir, amprenavir, efavirenz, nelfinavir, nevirapine, ritonavir, lopinavir + ritonavir (combination) may increase clearance or decrease levels. May decrease levels of didanosine and stavudine. May increase area under the curve of zidovudine.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Synthetic opioid analgesic; μ -agonist. Produces actions similar to morphine; acts on CNS and organs composed of smooth muscle. May also act as an N-methyl-D-aspartate (NMDA) receptor antagonist.

PHARMACOKINETICS

Absorption: Bioavailability (36-100%); C_{max} =124-1255ng/mL; T_{max} =1-7.5 hrs. **Distribution:** V_d =1-8L/kg; plasma protein binding (85-90%); found in breast milk and umbilical cord plasma. **Metabolism:** Hepatic N-demethylation; CYP3A4, 2B6, 2C19 (major); 2C9, 2D6 (minor). **Elimination:** Urine, feces; $T_{1/2}$ =7-59 hrs; (Tab) $T_{1/2}$ =8-59 hrs.

ASSESSMENT

Assess for respiratory status, history of acute bronchial asthma or chronic obstructive pulmonary disease, CNS depression, cardiac conduction abnormalities, increased ICP, acute abdominal conditions, volume depletion, hepatic/renal impairment, or any other conditions where treatment is contraindicated or cautioned. Assess hypersensitivity to drug, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, QT prolongation and arrhythmias, misuse or abuse of medication, physical dependence and tolerance, withdrawal symptoms, elevations in CSF pressure, orthostatic hypotension, and hypersensitivity reactions.

PATIENT COUNSELING

Inform that medication may impair mental/physical abilities; use caution when performing hazardous tasks (eg, operating machinery/driving). Advise to avoid using alcohol and other CNS depressants. Instruct to seek immediate medical care if signs/symptoms of arrhythmia (eg, palpitations, dizziness, syncope) or difficulty in breathing develops. Inform that orthostatic hypotension may occur. Instruct to keep out of reach of children. Warn to avoid abrupt withdrawal; taper dosing with medical supervision. Inform patients treated for opioid dependence that d/c may lead to relapse of illicit drug use. Educate about potential for abuse and to protect from theft. Reassure that dose of methadone will "hold" for longer periods of time as treatment progresses after initiation.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT S



Morphine

(morphine sulfate) - Various

BOXED WARNING

Oral sol is available in 10mg/5mL, 20mg/5mL, and 100mg/5mL concentrations. The 100mg/5mL (20mg/mL) concentration is indicated for use in opioid-tolerant patients only. Use caution when prescribing and administering to avoid dosing errors due to confusion between different concentrations and between mg and mL, which could result in accidental overdose and death. Ensure the proper dose is communicated and dispensed. Keep out of reach of children. Seek emergency medical help immediately in case of accidental ingestion.

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Relief of moderate to severe acute and chronic pain where use of an opioid analgesic is appropriate. (Sol, 100mg/5mL) Relief of moderate to severe acute and chronic pain in opioid-tolerant patients.

ADULT DOSAGE

Adults: Individualize dose. Opioid-Naive Patients: Initial: 10-20mg (sol) or 15-30mg (tab) q4h PRN for pain. Titrate based upon the individual patient's response to the initial dose. Conversion from Parenteral to PO Formulation: Anywhere from 3-6mg PO dose may be required to provide pain relief equivalent to 1mg parenteral dose. Conversion from Parenteral PO Non-Morphine Opioids to PO Morphine: Close observation and dose adjustment is required. Refer to published relative potency information. Conversion from Controlled-Release PO Formulation to PO Formulation: Dose adjustment with close observation is necessary. Maint: Continue to reevaluate with special attention to the maint of pain control and side effects. Periodically reassess the continued need for opioid analgesic use during chronic use especially for non-cancer-related pain (or pain associated with other terminal illness). Taper dose gradually. Elderly: Start at lower end of dosing range.

HOW SUPPLIED

Sol: 10mg/5mL [100mL, 500mL], 20mg/5mL [100mL, 500mL], 100mg/5mL [30mL, 120mL]; Tab: 15mg*, 30mg* *scored

CONTRAINDICATIONS

Respiratory depression in absence of resuscitative equipment, acute or severe bronchial asthma or hypercarbia, has or suspected of having paralytic ileus.

WARNINGS/PRECAUTIONS

Increased risk of respiratory depression in elderly or debilitated patients and in those with conditions accompanied by hypoxia, hypercapnia, or upper airway obstruction. Caution and consider alternative nonopioid analgesics with chronic obstructive pulmonary disease or cor pulmonale, substantially decreased respiratory reserve (eg, severe kyphoscoliosis), hypoxia, hypercapnia, or preexisting respiratory depression. Contains morphine sulfate, a Schedule II controlled substance, that has a high potential for abuse and is subject to misuse, abuse, or diversion. The possible respiratory depressant effects and the potential to elevate CSF pressure may be markedly exaggerated in the presence of head injury, intracranial lesions, or preexisting increase in intracranial pressure (ICP); may obscure neurologic signs of further increased ICP in patients with head injuries. May cause orthostatic hypotension and syncope in ambulatory patients. May cause severe hypotension when ability to maintain BP has been compromised by a depleted blood volume. Caution with circulatory shock. Avoid with GI obstruction, especially paralytic ileus; may obscure diagnosis or clinical course with acute abdominal conditions. Caution with biliary tract disease, including acute pancreatitis; may cause spasm of the sphincter of Oddi and diminish biliary and pancreatic secretions. Caution with and reduce dose in patients with severe renal or hepatic impairment, Addison's disease, hypothyroidism, prostatic hypertrophy, or urethral stricture, and in elderly or debilitated. Caution with CNS depression, toxic psychosis, acute alcoholism, and delirium tremens. May aggravate convulsions in patients with convulsive disorders and may induce seizures. May impair mental/physical abilities.

ADVERSE REACTIONS

Respiratory depression, apnea, circulatory depression, respiratory arrest, shock, cardiac arrest, lightheadedness, dizziness, constipation, somnolence, sedation, N/V, sweating.

DRUG INTERACTIONS

Caution with CNS depressants (eg, sedatives, hypnotics, general anesthetics, antiemetics, phenothiazines, tranquilizers, other opioids, illicit drugs, alcohol); may increase the risk of respiratory depression, hypotension, profound sedation, or coma. May enhance the neuromuscular-blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression. Avoid with mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol). Precipitated apnea, confusion, and muscle twitching reported with cimetidine. Potentiated action by MAOIs; allow at least 14 days after stopping MAOIs before initiating treatment. May result in increased risk of urinary retention and/or severe constipation, which may lead to paralytic ileus with anticholinergics or other medications with anticholinergic activity. Caution with P-glycoprotein inhibitors.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Opioid analgesic; precise mechanism unknown. Specific CNS opiate receptors and endogenous compounds with morphine-like activity have been identified throughout the brain and spinal cord and are likely to play a role in the expression and perception of analgesic effects. Causes respiratory depression, in part by a direct effect on the brainstem respiratory centers, and depresses cough reflex by direct effect on the cough center in the medulla.

PHARMACOKINETICS

Absorption: Bioavailability (<40%); C_{max} =78ng/mL (tab), 58ng/mL (sol). **Distribution:** V_d =1-6L/kg; plasma protein binding (20-35%); crosses placenta, found in breast milk. **Metabolism:** Liver via conjugation; 3- and 6-glucuronide (metabolites). **Elimination:** Urine (10% unchanged), feces (7-10%); $T_{1/2}$ =2 hrs (IV).

ASSESSMENT

Assess for degree of opioid tolerance, level of pain intensity, type of pain, patient's general condition and medical status, or any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for respiratory depression, CSF pressure elevation, orthostatic hypotension, syncope, hypotension, aggravation of convulsions/seizures, and other adverse reactions.

PATIENT COUNSELING

Advise to take only as directed and not to adjust dose without consulting a physician. Inform physician if pregnant or plan to become pregnant prior to therapy. Counsel on the importance of safely tapering the dose. Inform of potential for severe constipation. Inform that therapy may produce physical or psychological dependence. Caution against performing hazardous tasks (eg, operating machinery/driving). Advise to avoid alcohol or CNS depressants except by the orders of the prescribing physician during therapy. Instruct to keep in a secure place out of reach of children, and when no longer needed, instruct to destroy the unused tabs by flushing down the toilet.

ADMINISTRATION/STORAGE

Administration: Oral route. (Sol, 100mg/5mL) Used only for patients who have already been titrated to a stable analgesic regimen using lower strengths and who can benefit from use of a smaller volume of sol; always use the enclosed calibrated PO syringe. **Storage:** 15-30°C (59-86°F). Protect from moisture.

EXHIBIT T



Nembutal Sodium solution

(pentobarbital sodium) - Lundbeck

THERAPEUTIC CLASS

Barbiturate

INDICATIONS

Hypnotics, for the short-term treatment of insomnia; sedatives; preanesthetics; anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes.

ADULT DOSAGE

Adults: Individualize dose. Consider age, weight, and condition. IM: Usual: 150-200mg (max 5mL/inj) as a single deep inj. IV: Inject slowly (max 50mg/min). 70kg: Initial: 100mg. Debilitated: Reduce dose proportionally. May give additional small increments up to 200-500mg total dose for normal adults PRN. Debilitated/Renal Impairment/Hepatic Disease: Reduce dose. Elderly: Start at lower end of the dosing range.

PEDIATRIC DOSAGE

Pediatrics: Individualize dose. Consider age, weight, and condition. IM: Usual: 2-6mg/kg (max 5mL/inj) as a single deep inj. Max: 100mg. IV: Inject slowly (max 50mg/min). Reduce adult dose proportionally.

HOW SUPPLIED

Inj: 50mg/mL [20mL, 50mL]

CONTRAINDICATIONS

History of manifest or latent porphyria.

WARNINGS/PRECAUTIONS

Used only when PO administration is impossible or impractical. May be habit-forming; tolerance, psychological and physical dependence may occur with continued use. Limit the amount required for the interval until the next appointment to minimize the possibility of overdosage or the development of dependence. Abrupt cessation after prolonged use in the dependent patient may result in withdrawal symptoms; withdraw gradually from any patient taking excessive dose over long periods of time. Caution with acute or chronic pain, mental depression, suicidal tendencies, or history of drug abuse. May cause fetal harm. May cause marked excitement, depression, and confusion in elderly or debilitated patients. Caution with hepatic damage; reduce initial dose. Avoid use in patients showing the premonitory signs of hepatic coma. Avoid perivascular extravasation or intra-arterial inj; extravascular inj may cause local tissue damage with subsequent necrosis while consequences of intra-articular inj may vary from transient pain to gangrene of the limb. D/C inj if limb pain develops. Caution in elderly. (IV) Too rapid administration may cause respiratory depression, apnea, laryngospasm, or vasodilation with fall in BP. Administer minimum dose in convulsive states.

ADVERSE REACTIONS

Somnolence, agitation, hypoventilation, bradycardia, N/V, headache, inj-site reactions.

DRUG INTERACTIONS

May lower plasma levels of dicumarol, and may cause a decrease in anticoagulant activity as measured by PT. May induce hepatic microsomal enzymes resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants (eg, warfarin, acenocoumarol, dicumarol, and phenprocoumon). May require dose adjustment of anticoagulants or corticosteroids if barbiturates are added to or withdrawn from the dosage regimen. May decrease blood level of griseofulvin; avoid concomitant use. May shorten $T_{1/2}$ of doxycycline for as long as 2 weeks after barbiturate therapy is d/c; monitor response to doxycycline closely if given concurrently. Monitor phenytoin and barbiturate blood levels frequently when given concurrently. May decrease metabolism when given with sodium valproate and valproic acid; monitor barbiturate blood levels and adjust dose as indicated. May produce additive depressant effects with other CNS depressants (eg, other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol). May prolong effects with MAOIs. Pretreatment or concurrent use may decrease effect of estradiol. Pregnancy may occur during treatment with antiepileptics while taking oral contraceptives; use of alternative contraceptive method is recommended.

PREGNANCY

Category D, caution in nursing.

MECHANISM OF ACTION

Barbiturate; depresses the sensory cortex, decreases motor activity, alters cerebellar function, and produces drowsiness, sedation, and hypnosis.

PHARMACOKINETICS

Distribution: Distributed to all tissues and fluids; bound to plasma proteins in varying degrees; found in breast milk; crosses placenta. **Metabolism:** Hepatic microsomal enzyme system. **Elimination:** Urine (25-50% unchanged), feces; $T_{1/2}$ =15-50 hrs.

ASSESSMENT

Assess for known barbiturate sensitivity, history of manifest or latent porphyria, presence of acute or chronic pain, depression, suicidal ideation, history of drug abuse, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions. Assess use in pediatrics, elderly, or

debilitated patients.

MONITORING

Monitor for signs and symptoms of CNS depression, tolerance, psychological and physical dependence, withdrawal symptoms, extravasation, inj-site reactions, pain in limbs, and other adverse reactions. Monitor for induced paradoxical excitement and for masking of symptoms in patients with acute or chronic pain. Monitor for marked excitement, depression, and confusion in elderly and debilitated patients. Perform periodic laboratory evaluation of organ systems, including hematopoietic, renal, and hepatic systems during prolonged therapy. Monitor vital signs after IM inj of a hypnotic dose. Monitor BP, respiration, cardiac function, vital signs, and rate of inj during IV administration.

PATIENT COUNSELING

Inform of the possibility of physiological and/or physical dependence. Instruct to avoid increasing the dose without consulting a physician. Inform that the drug may impair mental/physical abilities required for the performance of hazardous tasks (eg, operating machinery, driving). Instruct to avoid alcohol intake while on therapy. Inform that use of other CNS depressants (eg, alcohol, narcotics, tranquilizers, and antihistamines) may result in additional CNS depressant effects.

ADMINISTRATION/STORAGE

Administration: IM/IV routes. Administer minimum dose in convulsive states. (IM) Administer deeply into a large muscle. (IV) Do not mix with any other medication or sol. **Storage:** 20-25°C (68-77°F); brief excursions permitted between 15-30°C (59-86°F). Avoid excessive heat. Protect from freezing.

EXHIBIT U



Onfi

(clobazam) - Lundbeck

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients ≥ 2 yrs of age.

ADULT DOSAGE

Adults: Individualize dose. >30 kg: Initial: 10mg/day. Starting Day 7: 20mg/day. Starting Day 14: 40mg/day. ≤ 30 kg: Initial: 5mg/day. Starting Day 7: 10mg/day. Starting Day 14: 20mg/day. For doses >5 mg/day, administer in divided doses bid (the 5mg dose can be administered as a single daily dose). Withdraw gradually; taper by decreasing the total daily dose by 5-10mg/day on a weekly basis until discontinuation. Elderly/CYP2C19 Poor Metabolizers/Mild to Moderate Hepatic Impairment (Child-Pugh Score 5-9): Refer to PI.

PEDIATRIC DOSAGE

Pediatrics: ≥ 2 Yrs: Individualize dose. >30 kg: Initial: 10mg/day. Starting Day 7: 20mg/day. Starting Day 14: 40mg/day. ≤ 30 kg: Initial: 5mg/day. Starting Day 7: 10mg/day. Starting Day 14: 20mg/day. For doses >5 mg/day, administer in divided doses bid (the 5mg dose can be administered as a single daily dose). Withdraw gradually; taper by decreasing the total daily dose by 5-10mg/day on a weekly basis until discontinuation. CYP2C19 Poor Metabolizers/Mild to Moderate Hepatic Impairment (Child-Pugh Score 5-9): Refer to PI.

HOW SUPPLIED

Sus: 2.5mg/mL [120mL]; Tab: 5mg, 10mg, 20mg

WARNINGS/PRECAUTIONS

Somnolence and sedation reported. May impair mental/physical abilities. Withdrawal symptoms occurred following abrupt discontinuation; withdraw gradually to minimize risk of precipitating seizures, seizure exacerbation, or status epilepticus. Monitor patients with history of substance abuse because of predisposition to habituation and dependence. May increase risk of suicidal thoughts or behavior; monitor for emergence or worsening of depression, suicidal thoughts/behavior, and/or any unusual changes in mood/behavior.

ADVERSE REACTIONS

Somnolence, pyrexia, upper respiratory tract infection, lethargy, drooling, aggression, vomiting, irritability, constipation, fatigue, sedation, ataxia, insomnia, cough, pneumonia.

DRUG INTERACTIONS

May potentiate effects of other CNS depressants or alcohol; monitor for somnolence and sedation. May decrease effects of hormonal contraceptives; additional forms of nonhormonal contraception are recommended. CYP2D6 substrates may require dose adjustment. Strong (eg, fluconazole, fluvoxamine, ticlopidine) and moderate (eg, omeprazole) inhibitors of CYP2C19 may increase exposure to N-desmethyloclobazam; may require dose adjustment of clobazam. Alcohol may increase maximum plasma exposure. May increase levels of dextromethorphan. May decrease levels of midazolam. Ketoconazole may increase area under the curve.

PREGNANCY

Category C, safety not known in nursing.

MECHANISM OF ACTION

Benzodiazepine; not established. Suspected to involve potentiation of GABAergic neurotransmission, resulting from binding at the benzodiazepine site of the GABA_A receptor.

PHARMACOKINETICS

Absorption: Rapid and extensive. T_{max} =0.5-4 hrs (tab, single- or multiple-dose), 0.5-2 hrs (sus, single-dose). **Distribution:** Plasma protein binding (80-90%, 70% N-desmethyloclobazam); V_d =100L; found in breast milk. **Metabolism:** Liver (extensive); via N-demethylation by CYP3A4 (primary), 2C19, 2B6; N-desmethyloclobazam (major, active metabolite). **Elimination:** Urine (82%, 2% unchanged), feces (11%, 1% unchanged); $T_{1/2}$ = 36-42 hrs, 71-82 hrs (N-desmethyloclobazam).

ASSESSMENT

Assess for hepatic impairment, history of substance abuse, pregnancy/nursing status, and possible drug interactions. Assess if patient is a CYP2C19 poor metabolizer.

MONITORING

Monitor for somnolence, sedation, withdrawal symptoms, physical/psychological dependence, emergence or worsening of depression, suicidal thoughts/behavior, and unusual changes in mood/behavior. Upon withdrawal of therapy, monitor for precipitation/exacerbation of seizures, or status epilepticus.

PATIENT COUNSELING

Instruct to take only as prescribed. Caution about operating hazardous machinery, including automobiles, until the effect of the treatment is known. Inform to consult physician before increasing the dose or abruptly discontinuing the drug. Advise patients that abrupt withdrawal may increase risk of seizure. Counsel women to also use nonhormonal methods of contraception when clobazam is used with hormonal contraceptives and to continue these alternative methods for 28 days after discontinuation. Inform of the increased risk of suicidal thoughts and behavior and counsel to be alert for emergence or worsening of symptoms of depression, any unusual changes in mood/behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self harm; instruct to immediately report behaviors of concern to healthcare providers. Encourage to enroll in North American Antiepileptic Drug Pregnancy Registry if they become pregnant. Instruct to notify physician if pregnant/breastfeeding or intending to breastfeed or become pregnant during therapy.

ADMINISTRATION/STORAGE

Administration: Oral route. Take with or without food. (Tab) May be administered whole, or crushed and mixed in applesauce. (Sus) Shake well before every administration. Refer to PI for administration instructions. **Storage:** 20-25°C (68-77°F). (Sus) Use within 90 days of 1st opening the bottle; discard any remainder.

EXHIBIT V



OxyContin

(oxycodone hcl) - Purdue Pharma

BOXED WARNING

Contains oxycodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit; assess each patient's risk for opioid abuse or addiction prior to prescribing. Routinely monitor for signs of misuse, abuse, and addiction. Respiratory depression, including fatal cases, may occur even when used as recommended; proper dosing and titration are essential. Should only be prescribed by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation or following a dose increase. Swallow tab intact; crushing, dissolving, or chewing tab may cause rapid release and absorption of potentially fatal dose. Accidental ingestion, especially in children, can result in a fatal overdose.

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period.

ADULT DOSAGE

Adults: Individualize dose. Initial: First Opioid Analgesic: 10mg q12h. Conversion from other Oral Oxycodone: 1/2 of total daily dose q12h. Conversion from other Opioids: Begin with 1/2 of the estimated daily requirement, then divide into 2 doses taken 12 hrs apart; provide rescue medication (eg, immediate-release oxycodone) to manage inadequate analgesia. Conversion from Transdermal Fentanyl: 10mg q12h for each 25mcg/hr fentanyl transdermal patch 18 hrs following removal of patch. Titrate: Determine dose that provides adequate analgesia and minimizes adverse reactions. May increase total daily dose by 25-50% of current dose every 1-2 days, or each time an increase is clinically indicated. Periodically reassess the continued need for opioid analgesics during chronic therapy, especially for noncancer-related pain (or pain associated with other terminal illnesses). Hepatic Impairment: Start at 1/3 to 1/2 the usual starting dose followed by careful dose titration. Renal Impairment: Follow conservative dose initiation and adjust accordingly. Discontinuation: Gradual downward titration; avoid abrupt discontinuation.

HOW SUPPLIED

Tab, Controlled-Release: 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg

CONTRAINDICATIONS

Significant respiratory depression, acute or severe bronchial asthma in unmonitored settings or absence of resuscitative equipment, known or suspected paralytic ileus and GI obstruction.

WARNINGS/PRECAUTIONS

Not for use as PRN analgesic, for acute or mild pain, pain not expected to persist for an extended period, pain in immediate postoperative period (first 24 hrs following surgery) for patients not previously taking the drug, and postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or postoperative pain is expected to be moderate to severe and persist for an extended period. 60mg and 80mg tabs, a single dose >40mg, or a total daily dose >80mg are only for use in opioid-tolerant patients. Respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients; monitor closely. Monitor for respiratory depression and consider alternative nonopioid analgesics in patients with significant chronic obstructive pulmonary disease (COPD) or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression. May cause severe hypotension, including orthostatic hypotension and syncope, in ambulatory patients; monitor for signs of hypotension after dose initiation or titration. Avoid with circulatory shock. Monitor for signs of sedation and respiratory depression in patients susceptible to the intracranial effects of carbon dioxide retention (eg, those with increased intracranial pressure [ICP] or brain tumors). May obscure clinical course in patient with head injury. Avoid with impaired consciousness or coma. Difficulty in swallowing tab, intestinal obstruction, and exacerbation of diverticulitis reported; consider alternative analgesic in patients who have difficulty swallowing or are at risk for underlying GI disorders resulting in small GI lumen. May cause spasm of sphincter of Oddi and increase in serum amylase; monitor for worsening of symptoms in patients with biliary tract disease (eg, acute pancreatitis). May aggravate convulsions with convulsive disorders and may induce or aggravate seizures in some clinical settings; monitor for worsened seizure control in patients with history of seizure disorders. May impair mental or physical abilities. Not recommended for use immediately prior to and during labor, when use of shorter-acting analgesics or other analgesic techniques are more appropriate.

ADVERSE REACTIONS

Respiratory depression, constipation, N/V, somnolence, dizziness, pruritus, headache, dry mouth, asthenia, sweating, apnea, respiratory arrest, circulatory depression, hypotension.

DRUG INTERACTIONS

Respiratory depression, hypotension, and profound sedation or coma may occur with other CNS depressants (eg, sedatives, hypnotics, anxiolytics, neuroleptics, muscle relaxants, tranquilizers, general anesthetics, phenothiazines, alcohol, other opioids); when combination is contemplated, start oxycodone at 1/3 to 1/2 the usual dose and use lower dose of the concomitant CNS depressant. May enhance neuromuscular blocking action of true skeletal muscle relaxants and increase respiratory depression. CYP3A4 inhibitors, such as macrolide antibiotics (eg, erythromycin), azole-antifungal agents (eg, ketoconazole), and protease inhibitors (eg, ritonavir) may increase levels of oxycodone, prolonging opioid effects. Decreased levels with CYP450 inducers (eg, rifampin, carbamazepine, phenytoin). CYP2D6 inhibitor (eg, quinidine, fluoxetine) may block the partial metabolism

to oxymorphone. Mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol) may reduce analgesic effect and/or precipitate withdrawal symptoms; avoid coadministration. May reduce efficacy of diuretics and lead to acute urinary retention. Anticholinergics or other medications with anticholinergic activity may increase risk of urinary retention and/or severe constipation and lead to paralytic ileus.

PREGNANCY

Category B, not for use in nursing.

MECHANISM OF ACTION

Pure μ -receptor opioid agonist; has not been established. Specific CNS opioid receptors have been identified throughout the brain and spinal cord and are thought to play a role in analgesic effect.

PHARMACOKINETICS

Absorption: Administration of variable doses resulted in different parameters. **Distribution:** $V_d=2.6L/kg$ (IV); plasma protein binding (45%); crosses placenta; found in breast milk. **Metabolism:** Extensively via CYP3A and 2D6 into noroxycodone (major metabolite), noroxymorphone (active major metabolite), and oxymorphone (active metabolite). **Elimination:** Urine; $T_{1/2}=4.5$ hrs.

ASSESSMENT

Assess for risk factors for drug abuse or addiction, pain type/severity, prior opioid therapy, opioid tolerance, respiratory depression, COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, asthma, GI obstruction, renal/hepatic impairment, pregnancy/nursing status, possible drug interactions, or any other conditions where treatment is contraindicated or cautioned.

MONITORING

Monitor for respiratory depression, sedation, CNS depression, aggravation/induction of seizures/convulsions, increase in ICP, hypotension/syncope, symptoms of worsening biliary tract disease, tolerance, physical dependence, and other adverse reactions. Monitor BP and serum amylase levels. Routinely monitor for signs of misuse, abuse, and addiction.

