

In re: Drug Products Labeled as Homeopathic } COMMENTS REGARDING
Draft Guidance for Food and Drug } FDA GUIDANCE
Administration Staff and Industry } FDA Docket FDA-2017-D-6580

I. SUMMARY OF COMMENTS

Submitted by the Institute for Health Research and the Natural Solutions Foundation

- 1. The Food and Drug Administration (FDA)’s attempt to restrict the development of homeopathy by applying pharmaceutical drug “risk/benefit” analysis was never authorized by Congress.**
- 2. FDA is required to conduct evaluations using appropriate methodological methods and tools. “Risk/Benefit” Analysis is a methodologically inappropriate tool when any potential benefit has been assumed, a priori, to be zero, as in the FDA’s use of “risk/benefit”.**
- 3. Biological individuality precludes the application of standard pharmaceutical “risk/benefit” analysis. One of the central premises upon which classical homeopathy is based is that biological individuality must be accounted for in order to apply a remedy for a clinical benefit. the proposed “risk/benefit” evaluation of this medical art which precludes consideration and evaluation of biological individuality is impossible, rendering “risk/benefit” analysis invalid in this application.**
- 4. “Risk/benefit” analysis is valid only when all variables are controlled for but this is impossible both in Holistic Health and in homeopathic interventions since the personalization of the requirements of each individual’s needs are so particularistic to preclude valid comparison or control subjects using the diagnostic schema of the systems themselves. Application of other diagnostic schemata for evaluation of “risk/benefit” values is a logical absurdity and renders any “risk/benefit” analysis meaningless, even if the presumption of zero benefit is nullified.**
- 5. Holistic health care, such as homeopathy, is not a proper subject for standard pharmaceutical “risk/benefit” analysis because it is not unitary and is highly personalized.**
- 6. Pharmaceutical care similarly becomes an improper subject for “risk/benefit” analysis once a single drug is no longer the subject of the evaluation and the subject has entered the realm of polypharmacy.**
- 7. The Homeopathic Pharmacopeia of the United States (HPUS) remains the appropriate non-governmental source of substantiated Homeopathic Proving.**
- 8. Homeopathic remedies are specifically protected by law (Citation) from being evaluated or regulated as if they were pharmaceuticals. The attempt by the FDA to do so is outside the regulatory and legal authority of that agency.**

9. **FDA lacks the legal authority to curtail access to, sale or use of Homeopathic remedies since they are part of the English Common Law Tradition as a protected under the Herbalists Charter.**
10. **The Case Law of the several States is clear: Americans have the right to seek to achieve and maintain a healthy status using means that are not part of standard, licensed medicine approved by Federal Agencies.**

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INTRODUCTION

The Institute for Health Research was founded in 1998 and is a recognized exempt nongovernmental organization (NGO). Ralph Fucetola JD is the President of the Institute. The Natural Solutions Foundation is a nonprofit NGO founded in 2004 by the late Maj. Gen. Albert N. Stubblebine III and Rima E. Laibow, MD (hereinafter the “NGOs”), The NGOs submit this Comment regarding the proposed **Drug Products Labeled as Homeopathic Draft Guidance for Food and Drug Administration Staff and Industry** (hereinafter the “Guidance”) on their behalf, and on behalf of the trustees and communicants thereof. The trustees and communicants personally use homeopathic remedies and will be aggrieved (and otherwise damaged) by the implementation of the Guidance.

The NGOs, trustees and communicants oppose the final adoption of the Guidance as:

1. **Unlawful and**
2. **Unsupported by competent science.**

The commenters request full public hearings.

III. HISTORY OF HOMEOPATHIC REGULATION

[1] Discovery and development of homeopathy.

Two of the great branches of the healing arts, allopathy and homeopathy have their roots in ancient history. Allopathy, or “opposites cure” is exemplified by the use of substances, such as Aspirin (from White Willow Bark), which suppress the symptoms of disease (in this example, fever).

