Kevin Díaz, OSB No. 970480 Email: kdiaz@aclu-or.org ACLU Foundation of Oregon

PO Box 40585 Portland, OR 97240

Tel.: (503) 227-6928; Fax: (503) 227-6948

Nathan Freed Wessler (pro hac vice)

Email: nwessler@aclu.org Ben Wizner (pro hac vice) Email: bwizner@aclu.org

American Civil Liberties Union Foundation

125 Broad Street, 18th Floor

New York, NY 10004

Tel.: (212) 549-2500; Fax: (212) 549-2654

Attorneys for the Plaintiffs-Intervenors

UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

PORTLAND DIVISION

OREGON PRESCRIPTION DRUG MONITORING PROGRAM, an agency of the STATE OF OREGON,

Plaintiff,

V.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the UNITED STATES DEPARTMENT OF JUSTICE,

Defendant.

Case No.: 3:12-cv-02023-HA

DECLARATION OF PROFESSOR ROBERT BAKER IN SUPPORT OF PLAINTIFFS-INTERVENORS' MOTION FOR SUMMARY JUDGMENT

JOHN DOE 1, et al.,

Plaintiffs-Intervenors,

ν.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, an agency of the UNITED STATES DEPARTMENT OF JUSTICE,

Defendant in Intervention.

I, Dr. Robert Baker, hereby declare and state as follows:

I am a Professor of Bioethics and the William D. Williams Professor of Philosophy at Union College and Director of the Union Graduate College-Icahn Mount Sinai School of Medicine Bioethics Program. I have been on the Union College faculty since 1973, where I teach courses on the history of medical ethics among other topics. I received a BA with Honors in History from the City College of New York and a PhD in Philosophy from the University of Minnesota. I have served as an American Philosophical Society fellow, an Institute for Health and Human Values fellow, an NYU Faculty Resources Network Scholar in Residence, a visiting scholar at the former Wellcome Institute for the History of Medicine in London, a senior scholar-in-residence at the American Medical Association Institute on ethics, and a College of Physicians of Philadelphia Wood Institute Fellow. I am a member of the American Philosophical Association, the American Association of Historians of Medicine, the International Association of Bioethics, and the American Society for Bioethics and Humanities, where I was founding chair, and currently co-chair, the Affinity Group on the History of Medical Ethics.

- Much of my research has focused on the history of medical ethics. I have authored, 2. coauthored, edited, and coedited several publications on this topic, including The Cambridge World History of Medical Ethics (coeditor); "Medical Ethics and Epidemics: A Historical Perspective" in Ethics and Epidemics (author and coeditor); and The Codification of Medical Morality: Historical and Philosophical Studies of the Formalization Of Medical Morality in the Eighteenth and Nineteenth Centuries, Volumes I and II (coeditor). I am currently in the final stages of authoring a book entitled Before Bioethics: A History of American Medical Ethics from the Colonial Period to the Bioethics Revolution. Two of my books on the history of medical ethics have been awarded a citation by Choice, the journal of archives and academic libraries, as an "outstanding" academic in its field. BioMedLib, a medical library reference service, cites one of my articles as the most cited in the history of medical ethics. I wrote the sections on the history of medical ethics and codes of medical ethics for several standard reference works in applied ethics, bioethics and the history of medicine, including the Encyclopedia of the History of Medicine, the Encyclopedia of Applied Ethics (2nd ed.), the forthcoming Springer Compendium & Atlas of Global Bioethics, and the Encyclopedia of Bioethics (4th ed.) To support my research I have been awarded a total of four National Endowment of the Humanities grants, three for my work in the history of medicine and medical ethics. A complete copy of my curriculum vitae is attached to this declaration.
- I have been asked to offer my expertise regarding standards and practices of medical confidentiality in colonial and founding-era America.
- 4. Until 1765, there was no formal medical education in America and almost all "regularly educated" eighteenth century American physicians (to use the terminology of the period)

studied at the University of Edinburgh Medical School in Scotland or under someone who had trained there. A "regular physician," is someone who received a Bachelors of Science degree or a Medical Doctorate from a university that has a curriculum similar to what one would expect a medical school to teach even today: anatomy, biology, chemistry, *materia medica*, physiology, and the theory of practice of physic (internal medicine) and surgery, supplemented by dissections, laboratory work, and clinical teaching at the bedside in hospitals.