PATIENT COUNSELING

Inform that the drug has potential for abuse; instruct not to share with others and to take steps to protect from theft or misuse. Discuss the risk of respiratory depression. Inform that accidental exposure may result in serious harm or death; advise to store securely and dispose unused tabs by flushing down the toilet. Inform that the concomitant use of alcohol can increase the risk of life-threatening respiratory depression. Instruct to not consume alcoholic beverages, or take prescription and OTC products that contain alcohol, during treatment. Inform that drug may cause orthostatic hypotension and syncope. Inform that drug may impair the ability to perform potentially hazardous activities (eg, driving or operating heavy machinery); advise to not perform such tasks until they know how they will react to medication. Advise of potential for severe constipation, including management instructions. Advise how to recognize anaphylaxis and when to seek medical attention. Instruct to inform physician if pregnant or planning to become pregnant.

ADMINISTRATION/STORAGE

Administration: Oral route. Swallow tab intact; do not cut, crush, dissolve, or chew. Do not pre-soak, lick, or wet tab prior to placing in mouth. Take 1 tab at a time with enough water. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT W



Provigil

(modafinil) - Cephalon

THERAPEUTIC CLASS

Wakefulness-promoting agent

INDICATIONS

To improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), shift work disorder (SWD). As adjunct to standard treatment for underlying obstruction in OSA.

ADULT DOSAGE

Adults: ≥17 yrs: 200mg qd. Max: 400mg/day as single dose. Narcolepsy/OSA: Take as single dose in am. SWD: Take 1 hr prior to start of work shift. Severe Hepatic Impairment: 100mg qd. Elderly: Consider dose reduction.

HOW SUPPLIED

Tab: 100mg, 200mg* *scored

WARNINGS/PRECAUTIONS

Rare cases of severe or life-threatening rash, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) reported; d/c treatment at first sign of rash. Angioedema, anaphylactoid reactions, multi-organ hypersensitivity and psychiatric adverse experiences reported; d/c treatment if symptoms develop. Caution with a history of psychosis, depression or mania. Caution with recent myocardial infarction (MI) or unstable angina. Avoid in patients with history of left ventricular hypertrophy or with mitral valve prolapse who have experienced mitral valve prolapse syndrome (eg, ischemic ECG changes, chest pain, arrhythmia) with CNS stimulants. May impair mental/physical abilities. Reduce dose with severe hepatic impairment. Use low dose in elderly. Doses up to 400mg/day have been well-tolerated, but there is no evidence that this dose confers additional benefit.

ADVERSE REACTIONS

Headache, nausea, nervousness, anxiety, insomnia, rhinitis, diarrhea, back pain, dizziness, dyspepsia, flu syndrome, dry mouth, anorexia, pharyngitis.

DRUG INTERACTIONS

Methylphenidate and dextroamphetamine may delay absorption. May reduce efficacy of steroidal contraceptives up to 1 month after d/c. Caution with MAOIs. CYP3A4 inducers (eg, carbamazepine, phenobarbital, rifampin) may decrease levels. CYP3A4 inhibitors (eg, ketoconazole, itraconazole) may increase levels. May increase levels of drugs metabolized by CYP2C19 (eg, diazepam, propranolol, phenytoin) or CYP2C9 (eg, warfarin). Monitor for toxicity with CYP2C19 substrates and PT/INR with warfarin. May increase levels of certain TCAs (eg, clomipramine, desipramine) and SSRIs in CYP2D6-deficient patients. May decrease levels of drugs metabolized by CYP3A4 (eg, cyclosporine, ethinyl estradiol, triazolam). May induce CYP1A2 and CYP2B6; caution with CYP1A2 and CYP2B6 substrates.

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Wakefulness-promoting agent; not established. Binds to dopamine transporter, inhibits dopamine reuptake, and results in increased extracellular dopamine levels in some brain regions.

PHARMACOKINETICS

Absorption: Rapid. T_{max} ≈2-4 hrs, delayed by 1 hr (fed). **Distribution:** V_d =0.9L/kg; plasma protein binding (60%). **Metabolism:** Liver via hydrolytic deamination, S-oxidation, aromatic ring hydroxylation, and glucuronide conjugation; CYP3A4. **Elimination:** Feces (1%), urine (80%, <10% parent compound); $T_{1/2}$ =15 hrs.

ASSESSMENT

Assess for hypersensitivity, hepatic impairment, pregnancy/nursing status, possible drug interactions, and a history of psychosis, depression, mania, left ventricular hypertrophy, or mitral valve prolapse. Assess for a recent history of MI or unstable angina. Use only in patients who have had complete evaluation of their excessive sleepiness, and in whom a diagnosis of either narcolepsy, OSA, and/or SWD has been made.

MONITORING

Monitor for serious rash, SJS, TEN, DRESS, angioedema, hypersensitivity, multi-organ hypersensitivity reactions, psychiatric adverse symptoms, and other adverse reactions. Monitor BP. If used adjunctively with continuous positive airway pressure (CPAP), monitor for CPAP compliance. Periodically reevaluate long-term usefulness if prescribed for an extended time.

PATIENT COUNSELING

Advise that this is not a replacement for sleep. Inform that drug may improve but does not eliminate sleepiness. Instruct to avoid taking alcohol during therapy. Caution against hazardous tasks (eg, driving, operating machinery) or performing other activities that require mental alertness.

Instruct to notify physician if pregnant or intend to become pregnant, or if nursing during therapy. Caution about increased risk of pregnancy when using steroidal contraceptives and for 1 month after d/c therapy. Instruct to inform physician if taking or planning to take any prescribed or OTC drugs. Instruct to contact physician if chest pain, rash, depression, anxiety, or signs of psychosis or mania develop. Inform of importance of continuing previously prescribed treatments. Instruct to d/c and notify physician if rash, hives, mouth sores, blisters, peeling skin, trouble swallowing or breathing, or other allergic reactions develop.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT X



Restoril

(temazepam) - Mallinckrodt

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Short-term treatment of insomnia (7-10 days).

ADULT DOSAGE

Adults: Administer at bedtime. Usual: 15mg. Range: 7.5-30mg. Transient Insomnia: 7.5mg may be sufficient. Elderly/Debilited: Initiate with 7.5mg until individual response is determined.

HOW SUPPLIED

Cap: 7.5mg, 15mg, 22.5mg, 30mg

CONTRAINDICATIONS

Women who are or may become pregnant.

WARNINGS/PRECAUTIONS

Initiate only after careful evaluation; failure of insomnia to remit after 7-10 days of treatment may indicate primary psychiatric and/or medical illness. Worsening of insomnia and emergence of thinking or behavior abnormalities may occur especially in elderly; use lowest possible effective dose. Behavioral changes (eg, decreased inhibition, bizarre behavior, agitation, hallucinations, depersonalization) and complex behavior (eg, sleep-driving) reported; strongly consider d/c if sleep-driving episode occurs. Amnesia and other neuropsychiatric symptoms may occur unpredictably. Worsening of depression, including suicidal thinking, reported. Withdrawal symptoms may occur after abrupt d/c. Rare cases of angioedema (eg, tongue, glottis, larynx) and anaphylaxis reported; do not rechallenge if angioedema develops. Oversedation, confusion, and/or ataxia may develop with large doses in elderly and debilitated patients. Caution with hepatic/renal impairment, chronic pulmonary insufficiency, debilitated, severe or latent depression, and if elderly. Abnormal LFTs, renal function tests, and blood dyscrasias reported.

ADVERSE REACTIONS

Drowsiness, headache, fatigue, nervousness, lethargy, dizziness, nausea.

DRUG INTERACTIONS

Increased risk of complex behaviors with alcohol and CNS depressants. Potential additive effects with hypnotics and CNS depressants. Possible synergistic effect with diphenhydramine.

PREGNANCY

Category X, caution in nursing.

MECHANISM OF ACTION

Benzodiazepine hypnotic agent.

PHARMACOKINETICS

Absorption: Well-absorbed; C_{max} =865ng/mL; T_{max} =1.5 hrs. **Distribution:** Plasma protein binding (96% unchanged); crosses placenta. **Metabolism:** Complete; conjugation. **Elimination:** Urine (80-90%); $T_{1/2}$ =3.5-18.4 hrs.

ASSESSMENT

Assess for physical and/or psychiatric disorder, medical illness, severe or latent depression, renal/hepatic dysfunction, chronic pulmonary insufficiency, pregnancy/nursing status, alcohol use, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of withdrawal, tolerance, abuse, dependence, abnormal thinking, behavioral changes, agitation, depersonalization, hallucinations, complex behaviors (including "sleep-driving"), amnesia, anxiety, neuropsychiatric symptoms, worsening of depression, suicidal thoughts and actions, angioedema (tongue, glottis, or larynx), driving/psychomotor impairment, worsening of insomnia, thinking or behavioral abnormalities, and possible abuse/dependence.

PATIENT COUNSELING

Inform about the benefits and risks of treatment. Instruct patient to take as prescribed. Inform about the risks and possibility of physical/psychological dependence, memory problems, and complex behaviors (eg, sleep-driving). Caution against hazardous tasks (eg, operating machinery/driving). Advise not to drink alcohol. Instruct to notify physician if pregnant/planning to become pregnant.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT Y



Ritalin

(methylphenidate hcl) - Novartis

BOXED WARNING

Caution with history of drug dependence or alcoholism. Marked tolerance and psychological dependence may result from chronic abusive use. Frank psychotic episodes may occur, especially with parenteral abuse. Careful supervision required for withdrawal from abusive use to avoid severe depression. Withdrawal following chronic use may unmask symptoms of underlying disorder that may require follow-up.

OTHER BRAND NAMES

Ritalin LA (Novartis), Ritalin SR (Novartis)

THERAPEUTIC CLASS

Sympathomimetic amine

INDICATIONS

(Cap, Extended-Release) Treatment of attention deficit hyperactivity disorder. (Tab; Tab, Sustained-Release) Treatment of attention deficit disorders and narcolepsy.

ADULT DOSAGE

Adults: Individualize dose. Reduce dose or d/c if paradoxical aggravation of symptoms occurs. D/C if no improvement after appropriate dose adjustment over a 1-month period. (Tab) 10-60mg/day divided bid-tid 30-45 min ac. Take last dose before 6 pm if insomnia occurs. (Tab, SR) May be used in place of immediate-release (IR) tab when the 8-hr dose corresponds to the titrated 8-hr IR dose. Swallow whole; do not crush or chew. (Cap, ER) Initial: 10-20mg qam. Titrate: May adjust weekly by 10mg. Max: 60mg/day. Currently on Methylphenidate: May be used in place of IR or SR tabs with a qd equivalent dose; refer to PI for recommended dosing. Swallow whole; do not crush, chew, or divide.

PEDIATRIC DOSAGE

Pediatrics: ≥6 yrs: Individualize dose. Reduce dose or d/c if paradoxical aggravation of symptoms occurs. D/C if no improvement after appropriate dose adjustment over a 1-month period. (Tab) Initial: 5mg bid before breakfast and lunch. Titrate: Increase gradually by 5-10mg weekly. Max: 60mg/day. (Tab, SR) May be used in place of IR tab when the 8-hr dose corresponds to the titrated 8-hr IR dose. Swallow whole; do not crush or chew. (Cap, ER) Initial: 10-20mg qam. Titrate: May adjust weekly by 10mg. Max: 60mg/day. Currently on Methylphenidate: May be used in place of IR or SR tabs with a qd equivalent dose; refer to PI for recommended dosing. Swallow whole; do not crush, chew, or divide.

HOW SUPPLIED

Cap, Extended-Release (Ritalin LA): 10mg, 20mg, 30mg, 40mg; Tab (Ritalin): 5mg, 10mg*, 20mg*; Tab, Sustained-Release (Ritalin SR): 20mg *scored

CONTRAINDICATIONS

Marked anxiety, tension, agitation, glaucoma, motor tics or family history or diagnosis of Tourette's syndrome. Treatment with or within a minimum of 14 days following d/c of an MAOI.

WARNINGS/PRECAUTIONS

Sudden death, stroke, and myocardial infarction (MI) reported; avoid with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease or other serious cardiac problems. May increase BP and HR; caution with preexisting HTN, heart failure, MI, or ventricular arrhythmias. Assess patients for cardiac disease prior to initiating therapy; promptly perform cardiac evaluation if symptoms suggestive of cardiac disease develop. May exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder. May induce mixed/manic episode in patients with bipolar disorder; assess for bipolar disease before starting therapy. May cause treatment-emergent psychotic or manic symptoms in children and adolescents without prior history of psychotic illness or mania at usual doses. Aggressive behavior or hostility reported. May cause growth suppression in children. May lower convulsive threshold; d/c if seizures occur. Visual disturbances reported. Not for use in children <6 yrs. (Tab; Tab, SR) Patients with an element of agitation may react adversely; d/c therapy if necessary. Not indicated in all cases of this behavioral syndrome, and in symptoms associated with acute stress reactions. D/C drug periodically to assess child's condition; therapy should not be indefinite. (Cap, ER) Periodically reevaluate the usefulness of therapy.

ADVERSE REACTIONS

Nervousness, insomnia, hypersensitivity, anorexia, nausea, dizziness, headache, dyskinesia, drowsiness, BP and pulse changes, tachycardia, weight loss, abdominal pain, decreased appetite.

DRUG INTERACTIONS

See Contraindications. Caution with pressor agents. May decrease effectiveness of antihypertensives. May inhibit metabolism of coumarin anticoagulants, anticonvulsants, TCAs; may need to adjust dose of these drugs downward and monitor plasma drug levels/coagulation times when starting/stopping methylphenidate therapy. Possible occurrence of neuroleptic malignant syndrome (NMS) with concurrent therapies associated with NMS; single report of NMS-like event possibly related with concurrent use of venlafaxine. (Cap, ER) Release may be altered by antacids or acid suppressants. May be associated with pharmacodynamic interaction when coadministered with direct and indirect dopamine agonists (eg, DOPA

and TCAs) as well as dopamine antagonists (antipsychotics, eg, haloperidol).

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Sympathomimetic amine; not established. CNS stimulant, thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of monoamines into the extraneuronal space. Presumably activates the brain stem arousal system and cortex to produce stimulant effect.

PHARMACOKINETICS

Absorption: (Cap, ER 20mg) Adults: $T_{max1}=2$ hrs, $C_{max1}=5.3$ ng/mL, $T_{max2}=5.5$ hrs, $C_{max2}=6.2$ ng/mL, $AUC=45.8$ ng•hr/mL. Pediatrics: $T_{max1}=2$ hrs, $C_{max1}=10.3$ ng/mL, $T_{max2}=6.6$ hrs, $C_{max2}=10.2$ ng/mL, $AUC=86.6$ ng•hr/mL. **Distribution:** (Cap, ER) Plasma protein binding (10%-33%); $V_d=2.65$ L/kg (d-methylphenidate), 1.8L/kg (l-methylphenidate). **Metabolism:** Rapid and extensive by carboxylesterase CES1A1; α -phenyl-2-piperidine acetic acid (major metabolite). **Elimination:** (Tab) Urine (78-97% metabolites, <1% unchanged), feces (1-3% metabolites). (Tab, SR) Urine (86% adults; 67% pediatrics). (Tab; Cap, ER) $T_{1/2}=3.5$ hrs (adults), 2.5 hrs (pediatrics).

ASSESSMENT

Assess for cardiac disease, psychotic disorders, bipolar disorder, seizures, history of drug dependence or alcoholism, acute stress reactions, and any other conditions where treatment is contraindicated or cautioned. Assess pregnancy/nursing status, and for possible drug interactions. Obtain baseline height/weight in children, and CBC, differential and platelet counts.

MONITORING

Monitor for signs and symptoms of cardiac disease, increased BP and HR, exacerbations of behavior disturbances and thought disorders, psychotic or manic symptoms, aggression, hostility, seizures, and visual disturbances. Monitor growth in children. In patients with bipolar disorder, monitor for mixed/manic episode. Perform periodic monitoring of CBC, differential, and platelet counts during prolonged therapy.

PATIENT COUNSELING

Inform about risks, benefits, and appropriate use of treatment. Instruct to read the Medication Guide.

ADMINISTRATION/STORAGE

Administration: Oral route. (Cap, ER) May sprinkle contents over spoonful of applesauce if desired. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Tab) Protect from light. (Tab, SR) Protect from moisture.

EXHIBIT Z



Sonata

(zaleplon) - King

THERAPEUTIC CLASS

Pyrazolopyrimidine (non-benzodiazepine)

INDICATIONS

Short-term treatment of insomnia.

ADULT DOSAGE

Adults: Individualize dose. Insomnia: 10mg qhs. Low Weight Patients: 5mg qhs. Max: 20mg/day. Elderly/Debilited: 5mg qhs. Max: 10mg/day. Mild to Moderate Hepatic Dysfunction/Concomitant Cimetidine: 5mg qhs. Take immediately prior to bedtime.

HOW SUPPLIED

Cap: 5mg, 10mg

WARNINGS/PRECAUTIONS

Failure to remit after 7-10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Use the lowest effective dose. Abnormal thinking and behavior changes including bizarre behavior, agitation, hallucinations, and depersonalization reported. Complex behaviors such as sleep-driving reported; d/c if sleep-driving occurs. Amnesia and other neuropsychiatric symptoms may occur unpredictably. Caution with depressed patients; worsening of depression, suicidal thoughts and actions reported. Anaphylaxis (eg, dyspnea, throat closing, N/V) and angioedema of the tongue, glottis and larynx leading to airway obstruction may occur. Patients who develop angioedema after treatment should not be rechallenged with the drug. May result in short-term memory impairment, hallucinations, impaired coordination, dizziness and lightheadedness when taken while still up. Caution in elderly. Abuse potential exists; avoid abrupt withdrawal. Caution with diseases or conditions affecting metabolism or hemodynamic responses, compromised respiratory function, and mild to moderate hepatic insufficiency. Not for use in severe hepatic impairment. May impair mental/physical abilities. Contains tartrazine, which may cause allergic reactions including bronchial asthma.

ADVERSE REACTIONS

Headache, dizziness, nausea, asthenia, abdominal pain, somnolence, amnesia, eye pain, dysmenorrhea, paresthesia.

DRUG INTERACTIONS

Coadministration with other psychotropic medications, anticonvulsants, antihistamines, narcotic analgesics, anesthetics, ethanol, and other CNS depressants may produce additive CNS-depressant effects. Avoid with alcohol. CYP3A4 inducers (eg, rifampin, phenytoin, carbamazepine and phenobarbital) increase clearance. CYP3A4 inhibitors (eg, erythromycin and ketoconazole) decrease clearance. Caution when coadministered with promethazine, imipramine, or thioridazine. Cimetidine reduces clearance.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Pyrazolopyrimidine class. Hypnotic agent; interacts with GABA-benzodiazepine receptor complex.

PHARMACOKINETICS

Absorption: Rapid and complete. Absolute bioavailability (30%); $T_{max}=1$ hr. **Distribution:** (IV) $V_d=1.4L/kg$; plasma protein binding (60%); found in breastmilk. **Metabolism:** Liver (extensive) via aldehyde oxidation. **Elimination:** Urine (<1% unchanged, 70% within 48 hrs, 71% within 6 days), feces (17% within 6 days); (IV, oral) $T_{1/2}=1$ hr.

ASSESSMENT

Assess for primary psychiatric and/or medical illness, diseases/conditions affecting metabolism or hemodynamic responses, compromised respiratory function (COPD, sleep apnea), depression, suicidal tendencies, hepatic/renal impairment, drug abuse/addiction, alcohol intake, pregnancy/nursing status, hypersensitivity and possible drug interactions.

MONITORING

Monitor for anaphylaxis (eg, dyspnea, throat closing, N/V), angioedema of the tongue, glottis and larynx, worsening of insomnia, abnormal thinking and behavior changes (eg, bizarre behavior, agitation, hallucinations, depersonalization), complex behaviors (eg, sleep-driving), amnesia, neuropsychiatric symptoms, worsening of depression, suicidal thoughts/actions, memory impairment, impaired coordination, dizziness, lightheadedness, physical/psychological dependence, withdrawal symptoms, hepatic and pulmonary functions and possible drug interactions. Monitor elderly and debilitated patients closely.

PATIENT COUNSELING

Instruct to take drug immediately prior to bedtime. Caution against hazardous tasks (eg, operating machinery/driving). Instruct to notify physician if sleep-driving or other complex behaviors occur. Inform about the benefits/risks, possibility of physical/psychological dependence and memory disturbances. Instruct to notify physician if pregnant/nursing or planning to become pregnant. Instruct to not increase dose or d/c drug before

consulting physician. Advise to avoid alcohol.

ADMINISTRATION/STORAGE

Administration: Oral route. Take immediately prior to bedtime. **Storage:** 20-25°C (68-77°F). Dispense in a light-resistant container.

EXHIBIT AA



Butorphanol Spray

(butorphanol tartrate) - Various

THERAPEUTIC CLASS

Opioid agonist-antagonist analgesic

INDICATIONS

Management of pain when the use of an opioid analgesic is appropriate.

ADULT DOSAGE

Adults: Initial: (1mg) 1 spray in 1 nostril. May give additional 1mg after 60-90 min if adequate relief is not achieved. May repeat in 3-4 hrs PRN after 2nd dose of the sequence. Severe Pain: Initial: (2mg) 1 spray in each nostril. Do not give single additional 2mg doses for 3-4 hrs. Elderly/Renal /Hepatic Impairment: Initial Dose Sequence: 1mg, then by 1mg in 90-120 min PRN. Repeated Dose Sequence: Determined by patient's response rather than at fixed times but generally no less than at 6 hr intervals.

HOW SUPPLIED

Nasal Spray: 10mg/mL [2.5mL]

CONTRAINDICATIONS

Hypersensitivity to benzethonium chloride.

WARNINGS/PRECAUTIONS

Not recommended for use in narcotic-dependent patients. Chronic use may precipitate withdrawal symptoms (eg, anxiety, agitation, mood changes, hallucinations, dysphoria, weakness, diarrhea). Caution with patients who have recently received repeated doses of narcotic analgesic medication. Episodes of abuse reported. May develop tolerance or physical dependence during prolonged, continuous use; abrupt d/c may result in withdrawal symptoms. Hypotension associated with syncope during the 1st hour of dosing reported rarely; avoid activities with potential risks. Caution with head injury, increased intracranial pressure, acute myocardial infarction (AMI), ventricular dysfunction, or coronary insufficiency; use only if benefits of use outweigh risks. Severe HTN reported; d/c if occurs. May impair mental/physical abilities. May produce respiratory depression especially in patients with CNS disease or respiratory impairment. Caution in elderly, hepatic, and renal impairment. Not recommended for use in induction or maintenance of anesthesia, and in labor.

ADVERSE REACTIONS

Somnolence, dizziness, N/V, nasal congestion, insomnia.

DRUG INTERACTIONS

Increased CNS depression with CNS depressants (eg, alcohol, barbiturates, tranquilizers, antihistamines); use smallest effective dose and reduced frequency of dosing. Diminished analgesic effect if administered shortly after sumatriptan nasal solution. Effects of other concomitant medications that affect hepatic metabolism of drugs (eg, erythromycin, theophylline) not known; smaller initial dose and longer intervals between doses may be needed. Decreased absorption rate with nasal vasoconstrictors (eg, oxymetazoline).

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

Opioid agonist-antagonist analgesic; has low intrinsic activity at receptors of μ -opioid type (morphine-like) and agonist at κ -opioid receptors.

PHARMACOKINETICS

Absorption: Absolute bioavailability (60-70%); C_{max} =0.9-1.04ng/mL; T_{max} =30-60 min. Parameters in elderly differ from younger, refer to PI. **Distribution:** V_d =305-901L; plasma protein binding (80%); crosses placental barriers, found in breast milk. **Metabolism:** Liver; Hydroxybutorphanol (major metabolite). **Elimination:** Urine (5% unchanged, 49% hydroxybutorphanol, <5% norbutorphanol), feces; $T_{1/2}$ =18 hrs (hydroxybutorphanol).

ASSESSMENT

Assess for hypersensitivity, head injury, elevated intracranial pressure, narcotic dependence, respiratory impairment, AMI, ventricular dysfunction or coronary insufficiency, CNS diseases, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions. Assess for age, weight, physical status, underlying pathologic condition, type of anesthesia, and surgical procedure involved.

MONITORING

Monitor for signs/symptoms of drug abuse/dependence/tolerance, hypotension, HTN, respiratory depression, withdrawal symptoms, and other adverse reactions.

PATIENT COUNSELING

Inform that medication may impair physical/mental abilities; do not perform dangerous tasks (eg, operating machinery/driving) for at least 1 hr or until

drug effects are no longer present. Instruct to avoid alcohol during medication and inform that use of drugs affecting the CNS may result in increased depressant effects such as drowsiness, dizziness, and impaired mental function. Counsel that therapy has the potential for abuse and should be handled accordingly. Instruct on the proper use of nasal solution.

ADMINISTRATION/STORAGE

Administration: Intranasal route. Refer to PI for administration instructions. **Storage:** 15-30°C (59-86°F).

EXHIBIT BB



Valium

(diazepam) - Roche Labs

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Management of anxiety disorders and short-term relief of anxiety symptoms. Symptomatic relief of acute alcohol withdrawal. Adjunct therapy for convulsive disorders and relief of skeletal muscle spasms.

ADULT DOSAGE

Adults: Individualize dose. Anxiety Disorders/Anxiety Symptoms: 2-10mg bid-qid. Acute Alcohol Withdrawal: 10mg tid-qid for 24 hrs. Reduce to 5mg tid-qid PRN. Skeletal Muscle Spasm: 2-10mg tid-qid. Convulsive Disorders: 2-10mg bid-qid. Elderly/Debilited: 2-2.5mg qd-bid initially. May increase gradually PRN if tolerated.

PEDIATRIC DOSAGE

Pediatrics: ≥6 Months: 1-2.5mg tid-qid initially. May increase gradually PRN if tolerated.

HOW SUPPLIED

Tab: 2mg*, 5mg*, 10mg* *scored

CONTRAINDICATIONS

Acute narrow-angle glaucoma, patients <6 months, myasthenia gravis, severe respiratory insufficiency, severe hepatic insufficiency, sleep apnea syndrome.