Homeopathy, or “like cures like”, is based on the concept that what will produce symptoms in high dose will allow the body to overcome those symptoms when given in low dose. The founding concept of homeopathy reaches back to ancient Greece, where the Oracle of Delphi, questioned about curing a certain general’s festering wound directed, “Find the sword which wounded; make a poultice therefrom.” – Like would cure like.¹

During the 1700s, Dr. Hahnemann, a German physician, searching for safer options than the highly toxic and dangerous substances used during the era of “heroic medicine” – when toxins such as mercury were touted as a cure for syphilis, or when invasive surgical procedures, such as blood-letting killed George Washington, used his skills as a physician to explore and observe beneficial clinical responses to conditions treated without toxic consequences.

He sought, instead, safer, gentler means to support the body’s innate ability to heal itself. Developing the concept of “Like cures like” further, he elaborated the central concept of ‘Proving’ a compound and its impact on health and disease. Provings are experiments with natural substances that, when given in highly diluted form (what would be identified as Nano-dilutions today) supported healing of the whole person or specific symptom.

The protected right to adopt such measures is part of the English Common Law since, in that tradition, such remedies are subsumed under the Herbalists Charter of Henry VIII². This Charter

¹ <http://healthy-ojas.com/systems/birth-homeopathy.html>

² <http://vitaminlawyerarchives.blogspot.com/2014/03/the-herbalists-charter-and-modern.html> When the States declared independence as Sovereign States, they adopted the Laws of England as the Common Law of the State. Among the Laws of England so adopted is the Herbalist's Charter, an Act of Henry the Eighth (in the Third Year of his reign). It is worth noting that many of the issues presented in this matter are similar to issues which the Act of Parliament addressed. In the Sixteenth Century, as in the Twentieth Century, licensed physicians and surgeons were going to Court to ban the activities of the competitors of their day.. Parliament ordered an end to this misuse of the Courts to enforce licensure, protecting the holistic healers of that time from "suit, vexation, trouble, penalty, or loss of their goods..." This ancient Act of Parliament applied to England and the King's "other dominions" including, of course, the American Colonies, and later, States. This Act has never been repealed, and thus remains part of our Common Law to this day, offering protection to persons such as homeopaths.

of Rights remains a part of the Common Law of the American States and is binding upon the Food and Drug Administration.

Starting with Dr. Samuel Hahnemann, physicians and researchers in a number of countries, including Germany, France, Great Britain, India and the United States developed a pharmacopeia of homeopathic dilutions, resulting in the United States in the Homeopathic Pharmacopeia of the United States (hereinafter, the “HPUS”).

[2] Regulation prior to the 1930s (Uniform State Medical Practices Acts)

Starting in the late 1800s when the first Medical Practices Acts were adopted in the various United States, homeopathy was recognized as part of medical practice. Various homeopathic schools and hospitals were founded and this branch of the healing arts was favored by many consumers.

By the 1930s, however, with the coming of the Commissioners on Uniform State Laws draft uniform Medical Practices Acts the legal definition of the “practice of medicine” was changed to a functional definition, to the effect that licensed medicine was restricted to prescribing for the treatment or curing of disease. The old statutory definitions which included terms such as “homeopathy” and the like were removed.³

Homeopathy was no longer restricted as a part of licensed medicine.

[3] Congressional grandfathering of HPUS

In 1938 when Congress adopted the Food, Drug and Cosmetic Act (hereinafter, the FDCA) greatly expanding the power of the FDA it set public policy by “grandfathering” the homeopathic formulations listed in the HPUS. This public policy of restricting FDA control over homeopathic remedies has not changed. Over the years some additional remedies have

³ For example, New Jersey first adopted a licensing law for medicine in 1894. In that law, the branches of medicine to be studied were said (in Section 7) to include "homeopathy or eclecticism...therapeutics; obstetrics and gynecology; practice of medicine, including diseases of the skin, nose and throat; surgery, including surgical anatomy and diseases of the eye, ear and genito-urinary organs...hygiene" Section 8 provided that without a license, no one could "prescribe, direct, recommend, advise, apply, give, or sell, for the use of any person or persons, any drug or medicine or other agency or application for the treatment, cure or relief of any bodily injury, infirmity or disease..." In 1939, the licensing structure was updated. Title 45:9-5.1 defined the practice of medicine and surgery as "any branch of medicine and/or surgery, and any method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition...[including] the practice of osteopathy and chiropractic..." Homeopathy, eclecticism (which was the practice of herbal medicine and nutritional treatment) and hygiene were excluded from the new definition, and no longer considered part of the standard practice of medicine.

been added to the HPUS and that nongovernmental organization continues to serve the public good.⁴

Americans remain free to use the principles of homeopathy and remain free to develop additional homeopathic remedies based on those principles, which permit, in addition to traditional homeopathic remedies listed in the HPUS, remedies such as nosodes (from pathogenic materials) and isodes (individualized remedies).