The earliest American medical schools, such as those associated with Columbia 5. University College of Physicians and Surgeons (founded 1767) and the University of Pennsylvania School of Medicine (founded 1765) were modeled after the University of Edinburgh Medical School and were started by physicians like Samuel Bard (1742-1821). Bard was George Washington's physician during the period when New York City was the nation's capital and routinely lectured his medical students at Columbia about medical ethics. We do not have an accurate census of the number of regularly educated physicians who studied medicine at Edinburgh or under someone educated there; however, by the end of the 18th century, virtually every physician with a medical degree in Philadelphia had either studied in Edinburgh or under someone who had studied there. Much the same was true in New York City. Turning southward: about 230 Virginia physicians studied at Edinburgh between 1765 and 1800, approximately half receiving formal degrees (the others typically studied between one and four years without receiving a degree). Although the number of irregularly trained medical practitioners exceeded these "regulars," even in New York, Pennsylvania and Virginia, it was the degree-

- holding Edinburgh-style "regularly educated" physicians, the "regulars," as they referred to themselves, who created mainstream American medical ethics.
- 6. Beginning in the 1730s, Bard and every other medical student matriculated at the University of Edinburgh was required to sign or affirm an oath swearing to "practice physic [i.e. medicine] cautiously, chastely and honourably," and "never, without great cause, to divulge anything that ought to be concealed, which may be heard or seen during professional attendance." Keeping patients' medical information confidential was a central ethical requirement of physicians at the time. That tradition finds its roots in the Hippocratic Oath, written during the fourth or fifth century BCE, which included a requirement that the physician keep whatever is seen or heard in medical practice as "holy secrets."
- 7. Physicians who had been educated at the University of Edinburgh, or by one of its alumni, were among the signers of the Declaration of Independence and delegates to the Constitutional Convention. Several physicians who signed the Declaration of Independence included Josiah Bartlett, Matthew Thornton, and Lyman Hall—and Benjamin Rush. Rush, who tended to George Washington's troops at Valley Forge, was

¹ The full Edinburgh University Medical Oath, circa 1732-35 onwards, reads:

Tum porro artem medicam caute, caste, probeque excercitaturum, et quoad portero omnia ad aegrotorum corporum salutem conducentia cum fide procuraturum quae denique inter medendum visa vel audita silere convenit non sine gravi causa vulgaturum. Ita presens spondenti adsit numen.

[[]I A. B. do solemnly declare that I will] practice physic cautiously, chastely, and honourably; and faithfully to procure all things conducive to the health of the bodies of the sick; and lastly, never, without great cause, to divulge anything that ought to be concealed, which may be heard or seen during professional attendance. To this oath let the Deity be my witness.

an also alumnus of the University of Edinburgh and like Bard affirmed the Edinburgh Oath on matriculation.²

- 8. Rush was also a professor at the medical college associated with what is today the University of Pennsylvania and he regularly lectured his students on medical ethics. A collection of these lectures was published in 1811, and one of these, delivered as part of a course offered in 1801, "On the Duties of Patients to their Physicians," addressed the physician-patient covenant. In this lecture Rush informed his students that patients were duty bound to confide in their physicians. "Let not a patient be afraid of making a physicians his friend," by confiding in him, Rush explained to his students, for "in doing so they impose an obligation of secrecy upon him, and thus prevent his making public what he cannot avoid seeing or hearing."
- 9. Bard and Rush were the first two American physicians to publish on medical ethics.

 They were extraordinarily influential on physicians throughout colonial and post-colonial America. As one commentator wrote, between 1779 and 1812 Rush is credited with "exerting more influence on the medical profession that any other person during the quarter century following the [Revolutionary] War for Independence. His students practiced throughout the country from Massachusetts to Georgia," i.e., from the northernmost and southernmost states in the union.⁴

² Affirmation was an alternative to signing for Quakers and others who believed that Christians could not sign oaths.

³ Rush, Benjamin [1801] 1811. "On the Duties of Patients to Their Physicians," in Sixteen Introductory Lectures upon the Institutes and Practice of Medicine, With a Syllabus of the Latter... Delivered in the University of Pennsylvania. Cite at

http://archive.org/stream/2569048R.nlm.nih.gov/2569048R#page/n333/mode/2up/search/322.

⁴ Brodsky, Alyn. 2004. *Benjamin Rush: Patriot and Physician*. New York: St. Martin's Press, 278.

- 10. Three physicians are known to have attended the Constitutional Convention of 1787—
 James McClurg of Virginia (1746-1823), James McHenry of Maryland, (1753-1816) and
 Hugh Williamson of North Carolina (1735-1819). McHenry received his medical
 education studying under Dr. Rush, and McClurg received his medical degree at the
 University of Edinburgh and would have signed or affirmed the Edinburgh oath. These
 men would have been well acquainted with the traditional ethical precept of keeping
 patients' medical information confidential.
- 11. In the eighteenth century, physicians would write prescription orders for their patients to fill at apothecaries. Although I am not aware of any specific historical record regarding the confidentiality of such prescriptions, I presume based on my general knowledge of medical ethical principles at the time that the same expectations of medical privacy discussed above applied in this context.
- 12. The first medical societies came into existence during the colonial period but did not begin to formalize their understanding of medical ethics into formal codes until the early nineteenth century. The earliest formal code of medical ethics was issued in 1823 by the Medical Society of the State of New York (MSSNY)—which traces back to a Society of Weekly Practitioners founded during the colonial period by Samuel Bard and his father, John Bard (1716-1789). A special section of that code dealt with confidentiality with respect to physicians' testimony in courts of law.
- 13. The following is the section on *Forensic Medical Police* from the first American Code of Medical Ethics published by an American medical Society. This code was published in 1823 by the Medical Society of the State of New York.

XXII. There are numerous accidents and offences, the nature and degree of criminality of which are determined by medical opinion. ... A physician should

always be in readiness to answer in these jurisdictional inquisition, and to give an opinion, on facts referred to his judgment, according to the approved doctrines of medicine and surgery, as far as these are ascertained....

XXIII. To well instructed physicians only two rules need to be recommended. The one relating to their conduct when they are called upon to give professional evidence; and the other, to the nature and extent of the secrecy which they are bound to maintain in relation to their patients.

1st. When physicians engaged in the decision of a forensic question are unbiased by the parties, and have no interest for plaintiff or defendant, (being well-informed of all the facts alleged in evidence) they have only to decide by known medical principles, and can therefore rarely disagree. It is their duty to obtain every possible information upon the case, and before giving in their declaration candidly and conscientiously to canvass each others opinions, so that erroneous ideas may be removed....

2nd. The second rule is that of secrecy upon facts with which physicians become professionally acquainted, or are invited to ascertain; such as whether an apparent pregnancy can be real; the gestation and birth of a child; its parentage, colour, and age; the judgment and treatment of syphilitic and gonorrheal disease; the able or disabled state of a person, in limb or constitution; the fallacy of virginity and other circumstances, to the confession of which, a degree of shame, and the idea of exposure is attached, and which are never mentioned but with an engagement to secrecy. This duty has been defined by comparing it to that of the Catholic Confessional, which admits of no disclosures except in cases of treason or murder. ⁵

14. The second medical society to formalize its understanding of medical ethics in a code was the Baltimore Medico-Chirurgical Society's *System of Medical Ethics*, which published its code in 1832. Prefatory comments to this code address the issue of confidentiality as both a duty incumbent on physicians and an essential for effectively practicing medicine.

No situation or pursuit in life can exact a more rigid adherence to the principles of virtue, integrity, benevolence and humanity, than that of the physician: Indeed, the very nature of his profession renders it requisite that he should possess the utmost probity and purity of character; for, to medical men are confided the dearest and most important interests of human nature. Not only are they the

⁵ Medical Society of the State of New York. 1823. *A System of Medical Ethics Published by the Order of the State Medical Society of New York*. New York: William Grattan.

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guardians of health, and the ministers whose duty it is to soften the pillow of sorrow and affliction, but to them are also intrusted the lives, the honor, and reputation of their patients..... In [physicians] bosom, too, we [patients] find a safe depository for our cares and our confidence, and in their sympathies and friendly admonitions, a mitigation of many of the ills and troubles of existence.—Confident in their virtue and integrity, we can unbosom to them our most secret thoughts and reflections—expose our faults and our foibles—our vices and delinquencies, and while we are encouraged to them by firmness and affliction, and to probity and firmness in our actions, we are secure against any violation of our confidence, or exposure of our faults and infirmities.

In a later section of the Baltimore Society's *System of Medical Ethics* explores the reciprocal relation between the physician's duty of confidentiality and a prerequisite of effective medical practice, the patient's duty of confiding to their physicians.

Patients should faithfully and unreservedly communicate to their physician, the history of the cause of their disease. This is the more important as many diseases of a mental origin simulate those depending on external causes, and yet are only to be cured by ministering to the mind diseased. A patient should never be afraid of thus making his physician his friend and adviser; he should always bear in mind, that a medical man is, or ought to be, under the strongest obligations of secrecy. Even the female sex should never allow feelings of shame or delicacy to prevent their disclosing the seat, symptoms, and causes of complaints peculiar to them. However commendable delicacy of mind may be in the common occurrences of life, its strict observance is medicine may often be attended with the most serious consequences, and a patient sink under a painful and loathsome disease, which might have been readily prevented had timely intimation been given to the physician. ⁶

This last point is pivotal to all discussions of medical confidentiality: the effective practice of medicine depends on the willingness of patients to engage with the healthcare system. Any perception that their personal medical information may become public is likely to chill their willingness to engage with the healthcare system, with, as noted in the above paragraph, "serious consequences," such as the failure to prevent treatment of "a painful and loathsome disease."

⁶ Medico-Chirurgical Society of Baltimore. 1832. A System of Medical Ethics Adopted by the Medico-Chirurgical Society of Baltimore; Being the Report of the Committee on Ethics, And published by order of the society. Baltimore: James Lucas and E. L. Deaver.

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15. In 1847, the American Medical Association was founded and issued its first Code of Medical Ethics. The code was adopted unanimously by the founding convention, to which representatives were sent from virtually every regular medical society, medical school, asylum, and hospital in the US, and, of more relevance to the issues in this case, many of the larger medical dispensaries (i.e., the pharmaceutical dispensaries of charitable institutions and hospitals). In 1855 this code became binding on all regular healthcare institutions in the US. Homeopaths and Osteopaths adopted versions of this code in 1884 and 1904 respectively. Their codes were modeled on the 1847 AMA Code of Medical Ethics and contain similar sections on confidentiality.

As in precursor codes, the 1847 AMA Code of Medical Ethics formalized traditions of medical morality dating to Bard, Rush and the colonial period. The following two sections deal with confidentiality.

Chap. I, Art. I, Sec. 2.

Every case committed to the charge of a physician should be treated with attention, steadiness and humanity.... Secrecy and delicacy, when required by peculiar circumstances, should be strictly observed; and the familiar and confidential intercourse to which physicians are admitted in their professional visits, should be used with discretion, and with the most scrupulous regard to fidelity and honor. The obligation of secrecy extends beyond the period of professional services-none of the privacies of personal and domestic life, no infirmity of disposition or flaw of character observed during professional attendance, should ever be divulged by him except when he is imperatively required to do so. The force and necessity of this obligation are indeed so great, that professional men have, under certain circumstances, been protected in their observance of secrecy by courts of justice.

Patients are held to have a reciprocal duty to confide in their physicians:

Chap. I, Art. II, Sec. 4.

Patients should faithfully and unreservedly communicate to their physician the supposed cause of their disease. This is the more important, as many diseases of a mental origin simulate those depending on external causes, and yet are only

to be cured by ministering to the mind diseased. A patient should never be afraid of thus making his physician his friend and adviser; he should always bear in mind that a medical man is under the strongest obligations of secrecy. Even the female sex should never allow feelings of shame and delicacy to prevent their disclosing the seat, symptoms and causes of complaints peculiar to them. However commendable a modest reserve may be in the common occurrences of life, its strict observance in medicine is often attended with the most serious consequences, and a patient may sink under a painful and loathsome disease, which might have been readily prevented had timely intimation been given to the physician.⁷

- 16. We have reason to believe that this notion of confidentiality was enforced by medical societies. Although medical society records of censure and expulsion are rare, this scholar encountered the following case in the records of the New York Academy of Medicine (NYAM).
- 17. The Expulsion of James Marion Sims for breaching patient confidentiality.

On November 11, 1869 Thomas C. Finnell (1826-1890), head of the Committee on Ethics of the New York Academy of Medicine (NYAM, founded 1847 and still functioning), charged a famous surgeon, J. Marion Sims (1813-1883), with violating confidentiality at the expense of a celebrity patient, the actress, Charlotte Cushman (1816-76), who was famous for her performances of Shakespeare and notorious for her open lesbianism. The charge read:

An eminent woman [Charlotte Cushman] applied to Sims for professional advice, the disease is mentioned [in a letter Sims wrote to the *New York Times*] and the Advice given is fully set forth. It is further stated that the patient "unfortunately followed other Advice"—An unjust and injurious reflection upon the professional advisors under whose care she saw fit to place herself for an operation concerning which there is great latitude of Opinion amongst Surgeons.

A portion of Paragraph 2, Article 1, "On the Duties of Physicians to their Patient," is as follows: "Secrecy and delicacy, when required by

⁷ Baker, Robert and Arthur Caplan, Linda Emanuel, and Stephen Latham, eds. 1999. *The American Medical Ethics Revolution*. Baltimore: the Johns Hopkins University Press, Appendix C, p. 324, 326.

peculiar circumstances, should be strictly observed. . . The obligation of secrecy extends beyond the period of professional services-none of the privacies of personal and domestic life, no infirmity of disposition or flaw of character observed during professional attendance, should ever be divulged by him except when he is imperatively required to do so."

The undersigned claims that the Code does not allow a physician to announce to the public, the disease of a patient, and that the communications of Dr. J. M. Sims is a violation of these paragraphs from which these quotations were made.

It is not improper to state that a leading daily paper in this city [The *New York Times*] upon the communications that its author made a statement in regard to the lady, entirely uncalled for, and thereby advertised himself as her physician.

The undersigned makes these charges from no malice; it is to him as to many others, a source of deep regret that one whose name is so honorably linked to the fame of our profession [i.e. James Marion Sims], should be placed in such a discreditable position but loyalty to our Code demands that all should be called to account whenever they appear guilty of violating any of its Articles.

After a review of the letter published in the New York Times, and reflection on the explanation offered by Sims in his defense, the committee "declared that the charges against Dr. J. Marion Sims are fully sustained and [that he be publicly] reprimanded by the President of the Academy." Rather than face such a public humiliation, with its requisite demand for a public apology, Sims took a steamer to London.

18. To review briefly, colonial American physicians inherited from Edinburgh, and more generally from the Hippocratic tradition, ethical conventions of confidentiality that were taught in American medical schools by teachers like Bard and Rush, and that were later formalized when American medical societies began to draft formal codes of ethics. When a colonial or early republic physician, like Samuel Bard, treated a patient, like George Washington, both physician and patient understood that what passed between, and what the physician observed in the course of medical practice, was to be kept

confidential. This presumption extended to whatever scripts physicians wrote to be

prepared by an apothecary or compounding pharmacist. Based on my knowledge of the

history of American medical ethics, it is my conclusion that our nation has a longstanding

tradition of valuing and protecting medical confidentiality. This tradition was firmly in

place at the time of the Fourth Amendment's ratification in 1791, was known to the

Constitution's framers, and continued into the nineteenth century and beyond.

Pursuant to 28 U.S.C. § 1746, I hereby declare and state under penalty of perjury that the

foregoing is true and correct to the best of my knowledge, information, and belief.

Robert Baker

Dated: June 2 ?, 2013