WARNINGS/PRECAUTIONS

Not recommended for the treatment of psychotic patients. Increase in frequency and/or severity of grand mal seizures may occur during adjunctive therapy and may require an increase in the dose of the standard anticonvulsant medication. May temporarily increase frequency and/or severity of seizures during abrupt withdrawal. Psychiatric and paradoxical reactions may occur; d/c if these occur. Lower dose with chronic respiratory insufficiency. Caution with history of alcohol and drug abuse. Prolonged use may result in loss of response to the effects of benzodiazepines.

ADVERSE REACTIONS

Drowsiness, fatigue, muscle weakness, ataxia, confusion, vertigo, constipation, blurred vision, dizziness, hypotension, stimulation, agitation, incontinence, skin reactions, hypersalivation.

DRUG INTERACTIONS

Mutually potentiates effects with phenothiazines, antipsychotics, anxiolytics/sedatives, hypnotics, anticonvulsants, narcotic analgesics, anesthetics, sedative antihistamines, narcotics, barbiturates, MAOIs, and other antidepressants. Alcohol enhances sedative effects; avoid concomitant use. Increased and prolonged sedation with cimetidine, ketoconazole, fluvoxamine, fluoxetine, and omeprazole. Diazepam decreases metabolic elimination of phenytoin.

PREGNANCY

Category D, not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; exerts anxiolytic, sedative, muscle-relaxant, anticonvulsant, and amnesic effects. Facilitates GABA, an inhibitory neurotransmitter in the CNS.

PHARMACOKINETICS

Absorption: T_{max} =1-1.5 hrs. **Distribution:** V_d =0.8-1.0L/kg; plasma protein binding (98%); crosses blood-brain/placental barrier, and appears in breast milk. **Metabolism:** Via N-demethylation and hydroxylation by CYP3A4 and CYP2C19 enzymes, glucuronidation; N-desmethyldiazepam, temazepam, oxazepam (active metabolites). **Elimination:** Urine; $T_{1/2}$ =48 hrs, 100 hrs (N-desmethyldiazepam).

ASSESSMENT

Assess for anxiety disorders/symptoms, acute alcohol withdrawal, skeletal muscle spasm, convulsive disorders, depression, and other conditions where treatment is contraindicated or cautioned. Assess for pregnancy/nursing status and possible drug interactions.

MONITORING

Monitor for hypersensitivity reactions, rebound or withdrawal symptoms, seizures, psychiatric and paradoxical reactions, and respiratory depression.

PATIENT COUNSELING

Advise to consult physician before increasing dose or abruptly d/c the drug. Advise against simultaneous ingestion of alcohol and other CNS depressants during therapy. Caution against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 15-30°C (59-86°F).

EXHIBIT CC



Vicodin

(acetaminophen, hydrocodone bitartrate) - Abbott

BOXED WARNING

Associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with acetaminophen (APAP) use at doses >4000mg/day, and often involve >1 APAP-containing product.

OTHER BRAND NAMES

Vicodin HP (Abbott), Vicodin ES (Abbott)

THERAPEUTIC CLASS

Opioid analgesic

INDICATIONS

Relief of moderate to moderately severe pain.

ADULT DOSAGE

Adults: Adjust dose according to severity of pain and response. (Vicodin) Usual: 1 or 2 tabs q4-6h PRN. Max: 8 tabs/day. (Vicodin ES/Vicodin HP) Usual: 1 tab q4-6h PRN. Max: 6 tabs/day. Elderly: Start at lower end of dosing range.

HOW SUPPLIED

Tab: (Hydrocodone-APAP) (Vicodin) 5mg-300mg*; (Vicodin ES) 7.5mg-300mg*; (Vicodin HP) 10mg-300mg* *scored

WARNINGS/PRECAUTIONS

Increased risk of acute liver failure in patients with underlying liver disease. Hypersensitivity and anaphylaxis reported; d/c if signs/symptoms occur. May produce dose-related respiratory depression, and irregular and periodic breathing. Respiratory depressant effects and CSF pressure elevation capacity may be markedly exaggerated in the presence of head injury, other intracranial lesions or a preexisting increased intracranial pressure. May obscure diagnosis or clinical course of head injuries or acute abdominal conditions. Potential for abuse. Caution with hypothyroidism, Addison's disease, prostatic hypertrophy, urethral stricture, severe hepatic/renal impairment, or in elderly/debilitated. Suppresses the cough reflex; caution with pulmonary disease and in postoperative use. Physical dependence and tolerance may develop.

ADVERSE REACTIONS

Acute liver failure, lightheadedness, dizziness, sedation, N/V.

DRUG INTERACTIONS

Additive CNS depression with other narcotics, antihistamines, antipsychotics, antianxiety agents, or other CNS depressants (eg, alcohol); reduce dose of one or both agents. Concomitant use with MAOIs or TCAs may increase the effect of either the antidepressant or hydrocodone. Increased risk of acute liver failure with alcohol ingestion.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Hydrocodone: Opioid analgesic; not established. Suspected to relate to the existence of opiate receptors in the CNS. APAP: Nonopiate, nonsalicylate analgesic and antipyretic; not established. Antipyretic activity is mediated through hypothalamic heat-regulating centers; inhibits prostaglandin synthetase.

PHARMACOKINETICS

Absorption: Hydrocodone: (10mg) C_{max} =23.6ng/mL; T_{max} =1.3 hrs. APAP: Rapid. **Distribution:** APAP: Found in breast milk. **Metabolism:** Hydrocodone: O-demethylation, N-demethylation, and 6-keto reduction. APAP: Liver (conjugation). **Elimination:** Hydrocodone: (10mg) $T_{1/2}$ =3.8 hrs. APAP: Urine (85%); $T_{1/2}$ =1.25-3 hrs.

ASSESSMENT

Assess for level of pain intensity, type of pain, patient's general condition and medical status, or any other conditions where treatment is contraindicated or cautioned. Assess for history of hypersensitivity, renal/hepatic function, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of hypersensitivity or anaphylaxis, respiratory depression, elevations in CSF pressure, drug abuse, tolerance, and dependence. In patients with severe hepatic/renal disease, monitor effects with serial hepatic and/or renal function tests.

PATIENT COUNSELING

Instruct to look for APAP on package labels and not to use >1 APAP-containing product. Instruct to seek medical attention immediately upon ingestion of >4000mg/day APAP, even if feeling well. Advise to d/c and contact physician if signs of allergy (eg, rash, difficulty breathing) develop. Inform that drug may impair mental/physical abilities, and to use caution if performing potentially hazardous tasks (eg, driving, operating machinery). Instruct to avoid alcohol and other CNS depressants. Inform that drug may be habit-forming; instruct to take only ud.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT DD



Vyvanse

(lisdexamfetamine dimesylate) - Shire

BOXED WARNING

Stimulants are subject to misuse, abuse, addiction, and criminal diversion. Misuse of amphetamines may cause sudden death and serious cardiovascular (CV) adverse events.

THERAPEUTIC CLASS

Sympathomimetic amine

INDICATIONS

Treatment of attention-deficit hyperactivity disorder (ADHD) in patients ≥ 6 yrs.

ADULT DOSAGE

Adults: Individualize dose. Initial: 30mg qam. Titrate: May adjust in increments of 10-20mg/week. Max: 70mg/day.

PEDIATRIC DOSAGE

Pediatrics: ≥ 6 Yrs: Individualize dose. Initial: 30mg qam. Titrate: May adjust in increments of 10-20mg/week. Max: 70mg/day.

HOW SUPPLIED

Cap: 20mg, 30mg, 40mg, 50mg, 60mg, 70mg

CONTRAINDICATIONS

Use with or within a minimum of 14 days following d/c of an MAOI.

WARNINGS/PRECAUTIONS

Sudden death, stroke, myocardial infarction (MI) reported; avoid with known serious structural cardiac and heart rhythm abnormalities, cardiomyopathy, coronary artery disease (CAD), or other serious cardiac problems. Promptly evaluate cardiac condition if symptoms of cardiac disease develop (eg, exertional chest pain, unexplained syncope). May cause modest increase in BP and HR; caution with conditions that could be compromised by BP or HR elevation (eg, preexisting HTN, heart failure, recent MI, or ventricular arrhythmia). May exacerbate symptoms of behavior disturbance and thought disorder in patients with preexisting psychotic disorder. Caution in patients with comorbid bipolar disorder; may cause induction of mixed/manic episode. May cause treatment-emergent psychotic/manic symptoms in children and adolescents without a prior history of psychotic illness or mania; may consider d/c if symptoms occur. Aggressive behavior or hostility reported; monitor for appearance or worsening. Monitor growth (weight and height) in pediatric patients; may need to d/c if patient is not growing or gaining weight as expected. May lower convulsive threshold; d/c if seizure develops. Difficulties with accommodation and blurring of vision reported. Exacerbation of motor and phonic tics, and Tourette's syndrome reported. Prescribe or dispense the least amount feasible at one time to minimize possibility of overdosage.

ADVERSE REACTIONS

N/V, insomnia, rash, upper abdominal pain, decreased appetite, dizziness, dry mouth, irritability, weight decrease, affect lability, anxiety, anorexia, diarrhea, jittery feeling.

DRUG INTERACTIONS

See Contraindications. Urinary acidifying agents (eg, ammonium chloride, sodium acid phosphate) and methamphetamine may increase urinary excretion. Urinary alkalinizing agents (eg, acetazolamide and some thiazides) may decrease urinary excretion. May inhibit adrenergic blockers. May counteract sedative effect of antihistamines. May antagonize the hypotensive effects of antihypertensives. May inhibit hypotensive effects of veratrum alkaloids. May delay intestinal absorption of ethosuximide, phenobarbital, and phenytoin. May produce a synergistic anticonvulsant action with phenobarbital and phenytoin. May enhance activity of TCAs or sympathomimetic agents. May potentiate analgesic effects of meperidine. Chlorpromazine and haloperidol may inhibit central stimulant effects. Lithium carbonate may inhibit anorectic and stimulatory effects. May enhance the adrenergic effect of norepinephrine. Propoxyphene overdose may potentiate CNS stimulation and cause fatal convulsions.

PREGNANCY

Category C, not for use in nursing.

MECHANISM OF ACTION

Sympathomimetic amine; prodrug of dextroamphetamine. Therapeutic action in ADHD not known; suspected to block reuptake of norepinephrine and dopamine into presynaptic neuron and increase the monoamine release into extraneuronal space.

PHARMACOKINETICS

Absorption: Rapid; $T_{max}=1$ hr (lisdexamfetamine), 3.5 hrs (dextroamphetamine). **Distribution:** Found in breast milk. **Metabolism:** Hydrolysis by RBC; dextroamphetamine, L-lysine (metabolites). **Elimination:** Urine (96%; 42% amphetamine, 2% unchanged), feces (0.3%); $T_{1/2}<1$ hr.

ASSESSMENT

Assess for psychiatric history (eg, family history of suicide, bipolar disorder, depression, drug abuse, or alcoholism), CV disease, tics or Tourette's syndrome, seizure, hypersensitivity or idiosyncratic reactions to other sympathomimetic amines, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for CV abnormalities, exacerbations of behavior disturbances and thought disorder, psychotic or manic symptoms, aggressive behavior, hostility, seizures, visual disturbances, and exacerbation of motor and phonic tics and Tourette's syndrome. Monitor BP and HR. Monitor height and weight in children.

PATIENT COUNSELING

Inform about benefits and risks of treatment, appropriate use, and drug abuse/dependence risk. Advise about serious CV risks (eg, sudden death, MI, stroke, and HTN); instruct to contact physician immediately if patient develop symptoms of cardiac disease (eg, exertional chest pain, unexplained syncope). Inform that treatment-emergent psychotic or manic symptoms may occur. Instruct parents or guardians of pediatric patients to monitor growth and weight during treatment. Advise to notify physician if pregnant or planning to become pregnant and to avoid breastfeeding. Inform that therapy may impair ability of engaging in dangerous activities (eg, operating machinery or vehicles); instruct patient to assess how the medication affects them before performing dangerous tasks.

ADMINISTRATION/STORAGE

Administration: Oral route. Take in am; avoid afternoon doses. Swallow cap whole or dissolve entire contents in glass of water; do not store once dissolved. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT EE

[print](#)[Close window](#)

Xanax

(alprazolam) - Pharmacia & Upjohn

THERAPEUTIC CLASS

Benzodiazepine

INDICATIONS

Management of anxiety disorders or short-term relief of anxiety symptoms. Treatment of panic disorder, with or without agoraphobia.

ADULT DOSAGE

Adults: Individualize dose. Anxiety: Initial: 0.25-0.5mg tid. Titrate: May increase at intervals of 3-4 days. Max: 4mg/day in divided doses. Panic Disorder: Initial: 0.5mg tid. Titrate: May increase by ≤ 1 mg/day at intervals of 3-4 days depending on response; slower titration for >4 mg/day. Usual: 1-10mg/day. Elderly/Advanced Liver Disease/Debilitating Disease: Initial: 0.25mg bid-tid. Titrate: Increase gradually PRN and as tolerated. Daily Dose Reduction/Discontinuation: Decrease dose gradually (≤ 0.5 mg every 3 days).

HOW SUPPLIED

Tab: 0.25mg*, 0.5mg*, 1mg*, 2mg* *scored

CONTRAINDICATIONS

Acute narrow-angle glaucoma, untreated open-angle glaucoma, concomitant ketoconazole or itraconazole.

WARNINGS/PRECAUTIONS

Risk of dependence. Seizures reported with dose reduction or abrupt d/c. Multiple seizures, status epilepticus, early morning/emergence of anxiety reported. Withdrawal reactions may occur; reduce dose or d/c therapy gradually. May impair mental/physical ability. Caution with impaired renal/hepatic/pulmonary function, severe depression, suicidal ideation/plans, debilitation, obesity, and in elderly. May cause fetal harm. Hypomania/mania reported with depression. Has a weak uricosuric effect.

ADVERSE REACTIONS

Drowsiness, lightheadedness, depression, headache, confusion, insomnia, dry mouth, constipation, diarrhea, N/V, tachycardia/palpitations, blurred vision, nasal congestion.

DRUG INTERACTIONS

See Contraindications. Not recommended with azole antifungals. Avoid with very potent CYP3A inhibitors. Additive CNS depressant effects with psychotropics, anticonvulsants, antihistaminics, and ethanol. Fluoxetine, fluvoxamine, nefazodone, cimetidine, and oral contraceptives may increase levels. CYP3A inducers (eg, carbamazepine), propoxyphene, and smoking may decrease levels. Caution with alcohol, other CNS depressants, diltiazem, isoniazid, macrolides (eg, erythromycin, clarithromycin), grapefruit juice, sertraline, paroxetine, ergotamine, cyclosporine, amiodarone, nicardipine, nifedipine, and other CYP3A inhibitors.

PREGNANCY

Category D, not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; mechanism unknown, presumed to bind at stereospecific receptors at several sites within the CNS.

PHARMACOKINETICS

Absorption: Readily absorbed; $T_{max}=1-2$ hrs; $C_{max}=8-37$ ng/mL (0.5-3mg). **Distribution:** Plasma protein binding (80%); found in breast milk; crosses the placenta. **Metabolism:** Extensive. Liver via CYP3A4; 4-hydroxyalprazolam and α -hydroxyalprazolam (major metabolites). **Elimination:** Urine; $T_{1/2}=11.2$ hrs.

ASSESSMENT

Assess for drug hypersensitivity, acute narrow-angle glaucoma, untreated open-angle glaucoma, depression, suicidal ideation, renal/hepatic/pulmonary function, debilitation, obesity, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for rebound/withdrawal symptoms (eg, seizures), episodes of hypomania/mania, renal/hepatic/pulmonary function. Monitor CBC, urinalysis, and blood chemistry periodically. Periodically reassess usefulness of therapy.

PATIENT COUNSELING

Advise to inform their physician about any alcohol consumption and medicines taken; alcohol should generally be avoided. Instruct to inform physician if pregnant, nursing, planning to be pregnant, or become pregnant while on therapy. Advise not to drive or operate dangerous machinery. Advise not to increase/decrease dose or abruptly d/c therapy without consulting a physician.

ADMINISTRATION/STORAGE

Administration: Oral route. **Storage:** 20-25°C (68-77°F).

EXHIBIT FF



Xyrem

(sodium oxybate) - Jazz

BOXED WARNING

Obtundation and clinically significant respiratory depression occurred at recommended doses; almost all patients in the trials were receiving CNS stimulants. Sodium oxybate is the Na⁺ salt of gamma hydroxybutyrate (GHB); abuse of GHB, alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreased level of consciousness, coma, and death. Available only through a restricted distribution program (Xyrem Success Program) because of risk of CNS depression, abuse, and misuse; prescribers and patients must enroll in the program.

THERAPEUTIC CLASS

CNS Depressant

INDICATIONS

Treatment of cataplexy and excessive daytime sleepiness in narcolepsy.

ADULT DOSAGE

Adults: Initial: 4.5g/night in 2 equally divided doses (2.25g qhs at least 2 hrs pc, then 2.25g taken 2.5-4 hrs later). Titrate: Increase by 1.5g/night (0.75g/dose) at weekly intervals. Effective Dose Range: 6-9g/night. Max: 9g/night. Hepatic Impairment: Initial: 2.25g/night in 2 equally divided doses (approximately 1.13g qhs at least 2 hrs pc, then 1.13g taken 2.5-4 hrs later). Elderly: Start at lower end of dosing range.

HOW SUPPLIED

Sol: 0.5g/mL [180mL]

CONTRAINDICATIONS

Concomitant use with sedative hypnotic agents and alcohol. Succinic semialdehyde dehydrogenase deficiency.

WARNINGS/PRECAUTIONS

May only be dispensed to patients enrolled in the Xyrem Success Program. May impair physical/mental abilities. Evaluate for history of drug abuse and monitor closely for signs of misuse/abuse. May impair respiratory drive, especially in patients with compromised respiratory function. Increased central apneas, oxygen desaturation events, and sleep-related breathing disorders may occur. Sleep-related breathing disorders tend to be more prevalent in obese patients, postmenopausal women not on hormone replacement therapy, and narcolepsy patients. Caution in patients with history of depressive illness and/or suicide attempt; monitor for emergence of depressive symptoms. Confusion, anxiety, and other neuropsychiatric reactions (eg, hallucinations, paranoia, psychosis, agitation) reported; carefully evaluate emergence of confusion, thought disorders, and/or behavior abnormalities. Parasomnias reported; fully evaluate episodes of sleepwalking. Contains high salt content; consider amount of daily Na⁺ intake in each dose in patients sensitive to salt intake (eg, heart failure [HF], HTN, renal impairment). Caution with hepatic impairment and in elderly.

ADVERSE REACTIONS

Obtundation, respiratory depression, N/V, dizziness, diarrhea, somnolence, enuresis, tremor, attention disturbance, pain, paresthesia, disorientation, irritability, hyperhidrosis.

DRUG INTERACTIONS

See Contraindications. Other CNS depressants (eg, opioid analgesics, benzodiazepines, sedating antidepressants or antipsychotics, general anesthetics, muscle relaxants, and/or illicit CNS depressants) may increase risk of respiratory depression, hypotension, profound sedation, syncope, and death; consider dose reduction or d/c of ≥ 1 CNS depressants (including sodium oxybate) if combination therapy is required. Consider interrupting therapy if short-term use of an opioid (eg, post- or perioperative) is required.

PREGNANCY

Category C, caution in nursing.

MECHANISM OF ACTION

CNS depressant; has not been established. Hypothesized that therapeutic effects on cataplexy and excessive daytime sleepiness are mediated through GABA_B actions at noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons.

PHARMACOKINETICS

Absorption: Rapid; absolute bioavailability (88%); T_{max}=0.5-1.25 hr. **Distribution:** V_d=190-384mL/kg; plasma protein binding (<1%). **Metabolism:** Krebs cycle, β -oxidation. **Elimination:** Lungs, urine (<5%), feces; T_{1/2}=0.5-1 hr.

ASSESSMENT

Assess for succinic semialdehyde dehydrogenase deficiency, alcohol intake, CNS depression-related events, history of drug abuse, compromised

respiratory function, history of depressive illness and/or suicide attempt, hepatic impairment, sensitivity to salt intake (eg, HF, HTN, renal impairment), pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for obtundation, respiratory depression, CNS depression, signs of abuse/misuse, sleep-disordered breathing, suicide attempt, confusion, anxiety, other neuropsychiatric reactions, thought disorders, behavior abnormalities, parasomnias, sleepwalking, and other possible adverse reactions.

PATIENT COUNSELING

Inform about the Xyrem Success Program. Instruct to see prescriber frequently (every 3 months) to review dose titration, symptom response, and adverse reactions. Instruct to store drug in a secure place, out of reach of children/pets. Inform that patients are likely to fall asleep quickly (within 5-15 min) after taking the drug; instruct to remain in bed after taking 1st dose. Advise not to drink alcohol or take other sedative hypnotics while on therapy. Inform that therapy can be associated with respiratory depression. Instruct to avoid operating hazardous machinery (eg, automobiles, airplanes) until patient is reasonably certain that therapy does not affect them adversely and for at least 6 hrs after the 2nd nightly dose. Advise to contact physician if depressed mood, markedly diminished interest or pleasure in usual activities, significant change in weight and/or appetite, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, or suicidal ideation develops. Inform that sleepwalking may occur; instruct to notify physician if this occurs. Inform patients who are sensitive to salt intake that drug contains a significant amount of Na⁺ and they should limit their Na⁺ intake.

ADMINISTRATION/STORAGE

Administration: Oral route. Take 1st dose at least 2 hrs pc. Refer to PI for important preparation and administration instructions. **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

EXHIBIT GG

**OREGON.gov**[Home](#) » [Data Requests](#)

Data Requests

Licensed healthcare providers and pharmacists may request an account to view system information online. Other entities may obtain PDMP information as well.

To obtain PDMP information these entities must submit a request form. PDMP Staff then run system reports for the requestor. Requests are fulfilled only for the purposes and under the provisions specified below.

For more information, click on the corresponding links located on the left menu.

Entities that May Request Information from the PDMP

Patients – To obtain their own controlled substance information as well as a list of system users who have access their records.

Healthcare Boards – To pursue to an active investigation of a specific individual who is licensed by the board conducting the investigation.

Law Enforcement – To gather information for an active drug-related investigation of an individual when permitted by a valid court order based on probable cause.

Researchers – For educational, research or public health purposes, but only when using de-identified information.

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Prescription Drug Monitoring Program - IPE | PO Box 14450

Portland, OR 97293-0450 Phone: 971-673-0741 | Fax: 971-673-0990

E-mail: pdmp.health@state.or.us

TTY: 971-673-0372

EXHIBIT HH

**OREGON.gov**

[Home](#) » [Data Requests](#) » [Law Enforcement](#)

Law Enforcement

A federal, state or local law enforcement agency engaged in an authorized drug-related investigation may request information from the PDMP for an individual that is the subject of the investigation. The request must be pursuant to a valid court order based on probable cause. ORS 431.966

A subpoena is not sufficient for the PDMP to release information. A law enforcement agency must provide a search warrant signed by a judge or a court order signed by a judge that indicates there is probable cause for the judge to issue the order.

Law Enforcement Information Request Procedure

Law enforcement agencies must perform the following steps to request information from the PDMP:

1. Click the Law Enforcement Info Request link located on the left menu.
2. Complete the fillable [Law Enforcement Information Request Form](#).
3. Print a hard copy of the completed Law Enforcement Information Request Form.
4. Sign the Law Enforcement Information Request Form.
5. Submit the signed Law Enforcement Information Request Form along with a copy of the court order documents to:

Mail: **Oregon Prescription Drug Monitoring Program-IPE**
PO Box 14450
Portland, OR 97293-0450

Or

Fax: 971-673-0990

The PDMP staff will review the application and contact the individual who submitted the request for validation.

If the form is complete and the court order is valid, PDMP staff will query the system for the requested information and provide a report to the law enforcement agency.

If the request or court order is not valid, PDMP staff will respond to the law enforcement agency providing an explanation for the denial.

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Prescription Drug Monitoring Program - IPE | PO Box 14450

Portland, OR 97293-0450 Phone: 971-673-0741 | Fax: 971-673-0990

E-mail: pdmp.health@state.or.us

TTY: 971-673-0372

EXHIBIT II

FILED 24 AUG '12 9:38 USDC-ORP

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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

UNITED STATES OF AMERICA,

'12-MC-298

Petitioner,

v.

**PETITION TO ENFORCE DEA
ADMINISTRATIVE SUBPOENA**

**STATE OF OREGON PRESCRIPTION
DRUG MONITORING PROGRAM,**

Respondent.

Petitioner, by S. Amanda Marshall, United States Attorney for the District of Oregon, and through Leslie J. Westphal, Assistant United States Attorney for the District of Oregon, petitions this Court to enforce an administrative subpoena.

Pursuant to Local Rule 7-1, the parties have made good faith efforts to resolve the dispute but have been unable to do so.

The United States hereby petitions this Court as follows:

1. This is a proceeding brought pursuant to 21 U.S.C. § 876(c) to judicially enforce a Drug Enforcement Administration (DEA) subpoena issued under the authority of 21 U.S.C. § 876(a). This Court has jurisdiction pursuant to 21 U.S.C. § 876(c) and 28 U.S.C. § 1345.

2. Tyler Warner is a Diversion Investigator for the DEA, United States Department of Justice. He is assigned to the Seattle Field Office, Portland District Office. He is authorized to serve subpoenas pursuant to 21 U.S.C. § 876(b). The Portland District Office is supervised by Lori Cassity, DEA Group Supervisor, who is authorized to issue DEA subpoenas pursuant to 21 U.S.C. § 876 and 28 C.F.R. Pt. 0, Subpart R, App. § 4(a).

3. As set forth in the declaration filed with this Petition, Investigator Warner is conducting an investigation concerning possible violations of the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, by an individual in the greater Portland area. To this end, on January 6, 2012, Investigator Warner served a subpoena, RF-12-237101, pursuant to 21 U.S.C. § 876, on the Oregon Prescription Drug Monitoring Program (PDMP), P.O. Box 14450, Portland, OR 97293-0450, Respondent in this matter. The subpoena sought a Physician Profile for all Schedule II-V controlled substance prescriptions written by the subject of the investigation from June 1, 2011 through January 6, 2012. The subpoena was issued by DEA Group Supervisor Lori Cassity on January 5, 2012. The compliance date on the subpoena was January 20, 2012.

4. As of this date, the PDMP has not complied with the subpoena. Through its counsel, the PDMP has informed the United States that it does not plan to comply with the subpoena because Oregon Revised Statute, Section 431.966(2)(a)(C) prohibits the production of

the requested materials absent a court order and a showing of probable cause. DEA administrative subpoenas must be enforced irrespective of Oregon state law because Federal law preempts the state statute and, therefore, a properly served administrative subpoena need not meet the additional requirements of Oregon state law.

5. This petition is supported by a memorandum of law.

WHEREFORE, the Petitioner respectfully requests:

1. That this Court find that Oregon Revised Statute, Section 431.966(2)(a)(C) is preempted by 21 U.S.C. § 876, to the extent that the Oregon statute imposes a requirement to obtain a court order supported by probable cause for a DEA administrative subpoena; and
2. That this Court enter an order directing Respondent to comply with all federal administrative subpoenas in their entirety; and
3. For such other relief as is just and proper.

Dated this 23rd day of August, 2012.

Respectfully Submitted,

S. AMANDA MARSHALL
United States Attorney
District of Oregon



LESLIE J. WESTPHAL
Assistant United States Attorney

EXHIBIT JJ

FILED 24 AUG '12 9:38 USDC-ORP

S. AMANDA MARSHALL, OSB # 95347

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District of Oregon

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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

UNITED STATES OF AMERICA,

Case No.: '12-MC-298

Petitioner,

v.

**DECLARATION OF LORI A. CASSITY
IN SUPPORT OF PETITION TO
ENFORCE DEA ADMINISTRATIVE
SUBPOENA**

**STATE OF OREGON PRESCRIPTION
DRUG MONITORING PROGRAM,**

Respondent.

Pursuant to 28 U.S.C. § 1746, Lori A. Cassity declares under penalty of perjury that the information stated hereafter is true and correct:

1. I, Lori A. Cassity, am a Supervisory Special Agent of the United States Drug Enforcement Administration (DEA). I have been a Special Agent with the DEA for 29 years, of which approximately 13 of those years I have supervised criminal investigations targeting violations of the Controlled Substance Act. Pursuant to 21 U.S.C. § 878(a)(2), I have authority to execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas

and summonses issued under the authority of the United States.

2. Title 21 U.S.C. § 876 empowers the Attorney General to issue administrative subpoenas in any investigation involving controlled substances. This authority has been delegated to the Drug Enforcement Administration under Title 28 C.F.R. § 0.100. DEA policies and procedures direct that administrative subpoenas issued as a result of this delegation may only request records relevant to a DEA investigation and that are lawfully available to DEA with an administrative subpoena. Records received by DEA, in response to an administrative subpoena, are case sensitive and governed by significant restrictions on the dissemination of information contained in received records, subjecting employees to discipline, termination, as well as civil and criminal sanctions for improper disclosure.

3. I am currently the Group Supervisor for the DEA Portland Tactical Diversion Squad. In this capacity, I am responsible for criminal investigations initiated and conducted targeting violations of the Controlled Substance Act, specifically those involving the diversion of pharmaceutical controlled substances from their lawful, intended purpose, to illicit use.

4. The diversion of pharmaceutical controlled substances is directly attributed to the rising nationwide rates of prescription drug abuse and overdose deaths and often begins with a prescription. The prescription may be fraudulently obtained by a patient, unlawfully issued by a physician or filled by a pharmacy. Ultimately, it is required that a DEA investigation targeting criminal diversion of pharmaceutical controlled substances determine whether the issuance, receipt or fulfillment of a physician's prescription is conducted in accordance with applicable laws. The Oregon Prescription Monitoring Program (PMP) is the only resource available to the DEA where information addressing each of these three actions is consolidated.

5. Expeditious, yet accountable access to this data compiled by the Oregon PMP will

be a crucial tool for DEA in its attempt to successfully stem the growth of pharmaceutical controlled substance abuse in Oregon, through the performance of timely and thorough investigations.

6. Given the DEA's current investigatory practices, I anticipate that we will issue additional administrative subpoenas to the Oregon PMP approximately two times a month for the foreseeable future.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 20th day of August, 2012, at Portland, Oregon.



LORI A. CASSITY
Group Supervisor
Portland Tactical Diversion Squad
Drug Enforcement Administration

EXHIBIT KK

S. AMANDA MARSHALL, OSB # 95347
United States Attorney
District of Oregon

FILED 24 AUG '12 9:38 USDC-ORP

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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

UNITED STATES OF AMERICA,

'12-MC-298

Petitioner,

v.

**MEMORANDUM IN SUPPORT OF
PETITION TO ENFORCE DEA
ADMINISTRATIVE SUBPOENA**

**STATE OF OREGON PRESCRIPTION
DRUG MONITORING PROGRAM,**

Respondent.

Petitioner, by S. Amanda Marshall, United States Attorney for the District of Oregon, and through Leslie J. Westphal, Assistant United States Attorney for the District of Oregon, submits this memorandum in support of a petition to enforce an administrative subpoena, pursuant to 21

U.S.C. § 876(c).¹ The issue posed by this petition is whether an administrative subpoena, properly executed and served under federal law, must also meet inconsistent requirements of Oregon law. Petitioner contends that fundamental Supremacy Clause principles require preemption of state legislation that is in conflict with federal law. Accordingly, this Court should order respondent to comply with the administrative subpoena.

BACKGROUND

On January 5, 2012, Drug Enforcement Administration (DEA) Group Supervisor Lori Cassity issued DEA Subpoena No. RF-12-237101, Exhibit A, pursuant to 21 U.S.C. § 876. On January 6, 2012, Investigator Tyler Warner served the subpoena on the Oregon Prescription Drug Monitoring Program (PDMP), Respondent in this action, in accordance with the requirements of 21 U.S.C. § 876(b). The subpoena requested a “Physician Profile for all Schedule II-V controlled substance prescriptions written by [the subject of the investigation] from 6/01/2011 through 1/06/2012.”² The compliance date for the subpoena was January 20, 2012. Warner Declaration, p. 2.

To date, the Respondent has not complied with the subpoena, and through counsel, has advised that it will not comply with the subpoena because to do so would violate Oregon law. Warner Declaration, p. 2. Respondent cites Oregon Revised Statute, Section 431.966 as the basis for its noncompliance, which “forbids the agency from disclosing the requested information unless

¹ “In the case of contumacy by or refusal to obey a subpoena [sic] issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpoena. The court may issue an order requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony touching the matter under investigation.” 21 U.S.C. § 876(c).

² Because the investigation is ongoing, the subject’s name is not included in this petition.

pursuant to ‘a valid court order based on probable cause and issued at the request of a federal, state or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.’” Oregon Department of Justice Letter, Ex. B.

ARGUMENT

I. THE DEA ADMINISTRATIVE SUBPOENA IS VALID.

Congress may authorize the executive branch to issue subpoenas for the production of records and information necessary to the performance of agency functions. *Oklahoma Press Publishing Co. v. Walling*, 327 U.S. 186, 209 (1946). Such subpoenas may be judicially enforced upon consideration of: “(1) whether Congress has granted the authority to investigate; (2) whether procedural requirements have been followed; and (3) whether the evidence is relevant and material to the investigation.” *United States v. Golden Valley Elec. Ass’n*, 11-35195, 2012 WL 3185827, at *3 (9th Cir. Aug. 7, 2012) (quoting *EEOC v. Children’s Hosp. Med. Ctr. of N. Cal.*, 719 F.2d 1426, 1428 (9th Cir. 1983) (en banc)).³

Judicial enforcement is appropriate in the instant matter. First, the DEA investigation is for

³ In its recent decision, *United States v. Golden Valley Electric Association*, the Ninth Circuit articulated an additional requirement: that “a fourth amendment reasonableness inquiry must also be satisfied.” *Golden Valley*, 2012 WL 3185827, at *3 (citing *Reich v. Mont. Sulphur & Chem. Co.*, 32 F.3d 444 n.5 (9th Cir. 1994)). “[I]t is sufficient [for Fourth Amendment purposes] if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant. The gist of the protection is in the requirement, expressed in terms, that the disclosure sought shall not be unreasonable.” *Id.* at *5 (quoting *Mont. Sulphur*, 32 F.3d at 448) (alterations in original). “[T]he requirement of reasonableness . . . comes down to [whether] specification of the documents to be produced [is] adequate, but not excessive, for the purposes of the relevant inquiry.” *Id.* (quoting *Oklahoma Press*, 327 U.S. at 209). “A ‘subpoena should be enforced unless the party being investigated proves the inquiry is unreasonable because it is overbroad or unduly burdensome.’” *Id.* (quoting *Children’s Hosp.*, 719 F.2d at 1428). The DEA administrative subpoena seeks a Physician Profile for controlled substance prescriptions written by a single physician, for a limited time period. Warner Declaration, p. 1–2. Because the PDMP has not shown the request to be overbroad or unduly burdensome, the Fourth Amendment reasonableness requirement has been satisfied.

an authorized purpose within the power of Congress. Congress specifically authorized investigations of the illegal distribution of controlled substances in the Comprehensive Drug Abuse Prevention and Control Act, and provided authority for the DEA to issue subpoenas in furtherance of such investigations. Title 21, United States Code, Section 876(a) grants the DEA the power to compel testimony or “require the production of any records . . . which the Attorney General finds relevant or material to the investigation” of any violation of the Comprehensive Drug Abuse Prevention and Control Act.⁴ “This statute was intended as a comprehensive federal program to place certain drugs and other substances under strict federal controls to be administered by the Attorney General.” *United States v. Hossbach*, 518 F. Supp. 759, 765 (E.D. Pa. 1980). The Ninth Circuit has acknowledged that “[t]he statute gives the Attorney General the authority to issue administrative subpoenas to investigate drug crimes.” *Golden Valley*, 2012 WL 3185827, at *3.

Second, all procedural requirements have been followed. The Attorney General may delegate the authority to issue administrative subpoenas to DEA law enforcement personnel. 21 U.S.C. § 878(a)(2). Authority to issue administrative subpoenas has been further delegated to DEA Group Supervisors. 28 C.F.R. Pt. 0, Subpt. R, App. § 4(a). In the instant matter, the administrative

⁴ This includes the power to request documents which constitute protected health information. *See* 45 C.F.R. § 164.512(f). The DEA’s request meets the requirements of 45 C.F.R. § 164.512(f)(1)(ii)(C), which permits disclosure by the responding entity upon administrative subpoena when “[t]he information sought is relevant and material to a legitimate law enforcement inquiry, . . . [t]he request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; . . . and [d]e-identified information could not reasonably be used.” In the instant case, the information sought is relevant to a legitimate DEA inquiry. The request was limited in scope insofar as it only sought a Physician Profile for prescriptions of specifically classified controlled substances prescribed by the subject of the investigation. Finally, redacted information could not have reasonably been used in the investigation. *See Warner Declaration*, p. 1–2.

subpoena was validly issued by DEA Group Supervisor Lori Cassity pursuant to these provisions.

Finally, the documents sought are relevant and material to the investigation the DEA is conducting. The Ninth Circuit has acknowledged that “[t]he relevance requirement is ‘not especially constraining,’” *Golden Valley*, 2012 WL 3185827, at *3 (quoting *EEOC v. Fed. Express Corp.*, 558 F.3d 842, 854 (9th Cir. 2009)), and a court “must enforce administrative subpoenas unless the evidence sought by the subpoena is plainly incompetent or irrelevant to any lawful purpose of the agency,” *id.* (quoting *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1076 (9th Cir. 2001)). The DEA is investigating a physician for illegal distribution of controlled substances. The subpoena requests a Physician Profile which details the prescription of certain controlled substances written by the subject. Warner Declaration, p. 1–2. Data regarding a physician’s prescription writing is plainly relevant to an investigation of that physician’s potentially illegal distribution of controlled substances; and even then, a physician’s conduct need not be proven illegal: “The information subpoenaed does not need to be relevant to a crime; in fact, it may be used to dissipate any suspicion of a crime. The information subpoenaed need only be relevant to an agency investigation.” *Golden Valley*, 2012 WL 3185827, at *4 (citing *Fed. Express Corp.*, 558 F.3d at 854). Because the requested information is relevant to a legitimate DEA investigation, the subpoena should be enforced.

II. STATE LAW MAY NOT EXCUSE A RESPONDENT FROM COMPLIANCE WITH FEDERAL LAW BECAUSE THE FEDERAL STATUTE PREEMPTS STATE LAW.

Through its counsel, the PDMP stated that it will not comply with the subpoena because compliance would violate state law. Warner Declaration, p. 2. Specifically, the PDMP asserts that Or. Rev. Stat. § 431.966(2)(a)(C) does not allow for compliance with an administrative subpoena, absent “a valid court order based on probable cause and issued at the request of a federal, state or

local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.” To the extent this Oregon statute precludes compliance with a validly issued DEA administrative subpoena, or seeks to set a higher standard for production than that which is required by federal statute, it is in conflict with federal law. Under such circumstances, federal law preempts the state statute, and the subpoena should be enforced regardless of whether it complies with state law.

The power of Congress to preempt state law is a fundamental principle underlying the Supremacy Clause of the United States Constitution. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Preemption of state law by federal law may be apparent from the express terms of a federal statute or it may be implicit in the statute. *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203–04 (1983). Implicit preemption occurs when: (1) Congress intends federal law to “occupy the field,” or (2) “state law is naturally preempted to the extent it conflicts with a federal statute.” *Crosby*, 530 U.S. at 372.

The Controlled Substances Act, at 21 U.S.C. § 903, expressly sets forth when it should preempt state law, and mandates preemption when a conflict exists:

No provision of [the Act] shall be construed as indicating an intent on the part of Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, *unless there is a positive conflict between that provision . . . and that State law* so that the two cannot consistently stand together.

21 U.S.C. § 903 (emphasis added). This provision “disclaims field pre-emption, and affirmatively *prescribes* federal pre-emption whenever state law creates a conflict.” *Gonzales v. Oregon*, 546 U.S. 243, 289–90 (2006) (emphasis in original). “Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually

conflicts with federal law.” *Hillsborough County, Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 713 (1985) (internal quotation marks and citations omitted).

Therefore, as a matter of both statutory and Constitutional analysis, the issue before this court is whether Oregon’s statute implicitly conflicts with the federal statute authorizing administrative subpoenas. Preemption must occur when “compliance with both federal and state regulations is a physical impossibility” or when the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 152–53 (1982) (internal quotation marks and citations omitted).

A. THE OREGON STATUTE’S PROBABLE CAUSE REQUIREMENT EXPRESSLY CONFLICTS WITH TITLE 21, UNITED STATES CODE, SECTION 876.

Oregon Revised Statute, Section 431.966 (2)(a)(C) creates a positive conflict with Title 21, United States Code, Section 876(a). The federal statute permits the DEA to issue administrative subpoenas in conjunction with both criminal investigations and civil enforcement matters without a showing of probable cause. The state provision, on the other hand, requires a specific finding of probable cause. The imposition of a probable cause requirement on administrative subpoenas would prevent the DEA from acquiring information through properly issued subpoenas when the investigation had not developed probable cause.

“The Supreme Court has refused to require that an agency have probable cause to justify issuance of a subpoena.” *Golden Valley*, 2012 WL 3185827, at *6. “The requirement of ‘probable cause, supported by oath or affirmation’ literally applicable in the case of a warrant is satisfied, in that of an order for production, by the court’s determination that the investigation is authorized by Congress, is for a purpose Congress can order, and the documents sought are relevant to the

inquiry.” *Oklahoma Press Pub. Co. v. Walling*, 327 U.S. 186, 209 (1946) (finding probable cause was unnecessary for an administrative subpoena issued pursuant to a Department of Labor investigation authorized by Congress). *See also United States v. Powell*, 379 U.S. 48, 57 (1964) (finding probable cause was unnecessary for the Internal Revenue Service to issue an administrative summons). Because the Oregon law requires a showing of probable cause to obtain the information requested in the administrative subpoena, yet a federal agency need not make a showing of probable cause to justify the issuance of an administrative subpoena, the Oregon law stands in contravention of the execution of the subpoena, frustrating the operation of 21 U.S.C. § 876 and refusing its provisions their natural effect. *See Crosby*, 530 U.S. at 373. Therefore, the laws are in direct conflict and the Oregon law stands as an obstacle to the DEA’s congressionally mandated efforts to accomplish its investigation.

B. THE OREGON STATUTE’S REQUIREMENT FOR A COURT ORDER IS NOT MERELY AN ADDITIONAL BURDEN ON THE AGENCY, BUT RATHER AN IMPERMISSIBLE OBLIGATION THAT CONFLICTS WITH TITLE 21, UNITED STATES CODE, SECTION 876 AND THE DEA’S CONGRESSIONALLY MANDATED OBJECTIVE.

The DEA, in conjunction with an investigation, may issue an administrative subpoena to obtain information regarding controlled substances without a court order,⁵ but Or. Rev. Stat. § 431.966(2)(a)(C) requires a court order to obtain controlled substances records from PDMP. Therefore, the Oregon law unlawfully encumbers the DEA’s investigatory mandate.

“If the purpose of [a federal] act cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated and its provisions be refused their natural effect—the state

⁵ *See* 28 C.F.R. Pt. 0, Subpt. R, App. § 4(a). Among others, “DEA Special Agent Group Supervisors . . . are authorized to sign and issue subpoenas with respect to controlled substances, listed chemicals, tableting machines or encapsulating machines under 21 U.S.C. 875 and 876 in regard to matters within their respective jurisdictions.” *Id.*

law must yield to the regulation of Congress within the sphere of its delegated power.” *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (quoting *Savage v. Jones*, 225 U.S. 501, 533 (1912)). Therefore, in the instant matter, there must be a determination if the provisions of the Controlled Substances Act (CSA)⁶—including its allowance for the issuance of administrative subpoenas without a court order—can be given their natural effect, in light of the Oregon law’s requirements:

The Controlled Substances Act was intended as a comprehensive federal program to place certain drugs and other substances under strict federal controls to be administered by the Attorney General. The Act provided the Attorney General with broad administrative duties as well as enforcement duties, both criminal and civil. . . . To assist the Attorney General in enforcing the Controlled Substances Act, Congress granted him the authority to issue investigative, or administrative subpoenas.

United States v. Mountain States Tel. & Tel. Co., Inc., 516 F. Supp. 225, 228–29 (D. Wyo. 1981).

With regard to that subpoena power:

[The CSA] authorizes the Attorney General to . . . compel production of records or other tangible things which constitute or contain evidence and upon which he has made a finding as to materiality or relevancy. . . . [The CSA] provides that the Attorney General may designate the person to serve the subpoena, . . . [and] refusal to respond to a subpoena allows the Attorney General to invoke court aid

H.R. Rep. No. 91-1444, at 4620–21 (1970).

A requirement that the DEA obtain a court order to validate its subpoena is more than a nuisance to the investigative process; it is in conflict with Congress’ intention to allow the DEA to issue investigatory subpoenas without the burden of additional requirements. Furthermore, 21 U.S.C § 876(c) plainly allows for judicial review “[i]n the case of contumacy by or refusal to obey a subpoena issued to any person . . . to compel compliance with the subpoena”—the very allowance

⁶ The Controlled Substances Act is Title II of the Comprehensive Drug Abuse Prevention and Control Act, Pub. L. No. 91-513, 84 Stat. 1236.

of which suggests that a court order is not otherwise required, nor should it be. Therefore, the state's requirement of a court order expressly conflicts with the federal statute's allowance that authorizes federal agencies to issue administrative subpoenas without a court order, and thus the federal law must preempt the state law.

C. OTHER COURTS, FACED WITH SIMILAR STATE RESTRICTIONS ON SECTION 876 ADMINISTRATIVE SUBPOENAS, HAVE FOUND EXPRESS CONFLICTS REQUIRING PREEMPTION.

The District of Colorado was faced with a similar question when a Section 876 administrative subpoena was served on the Colorado Board of Pharmacy. *United States Department of Justice v. Colorado Board of Pharmacy*, No. 10-cv-01116, 2010 WL 3547896 (D. Colo. Sept. 3, 2010), *adopting* 2010 WL 3547898 (D. Colo. Aug. 13, 2010). The subpoena sought information about a provider's prescription of controlled substances. *Colorado Board of Pharmacy*, 2010 WL 3547898, at *1. Colorado's law prohibited release when requested information was not specific to a particular individual, and the Board of Pharmacy argued it could not comply with a subpoena lacking that specificity. *Id.* at *2. Because the state law stood "as an obstacle to the DEA's efforts to accomplish its investigation," the Colorado statute unreasonably restricted the DEA's ability to conduct its investigation and therefore was preempted by 21 U.S.C. § 876. *Id.* at *4.

United States v. Michigan Department of Community Health, No. 1:10-MC-109, 2011 WL 2412602 (W.D. Mich. June 9, 2011), similarly found that a confidentiality law restricting disclosure of patient names was preempted by 21 U.S.C. § 876 because it stood as an obstacle to the federal law's subpoena power to obtain relevant drug investigation information, and was "nullified to the extent it conflicts with the federal law by preventing the federal government's

exercise of its subpoena power under § 876.” *Id.* at *13. The court did not limit the scope of the subpoena to information that was allowed by state law, but rather required that the state law yield to § 876.

A similar result is compelled here. The United States does not contend that it presently has a court order or articulable probable cause to support the administrative subpoena at issue, nor does it need them. Accordingly, imposing the requirements of Oregon law on this administrative subpoena will frustrate a legitimate DEA investigation; one which Congress clearly authorized, and for which it provided the subpoena as a means to carry out an investigation without the aid of a court. Under these circumstances, Or. Rev. Stat. § 431.966(2)(a)(C) must be preempted, and this court should order enforcement of the administrative subpoena.

D. THIS MATTER SHOULD BE DECIDED ON THE BASIS OF PREEMPTION AND NOT MERELY THE SUBPOENA’S VALIDITY, OTHERWISE EACH FUTURE REQUEST TO THE PDMP WILL REQUIRE AN ADDITIONAL COURT ORDER AND FURTHER EXPENDITURE OF JUDICIAL RESOURCES.

In the interest of judicial efficiency, it is imperative that this court decide the question of preemption, as a court order pursuant to 21 U.S.C. § 876(c) absent guidance regarding preemption will result in unnecessary future litigation whenever additional administrative subpoenas are issued to the PDMP. Or. Rev. Stat. § 431.966(2)(a)(C), as interpreted by the PDMP, substantially inhibits and frustrates the purpose of the CSA, and results in the unnecessary use of government resources in order to comply with the state law, given the more permissive allowance of federal law to obtain administrative subpoenas without court order. The DEA relies on the PDMP’s database as a crucial investigatory tool, and given current law enforcement objectives, it expects to issue numerous administrative subpoenas of a similar nature to the PDMP each year. Cassity Declaration, p. 2. Therefore, to avoid the need for the issuance of an order and use of the court’s

resources upon each administrative subpoena issued to the PDMP, it is imperative that the court decide the question of preemption at this juncture.

III. CONCLUSION

Therefore, the United States petitions this Court for an order finding that Oregon Revised Statute, Section 431.966 (2)(a)(C) is preempted by Title 21, United States Code Section 876, to the extent the Oregon statute requires a court order or a showing of probable cause as antecedent and additional requirements to compliance with federal administrative subpoenas. In addition, Petitioner asks the court to order Respondent to comply with all federal administrative subpoenas in their entirety.

Dated this 20th day of August, 2012.

Respectfully Submitted,

S. AMANDA MARSHALL
United States Attorney
District of Oregon

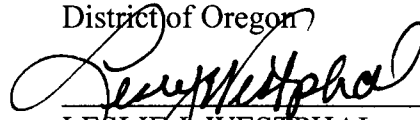

LESLIE J. WESTPHAL
Assistant United States Attorney

EXHIBIT LL

FILED 24 AUG '12 9:38 USDC-ORP

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UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

UNITED STATES OF AMERICA,

Petitioner,

Case No.: **'12-MC-298**

v.

**STATE OF OREGON PRESCRIPTION
DRUG MONITORING PROGRAM,**

**DECLARATION OF TYLER D.
WARNER IN SUPPORT OF PETITION
TO ENFORCE DEA ADMINISTRATIVE
SUBPOENA**

Respondent.

Pursuant to 28 U.S.C. § 1746, Tyler D. Warner declares under penalty of perjury that the information stated hereafter is true and correct:

1. I, Tyler D. Warner, am a Diversion Investigator of the United States Drug Enforcement Administration. Pursuant to 21 U.S.C. § 878(a)(2), I have authority to execute and serve administrative inspection warrants, subpoenas and summonses issued under the authority of the United States.

2. I have been involved in an ongoing investigation of the possible violations of the federal Controlled Substances Act, 21 U.S.C. § 801 et seq., by various individuals in the Portland, Oregon metro area.

3. On January 5, 2012, DEA Group Supervisor Lori Cassity issued DEA administrative subpoena number RF-12-237101 pursuant to 21 U.S.C. § 876 to the Oregon Prescription Drug Monitoring Program in Portland, Oregon, to provide, "a Physician Profile for all Schedule II-V controlled substance prescriptions written [by Dr. . . .] from 06/01/2011 through 01/06/2012" for the physician listed in the subpoena. These records are relevant to my ongoing investigation, in that I suspect that the physician may be involved in the unauthorized distribution of controlled substances. The name listed on the subpoena has been redacted for filing with the Court.

4. On January 6, 2012, I personally served a copy of the subpoena on the Oregon Prescription Drug Monitoring Program's designated agent. The compliance date on the subpoena was January 20, 2012, at 9:00 AM.

5. To date, the Oregon Prescription Drug Monitoring Program has not complied with the subpoena. I was informed on January 18, 2012, through Oregon Assistant Attorney General Thomas Castle, that due to Oregon law, the Oregon Prescription Drug Monitoring Program will not honor the subpoena.

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6. Protected health information must be disclosed through an administrative subpoena if redacted information could not reasonably be used in the investigation. Redacted protected health information could not reasonably have been used in the investigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 21st day of August, 2012, at Portland, Oregon.

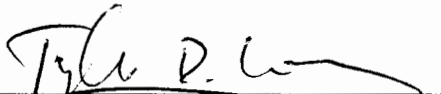

TYLER D. WARNER
Diversion Investigator
Drug Enforcement Administration

EXHIBIT MM

UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
PORTLAND DIVISION

UNITED STATES OF AMERICA,

'12-MC-298

Petitioner,

ORDER TO ENFORCE DEA
ADMINISTRATIVE SUBPOENA

v.

STATE OF OREGON PRESCRIPTION
DRUG MONITORING PROGRAM,

Respondent.

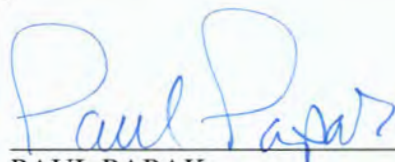
On Petition of the government,

IT IS HEREBY ORDERED:

That Oregon Revised Statute, Section 431.966(2)(a)(C) is preempted by Title 21 United States Code, Section 876, to the extent that the state statute requires a court order or showing of probable cause before compliance with an administrative subpoena from a federal agency; and

That the State of Oregon Prescription Drug Monitoring Program shall promptly comply with all federal administrative subpoenas henceforth.

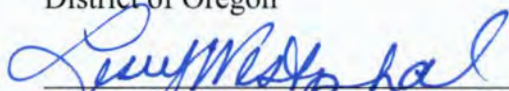
Dated this 27th day of August, 2012.



PAUL PAPAK
United States Magistrate Judge

Submitted by:

S. AMANDA MARSHALL, OSB#95347
United States Attorney
District of Oregon



LESLIE J. WESTPHAL, OSB #83344
Assistant United States Attorney

EXHIBIT NN



How Privacy Considerations Drive Patient Decisions and Impact Patient Care Outcomes

Trust in the confidentiality of medical records influences when, where, who and what kind of medical treatment is delivered to patients

Research and analysis conducted by New London Consulting

September 13, 2011

Sponsored by



Notices

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Purpose of the Study and Executive Overview Report

In mid 2011, FairWarning® commissioned New London Consulting to develop a survey of U.S. consumers, or patients, of care providers to determine how ***patient privacy considerations impact the actual delivery of healthcare***. The survey was designed to garner a baseline understanding of patient beliefs relative to a care providers' legal, ethical and moral responsibility to protect patient privacy. More importantly, the survey sought to measure how privacy considerations affect patient behaviors and decisions and influence patient care outcomes.

The survey was conducted using an online platform. Survey invitations were sent to more than 10,000 consumers across the United States. Invitations to participate were sent to a population that mirrors U.S. census demographics relative to race, economic class, age and gender. The survey invitation resulted in participation of 1265 respondents. The survey was live for approximately 120 days. The full survey methodology is detailed in Appendix 1.

Of special note, 59.6 percent of respondents were women. According to a U.S. Department of Labor report, women make 80 percent of the healthcare decisions for their families. Statistically, responses garnered in this survey approximate an accurate picture of what influences the decision making process relative to healthcare and where and from whom medical treatment is delivered to the household.

Purpose of the Survey

A series of 29 questions were posed that sought to reveal how privacy concerns impact patients' healthcare decisions and more specifically measure to what degree:

- ***Privacy considerations influence who patients seek care from***
- ***Privacy considerations influence when they receive care***
- ***Privacy considerations influence from where they seek care.***
- ***Privacy considerations influence what information they disclose, thereby affecting the care they receive***

This research documents how privacy concerns influence the healthcare decisions of U.S. patients. These concerns and expectations impact when, where and from which care providers patients seek medical treatment as well as their truthfulness with their provider regarding sensitive medical conditions due to privacy concerns. Additionally, the research maps the privacy expectations of the patient to healthcare practices and technologies employed to protect patient privacy as previously examined in FairWarning®'s report "[***Industry Best Practices for Patient Privacy in Electronic Health Records***](#)," released April 15, 2011.

The Executive Overview Report highlights several noteworthy findings and reveals patient attitudes, expectations, and actions regarding the protection of privacy. Additionally, this report provides insights for care providers to change the course of care through the integration of privacy initiatives, the adoption of a privacy-based culture and effective communication with patients about privacy.

Executive Overview - Summary of Key Findings

Trust in the confidentiality of medical records is influencing when, where, who and what kind of medical treatment is delivered to patients. These privacy concerns affect the flow of information to providers to use in the diagnosis and care of their patients.

85.2 percent of participants indicated that if they had a sensitive medical condition, a care provider's reputation for protecting privacy would influence their choice to seek care from that provider. 27.1 percent of patients stated they would withhold information from their care provider based on privacy concerns. 27.6 percent stated they have or would postpone seeking care for a sensitive medical condition due to privacy concerns. More than 1 out of 2 patients indicated they would seek care outside of their community due to privacy concerns with 35 percent indicating they would travel more than 50 miles. By withholding medical information, patients are impacting the care received and hence the outcome. More specific industry and academic research and study is required to fully appreciate the extent to which patient outcomes are influenced by privacy. Accurate information is the bedrock upon which physicians assess medical conditions, and hence determines the treatment patients receive. When this information is withheld or even falsified, fundamental treatment assumptions are impacted.

More than 1 out of 4 patients stated that if they had a sensitive medical condition, they would withhold information from their care provider or postpone seeking care out of privacy concerns.

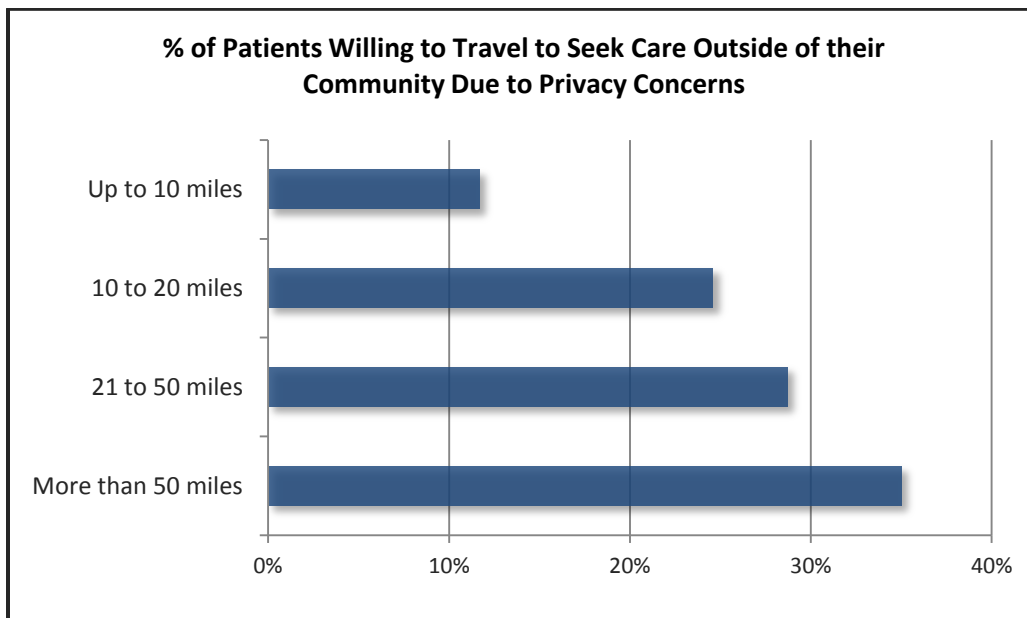


Figure 1. Patients Willingness to Travel to Avoid Privacy Concerns

Consumers have a significant negative response when a privacy violation occurs. This break in trust results in patient attrition and damage to the provider’s reputation.

When privacy violations occur within their care provider, patients have a significant negative response and report that their initial reaction was intent to stop seeking care ranging from 19.1 percent to 61.4 percent. Intent to stop seeking care is three times greater, 64.1 percent versus 19.1 percent when the patient learns of the breach through the media rather than the provider.

60 percent of patients who were victims of a privacy breach no longer seek care from that care provider.

84.8 percent of patients that a care provider’s reputation is a significant consideration when choosing a provider. When a care provider suffers a major privacy breach or a series of privacy breaches, 74.2 percent of survey respondents state it damages or severely damages the provider’s reputation, while 21.8 percent note it mildly damages the provider’s reputation. The damage to the provider’s reputation will have a negative impact on the growth of the medical practice and likely result in loss of patients.

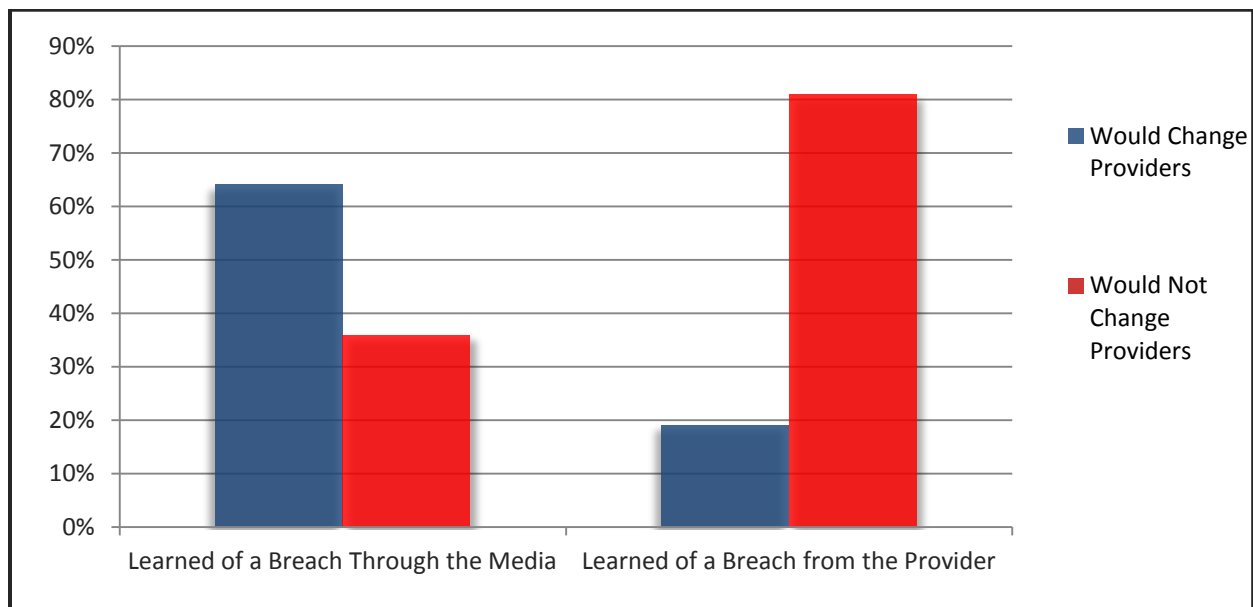


Figure 2. Intention to Change Providers over Source of Breach Notification

Patients who had experienced a breach of their private medical information validated the attitudes and anticipated actions of non-breached respondents. The consequences of the breach they experienced also validates industry studies on the patient impact of a privacy breach.

6 percent of patient respondents indicated they had been alerted their medical records had been compromised. As a result of the breach, 60 percent indicated they no longer seek care from that provider. These respondents note that when alerted initially, the top three consequences of concern included: identity theft, leaking of sensitive medical/personal information and medical identity theft.

The top three consequences of the breach most commonly reported included:

- A sensitive medical issue was no longer private
- The patient required credit monitoring to ensure their identity was not compromised
- The patient became the victim of identity and/or medical identity theft.

Further academic and industry study is needed to more completely understand the emotional, financial, family and career impact to the lives of patients who have suffered loss of privacy. This subject is deserving of greater research regarding long-term impact.

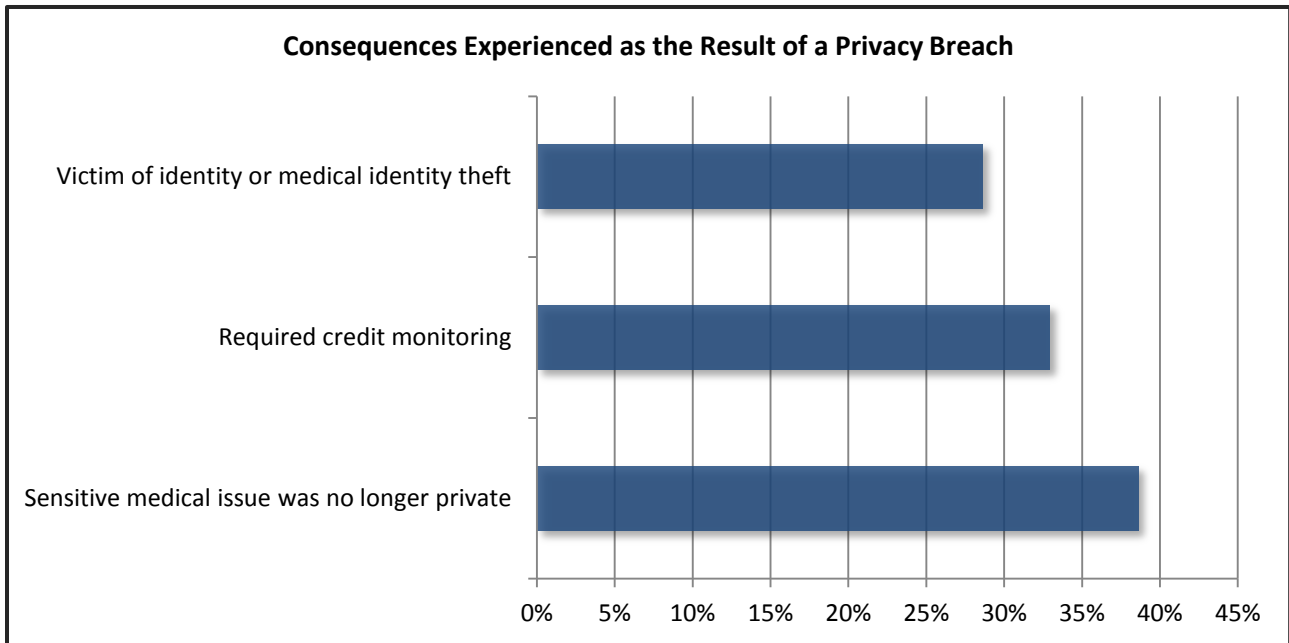


Figure 3. Patient Consequences Resulting from Privacy Breach

Breach victims reported that in 21.4 percent of cases a family member breached their records and in 20 percent of cases, it was an employee of the care provider.

Survey results suggest that providers who embrace a culture of privacy have an opportunity to positively influence choice of provider by patients with sensitive medical conditions.

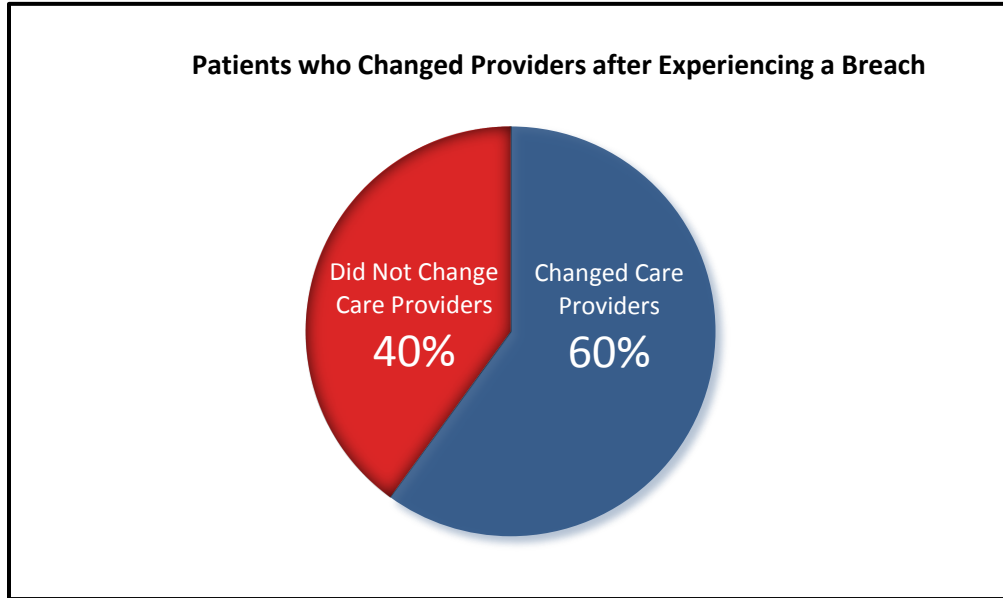


Figure 4. Patients Who Actually Changed Providers

Complete Survey Findings

Trust in the confidentiality of medical records is influencing when, where, who and what kind of medical treatment is delivered to patients. Patients demonstrate that privacy concerns impact how quickly they seek care, the medical information they share with their provider, and from whom they seek care. These privacy concerns affect how providers can diagnose medical conditions and deliver appropriate care.

- 85.2 percent of participants indicated that if they had a sensitive medical condition, a care provider's reputation for protecting privacy would influence their choice to seek care from that provider.
- 27.1 percent of patients stated they would withhold information from their care provider based on privacy concerns
- 27.6 percent stated they have or would postpone seeking care for a sensitive medical condition due to privacy concerns.
- More than 1 out of 2 patients indicated they would seek care outside of their community due to privacy concerns with 35 percent indicating they would travel more than 50 miles. An additional 28.7 percent of patients noted they would travel between 20 and 50 miles.
- 58.8 percent of patients report that their belief that their care provider keeps their information private influences their choice to seek care from that provider.
- The reputation of a care provider ranked as the most consistent influencer, with 84 percent of patients noting a provider's reputation influences their choice to seek care from that provider.
- 74.2 percent of patients assert that if a care provider suffers a major privacy breach or series of privacy breaches, the provider's reputation will be damaged or severely damaged.

When privacy violations occur, patients have a strongly negative response to the care provider particularly when they learn of the breach through the media.

- When privacy violations occur within their care provider, patients have a significant negative response and report high levels of attrition ranging from 19.1 percent to 61.4 percent.
- 64.1 percent of patients indicated that if their care provider suffered a privacy breach and the patient learned of the breach in the media, they would no longer seek care from this provider.
- 19.1 percent of patients indicated that if their care provider suffered a privacy breach and the patient learned of the breach from the provider first, they would no longer seek care from this provider.

Patients are 3 times more likely to stop seeking care from a provider when they learn of a breach through the media, further demonstrating the importance of timely communication from the provider to the patient regarding breaches.

- Patients are 3 times more likely to stop seeking care from the provider when they are surprised through media, further demonstrating the importance of timely communication from the provider to the patient regarding breaches as documented in this report.
- When a care provider suffers a major privacy breach or a series of privacy breaches, 74.2 percent of survey respondents state it damages or severely damages the reputation of the care provider, while 21.8 percent note it mildly damages the provider's reputation.

Patients who had experienced a breach of their private medical information validated the attitudes and anticipated actions of non-breached respondents. The consequences of the breach they experienced also validates industry studies on the patient impact of a privacy breach.

- 6 percent of patient respondents indicated they had been alerted their medical records had been compromised. As a result of the breach, 60 percent indicated they no longer seek care from that provider.
- Breach victims state that when alerted initially, the top three consequences of concern included: identity theft, leaking of sensitive medical/personal information and medical identity theft.
- The top three consequences of the breach most commonly reported included: a sensitive medical issue was no longer private, the patient required credit monitoring to ensure their identity was not compromised and they became the victim of identity and/or medical identity theft.
- 62.8 percent of the victims were alerted by care provider of the breach within 60 days. 5.7 percent of victims discovered the breach on their own.
- 52.9 percent of the victims stated they were satisfied with the care provider's resolution of the breach.
- Breach victims reported that in 21.4 percent of cases a family member breached their records and in 20 percent of cases, it was an employee of the care provider. The remaining breaches were committed by friends, co-workers, a stranger, or unknown. These numbers are consistent with industry studies on healthcare privacy breaches ([Best Practices & Breach Findings Report](#)).

Nearly 2 out of 3 patients have high expectations with regard to care providers' confidential treatment of their medical records.

- 66.4 percent of patients report when a privacy breach occurs, their trust in electronic health records is affected.
- 61.4 percent of patients expect their care provider to comply with Federal privacy regulations.
- 58.5 percent of patients expect care provider to foster a culture of trust.
- 59.7 percent of patients expect to be alerted in a timely manner if their medical record inappropriately accessed.
- 60.8 percent of patients expect to have inappropriate access resolved in a timely manner.
- 59.5 percent of patients expect care provider to respond quickly as to who assessed their records.

- 58.8 percent of patients report that their belief that their care providers keep their information private influences their choice to seek care from them.
- 61.4 percent indicate that knowledge regarding technology and processes which protect the confidentiality of their medical records would influence their decision to seek care from that provider.

Care providers have an opportunity to change the course of patient care by utilizing best practices for protecting patient privacy and initiating a dialog with patients regarding how they proactively protect patient privacy.

- 80 percent of respondents believe that their care providers have safeguards in place to protect private medical information however, only 48.4 percent of patients believe their care provider is committed to protecting their privacy.
- 58.5 percent of patients expect their care provider to foster a culture of patient privacy.
- Nearly 2 out of 3 patients expect their care provider to proactively detect unauthorized access to their private record and respond quickly to the patient’s inquiry as to who has accessed their record.
- 53.7 percent of patients stated that open communication with patient regarding privacy efforts would make them feel that their care provider takes patient privacy seriously.
- 61.4 percent of patients state that if they knew that a care provider had invested in technologies and processes that detect and prevent privacy breaches, that they would be more likely to seek care from this provider.

61 percent of patients indicated that they would be more likely to seek care from a provider that invested in technologies and processes to detect and prevent privacy breaches.

Patients believe care providers are ethically and legally obligated to protect privacy and indicated consistent and strong responses regarding breach protection expectations.

Survey responses illustrate that patients have high expectations with regard to the confidential treatment of their medical records by care providers. When survey questions became more specific to privacy violations and expectations associated with protection against privacy violations, patients were more assertive in their responses. This suggests there a segment of the respondents fundamentally trust care providers to “do the right things” with regard to privacy, but react quite emotionally when surprised by a privacy violation.

- 97.2 percent of patients believe care providers have a legal and ethical responsibility to protect patients’ medical records and privacy information
- Patients note that they expect the following from their care provider relative to the protection of their privacy:
 - 74.4 percent state they expect their care provider to deliver clear and consistent communication to staff regarding what constitutes inappropriate access to patient records

- 73.9 percent state they expect consistent training of staff on privacy laws and the care provider's privacy policies
- 73.3 percent expect clearly defined penalties for unauthorized access to patient records
- When care provider staff members inspect patient records out of curiosity, patients indicated suspension (15.6 percent), termination (24.7 percent), and report offense to authorities (16.3 percent) were all appropriate punishments.
- When care provider staff members inspect patient records with intent to do harm, patients indicated suspension (5.9 percent), termination (30.6 percent), and reporting offense to authorities (51.7 percent) were all appropriate punishments.

Patients are optimistic about electronic health records, but demonstrate very little substantive knowledge of the risks of paper versus electronic health records.

- 74.2 percent of patients believe that moving from medical records to electronic health records will help healthcare professionals to deliver better care.
- Patients ranked the following respectively as the top three benefits of electronic health records and reasons for optimism:
 - The ability of doctors to share my medical information freely with other medical professional who need it for my treatment
 - Up to date/real time medical information
 - Easy access to my medical records
- 32 percent of patients feel that providers are more equipped to protect the privacy of electronic records, 39.7 percent responded neutrally, and 28 percent feel that providers are more equipped to protect the privacy of paper records than electronic records.
- 48.4 percent believe their care provider is currently committed to protecting their privacy, 25.5 percent responded neutral and 26.1 percent of patients responded their provider is not committed to protecting their privacy.

Survey data indicates that the majority of patients feel that privacy laws, government enforcement and sanctions for privacy breaches have a neutral or no effect on the motivation of care providers to protect patient privacy.

- 61.4 percent of patients expect their care provider to comply with Federal privacy regulations.
- 64.6 percent of patients believe that there are adequate laws in place which mandate the protection of patient privacy however 72.2 percent of patients believe that the passing of additional laws would have a neutral or no impact on the number of privacy breaches among care providers.
- 48.9 percent of respondents believe the government adequately enforces healthcare privacy laws.
- Nearly 1 in 2 patients state that stronger enforcement of current privacy laws would have a neutral or no effect in reducing the number of privacy breaches.

- A slight majority, 50.9 percent of consumers believe that the government should impose heavy fines against care providers for privacy breaches.
- 31.4 percent of patients believe that passing additional privacy laws would distract care providers from delivering quality care.

Survey Observations, Analysis and Further Research

- Further research and discussion regarding how privacy concerns are changing the course of care, including exploration of the concept that patients are withholding medical information, traveling outside of their community and delaying care based on privacy concerns. This is the key finding of the report
- Further research and discussion of how care providers can leverage the privacy work they have already initiated and integrated to demonstrate to patients their level of commitment to privacy
- Privacy is not top of mind to patients. However, the survey demonstrated that when asked specific questions about privacy, patients expressed concerns regarding privacy and noted privacy as an influencer in their decision to seek care from a specific provider. Although most patients have high expectations with regard to the confidential treatment of their medical records by care provider, more consistent responses were received as survey question became more specific to privacy violations and expectations associated with protecting against privacy violations. This suggests that a segment of respondents fundamentally trust care providers to do the right things with regard to privacy, but react quite emotionally when surprised by a privacy violation
- The relatively uniform or even random responses by patients suggest a lack of substantive knowledge of privacy risks associated with electronic health records versus paper records. Privacy advocates as well as electronic health record vendors seeking to promote their positions on privacy should focus on sober consumer education rather than emotional histrionics, threats and defensive behavior when it comes to privacy
- Many consumers may not have an adequate understanding of privacy laws. They know they exist however, answers demonstrate that although 3 out of 4 want quick responses from their providers regarding access they may be unaware of disclosure laws. Additionally, nearly 30 percent of respondents note that they don't expect their provider to comply with Federal privacy regulations

Appendix 1

In February 2011, FairWarning® commissioned New London Consulting to develop a survey of US consumers, or patients of care providers to determine how *patient privacy considerations impact the actual delivery of healthcare*. The survey was designed garner a baseline understanding of patient beliefs relative to a care providers’ legal, ethical and moral responsibility to protect patient privacy. More importantly, the survey sought to measure how privacy considerations affect patient behaviors and decisions and influence patient care outcomes.

New London Consulting and FairWarning® developed a survey consisting of 29 questions. The survey was conducted using an online platform. Survey invitations were sent to more than 10,000 consumers across the US. Invitations to participate were sent to a population that mirrors US census demographics relative to race, economic class, age and gender. The survey invitation resulted in participation of 1265 individuals. The survey was live for approximately 120 days.

Gender

Female*	59.6 percent
Male	40.4 percent

* Of note, the majority of respondents were women. According to a U.S. Department of Labor report, women make 80 percent of the healthcare decisions for their families. Statistically, responses garnered in this survey represent a more actual picture of what influences the decision making process relative to healthcare and where and from whom medical treatment is delivered to the household.

Ethnicity

White, not Hispanic	68.9 percent
Hispanic/ Latino	16.1 percent
African American	10.7 percent
Asian American	5.1 percent
Other	3.7 percent
Prefer not disclose	1.9 percent

Highest Level of Education Completed

Less than high school	2.2 percent
High school graduate	18.0 percent
Some college	33.1 percent
College graduate	32.9 percent
Graduate or professional degree	13.8 percent

U.S. States Represented

Survey participants represented 49 US States.

14 There were no survey participants from Wyoming.

EXHIBIT OO

patientprivacyrights

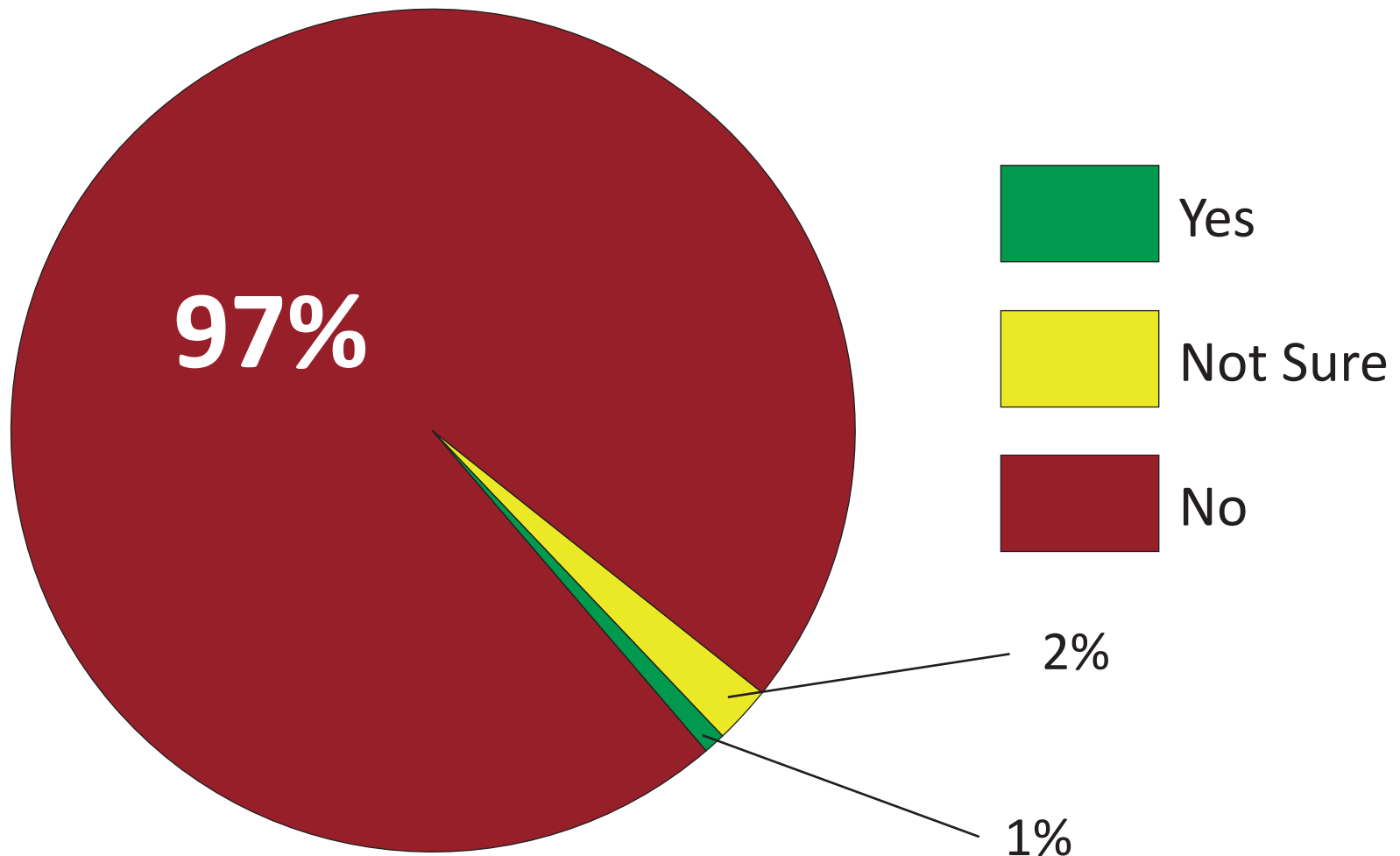
Results From a Zogby International Online Poll

2000 Adults' Views on Privacy, Access to Health Information, and Health Information Technology

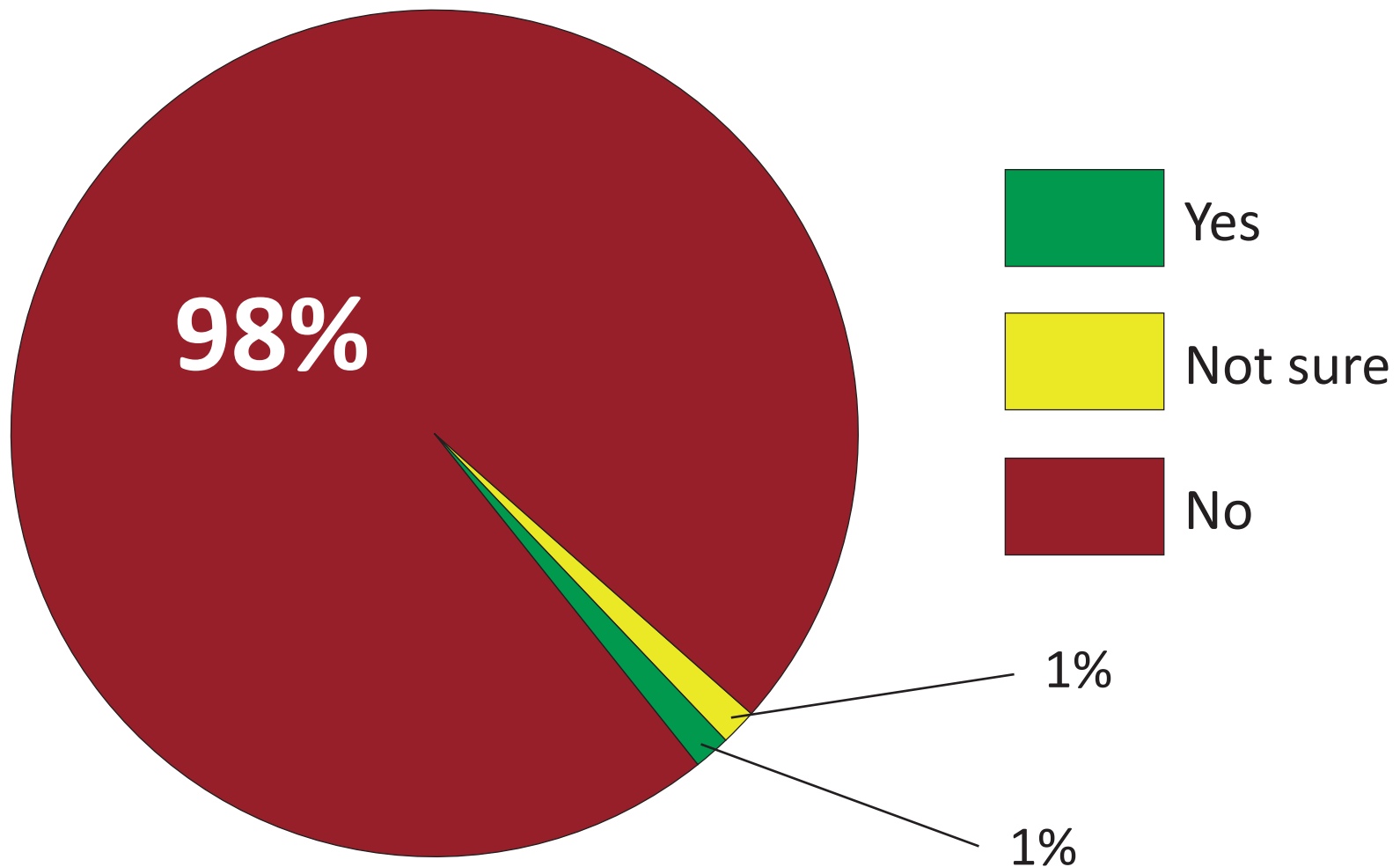
Zogby Interactive Survey of Adults 08/24/10 - 08/26/10 MOE +/- 2.2 Percentage Points

See more at <http://patientprivacyrights.org/patient-privacy-poll/>

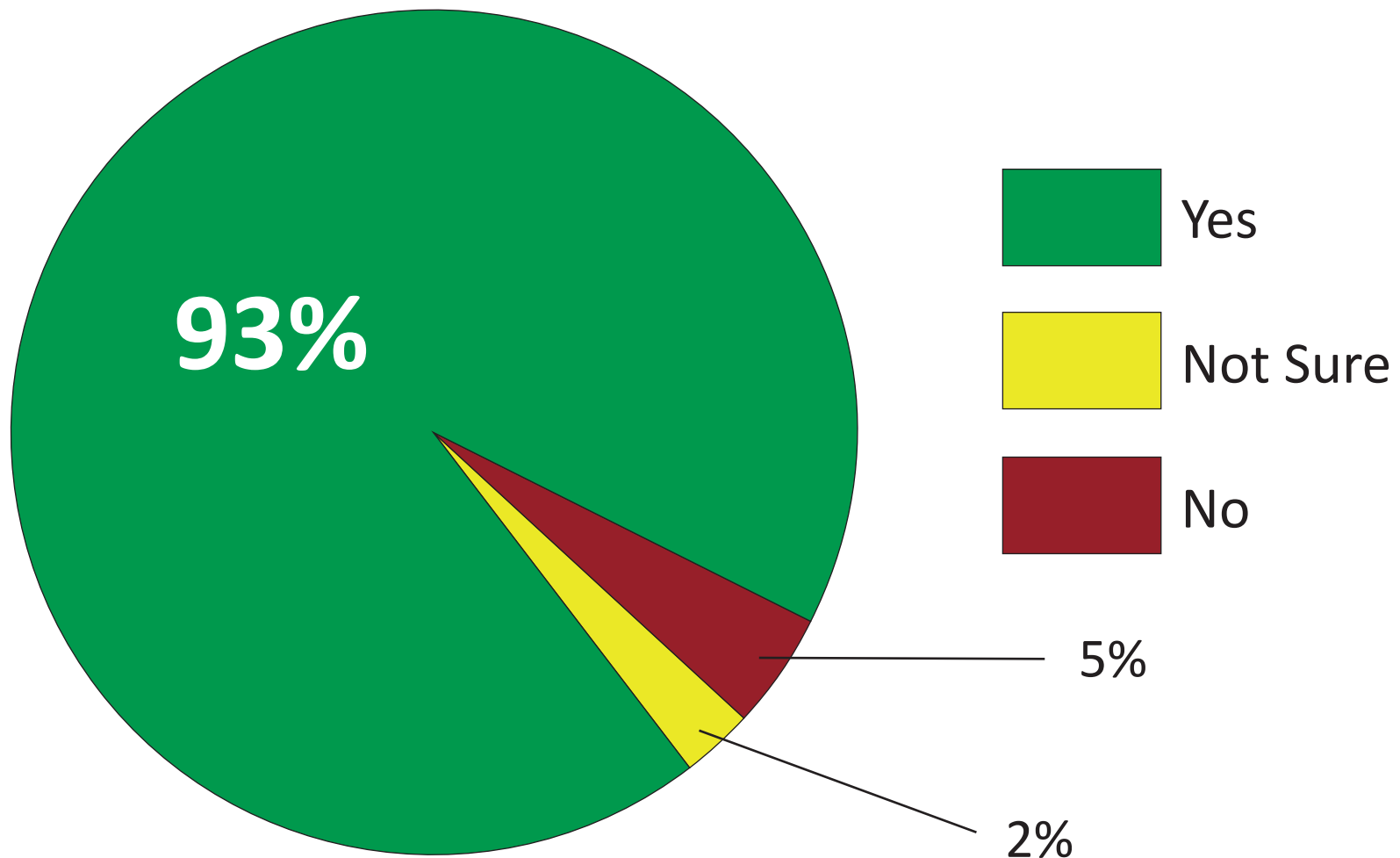
Should doctors, hospitals, labs and health technology systems be allowed to share or sell your sensitive health information without your consent?



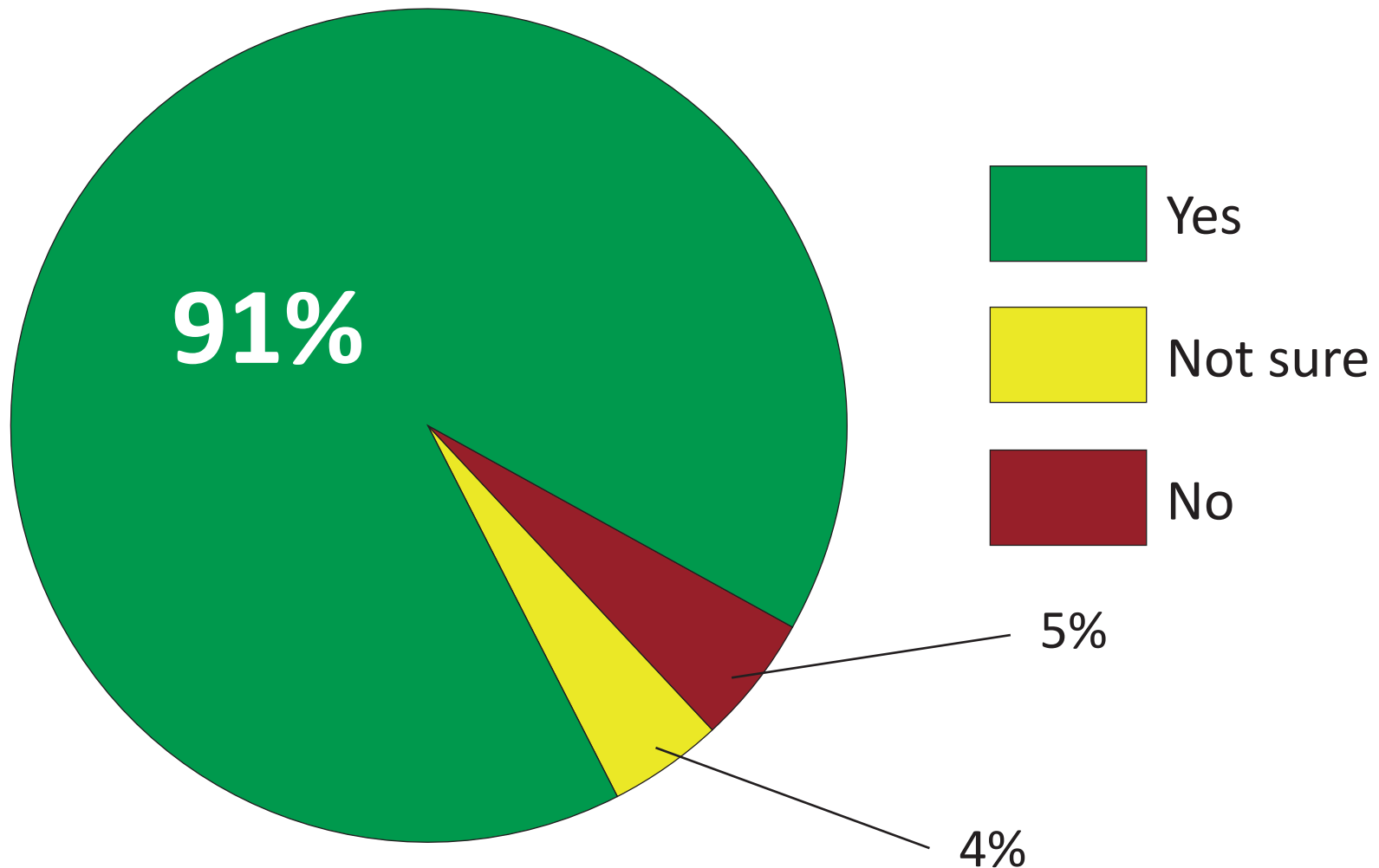
Should insurance companies be allowed to share or sell your health information without your consent?



If you have electronic health records, do you want to decide what companies and government agencies can access them?



When your medical records are kept in electronic systems, would you want to decide which individual people can see and use them?



How likely are you to use a website that allowed you to decide who can see and use all your health information?

Very Likely



Somewhat Likely



Somewhat Unlikely



Very Unlikely



Not Sure



Who should make the decision on whether corporations and researchers can see and use the information in your health records without your permission?

The government through laws and regulations

5%

You personally

87%

Your physician or other medical personnel

5%

Other

1%

Not Sure

2%

EXHIBIT PP

Public Attitudes Toward Medical Privacy

Submitted to:

The Institute for Health Freedom

September, 2000

Submitted by:

THE GALLUP ORGANIZATION

47 Hulfish Street
Princeton, New Jersey 08542

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Introduction

This report is based on the results of a survey conducted by The Gallup Organization on behalf of the Institute for Health Freedom. The opinions of a national cross-section of adults in telephone owning households, 18 years of age or older, concerning access and the confidentiality of their medical records were obtained.

A national cross-section of telephone households was systematically selected using random digit dialing techniques to ensure the inclusion of households with both listed and unlisted telephone numbers. Everyone was interviewed between August 11, 2000 to August 26, 2000. A total of 1,000 interviews were completed. Results based on the entire sample are accurate with a plus or minus 3-percentage point margin of error at the 95% confidence level. The sampling tolerances will be found in the technical appendix of this report.

Overview of Survey Findings

For most adults the confidentiality of their medical records is very important, and only the confidentiality of financial information is judged very important by a greater proportion. Over eight in ten adults (84%) report it is very important that their financial information be kept confidential. Almost as many (78%) feel it is very important that their medical records be kept confidential. While important to many adults, less than half (39%) feel it is very important that their employment history be kept confidential, and fewer (30%) feel it is very important that their educational history be kept confidential.

Women are more likely than men to feel it is very important their medical records should be kept confidential (81% and 74%, respectively). In addition, older adults, particularly those 35 to 49, are more likely than adults 18 to 34 years of age to say it is very important that their medical records be kept confidential.

Given the importance attached to keeping their medical records confidential, it is not surprising that many adults oppose access by any group. Asked if they favored or opposed allowing various groups to see their medical records without permission there is no group that a majority of adults would favor allowing access to their medical records without their authorization.

The most “acceptable” group would be pharmacists, four in ten adults (40%) would favor allowing pharmacists to see their medical records without permission while 59% would be opposed.

There is strong opposition to non-medical groups gaining access to their medical records. Nine out of ten (92%) oppose giving government agencies access. About as many (88%) oppose the police or lawyers, or employers (84%) being allowed to see their medical records. Similarly, 82% oppose letting insurance companies see their medical records without permission. Over nine in ten (95%) oppose allowing banks to see their medical records without permission.

Local and state health departments are acceptable to a larger proportion compared to government agencies overall, nevertheless, 71% oppose giving these agencies access to medical information without permission.

Opinion is no different when it comes to medical doctors other than those given permission by the respondent. Seven in ten (71%) oppose giving doctors access to their medical records without permission. Medical researchers would be denied access too – two-thirds (67%) oppose allowing researchers permission to see their medical records without permission.

While controlling access to their medical records is important to many, relatively few adults (16%) have heard or read anything recently about new federal regulations that would change the rules regarding access to medical records. Adults, age 50 or older (20%) and college-educated adults (19%) are more likely than others to say they have heard about the issue.

Asked their opinion of keeping their medical records in a national computerized database, most adults (88%) are opposed. Only 10% would favor keeping records in a national database. Adults, ages 35 to 49 are more likely than younger or older adults to oppose a national database for medical records. Similarly, college-educated adults are more likely than those with fewer years of formal education to oppose a national database (93% and 83%, respectively).

Few adults (12%) have seen or heard anything recently about a proposal to assign medical identification numbers. Even fewer (8%) adults support a plan that requires every American to be assigned a medical identification number. Adults 35 years of age or older are more likely than younger adults to be aware of the medical identification proposals.

Over nine in ten adults (95%) say doctors and hospitals should have to obtain their permission before releasing medical records to a national database. In addition, only 4% believe personal information told a doctor in confidence and entered into their medical records should be included in the national database.

Most adults (86%) feel a physician should ask permission first before running additional tests, during the course of regular testing, for genetic factors that may be related to possible health

problems. Approximately one in seven (14%) feel the physician should be allowed to run the additional tests without asking permission.

Over nine in ten adults (93%) feel medical and government researchers should obtain permission before studying a person's genetic information. Less than one in ten (6%) feel it isn't necessary to obtain the person's permission.

Detailed Findings

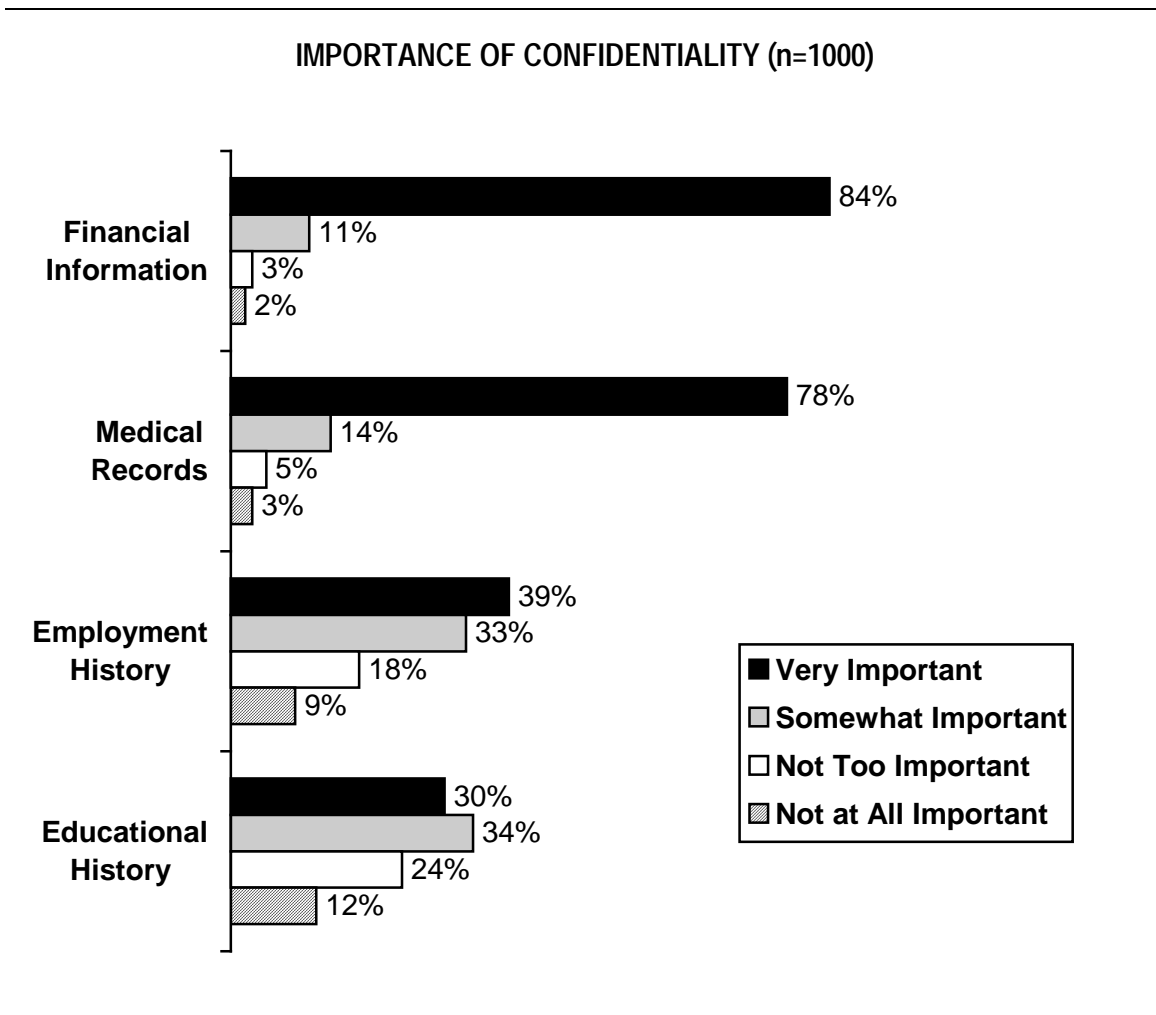
Importance of Confidentiality of Information

Question 1

How important is it to you that information in the following areas be kept confidential; that is, no one can see it without your permission - very important, somewhat important, not too important, or not at all important?

- Financial information*
- Employment history*
- Medical records*
- Educational history*

Over eight in ten adults (84%) report it is very important that their financial information be kept confidential. Almost as many (78%) feel it is very important that their medical records be kept confidential. While important to most adults, less than half (39%) feel it is very important that their employment history be kept confidential, and fewer (30%) feel it is very important that their educational history be kept confidential.



- Women are more likely than men to feel it is very important their medical records should be kept confidential (81% and 74%, respectively).
- Older adults, particularly those 35 to 49 (83%), are more likely than adults 18 to 34 years of age (71%) to say their medical records should be kept confidential.
- Women and adults, 35 to 49 years of age, are more likely than others to consider keeping their financial information confidential very important.

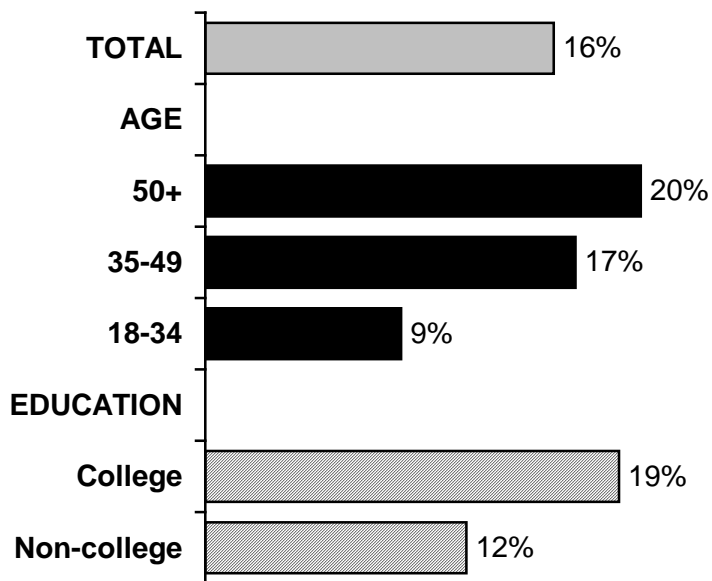
Awareness of Federal Regulations Regarding Access to Medical Records

Question 2

Have you heard, read or seen anything recently about new federal regulations that would change the rules regarding who is allowed to see your medical records?

Relatively few adults (16%) have heard or read anything recently about new federal regulations that would change the rules regarding access to medical records. Adults, age 50 or older (20%) and college-educated adults (19%) are more likely than others to say they have heard about the issue.

AWARE OF NEW FEDERAL REGULATIONS REGARDING MEDICAL RECORDS (n=1000)



Favor or Oppose Access to Medical Records by Selected Groups

Question 3

Who do you think should be allowed to see your medical records without your permission? I am going to read you a list of some groups; for each, please tell me whether you favor or oppose allowing them to see YOUR medical records without FIRST obtaining YOUR permission. How about . . . ?

- Medical doctors OTHER than the ones you have given permission*
- Pharmacists*
- Medical researchers*
- The police or lawyers*
- Local and state health departments*
- Banks*
- Insurance companies*
- Employers*
- Government agencies*

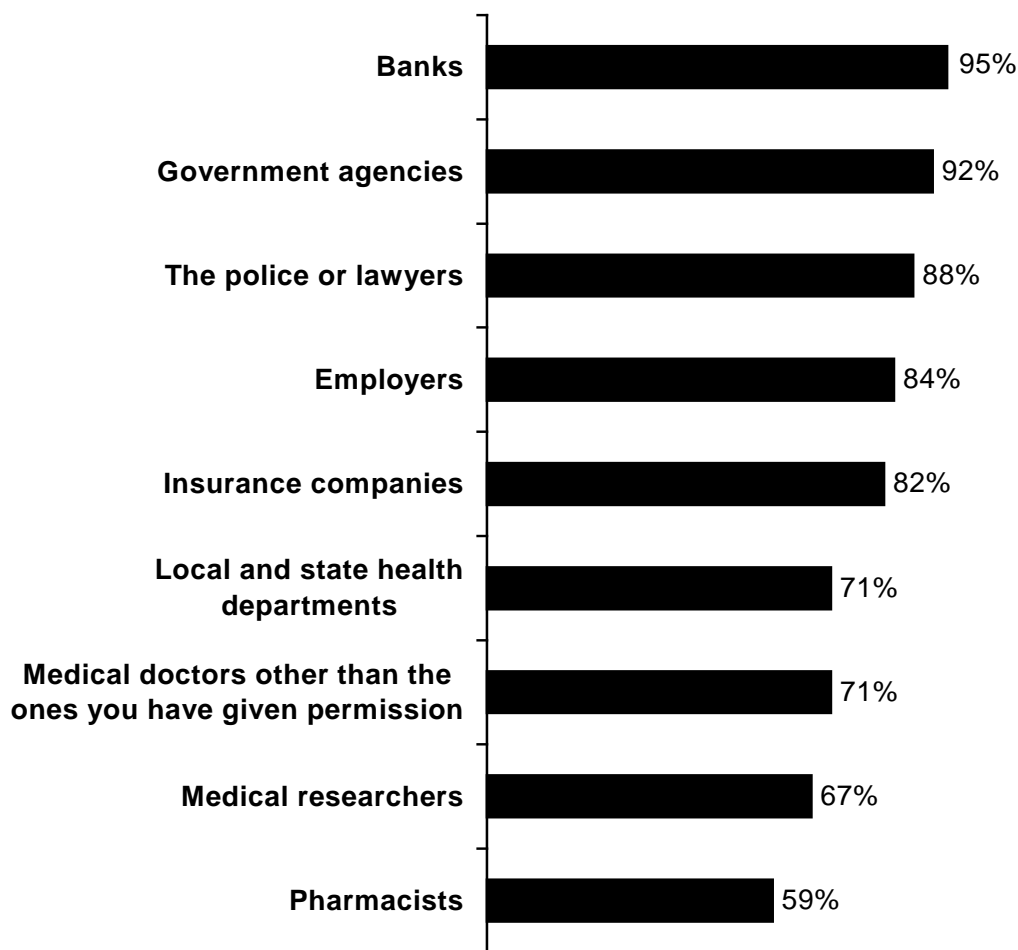
Asked if they favored or opposed allowing various groups to see their medical records without permission there is no group that a majority of adults would favor allowing access to their medical records without their authorization.

The most “acceptable” group would be pharmacists. Four in ten adults would favor allowing pharmacists to see their medical records without permission while 59% would be opposed. In contrast, the least “acceptable” group would be banks, only 5% would favor allowing banks to see their medical records without permission.

There is strong opposition to other non-medical groups seeing their medical records. Nine out of ten (92%) oppose giving government agencies access. About as many (88%) oppose the police or lawyers, or employers (84%) being allowed to see their medical records. Similarly, 82% oppose letting insurance companies see their medical records without permission.

Local and state health departments are acceptable to a larger proportion compared to government agencies overall, however, 71% oppose giving these agencies access to medical information without permission, too. Opinion is no different when it comes to medical doctors other than ones given permission by the respondent. Seven in ten (71%) oppose giving doctors access to their medical records without permission. Medical researchers fare no better than doctors – two-thirds (67%) oppose allowing researchers permission to see their medical records without permission.

PROPORTION OPPOSED TO ALLOWING GROUP TO SEE MEDICAL RECORDS (n=1000)



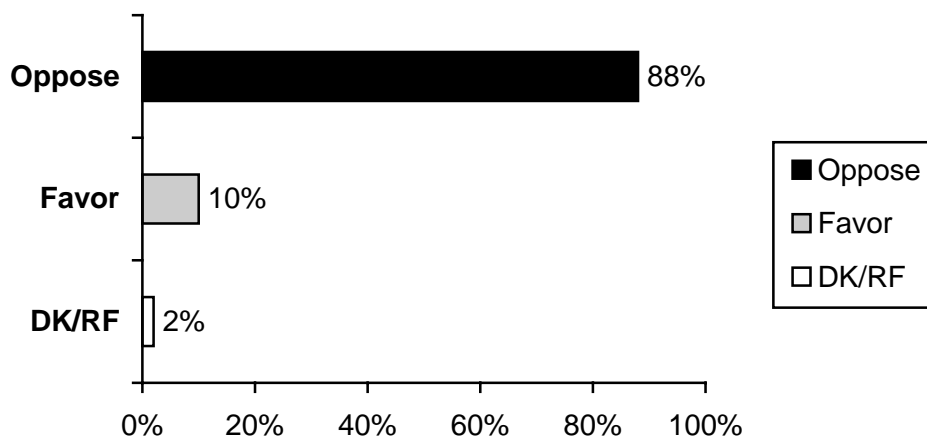
Attitude Toward National Database

Question 4

There has been a lot of discussion lately about REQUIRING that all patient medical records be stored in a national computerized database. The database would store medical records on patients over their lifetime. Others would be able to use the information without first obtaining a patient's permission. Would you favor or oppose keeping your medical records this way?

Most adults (88%) are opposed to keeping their medical records in a national computerized database. Only 10% would favor the plan described to them.

FAVOR/OPOSE STORING MEDICAL RECORDS IN COMPUTERIZED DATABASE (n=1000)



-
- Adults, ages 35 to 49 are more likely than younger or older adults to oppose a national database for medical records (92%).
 - College-educated adults are more likely than those with fewer years of formal education to oppose a national database (93% and 83%, respectively).

Awareness and Support for Medical Identification Numbers

Question 5

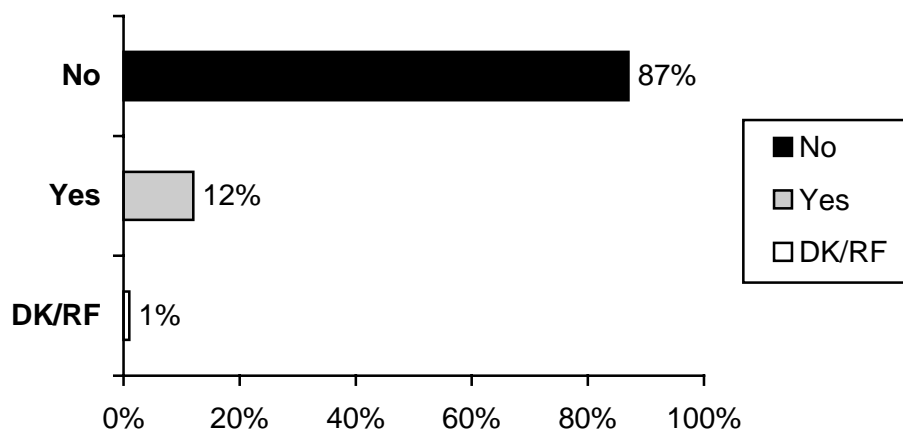
Have you heard, read or seen anything recently about a federal proposal to assign medical identification numbers, similar to a social security number, to you and all other Americans to create a national database of medical records?

Question 6

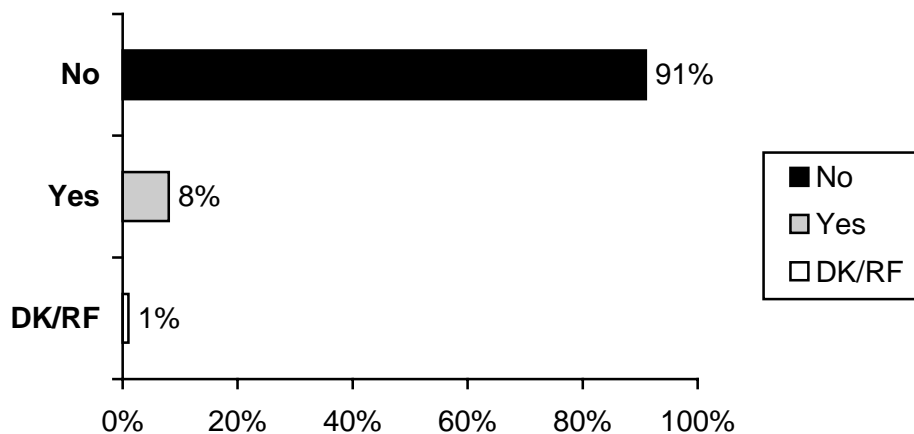
*Would you support a plan that **REQUIRES** every American, including you, to be assigned a medical identification number, similar to a social security number, to track your medical records and place them in a national computer database without your permission?*

One in eight adults (12%) have seen or heard something recently about a proposal to assign medical identification numbers. Somewhat fewer (8%) adults support a plan that requires every American to be assigned a medical identification number.

AWARE OF FEDERAL PROPOSAL REGARDING MEDICAL ID NUMBERS (n=1000)



SUPPORT PLAN THAT REQUIRES ASSIGNED MEDICAL ID NUMBER (n=1000)



-
- Adults 35 years of age or older are more likely than younger adults to be aware of the medical identification proposals (14% and 7%, respectively).
 - College-educated adults (16%) are more likely than those with less than a college education (8%) to say they are aware of proposals for medical identification numbers.
 - Support for medical identification numbers is highest in the Midwest (12%) and lowest in the West (3%).

Should Permission Be Obtained Before Releasing Information to National Database?

Question 7

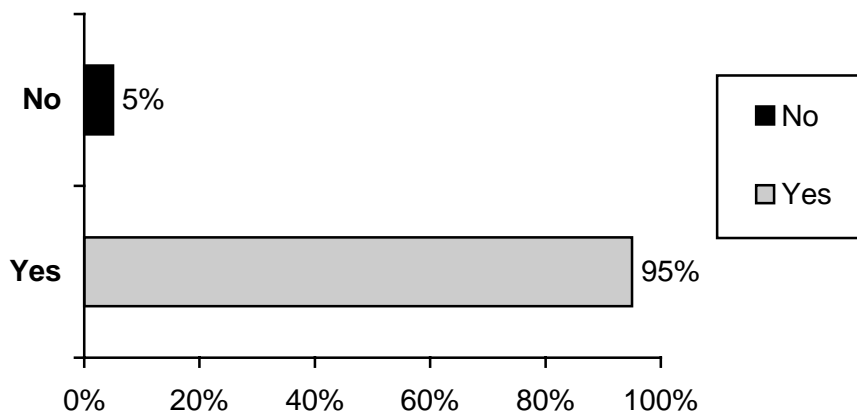
Do you think doctors and hospitals should have to obtain your PERMISSION before they could release your medical records to a national computerized database?

Question 8

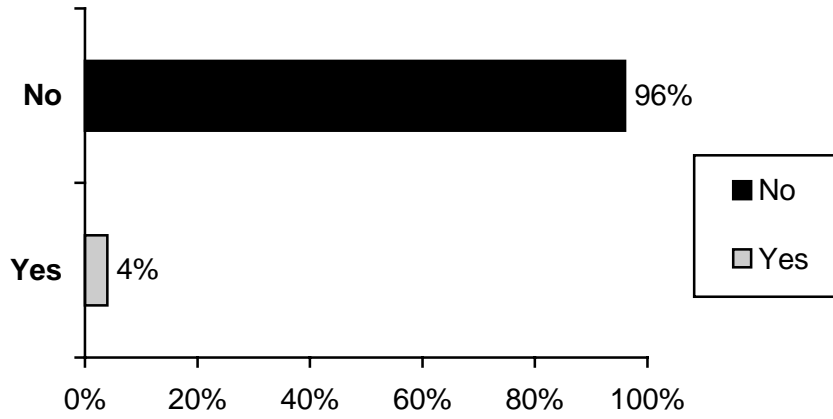
If you tell a doctor personal things about yourself in confidence, and the doctor records that information in your medical records, should the doctor be required to include that information in a national database without your permission?

Over nine in ten adults (95%) say doctors and hospitals should have to obtain their permission before releasing medical records to a national database. In addition, only 4% believe personal information told a doctor in confidence and entered into their medical records should be included in the national database.

PERMISSION SHOULD BE OBTAINED BEFORE RELEASING MEDICAL RECORDS (n=1000)



SHOULD PERSONAL INFORMATION TOLD TO MEDICAL DOCTOR IN CONFIDENCE BE INCLUDED IN NATIONAL DATABASE? (n=1000)



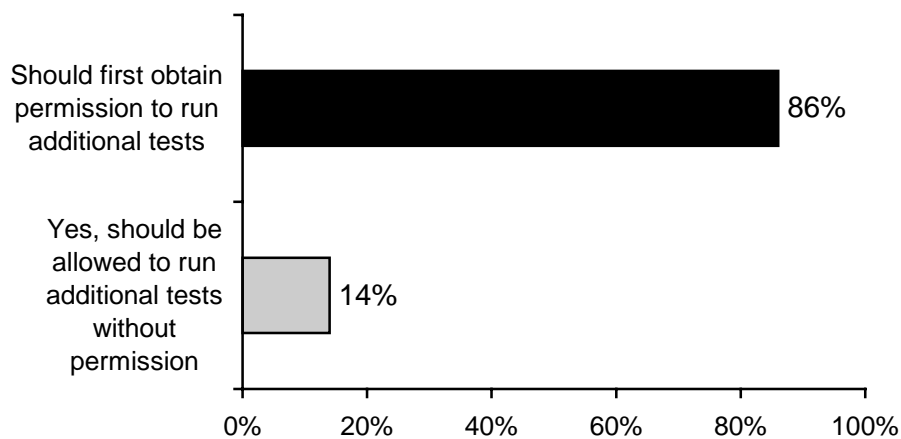
Should Physicians Be Allowed to Test for Genetic Factors Without Permission?

Question 9

If you go to a DOCTOR to have your blood tested for sugar or for high cholesterol, should your doctor also be allowed to test your blood for genetic factors that, for example, could reveal whether you are prone to cancer later in life, without first obtaining your permission, or do you feel your doctor should first obtain your permission?

Most adults (86%) feel a physician should ask permission first before running additional tests, during the course of regular testing, for genetic factors that may be related to possible health problems. Approximately one in seven (14%) feel the physician should be allowed to run the additional tests without asking permission.

SHOULD DOCTOR TEST FOR GENETIC FACTORS WITHOUT PERMISSION? (n=1000)



- Women (88%) are more likely than men (84%) to feel a physician should ask permission before conducting additional tests.

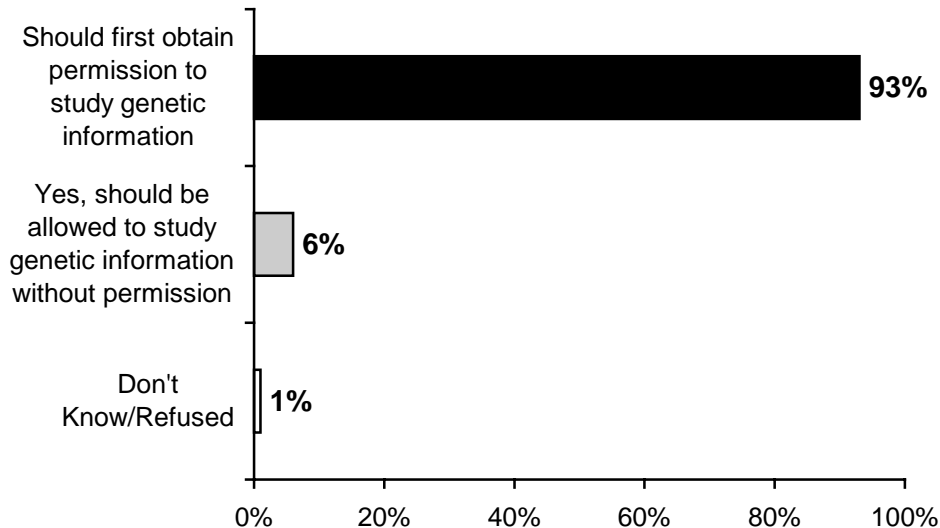
Should Researchers Be Allowed to Study Genetic Information Without Permission?

Question 10

Should medical and government RESEARCHERS be allowed to STUDY your genetic information (for example, to identify genes thought to be associated with various medical conditions) without first obtaining your permission, or do you feel they should first obtain your permission?

Over nine in ten adults (93%) feel medical and government researchers should obtain permission before studying a person's genetic information. Less than one in ten (6%) feel it isn't necessary to obtain the person's permission.

SHOULD RESEARCHERS BE ALLOWED TO STUDY GENETIC INFORMATION WITHOUT PERMISSION? (n=1000)



Appendix A
Sampling Tolerances

Sampling Tolerances

In interpreting survey results, it should be borne in mind that all sample surveys are subject to sampling error, that is, the extent to which the results may differ from what would be obtained if the whole population had been interviewed. The size of such sampling errors depends largely on the number of interviews.

The following tables may be used in estimating the sampling error of any percentage in this report. The computed allowances have taken into account the effect of the sample design upon sampling error. They may be interpreted as indicating the range (plus or minus the figure shown) within which the results of repeated samplings in the same time period could be expected to vary, 95 percent of the time, assuming the same sampling procedures, the same interviewers, and the same questionnaire.

The first table shows how much allowance should be made for the sampling error of a percentage:

	Recommended Allowance for Sampling Error of a Percentage						
	In Percentage Points (at 95 in 100 confidence level)*						
	Sample Size						
	1000	800	600	400	300	200	
PERCENTAGES NEAR 10	2	2	3	3	4	5	
PERCENTAGES NEAR 20	3	3	4	4	5	6	
PERCENTAGES NEAR 30	3	3	4	5	6	7	
PERCENTAGES NEAR 40	3	4	4	5	6	7	
PERCENTAGES NEAR 50	3	4	4	5	6	8	
PERCENTAGES NEAR 60	3	4	4	5	6	7	
PERCENTAGES NEAR 70	3	3	4	5	6	7	
PERCENTAGES NEAR 80	3	3	4	4	5	6	
PERCENTAGES NEAR 90	2	2	3	3	4	5	

* THE CHANCES ARE 95 IN 100 THAT THE SAMPLING ERROR IS NOT LARGER THAN THE FIGURE SHOWN.

The table would be used in the following manner: Let us say a reported percentage is 33 for a group which includes 1000 respondents. Then we go to row "percentages near 30" in the table and go across to the column headed "1000". The number at this point is 3, which means that the 33 percent obtained in the sample is subject to a sampling error of plus or minus 3 points.

Another way of saying it is that very probably (95 chances of 100) the true figure would be somewhere between 30 and 36, with the most likely figure the 33 obtained.

In comparing survey results in two samples, such as, for example, men and women, the question arises as to how large a difference between them must be before one can be reasonably sure that it reflects a real difference. In the tables below, the number of points which must be allowed for in such comparisons is indicated.

Two tables are provided. One is for percentages near 20 or 80; the other for percentages near 50. For percentages in between, the error to be allowed for is between those shown in the two tables.

		Recommended Allowance for Sampling <u>Error of the Difference</u> In Percentage Points (at 95 in 100 confidence level)* <u>Percentages near 20 or percentages near 80</u>					
TABLE A							
	1000	800	600	400	300	200	
1000	4						
800	4	4					
600	4	5	5				
400	5	5	6	6			
300	6	6	6	7	7		
200	7	7	7	7	8	9	

TABLE B		<u>Percentages near 50</u>					
	1000	800	600	400	300	200	
1000	5						
800	5	5					
600	6	6	6				
400	6	7	7	8			
300	7	7	8	8	9		
200	8	9	9	9	10	11	

* THE CHANCES ARE 95 IN 100 THAT THE SAMPLING ERROR IS NOT LARGER THAN THE FIGURE SHOWN.

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EXHIBIT QQ



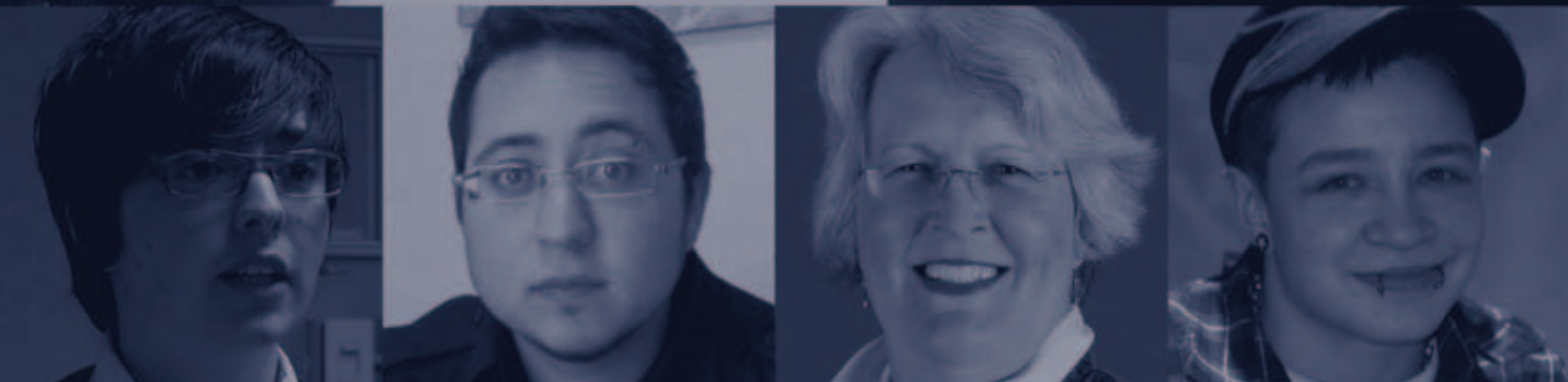
Injustice at Every Turn

A Report of the National Transgender Discrimination Survey

Lead authors in alphabetical order:

Jaime M. Grant, Ph.D.
Lisa A. Mottet, J.D.
Justin Tanis, D.Min.

with Jack Harrison
Jody L. Herman, Ph.D.
and Mara Keisling



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About the National Center for Transgender Equality

The National Center for Transgender Equality is a national social justice organization devoted to ending discrimination and violence against transgender people through education and advocacy on national issues of importance to transgender people. By empowering transgender people and our allies to educate and influence policymakers and others, NCTE facilitates a strong and clear voice for transgender equality in our nation's capital and around the country.

About the National Gay and Lesbian Task Force

The mission of the National Gay and Lesbian Task Force is to build the grassroots power of the lesbian, gay, bisexual and transgender (LGBT) community. We do this by training activists, equipping state and local organizations with the skills needed to organize broad-based campaigns to defeat anti-LGBT referenda and advance pro-LGBT legislation, and building the organizational capacity of our movement. Our Policy Institute, the movement's premier think tank, provides research and policy analysis to support the struggle for complete equality and to counter right-wing lies. As part of a broader social justice movement, we work to create a nation that respects the diversity of human expression and identity and creates opportunity for all.

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RECOMMENDED CITATION

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This study was undertaken with the dogged commitment of the National Center for Transgender Equality and the National Gay and Lesbian Task Force to bring the full extent of discrimination against transgender and gender non-conforming people to light. Executive directors Mara Keisling and Rea Carey committed considerable staff and general operating resources to this project over the past three years to create the original survey instrument, collect the data, analyze thousands of responses and, finally, present our findings here.

Key Task Force and NCTE staff, as well as our data analyst, are credited on the masthead of this report but many former staff, pivotal volunteers and visiting fellows put their unflinching effort and best thinking to this enormous task.

We are deeply grateful to Dr. Susan (Sue) Rankin of Pennsylvania State University, a nationally recognized LGBT researcher, for hosting our study through Penn State's Consortium on Higher Education. This allowed the survey to go through the Institutional Review Board process, to ensure the confidentiality and humane treatment of our survey participants. We are most grateful to M. Somjen Frazer who first as a volunteer and then later as a staff analyst made a crucial contribution in the questionnaire development, data cleaning and variable development phase of the research. Former Task Force Policy Institute staff member Nicholas Ray also did a wonderful job convening and guiding the many staff and volunteers who participated in developing the questionnaire.

A number of Vaid Fellows at the Task Force made crucial contributions to this work in the data cleaning, field work and early analytical stages of this report including Morgan Goode, Amanda Morgan, Robert Valadéz, Stephen Wiseman, Tey Meadow and Chloe Mirzayi. Morgan's work interfacing with staff at homeless shelters, health clinics and other direct service programs serving transgender and gender non-conforming people greatly increased participation in the study by transgender people often shut out of research projects.

Transgender community leaders made a major contribution to our thinking in developing the survey and field work, including Marsha Botzer, Moonhawk River Stone, M.S., LMHC and Scout, Ph.D. All of these leaders made important suggestions in the development of the questionnaire and our data collection process. We are grateful to Marsha, as the Task Force board chair, and Hawk, a member of the Task Force board, for championing this work institutionally.

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This study has obviously been a labor of love by a community of dedicated advocates, and we are honored to be able to offer the collective fruits of our labor to the community.

EXECUTIVE SUMMARY

This study brings to light what is both patently obvious and far too often dismissed from the human rights agenda. Transgender and gender non-conforming people face injustice at every turn: in childhood homes, in school systems that promise to shelter and educate, in harsh and exclusionary workplaces, at the grocery store, the hotel front desk, in doctors' offices and emergency rooms, before judges and at the hands of landlords, police officers, health care workers and other service providers.

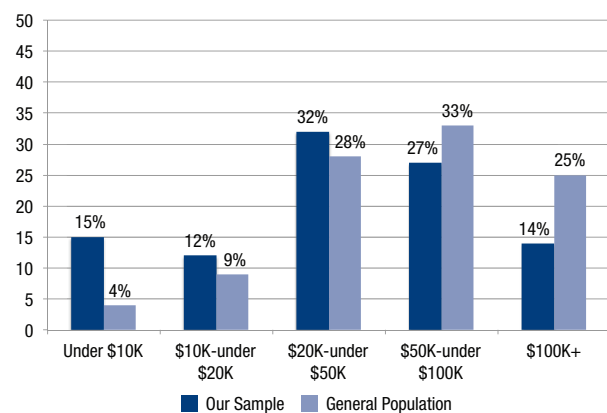
The National Gay and Lesbian Task Force and the National Center for Transgender Equality are grateful to each of the 6,450 transgender and gender non-conforming study participants who took the time and energy to answer questions about the depth and breadth of injustice in their lives. A diverse set of people, from all 50 states, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands, completed online or paper surveys. This tremendous gift has created the first 360-degree picture of discrimination against transgender and gender non-conforming people in the U.S. and provides critical data points for policymakers, community activists and legal advocates to confront the appalling realities documented here and press the case for equity and justice.

KEY FINDINGS

Hundreds of dramatic findings on the impact of anti-transgender bias are presented in this report. In many cases, a series of bias-related events lead to insurmountable challenges and devastating outcomes for study participants. Several meta-findings are worth noting from the outset:

- Discrimination was pervasive throughout the entire sample, yet **the combination of anti-transgender bias and persistent, structural racism was especially devastating**. People of color in general fare worse than white participants across the board, with African American transgender respondents faring worse than all others in many areas examined.
- Respondents **lived in extreme poverty**. Our sample was nearly four times more likely to have a household income of less than \$10,000/year compared to the general population.¹
- A staggering **41% of respondents reported attempting suicide** compared to 1.6% of the general population,² with rates rising for those who lost a job due to bias (55%), were harassed/bullied in school (51%), had low household income, or were the victim of physical assault (61%) or sexual assault (64%).

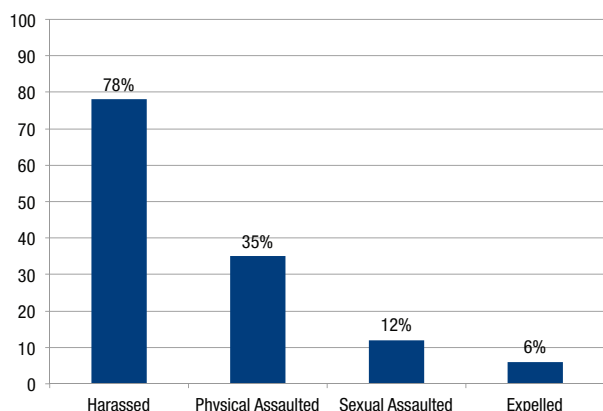
Household Incomes of Respondents³



HARASSMENT AND DISCRIMINATION IN EDUCATION

- Those who expressed a transgender identity or gender non-conformity while in grades K-12 reported **alarming rates of harassment (78%), physical assault (35%) and sexual violence (12%)**; harassment was so severe that it led **almost one-sixth (15%) to leave a school** in K-12 settings or in higher education.
- Respondents who have been **harassed and abused by teachers** in K-12 settings showed dramatically worse health and other outcomes than those who did not experience such abuse. Peer harassment and abuse also had highly damaging effects.

Harassment, Assault and Discrimination in K-12 Settings



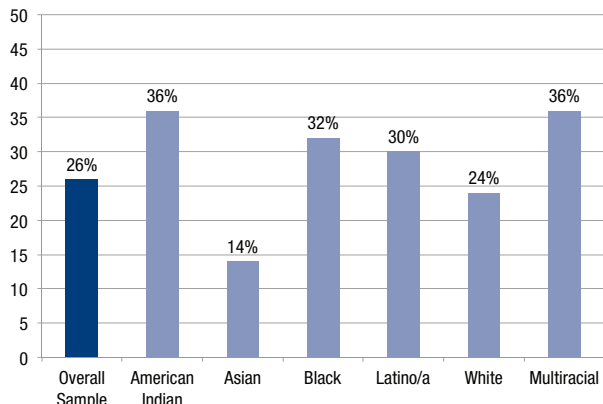
Respondents Income by Mistreatment in School⁴

	General Population	No school mistreatment	Mistreated in school
Under \$10K	4%	12%	21%
\$10K - under \$20K	9%	11%	15%
\$20K - under \$50K	28%	31%	33%
\$50k - under \$100k	33%	30%	21%
\$100k+	25%	16%	9%

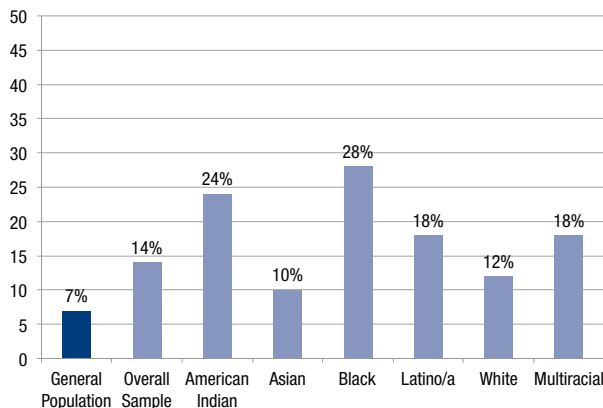
EMPLOYMENT DISCRIMINATION AND ECONOMIC INSECURITY

- **Double the rate of unemployment:** Survey respondents experienced unemployment at twice the rate of the general population at the time of the survey,⁵ with rates for people of color up to four times the national unemployment rate.
- Widespread mistreatment at work: **Ninety percent (90%) of those surveyed reported experiencing harassment, mistreatment or discrimination** on the job or took actions like hiding who they are to avoid it.
- Forty-seven percent (47%) said they had experienced an adverse job outcome, such as **being fired, not hired or denied a promotion** because of being transgender or gender non-conforming.
- **Over one-quarter (26%) reported that they had lost a job** due to being transgender or gender non-conforming and 50% were harassed.
- Large majorities attempted to avoid discrimination by **hiding their gender or gender transition (71%)** or delaying their gender transition (57%).
- The **vast majority (78%)** of those who transitioned from one gender to the other reported that they **felt more comfortable at work and their job performance improved**, despite high levels of mistreatment.
- Overall, **16% said they had been compelled to work in the underground economy** for income (such as doing sex work or selling drugs).
- **Respondents who were currently unemployed experienced debilitating negative outcomes**, including nearly double the rate of working in the underground economy (such as doing sex work or selling drugs), twice the homelessness, 85% more incarceration, and more negative health outcomes, such as more than double the HIV infection rate and nearly double the rate of current drinking or drug misuse to cope with mistreatment, compared to those who were employed.
- **Respondents who had lost a job due to bias also experienced ruinous consequences such as four times the rate of homelessness**, 70% more current drinking or misuse of drugs to cope with mistreatment, 85% more incarceration, more than double the rate working in the underground economy, and more than double the HIV infection rate, compared to those who did not lose a job due to bias.

Loss of Job by Race



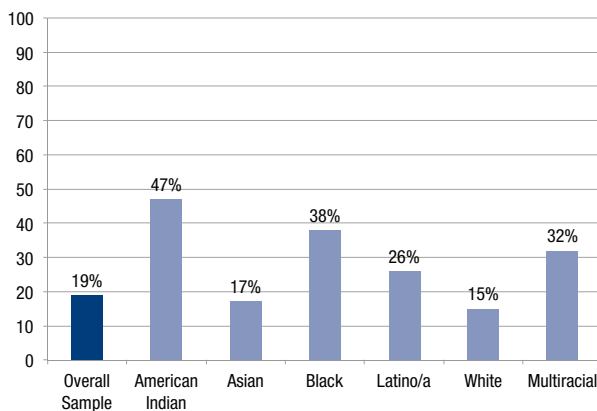
Unemployment Rates including by Race



HOUSING DISCRIMINATION AND HOMELESSNESS

- Respondents reported various forms of direct housing discrimination — **19% reported having been refused a home or apartment** and 11% reported being evicted because of their gender identity/expression.
- **One-fifth (19%) reported experiencing homelessness** at some point in their lives because they were transgender or gender non-conforming; **the majority of those trying to access a homeless shelter were harassed by shelter staff or residents (55%), 29% were turned away altogether,** and 22% were sexually assaulted by residents or staff.
- **Almost 2% of respondents were currently homeless,** which is almost twice the rate of the general population (1%).⁶
- Respondents reported **less than half the national rate of home ownership:** 32% reported owning their home compared to 67% of the general population.⁷
- **Respondents who have experienced homelessness were highly vulnerable** to mistreatment in public settings, police abuse and negative health outcomes.

“I was denied a home/apartment” by Race



DISCRIMINATION IN PUBLIC ACCOMMODATIONS

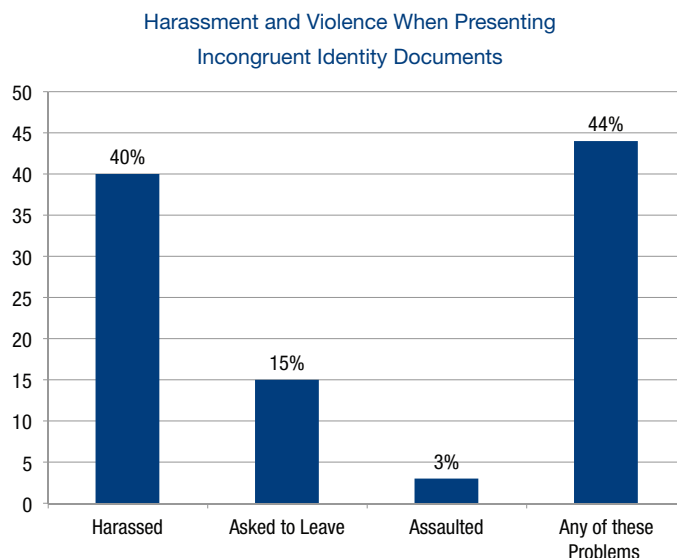
- Fifty-three percent (53%) of respondents reported being verbally harassed or disrespected in a place of public accommodation, including hotels, restaurants, buses, airports and government agencies.
- Respondents experienced widespread abuse in the public sector, and were often abused at the hands of “helping” professionals and government officials. One fifth (22%) were denied equal treatment by a government agency or official; 29% reported police harassment or disrespect; and 12% had been denied equal treatment or harassed by judges or court officials.

Experiences of Discrimination and Violence in Public Accommodations

Location	Denied Equal Treatment	Harassed or Disrespected	Physically Assaulted
Retail Store	32%	37%	3%
Police Officer	20%	29%	6%
Doctor’s Office or Hospital	24%	25%	2%
Hotel or Restaurant	19%	25%	2%
Government Agency/Official	22%	22%	1%
Bus, Train, or Taxi	9%	22%	4%
Emergency Room	13%	16%	1%
Airplane or Airport Staff/TSA	11%	17%	1%
Judge or Court Official	12%	12%	1%
Mental Health Clinic	11%	12%	1%
Legal Services Clinic	8%	6%	1%
Ambulance or EMT	5%	7%	1%
Domestic Violence Shelter/ Program	6%	4%	1%
Rape Crisis Center	5%	4%	1%
Drug Treatment Program	3%	4%	1%

BARRIERS TO RECEIVING UPDATED ID DOCUMENTS

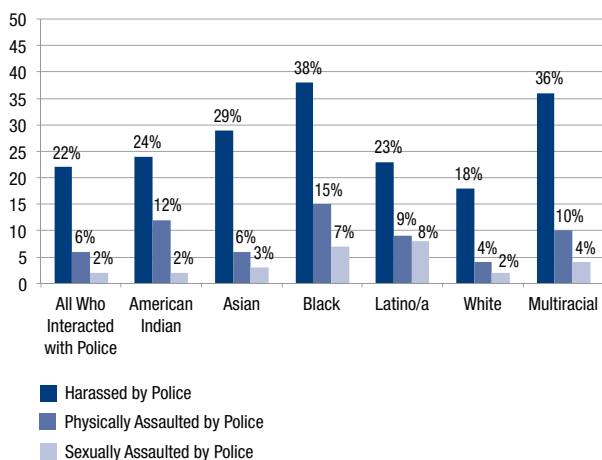
- Of those who have transitioned gender, only one-fifth (21%) have been able to update all of their IDs and records with their new gender. One-third (33%) of those who had transitioned had updated none of their IDs/records.
- Only 59% reported updating the gender on their driver’s license/state ID, meaning 41% live without ID that matches their gender identity.
- Forty percent (40%) of those who presented ID (when it was required in the ordinary course of life) that did not match their gender identity/expression reported being harassed, 3% reported being attacked or assaulted, and 15% reported being asked to leave.



ABUSE BY POLICE AND IN PRISON

- **One-fifth (22%) of respondents** who have interacted with police **reported harassment by police**, with much higher rates reported by people of color.
- Almost half of the respondents (46%) reported **being uncomfortable seeking police assistance**.
- **Physical and sexual assault in jail/prison is a serious problem:** 16% of respondents who had been to jail or prison reported being physically assaulted and 15% reported being sexually assaulted.

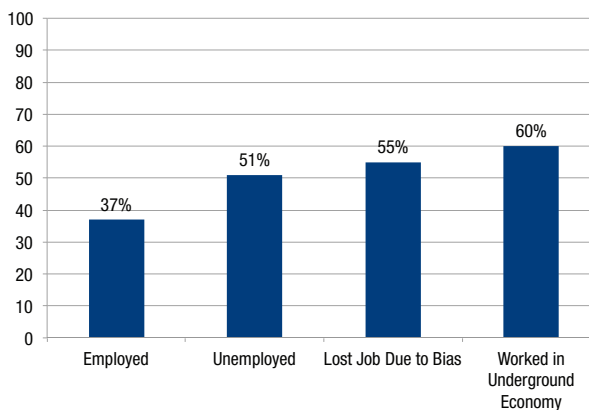
Police Harassment and Assault, Due to Bias, by Race



DISCRIMINATION IN HEALTH CARE AND POOR HEALTH OUTCOMES

- **Health outcomes for all categories of respondents show the appalling effects of social and economic marginalization**, including much higher rates of HIV infection, smoking, drug and alcohol use and suicide attempts than the general population.
- **Refusal of care: 19% of our sample reported being refused medical care** due to their transgender or gender non-conforming status, with even higher numbers among people of color in the survey.
- **Uninformed doctors: 50% of the sample reported having to teach their medical providers about transgender care.**
- **High HIV rates:** Respondents reported **over four times the national average of HIV infection, with rates higher among transgender people of color.**⁸
- **Postponed care:** Survey participants reported that when they were sick or injured, **many postponed medical care due to discrimination (28%) or inability to afford it (48%).**

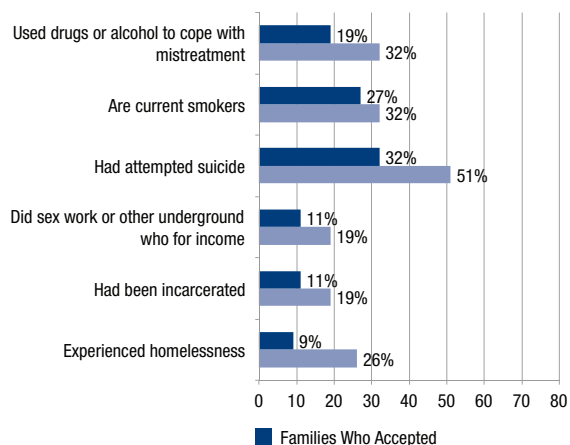
Suicide Attempt by Employment



FAMILY ACCEPTANCE OF GREAT IMPORTANCE

- **Forty-three percent (43%) maintained most of their family bonds**, while 57% experienced significant family rejection.
- In the face of extensive institutional discrimination, **family acceptance had a protective affect against many threats to well-being** including health risks such as HIV infection and suicide. Families were more likely to remain together and provide support for transgender and gender non-conforming family members than stereotypes suggest.

Impact of Family Acceptance

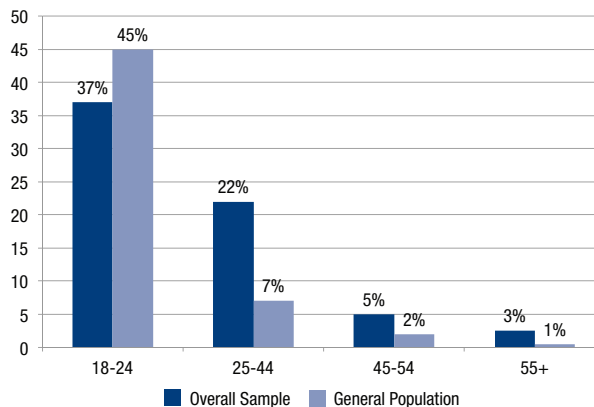


RESILIENCE

Despite all of the harassment, mistreatment, discrimination and violence faced by respondents, study participants also demonstrated determination, resourcefulness and perseverance:

- Although the survey identified major structural barriers to obtaining health care, 76% of transgender respondents have been able to receive hormone therapy, indicating a determination to endure the abuse or search out sensitive medical providers.
- Despite high levels of harassment, bullying and violence in school, many respondents were able to obtain an education by returning to school. Although fewer 18 to 24-year-olds were currently in school compared to the general population, respondents returned to school in large numbers at later ages, with 22% of those aged 25-44 currently in school (compared to 7% of the general population).¹⁰
- Over three-fourths (78%) reported feeling more comfortable at work and their performance improving after transitioning, despite reporting nearly the same rates of harassment at work as the overall sample.
- Of the 26% who reported losing a job due to bias, 58% reported being currently employed and of the 19% who reported facing housing discrimination in the form of a denial of a home/apartment, 94% reported being currently housed.

Status as a Student by Age⁹



CUMULATIVE DISCRIMINATION

Sixty-three percent (63%) of our participants had experienced a serious act of discrimination — events that would have a major impact on a person's quality of life and ability to sustain themselves financially or emotionally. These events included the following:

- Lost job due to bias
- Eviction due to bias
- School bullying/harassment so severe the respondent had to drop out
- Teacher bullying
- Physical assault due to bias
- Sexual assault due to bias
- Homelessness because of gender identity/expression
- Lost relationship with partner or children due to gender identity/expression
- Denial of medical service due to bias
- Incarceration due to gender identity/expression

Almost a quarter (23%) of our respondents experienced a catastrophic level of discrimination — having been impacted by at least three of the above major life-disrupting events due to bias. These compounding acts of discrimination — due to the prejudice of others or lack of protective laws — exponentially increase the difficulty of bouncing back and establishing a stable economic and home life.

CONCLUSION

It is part of social and legal convention in the United States to discriminate against, ridicule, and abuse transgender and gender non-conforming people within foundational institutions such as the family, schools, the workplace and health care settings, every day. Instead of recognizing that the moral failure lies in society's unwillingness to embrace different gender identities and expressions, society blames transgender and gender non-conforming people for bringing the discrimination and violence on themselves.

Nearly every system and institution in the United States, both large and small, from local to national, is implicated by this data. Medical providers and health systems, government agencies, families, businesses and employers, schools and colleges, police departments, jail and prison systems—each of these systems and institutions is failing daily in its obligation to serve transgender and gender non-conforming people, instead subjecting them to mistreatment ranging from commonplace disrespect to outright violence, abuse and the denial of human dignity. The consequences of these widespread injustices are human and real, ranging from unemployment and homelessness to illness and death.

This report is a call to action for all of us, especially for those who pass laws and set policies and practices, whose action or continued inaction will make a significant difference between the current climate of discrimination and violence and a world of freedom and equality. And everyone else, from those who drive buses or teach our children to those who sit on the judicial bench or write prescriptions, must also take up the call for human rights for transgender and gender non-conforming people, and confront this pattern of abuse and injustice.

We must accept nothing less than a complete elimination of this pervasive inhumanity; we must work continuously and strenuously together for justice.

Endnotes

- 1 U.S. Census Bureau, "Current Population Survey," Annual Social and Economic Supplement (Washington, DC: GPO, 2008).
- 2 "U.S.A. Suicide: 2002 Official Final Data," prepared for the American Association of Suicidology by John L. McIntosh, Ph.D. Official data source: Kochanek, K.D., Murphy, S.L., Anderson, R.N., & Scott, C. (2004). Deaths: Final data for 2002. National Vital Statistics Reports, 53 (5). Hyattsville, MD: National Center for Health Statistics DHHS Publication No. (PHS) 2005-1120. Population figures source: table I, p.108. of the National Center for Health Statistics (Kochanek et al., 2004), see http://www.sprc.org/library/event_kit/2002datapgv1.pdf.
- 3 General population data is from U.S. Census Bureau, "Current Population Survey," Annual Social and Economic Supplement (Washington, DC: GPO, 2008).
- 4 See note 3. "Mistreatment" includes harassment and bullying, physical or sexual assault, discrimination, or expulsion from school at any level based on gender identity/expression.
- 5 Seven percent (7%) was the rounded weighted average unemployment rate for the general population during the six months the survey was in the field, based on which month questionnaires were completed. See seasonally unadjusted monthly unemployment rates for September 2008 through February 2009. U.S. Department of Labor, Bureau of Labor Statistics, "The Employment Situation: September 2008," (2008): http://www.bls.gov/news.release/archives/empsit_10032008.htm.
- 6 1.7% were currently homeless in our sample compared to 1% in the general population. National Coalition for the Homeless, "How Many People Experience Homelessness?" (July 2009): http://www.nationalhomeless.org/factsheets/How_Many.html.
- 7 U.S. Department of Housing and Urban Development, "U.S. Housing Market Conditions, 2nd Quarter, 2009" (Washington, DC: GPO, 2009): http://www.huduser.org/portal/periodicals/ushmc/summer09/nat_data.pdf.
- 8 The overall sample reported an HIV infection rate of 2.6% compared to .6% in the general population. United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization (WHO), "2007 AIDS Epidemic Update" (2007): http://data.unaids.org/pub/EPISlides/2007/2007_epiupdate_en.pdf. People of color in the sample reported substantially higher rates: 24.9% of African-Americans, 10.9% of Latino/as, 7.0% of American Indians, and 3.7% of Asian-Americans in the study reported being HIV positive.
- 9 U.S. Census Bureau, "Current Population Survey: Enrollment Status of the Population 3 Years Old and Over, by Sex, Age, Race, Hispanic Origin, Foreign Born, and Foreign-Born" (Washington, DC: GPO, October 2008): Table 1. <http://www.census.gov/population/www/socdemo/school/cps2008.html>. The last category, over 55, was not rounded to its small size.
- 10 See note 9.