The Guidance fails to take into account how American consumers actually use homeopathy and this is also a reason for the Guidance not to be finalized.

[4] Recent developments in Homeopathic Regulation Leading to the Guidance

In the United States, after Congress acted to protect homeopathy from enhanced FDA power, the modality benefited from the government's benign neglect and slowly grew in popularity, with many homeopathic remedies available through health stores nation-wide. This was a world-wide trend, with homeopathy generating special interest in, for examples, India (where it is a recognized, free-standing branch of Medicine under AYUSH legislation, Germany and the UK.)

For over a half century the United Kingdom's "National Health Service" paid for special homeopathic hospitals and herbal dispensaries. All that changed in mid-2017 when the "single payer" determined that a "risk/benefit" analysis causes that government to reject homeopathy as a health care modality. The "National Health Service" will no longer pay for either and it is expected that many will now be forced to close.⁵

It is critically important to note that the modeling tool, "risk/benefit" analysis, is singularly inappropriate for the use to which it was put. The supposed, a priori assumed, lack of any benefit is not only an inaccurate and biased presumption which renders the 'analysis' moot, it also renders the tool mathematically and methodologically inappropriate since any number, in this case any supposed risk, divided by zero becomes infinite. There is no clinical, epidemiological or other data to support the notion that the use of Nano dilute substances leads to infinite harm.

Science is hardly being served through the bogus use of this statistical slight-of-hand, nor is US law, since, unsurprisingly, the FDA is following suit, despite the fact that Homeopathy and the US Homeopathic Pharmacopoeia (USHP) are protected by specific statutes in the US.

During 2017 the Drug Enforcement Administration (DEA) and the FDA came out publicly saying, for example, that Cannabidiol, CBD, a neurotransmitter produced by mammalian (including human) bodies, was not a lawful nutrient, although the agencies have stopped short of

⁴ https://en.m.wikipedia.org/wiki/Regulation_and_prevalence_of_homeopathy

⁵ <http://www.telegraph.co.uk/news/2017/07/21/nhs-ban-homeopathy-herbal-medicine-misuse-resources/>

raiding health food stores [as FDA used to do in the 1990s, before the 1994 Dietary Supplement Health and Education Act (DSHEA)] to enforce this unlawful dictate.⁶

On December 18th of 2017 FDA issued new regulations that have a strong potential to restrict unlawfully homeopathic oral and injectable remedies despite the fact that these remedies are protected by long-standing law. Indeed, the NGOs believe that the sole purpose of this new regulation is precisely that: to restrict unlawfully homeopathic and oral injectable remedies. This blatant attack on our health freedom choices is part of a long-term, well-financed conspiracy and, sadly, comes as no surprise.⁷

It should be noted that a major portion of the operating fees of the FDA are provided directly by pharmaceutical companies and that homeopathic remedies are sought-out in growing numbers by holistically-minded consumers and practitioners precisely because they are an alternative -- and thus compete -- with pharmaceuticals and do so, in the opinion of their users, successfully.

On behalf of the Institute for Health Research and the Natural Solutions Foundation we submitted comments at the Regulations.gov site when the agency started the “regulatory review” of homeopathy during 2015, urging the agency to leave our natural remedies alone! The “review” began “innocently enough” during that previous presidential administration. FDA asked for comments on how it should “modernize” homeopathy regulations. That is often the government’s first step toward ratcheting-up control.

That is the step to which we had previously replied, telling the agency, among other things:

"FDA does not have authority from Congress to interfere with traditional homeopathy, nor does Congress have authority to permit such interference. Individuals have the right, under international humanitarian law binding on the United States, of Informed Consent to exercise their Freedom of Choice in health care without government burdening that fundamental right."⁸

As noted above these new regulations followed similar recent action in the UK by its “single payer” nationalized health care system. The UK “National Health Service” has ended its long-standing history of support for safe, gentle and effective homeopathy and herbalism in favor of dangerous, deadly and ineffective pharmaceuticals. This trend toward pharmaceutical monopoly has “crossed the pond” as the FDA has begun the process to unlawfully restrict legally protected homeopathy in the USA.

This was done in three steps that we have documented.

⁶ <http://vitaminlawyerhealthfreedom.blogspot.com/2017/01/ftc-wants-disclaimers-on-homeopathy.htm>

⁷ <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm589373.pdf>

⁸ <http://vitaminlawyerhealthfreedom.blogspot.com/2015/06/comments-to-fda-re-homeopathy-fda-has.html>

First in 2015, the FDA asked for public comments about regulating homeopathy. That's when we submitted the comments referenced above. By the way, by submitting comments telling FDA they were acting illegally, we preserved the legal right to complain to the courts; we preserved "standing to sue."

Second, as noted in a blog entry posted January 2017, FDA was toying with the idea of unlawfully requiring "disclaimers" on homeopathic products, disclaimers not required by the statute that protects homeopathy in the USA⁹.

Third, the action commented upon here, which illegally attempts to treat HPUS standard homeopathic remedies as unapproved pharmaceutical drugs, requiring a "risk/benefit analysis" which will effectively ban many, if not most, homeopathic remedies. The findings of infinite risk against absent benefits is unscientifically guaranteed by the presumption that there are no benefits in homeopathic remedy usage so no risk can be balanced by such benefits.

Further, the unscientific "analysis" assumes that homeopathic remedies result in harm. The clinical experience, published and empirical results of its uses supports neither assumption so the 'analysis' has no foundation in either methodology or reality. It is a stalking horse to allow the pharmaceutically-biased Agency to destroy a competitor to the modality to which it owes significant fealty.

This pseudo-scientific analysis starts with the false claim that homeopathic remedies have no benefit and implies an alleged "risk" that people using such natural remedies will fail to use government approved, dangerous, "side-effect" producing pharmaceutical drugs as if such use could be assumed, without any question, to be a benefit to the user.

There is a significant literature which documents that no such presumption is warranted and that the proper use of pharmaceutical drugs is, in itself, a leading cause of death around the world. No such documentation exists to show that any homeopathic remedy causes either morbidity or mortality so the equivalence of the two modalities is, once again, not established, nor can risks or benefits be compared using this methodological tool since the orders of magnitude of effect are in no way comparable, resulting in statistics so skewed as to render them, once again, meaningless.¹⁰

It further assumes that use of homeopathic remedies is symptom-based, as is the use of pharmaceutical drugs when, in fact, suitable use of homeopathic is based on constitutional and organism-specific conditions so that patients with the same conditions from an allopathic diagnostic point of view may be treated with totally different remedies. Therefore, comparing risks and outcomes from similar treatment directions by looking at the pharmaceutical natural history of a disorder (risks, benefits of the drug used in a particular condition) is not applicable to the evaluation of outcomes in homeopathic remedy use so that the underlying condition of one

⁹ <http://www.hpus.com/legal-status.php>

¹⁰ <http://www.webster.edu/irb/policy/risk>

patient may be much graver than that of another with the same symptoms. Thus there are, practically speaking, very few control subjects with the same nutritional, genetic, constitutional and other factors with the same condition to compare with any given patient in order to evaluate either risk *e* benefit.

Since biological individuality is ignored almost totally in allopathic medicine, and is critically important in classical homeopathy, the comparison of the two as if they were somehow both intellectually and mathematically equivalent is bound to fail logically, scientifically and methodologically – unless the fix is in and science has been sacrificed on the alter of pharmaceutical power by the Agency.

A most critical question which this unscientific ‘risk/benefit’ approach ignores totally is “*What risk?*” Since government approved drugs are the main cause of preventable death in the USA, we ask the Agency, what risk?¹¹

If a true “risk/benefit’ analysis of pharmaceutical drugs was to be conducted, it is doubtful that most currently lawfully prescribed pharmaceutical substances would be permitted to be available.

