Radiopharmaceuticals in Nuclear Medicine

A Most Unstable Form of Imaging

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Discussion Topics

- 99mTechnetium (99mTc) production cycle
- Highly Enriched Uranium (HEU) vs. Low Enriched Uranium (LEU) and the mandate for conversion
- Current State of Molybdenum-99 (MO-99) Production
- Other Radiopharmaceutical Challenges
Technetium 99m: The Workhorse

- Used in 80% of the world’s use of medical isotopes
  - 80% are cardiac and bone
- 30 million studies done globally/year
- 6 hour half life
- Produced from decay of Molybdenum-99
The majority of the world’s supply of Mo-99 comes from the fission of Uranium (U-235) in research reactors.

There are currently eight reactors around the world producing >98% of the Mo-99 used for medical isotope production.

There are five primary processors using these reactors to produce Mo-99.
Current U.S. Mo-99 Supply Matrix

<table>
<thead>
<tr>
<th>Reactor</th>
<th>Mo-99 Extraction</th>
<th>Mo-99 Purification</th>
<th>Tc-99m Generator Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maria</td>
<td>Mallinckrodt</td>
<td></td>
<td>Mallinckrodt</td>
</tr>
<tr>
<td>HFR</td>
<td></td>
<td></td>
<td>U.S.</td>
</tr>
<tr>
<td>BR2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVR-15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OSIRIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safari</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRU</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>OPAL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NTP</td>
<td></td>
<td>Lantheus</td>
</tr>
<tr>
<td></td>
<td>AECL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nordin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ANSTO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Why Are We Talking About This?

- Mid 2015- BR2 reactor is scheduled to go off-line 14-16 months for refurbishing.
- 2016 NRU reactor scheduled to scale down production of Mo-99.
  - Will ramp up if there are shortages
  - ?????
- These supply 50% of the world’s technetium
- Conversion from HEU to LEU mandated by law: 2020.
Nuclear Enterprise: 2 Extremes

- Limitless source of clean energy
- Harbinger of nuclear annihilation
- Russia, China, and India are accelerating their production and programs
- U.S & Germany and others scale back each time there is a nuclear disaster
  - Three Mile Island
  - Chernobyl
  - Fukushima
The Last 20 Months Have Been Challenging

- The HFR was down from November 2012-June 2013.
- The HFR has been down since September 28, 2013.
- The Molybdenum-99 (Mo-99) production facility at NTP has been down since November 2, 2013.
- The Mo-99 processing facility in Petten has been down since October 30, 2013.
- The NRU was down briefly in November 2013.
Molybdenum

- Used in industry and in medical imaging
  - Stable forms are traded on US stock exchange
- 35 known isotopes of Molybdenum
  - 7 occur naturally
- MO – 98 is the most common form (24.1%) found on earth
- Mo-100 mined primarily in Russia.
  - High percentage of impurities
- MO – 99 currently produced by irradiating solid targets containing Uranium – 235
  - Peaked usage occurred in 2010 (12,000 Ci/week compared to 10,000 Ci/week in 2014)
World Wide Research Reactors

1. Are used mainly for other reasons
   • Mo-99 is a “side-line” business
   • Also make I-131 and Xe-133
2. Governments largely subsidize Mo-99 production
3. Full cost recovery may be difficult to achieve
4. Are aging
5. No U.S. production of Mo-99
   • We are vulnerable to interruptions
6. Mo-99 produced from reactor fission HEU most efficient and effective
# Global Mo-99 Sources

<table>
<thead>
<tr>
<th>Reactor</th>
<th>Location</th>
<th>Commissioning Date</th>
<th>Target Type</th>
<th>Global Mo-99 Processor</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRU</td>
<td>Chalk River, Canada</td>
<td>1957</td>
<td>HEU</td>
<td>Nordion</td>
</tr>
<tr>
<td>HFR</td>
<td>Petten, Netherlands</td>
<td>1961</td>
<td>HEU*</td>
<td>Mallinckrodt/IRE</td>
</tr>
<tr>
<td>BR2</td>
<td>Mol, Belgium</td>
<td>1961</td>
<td>HEU*</td>
<td>Mallinckrodt/IRE</td>
</tr>
<tr>
<td>OSIRIS</td>
<td>Saclay, France</td>
<td>1966</td>
<td>HEU</td>
<td>Mallinckrodt/IRE</td>
</tr>
<tr>
<td>SAFARI</td>
<td>Pelindaba, South Africa</td>
<td>1965</td>
<td>HEU/LEU</td>
<td>NTP</td>
</tr>
<tr>
<td>MARIA</td>
<td>Otwock-Swierk, Poland</td>
<td>1974 1993 (rebuilt)</td>
<td>HEU*</td>
<td>IAE-Polatom/Mallinckrodt</td>
</tr>
<tr>
<td>LVR-15</td>
<td>Rez, Czech Republic</td>
<td>Mid 1950’s</td>
<td>HEU</td>
<td>Czech Nuclear Research Institute/IRE</td>
</tr>
<tr>
<td>OPAL</td>
<td>Lucas Heights, Australia</td>
<td>2007</td>
<td>LEU</td>
<td>ANSTO</td>
</tr>
</tbody>
</table>

*In the process of converting to LEU targets
** In the process of converting to LEU fuel

LEU=low enriched uranium
HEU=highly enriched uranium

2/7/2014
The American Medical Isotope Production Act of 2011

- Requires the radioisotope industry to convert from HEU to nHEU
- Supports the production of Mo-99 for medical use in the U.S. by non federal entities.
- Mandates that the U.S. must phase out the export of HEU for production of Mo-99 within seven years (2020)
HEU and nHEU... What’s this All About?

- Uranium isotope used for fission is U-235
  - In nature, U-235 is 0.7% while U-238 is 99.3%
- Low enriched uranium (LEU) is defined as U-235<20%
- High enriched uranium (HEU) is defined as U-235≥20%
- Most HEU used in medical isotope production is >90% U-235
- nHEU-based Tc-99m is produced in a manner not using HEU (i.e., LEU, accelerator production, neutron capture, cyclotron)
- U.S. Department of Energy (DOE) and The White House support the transition to nHEU for medical isotope production.
The Production Cycle of 99mTc:

1. HEU (and some LEU) shipped from the U.S. to France
2. U-235 converted from ingot to powder
3. U-235 pressed into flat “dispersion” targets
4. Transported to reactor sites
5. U-235 irradiated in reactor – U-235(n,f) =>Mo-99 (fission)
6. Transport of irradiated targets to Mo-99 production sites
   a) Purify Mo-99 targets
   b) Tc-99m generator manufacturer
7. Generators shipped
Global Reactor Locations

- **Maria**
  - Poland

- **LVR-15**
  - Czech Republic

**MOLYBDENUM-99 SOURCES**

- NRU
  - Canada
- Osiris
  - France
- Safari
  - South Africa

**Uses highly enriched uranium-235 targets**

**Uses low-enriched uranium-235 targets**

- HFR
  - Netherlands
- BR2
  - Belgium
- OPAL
  - Australia
HEU CAN BE USED TO MAKE WMDS, LEU CAN’T.
Where is nHEU-Based Mo-99 Currently Produced?

- Only two reactors in the world currently use LEU targets for production of Mo-99 (Safari in South Africa and OPAL in Australia)
- A small percentage of the global Mo-99 supply currently comes from the fission of LEU targets.
- Cyclotron produced Tc-99m.
  - Avoids the Mo-99 “middle man”
  - Being trialed in Canada.
  - Deliveries are local (6 hr. ½ life of Tc-99m)
  - Small yield
Cost Impact of nHEU Conversion

- Multiple cost components related to development and use of new LEU targets
  - Upfront development costs
  - Facility modification costs
  - Regulatory and other transitional costs
  - Operational costs of using new targets
- These costs require upfront investment several years before LEU-based Mo-99 is produced
- Conversion to LEU targets will lead to inherent loss of efficiency
  - Conversion from 93% to <20% U-235 enrichment, plus the loss of capacity (i.e., target yields)
- The cost of conversion yield capacity will cause the cost to produce Mo-99 to rise significantly
CMS- Preferential Reimbursement Program ($10 additional payment for Non HEU 99mTc)

- Hospital only
- Only paid if Tc-99m generator contains >95% non-HEU-based Mo-99
- Use the new Q code when filing for reimbursement
- Q9969 – “NHEU Tc99m – add on per study done
Patients to pay a $2.00 co-insurance”
The CMS Preferential Reimbursement Program at the Hospital

- Implementation at the hospital
  - Training of coding personnel for the proper use of the new “Q” code
  - Higher administrative costs due to necessary charge master changes to reflect both HEU and Non-HEU-based Tc-99m doses
  - Proper documentation requirements of 95% non-HEU-based Tc-99m doses for CMS audits
  - Higher cost associated with 95% non-HEU-based Tc-99m
The CMS Preferential Reimbursement Program at the Nuclear Pharmacy

- Implementation and dispensing 95% non-HEU-based Tc-99m at the pharmacy
  - Loss of efficiency in the nuclear pharmacy
  - Only a limited number of non-HEU-based Tc-99m generators will be available
  - Concern over fraudulent reporting of 95% non-HEU-based Tc-99m doses
  - Inability for the nuclear pharmacy to reconstitute “mega-kits”
  - Purchasing the correctly sized generator to cover fluctuating prescriptions from eligible Medicare hospital outpatient procedures
  - Higher cost associated with 95% non-HEU-based Tc-99m
Managing a Tc-99m Shortage

1. Rational use of Tc-99m
2. New faster scanners
3. Other radiopharmaceuticals
   1. Sestamibi → TI-201
4. Use other diagnostic studies
The Good News Bad News:

• Dose has been reduced
  • Reduced radiation exposure
• Real time live “research” is Tc-99m really better than TI-201?
  • Yes.
• Some referral patterns to other diagnostics have not reverted back to nuclear medicine
The Future of Mo-99 Production

- Conversion of existing HEU reactors to LEU
- More reactors coming online using only LEU
- Cyclotron produced for small providers
- Alternative methods of nHEU-based Mo-99 production are in development by various entities
  - Production of Mo-99 ($^{100}$Mo(y,n)$^{99}$Mo) in accelerators, but material produced is Low Specific Activity
  - Neutron activation using Mo-98 ($^{98}$Mo(n,y)$^{99}$Mo) in reactors, but material produced is Low Specific Activity. (NorthStar)
    - Need a different generator due to LSA
  - May 2015, NorthStar produced a small amount of Mo-99 from MURR* (Neutron Activation)
    - Proof of concept that NorthStar can produce, package and ship Mo-99
  - Accelerator Driven fission process using LEU solution (Shine)
    - Can use current generator due to fissioned Mo-99 (HSA)
  - Other recent (spring 2015) entrants
    - National Security Technologies/Global Medical Isotope Systems
    - Coqui Pharma building a production facility in Florida
- None have produced significant commercial quantities to date
- * Fissioned U-235 Mo-99 is desirable due to HSA of Moly-99.
Current Mo-99 Manufacturers

- Are Currently buying more reactor “cells”
- Will use cells when other reactors go down
- Must pay for them even if they are not used
Replacement Reactors

NRU → ZENITH 2016

HFR → PALLAS (2024)

OSIRIS → JHR (2016)

BR2 → MYRRHA (2023)
NorthStar’s Mo-99 Generator Submitted to FDA for Approval
Other Radiopharmaceuticals That Challenge Us

- $^{223}$Ra (Xofigo)
- $^{82}$Rb
- $^{123}$I-Ioflupane (DatScan)
- $^{18}$F – Amyloid Imaging
- 99mTc-MAA
- 99mTC DTPA
- CCK
Radium 223

- Was discovered 115 years ago by Madame Curie
- Alpha emitter (93.5%) gamma 1.1% @ 70keV
  - Short range 50 – 80 micrometers (µm)
  - High linear transfer energy
    - 100keV / µm vs. beta 0.2keV / µm
    - Produces double strand DNA breaks vs. single strand DNA breaks from beta
- More specific tumor killing with less damage to surrounding tissue.
- Mimics calcium and forms complexes with bone mineral hydroxyapatite in areas of high bone turnover such as bone metastasis.
Penetrating Distances of Radiation

\( \alpha \)

\( \beta \)

\( \gamma \)

\( n \)
**Ra-223 Dichloride (Xofigo) