InformedCHOICEWA
PROTECTING OUR MEDICAL FREEDOM

July 19, 2018
RE: HHS Failure of Compliance with 1986 NCVIA

Dear WA DOH VAC Committee Members:

On October 19, 2017, Informed Choice WA provided each of you with a letter alerting you to the ICAN Notice to HHS on the National Childhood Vaccine Injury Act of 1986. The Notice requested confirmation from the Secretary of HHS that certain obligations regarding vaccine safety required under the 1986 Act had been fulfilled. HHS did not respond to this notice until legal action was taken. That action was settled on July 9, 2018. The attached stipulated order reveals that HHS has failed to fulfill critical duties regarding vaccine safety. Next legal steps are being taken.

The 1986 Act required the Secretary of HHS to consult with the Institute of Medicine (IOM) to conduct a review of the scientific literature related to a set of serious adverse events following immunizations recommended for use in children. This portion of the law was fulfilled—but HHS failed repeatedly to act upon the results and recommendations of the IOMs reviews. Over the past thirty years, the CDC has conducted some epidemiological studies, but not of sufficient design or number to address IOM concerns or fulfill the requirements of the law. Many post-vaccinal adverse reactions have never been studied at all to rule in or rule out causal effect. In their 2012 review, the IOM found the scientific literature was insufficient to make any sort of conclusion about 135 serious adverse events commonly reported after vaccination.

The magnitude of HHS's failure is reflected in a 2015 CDC White Paper[1], on which doctors **Stanley Plotkin, Edgar Marcuse, Walter Orenstein,** and others, served as Subject Matter Experts.

The White Paper study team identified 47 adverse outcomes from the 2012 IOM Report they deemed plausible in regards to exposure to the pediatric vaccine schedule. The Subject Matter Experts reviewed each of the 47 outcomes, "focusing on biologic plausibility, relevance to the entire immunization schedule, and feasibility to study in the VSD." They excluded just 4 outcomes due to their extreme rarity. The Subject Matter Experts agreed that the remaining 43 adverse outcomes met the criteria. The list includes allergy, asthma, autism spectrum disorders, Crohn's disease, meningitis, and learning, communication, and developmental disorders.

What does this mean to the WA Department of Health?

Washington State law regarding vaccination is built upon the premise that safety is being properly addressed at the federal level. HHS's failure to do so directly impacts the integrity of all state laws and policies regarding vaccination, including DOH's mandate to increase vaccination rates.

In light of this, the WA DOH must cease pressuring for indiscriminate vaccine uptake. Instead, the DOH should be providing the most accurate data (or acknowledge the lack thereof) on each vaccine-disease pair needed to make fully informed vaccination decisions and protect the right to opt-out.

Sincerely,
Bernadette Pajer
Drella Stein
Co-Presidents
InformedChoiceWA.com

COALITION FOR CIC INFORMED CONSENT

[1] White Paper on the Safety of the Childhood Immunization Schedule Vaccine Safety Datalink, Centers for Disease Control and Prevention | 1600 Clifton Road | Atlanta GA 30329 |

Note: In the Executive Summary of the **White Paper on the Safety of the Childhood Immunization Schedule** it is stated that the IOM undertook the 2012 review because of parental concern over vaccine safety. That is not true. While parents are highly concerned over the safety of the immunization schedule, that was not the reason for the review. The IOM writes:

"The Institute of Medicine (IOM) was charged by Congress when it enacted the National Childhood Vaccine Injury Act in 1986 with reviewing the literature regarding the adverse events associated with vaccines covered by the program, a charge which the IOM has addressed 11 times in the past 25 years. Following in this tradition, the task of this committee was to assess dispassionately the scientific evidence about whether eight different vaccines cause adverse events (AE), a total of 158 vaccine-AE pairs, the largest study undertaken to date, and the first comprehensive review since 1994."

The methodological research approaches suggested in the White Paper for using the VSD data to study these outcomes will not provide meaningful results. To the contrary, the approaches seemed to be designed to further obfuscate the truth.

Only rigorous, independently designed and executed studies of the VSD data, as well as properly designed biological mechanism studies in animal models, will provide the answers we need. Some biomarkers of vaccine injury are already known, and others must be found and utilized to detect immediate and unfolding (latent) adverse reactions as soon as possible so that appropriate biomedical treatments can be implemented.

Denying that vaccine injuries are frequently occurring– without proper medical investigation – must end.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,

Plaintiff,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Defendant.

STIPULATION

18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows:

> (a) General rule
>
> In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—
>
> > (1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and
> >
> > (2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.
>
> . . .
>
> (c) Report
>
> Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the

> actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, on August 25, 2017, Informed Consent Action Network ("ICAN") submitted a Freedom of Information Act request (the "FOIA Request") to the Department of Health and Human Services ("HHS" or the "Department"), which was assigned control number 2017-01119-FOIA-OS, that sought the following records:

> **Any and all reports transmitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate by the Secretary of HHS pursuant to 42 U.S.C. §300aa-27(c).**

WHEREAS, on April 12, 2018, ICAN filed a Complaint for Declaratory and Injunctive Relief in the United States District Court, Southern District of New York against HHS seeking records, if any, responsive to the FOIA Request;

WHEREAS, the HHS Immediate Office of the Secretary ("IOS") maintains the official correspondence file of the Secretary of HHS, including reports to Congress by the Secretary of HHS, and therefore those files were most likely to contain records responsive to the FOIA Request;

WHEREAS, on June 27, 2018, HHS sent ICAN the following response to the FOIA Request:

> The [Department]'s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

WHEREAS, ICAN believes the foregoing response from HHS now resolves all claims asserted in this action;

IT IS HEREBY STIPULATED AND AGREED, by and between the parties by and through their respective counsel:

1. That the above-captioned action is voluntarily dismissed, with prejudice, pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(ii), each side to bear its own costs, attorney fees, and expenses; and

2. That this stipulation may be signed in counterparts, and that electronic (PDF) signatures may be deemed originals for all purposes.

Dated: July 6, 2018
New York, New York

KENNEDY & MODONNA LLP
Attorney for Plaintiff

By: _____
Robert F. Kennedy, Jr.
48 Dewitt Mills Road
Hurley, NY 12443
(845) 481-2622

Dated: July 6, 2018
New York, New York

GEOFFREY S. BERMAN
United States Attorney
Attorney for Defendant

By: _____
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SO ORDERED:

_____
HON. JESSE M. FURMAN, U.S.D.J.

Dated: New York, New York
July 6, 2018

Any pending motions are moot. All conferences are vacated. The Clerk of Court is directed to close the case.

Informed Consent Action Network

For Immediate Release: June 13, 2018

US District Court Judge signs order granting Plaintiff, Informed Consent Action Network (ICAN) and counsel, Robert F. Kennedy, Jr., the relief sought in a lawsuit against the US Department of Health and Human Services (HHS)

On Monday, June 9th, the United States District Court for the Southern District of New York signed an order granting Plaintiff, the nonprofit Informed Consent Action Network (ICAN),, the relief it sought against the Defendant, the United States Department of Health and Human Services, HHS. ICAN was represented by Robert F. Kennedy, Jr.

In May 2017, ICAN Founder, Del Bigtree, Robert F. Kennedy, Jr.. and a handful of other individuals concerned about vaccine safety were selected by the White House to participate in a seminal meeting with the Counselor to the Secretary of HHS, the heads of the National Institute of Health, NIH, the Center for Disease Control, CDC, and Food and the Drug Administration, FDA. Del Bigtree and Robert F. Kennedy, Jr. suspected that HHS was not fulfilling its critical vaccine safety obligations as required by Congress in The National Childhood Vaccine Injury Act of 1986.

The 1986 Act granted unprecedented, economic immunity to pharmaceutical companies for injuries caused by their products and eviscerated economic incentive for them to manufacture safe vaccine products or improve the safety of existing vaccine products. Congress therefore charged the Secretary of HHS with the explicit responsibility to assure vaccine safety.

Hence, since 1986, HHS has had the primary and virtually sole responsibility to make and assure improvements in the licensing, manufacturing, adverse reaction reporting, research, safety and efficacy testing of vaccines in order to reduce the risk of adverse vaccine reactions. In order to assure HHS meets its vaccine safety obligations, Congress required as part of the 1986 Act that the Secretary of HHS submit a biannual reports to Congress detailing the improvements in vaccine safety made by HHS in the preceding two years.

ICAN therefore filed a Freedom of Information Act, FOIA, request on August 25th, 2017 to HHS seeking copies of the biannual reports that HHS was supposed to submit to Congress, starting in 1988, detailing the improvements it made every two years to vaccine safety. HHS stonewalled ICAN for eight months refusing to provide any substantive response to this request.

ICAN
Informed Consent Action Network

ICAN was therefore forced to file a lawsuit to force HHS to either provide copies of its biannual vaccine safety reports to Congress or admit it never filed these reports. The result of the lawsuit is that HHS had to finally and shockingly admit that it never, not even once, submitted a single biannual report to Congress detailing the improvements in vaccine safety. This speaks volumes to the seriousness by which vaccine safety is treated at HHS and heightens the concern that HHS doesn't have a clue as to the actual safety profile of the now 29 doses, and growing, of vaccines given by one year of age.

In contrast, HHS takes the other portions of the 1986 Act, which require promoting vaccine uptake, very seriously, spending billions annually and generating a steady stream of reports on how to improve vaccine uptake. Regrettably, HHS has chosen to focus on its obligation to increase vaccine uptake and defend against any claim vaccines cause harm in the National Injury Vaccine Compensation Program (aka, the Vaccine Court) to such a degree that it has abandoned its vaccine safety responsibilities. If HHS is not, as confirmed in Court this week, even fulfilling the simple task of filing a biannual report on vaccine safety improvements, there is little hope that HHS is actually tackling the much harder job of actually improving vaccine safety.

For additional information or interviews please contact:
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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This study was supported by Contract No. HHSH230200446009I, Task Order 13 between the National Academy of Sciences and the Health Resources and Services Administration of the U.S. Department of Health and Human Services. The Centers for Disease Control and Prevention and the National Vaccine Program Office also provided support through that contract. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

Suggested citation: IOM (Institute of Medicine). 2012. *Adverse effects of vaccines: Evidence and causality.* Washington, DC: The National Academies Press.

Although the committee is optimistic that more can and will be known about vaccine safety in the future, the limitations of the currently available peer-reviewed data meant that, more often not, we did not have sufficient scientific information to conclude whether a particular vaccine caused a specific rare adverse event. Where the data were inadequate to reach a scientifically defensible conclusion about causation, the committee specifically chose not to say which way the evidence "leaned," reasoning that such indications would violate our analytic framework. Some readers doubtless will be disappointed by this level of rigor. The committee particularly counsels readers not to interpret a conclusion of inadequate data to accept or reject causation as evidence either that causation is either present or absent. Inadequate data to accept or reject causation means just that—inadequate. It is also important to recognize what our task was not. We were not charged with assessing the benefits of vaccines, with weighing benefits and costs, or with deciding how, when, and to whom vaccines should be administered. The committee was not charged with making vaccine policy. We did receive calls to stride into this contentious debate, but others, such as the Food and Drug Administration and the CDC, are tasked with formulating recommendations for use that balance the risk of vaccines with the benefits, with studying the safety of the vaccines during pre-release trials, and monitoring them closely once the vaccine is in use in the population.

Our work could not have been accomplished without the concerted efforts of the committee members who did their work carefully with good cheer and open minds. The committee's talented and intrepid staff, Trevonne Walford, Erin Rusch, and Andrew Ford, led by the wisdom and experience of Kathleen Stratton, could not have been more wonderful to work with or more essential to the committee's task.

Ellen Wright Clayton, *Chair*
Committee to Review Adverse Effects of Vaccines

Executive Summary

Routine vaccination in the United States is widely viewed as one of the greatest public health achievements of the past century. Despite this success, an increasing number of parents have been expressing concerns about vaccine safety over the last two decades. Parental vaccine worries have traditionally focused on specific vaccines, ingredients and types of adverse events. More recently, parents have been voicing concerns about the safety of the recommended immunization schedule as a whole, with opinions that children receive too many vaccines at too young of an age, and that early childhood immunization overwhelms the immune system. These sentiments reflect the number, frequency and timing of recommended vaccines, leading some parents to refuse or delay vaccinations for their children.

In response to these concerns, the Institute of Medicine (IOM) in 2012 convened a committee to gather stakeholder input and scientific evidence on the safety of the recommended childhood immunization schedule.[1] The committee concluded that, while available evidence indicated that the current U.S. immunization schedule was safe, few published investigations had specifically examined the safety of the recommended childhood schedule as a whole. The committee recommended that additional observational studies of the safety of the schedule were warranted, and stated that the Vaccine Safety Datalink (VSD) project[2] represents one of the best resources in the nation for conducting such studies. The VSD is an established collaboration of nine managed care organizations (MCOs) where electronic health record (EHR) data on over 9 million people are used to conduct observational studies on vaccine safety.

The IOM report also highlighted four research questions of highest priority to stakeholders: 1) how do child health outcomes compare between fully vaccinated and unvaccinated children; 2) how do child health outcomes compare between fully vaccinated children and children whose parents have refused specific vaccines; 3) do short- and long-term health outcomes differ when comparing children vaccinated according to the recommended schedule to children receiving fewer vaccines per visit or receiving vaccines at later ages; and 4) are some subpopulations of children at increased risk of adverse events following immunization (for example, children with a family history of allergic or autoimmune disease).

To address these research questions, the IOM report emphasized the need to carefully consider the potential impact of confounding and bias. In particular, the committee stressed that decisions to initiate future safety studies should include an assessment of the following: 1) epidemiological evidence of adverse events; 2) biologic plausibility of associations between the immunization schedule and adverse events of interest; and 3) stakeholder concerns about the safety of the schedule.

Guided by the IOM committee's assessment of the unique and important role the VSD could play in this area of study, the Immunization Safety Office (ISO) of the Centers for Disease Control and Prevention (CDC) issued a request for a White Paper. The focus of the White Paper was to be determine how the VSD could be used to study the safety of the entire childhood immunization schedule.

evaluated potential mechanisms by which receipt of all childhood immunizations could impact biological functions leading to the development of an adverse event. To assess appropriateness of evaluating an outcome relative to the entire schedule, the study team considered the acute/chronic nature of the outcome and the age at peak incidence. In addition, the team reviewed the existing epidemiological evidence to determine if outcomes could be clearly linked to a specific vaccine or combination of vaccines, suggesting that such outcomes should not be studied in relation to the entire schedule.

After internal discussions among the study team using these criteria, 28 outcomes were removed from the list. For example, outcomes such as stroke and myocardial infarction were not considered plausible for evaluation relative to the childhood immunization schedule given the later age of peak incidence and relatively low incidence among children. Additionally, outcomes such as serum sickness/Arthus reaction and measles inclusion body encephalitis were not considered plausible because of the direct association with specific vaccines and lack of biological plausibility for an association with the immunization schedule as a whole. Similarly, thrombocytopenia and immune thrombocytopenic purpura were excluded since they are known acute adverse events of specific vaccines.

At the conclusion of phase 1, the list of 75 outcomes was reduced to 47 plausible outcomes that could be studied relative to the childhood immunization schedule as a whole (Table 3.a).

Table 3.a: List of 75 outcomes identified for evaluation; 47 bolded outcomes were initially considered plausible to study relative to the childhood immunization schedule

All Cause
- **1. All cause morbidity**
- **2. All cause mortality**

Allergy/allergic condition
- **3. Allergy development**
- **4. Asthma development**
- **5. Anaphylaxis**
- **6. Chronic urticaria**
- **7. Asthma exacerbation**

Autoimmune disease
- **8. Crohn's disease and ulcerative colitis**
- **9. Kawasaki's disease**
- **10. Type 1 Diabetes**
- **11. Autoimmune hepatitis**
- **12. Psoriatric arthritis**
- **13. Juvenile rheumatoid arthritis**
- **14. Systemic lupus erythematosus**
- **15. Multiple sclerosis**
- **16. Autoimmune thyroiditis (Hashimoto's)**
- **17. Autoimmune thyroiditis (Grave's)**
- **18. Rheumatoid arthritis**

Blood/circulatory system disorders
- 19. Hypercoaguable states
- 20. Immune thrombocytopenia purpura
- 21. Polyarteritis nodosa
- 22. Thrombocytopenia
- 23. Thromboembolic events

Bone/joint
- 24. Ankylosing spondylitis
- 25. Arthropathy / chronic arthropathy
- 26. Arthalgia (chronic and transient)
- 27. Juvenile idiopathic arthritis
- 28. Polymyalgia rheumatica
- 29. Reactive arthritis

Demyelinating neurologic disorders
- **30. Acute disseminated encephalomyelitis**
- **31. Chronic inflammatory demyelinating polyneuropathy**
- **32. First demyelinating event**
- **33. Guillain-Barre syndrome**
- **34. Neuromyelitis optica**
- **35. Optic neuritis**
- **36. Transverse myelitis**

Cardio/cerebro-vascular system
- 37. Myocardial infarction
- 38. Myocarditis and pericarditis
- 39. Stroke

Seizures
- **40. Epilepsy**
- **41. Infantile spasms**
- **42. Afebrile seizures**
- **43. Febrile seizures**
- **44. Other seizures**

Other:
- 45. Erythema nodusum
- 46. Fibromyalgia
- 47. Oculorespiratory syndrome
- 48. Pancreatitis
- 49. Serum sickness and arthus reaction
- 50. Sudden infant death syndrome
- 51. Uveitis

Neurologic system
- **52. Autism spectrum disorders**
- **53. Bell's Palsy**
- **54. Brachial neuritis**
- **55. Cerebellar ataxia/ ataxia**
- **56. Encephalitis**
- **57. Encephalopathy**
- **58. Meningitis**
- **59. Narcolepsy and cataplexy**
- **60. Syncope and vasovagal reaction**
- **61. Learning, communication, and developmental disorders**
- **62. Attention deficit disorder**
- **63. Tourette's syndrome**
- **64. Tics**
- **65. Chronic fatigue syndrome**
- **66. Amyotrophic lateral sclerosis**
- **67. Chronic headache**
- **68. Hearing loss**
- **69. Opsoclonus myoclonus syndrome**
- **70. Small fiber neuropathy**

Varicella-zoster virus related conditions
- 71. Disseminated Oka varicella zoster virus, with subsequent infection
- 72. Disseminated Oka varicella zoster virus without organ involvement
- 73. Varicella zoster virus reactivation with subsequent infection
- 74. Varicella zoster virus reactivation without organ involvement

Measles virus related conditions
- 75. Measles inclusion body encephalitis

3.3 Subject Matter Expert (SME) engagement (Phase 2)

Once the initial list of 47 outcomes was in place, Emory University hosted a day-long meeting on February 25th, 2014, with VSD staff and three outside, internationally regarded experts in the area of vaccine science. The subject matter experts were Dr. Walter Orenstein of Emory University, Dr. Stanley Plotkin of the University of Pennsylvania, and Dr. Edgar Marcuse of the University of Washington. The objective of the meeting was to gain additional insight into the appropriateness of studying specific outcomes in the context of the childhood immunization schedule and to conduct an initial prioritization of the outcomes.

For the first two hours of the meeting, the study team and SMEs had an open discussion about each of the 47 outcomes, focusing on biologic plausibility, relevance to the entire immunization schedule, and feasibility to study in the VSD. After the discussion, the SMEs were instructed to classify each outcome as "include" or "exclude". The SMEs were also asked to comment on whether additional information (or data) was needed to determine the feasibility of studying the outcome relative to the entire immunization schedule within the VSD.

Of the 47 outcomes, the SMEs concluded that the following 4 outcomes could be excluded: Hashimoto's thyroiditis, Grave's disease, opsoclonus myoclonus syndrome and small fiber neuropathy. The first two were excluded because they rarely occur during childhood; the latter two were eliminated because they are extremely rare in the general population.

For the remaining 43 outcomes, the SMEs made several suggestions. First, since the emphasis was on long-term outcomes, the SMEs were concerned that outcomes with insidious onsets, long latencies, or unclear diagnostic characteristics (e.g., narcolepsy, fibromyalgia) would be difficult to study. They therefore stressed the importance of focusing on outcomes with clear diagnostic criteria, such as those having a definitive clinical diagnostic test or by having the ability to confirm case status with a manual medical record review. Second, the SMEs expressed the need to strongly consider public concern when deciding on outcomes to study. They said that, in certain instances, public concern may be a more important consideration than biologic plausibility. Some of the outcomes on the list – such as all cause morbidity/mortality and attention deficit disorder – reflect this opinion. Finally, the SMEs were concerned that many of the outcomes may be too rare to study in the VSD, and requested additional age-specific incidence data. They further suggested that several of the outcomes represented classes of conditions that could be grouped together (Table 3.b). For example, the SMEs recommended that a single outcome grouping called "first demyelinating events" could include acute disseminated encephalomyelitis, chronic inflammatory demyelinating polyneuropathy, Guillain-Barre syndrome, neuromyelitis optica, optic neuritis, and transverse myelitis.

Table 3.b: Individual outcomes that were grouped

Outcome group	Individual Outcomes
First demyelinating event	• Acute disseminated encephalomyelitis • Chronic inflammatory demyelinating polyneuropathy • Guillain-Barre syndrome • Neuromyelitis optica • Optic neuritis • Transverse myelitis
Seizures	• Febrile seizure • Afebrile seizure • Other seizures (seizures not otherwise specified)
Tics	• Tics • Tourette's syndrome

Despite the emphasis on long-term outcomes, there was also considerable discussion on the appropriateness of studying anaphylaxis, which is generally considered to be an acute event triggered by an acute exposure. However, since hypersensitivity reactions need prior sensitization to occur, it is possible that repeated exposures to a particular antigen or vaccine component could lead to the development of an underlying hypersensitivity state, which could be triggered by a follow-up booster dose. Therefore, it was concluded that anaphylaxis represents an acute event that may be evaluated in the context of the childhood immunization schedule. The final result of the SME meeting was an initial list of 31 prioritized outcomes.

3.4 Final prioritization (Phase 3)

Between April and July 2014, the study team reviewed the transcripts and formally prioritized the list of 31 outcomes using an iterative process.