IV. LEGAL STATUS OF HOMEOPATHIC APPROACHES TO HEALTH

As noted above, Congress grandfathered Homeopathy. This means the power to forbid or restrict traditional homeopathy has been denied to the agencies of the Federal Government.

The Homeopathic Tradition predates the founding of the Federal Government. The concept of a Traditional Use is well-founded in law. Here is the Federal Trade Commission (hereinafter the “FTC”) position on Traditional Uses,

"Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional

¹¹ <http://www.webdc.com/pdfs/deathbymedicine.pdf>

medicine products under DSHEA and FDA labeling rules. * * * The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate."¹²

The Case Law of the several States is clear: Americans have the right to seek to achieve and maintain a healthy status using means that are not part of standard, licensed medicine approved by State or Federal Agencies.

In *Hillman/Kohan Eyeglasses, Inc v New Jersey State Board*, 169 NJ Super 259, the Court observed that, absent compelling health reasons, consumers should have choices in the competitive marketplace, and further, that if the legislature had intended to create a monopoly, it would have done so by specific grant of monopoly, which it did not do in the case of optometry, nor, we assert, in the case of medicine.

Americans have the right to obtain unlicensed, private professional health care services. The Southern District of Texas case of *Andrews v Ballard* (498 F Supp 1038, 1980) is cited as a leading authority for the propositions that (1) a decision to obtain (in this case) acupuncture needle treatments from one not licensed as a medical doctor is a constitutional right encompassed by the right of privacy (p.1048) and (2) the provisions of the medical practices act, insofar as they limit the use of acupuncture needles to licensed physicians, are unconstitutional (p.1051, *et seq.*).

In the case of *State v Biggs* (46 SE Reporter 401, 1903) the North Carolina Supreme Court dealt with a person who was advising people as to diet, and administering massage, baths and physical culture. In the *Biggs* case, the defendant "advertised himself as a 'nonmedical physician'...[and] held himself out to the public to cure disease by 'a system of drugless healing'..." p.401. That Court held that there could be no "state system of healing" p.402 and while "Those who wish to be treated by practitioners of medicine and surgery had the guaranty that such practitioners had been duly examined...those who had faith in treatment by methods not included in the 'practice of medicine and surgery' as usually understood, had reserved to them the right to practice their faith and be treated, if they chose, by those who openly and avowedly did not use either surgery or drugs in the treatment of diseases..." p.402. Biggs was acquitted.

In *Andrew v Ballard*, 498 F. Supp. 1038, 1980 an acupuncturist was attacked for practicing medicine as he was using needles to treat disease. The Federal District Court held that, where a state sought to prohibit all but licensed physicians from using needles in treatment, such prohibition violated fundamental rights.

¹² <https://www.ftc.gov/tips-advice/business-center/guidance/dietry-supplements-advertising-guide-industry>

Of particular significance in judging the attempt of the Guidance to restrict Homeopathy is the leading United States Supreme Court case of *Thompson vs Western States* (535 US 357, 2002). The case is about Speech, and Homeopathic Labels are a type of Speech. This It concerns a clause in the Food, Drug and Cosmetics Act that allows pharmacists to "compound" medications for specific prescriptions without safety testing and FDA prior approval but forbids pharmacists from advertising the specific compounds they make. The Supreme Court held that the restriction was unconstitutional, using language that supports the right of the consumers to health care modalities not previously approved by the FDA. Some of that language used in Justice O'Connor's Majority Decision is as follows:

"If the First Amendment means anything, it means that regulating speech must be a last - not first - resort."

"We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."

"Even if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."¹³

The basic rule announced by the case to determine what government restrictions on Commercial Speech (speech that makes or is about an offer for a transaction) is permitted by the Constitution is a Two Prong Test: the first prong is to ask two questions: (1) is the speech in question about unlawful activity and (2) is the speech misleading. If "no" to both, the speech is entitled to protection unless the Government can carry its burden and prove (1) the governmental interest involved is "substantial", (2) the regulation must "directly advance" the governmental interest and (3) the regulation of Commercial Speech cannot be "more extensive than is necessary to serve that interest" (quoting *Central Hudson v Public Service*, 447 US 557, at 566).

The proposed Guidance is, in effect, a restriction on Speech about Traditional Homeopathic remedies and labels. As such the attempt to implement a "risk/benefit" analysis is not supported by the law governing health care in the United States.

V. "RISK/BENEFIT" ANALYSIS IS INAPPROPRIATE

The Commenters herein are of the opinion that the Guidance illegally attempts to treat HPUS or other homeopathic remedies as unapproved pharmaceutical drugs, requiring a "risk/benefit

¹³ This alternative, more in keeping with the First Amendment, has not been proposed by the FDA.

analysis" which will effectively ban many, if not most, homeopathic remedies. Such remedies, being Nano-dilutions, have no measurable level of any drug substance in them.

This pseudo-scientific analysis starts with the false claim that homeopathic remedies have no benefit and implies an alleged "risk" that people using such natural remedies will fail to use government approved, dangerous, "side-effect" producing pharmaceutical drugs.

At their root, holistic approaches to health, such as homeopathy, with its traditional reliance on biological individuality, are not subject to standard scientific "risk/benefit" analysis.

One of the central premises upon which classical homeopathy is based is that biological individuality must be accounted for in order to apply a remedy for a clinical benefit. the proposed "risk/benefit" evaluation of this medical art which precludes consideration and evaluation of biological individuality is impossible, rendering "risk/benefit" analysis invalid in this application.

"Risk/benefit" analysis is valid only when all variables are controlled for but this is impossible both in Holistic Health and in homeopathic interventions since the personalization of the requirements of each individual's needs are so particularistic to preclude valid comparison or control subjects using the diagnostic schema of the systems themselves. Application of other diagnostic schemata for evaluation of "risk/benefit" values is a logical absurdity and renders any "risk/benefit" analysis meaningless, even if the presumption of zero benefit is nullified.

Each individual is a unique pattern that leads to a unique health care approach. Analyses based on statistical "risk/benefit" numerical tallying miss the potential benefits to the individual. When there is no risk from the remedy, as with the Nano-dilutions of homeopathy, the whole concept of "risk/benefit" analysis fails.

VI. CONCLUSION

These comments are submitted to urge the FDA and the Trump White House to stop this unlawful assault on health freedom. Do not approved the Guidance. Reconsider the application of "risk/benefit" analysis to holistic approaches to achieving and maintaining a healthy status. We request full public hearings.

These comments are further submitted on behalf of the NGOs, trustees and communicants to preserve legal standing and the right to object to this latest FDA action, by exhausting our administrative remedies before seeking redress of grievances in the honorable courts of the United States.

In conclusion we note the wise words of the Supreme Court of North Carolina, determining the scope of the original Medical Practices Act in that State:



"The state has not restricted the cure of the body to the practice of medicine and surgery - - allopathy, as it is termed, -- nor required that, before anyone can be treated for any bodily ill, the physician must have acquired a competent knowledge of allopathy and be licensed by those skilled therein. To do that would be to limit progress by establishing allopathy as the state system of healing, and forbidding all others. This would be as foreign to our system as a state church for the cure of souls. All the state has done has been to enact that, when one wished to practice medicine or surgery, he must, as a protection to the public [not to the doctor], be examined and licensed by those skilled in surgery and medicine. To restrict all healing to that one kind -- to allopathy, excluding homeopathy, osteopathy, and all other treatments -- might be a protection to doctors in surgery and medicine; but that is not the object of the act, and might make it unconstitutional, because creating a monopoly." North Carolina's Supreme Court in *State v MacKight*, 42 S.E. 580, 1902 at p 582.

Further that Court taught us, in *State v Biggs*, (46 SE Reporter 401, 1903)

"Medicine is an experimental, not an exact science. All the law can do is to regulate and safeguard the use of powerful and dangerous remedies, like the knife and drugs, but it cannot forbid dispensing with them. When the Master, who was himself called the Good Physician, was told that other than his followers were casting out devils and curing diseases, he said, 'Forbid them not.'" (p.405).

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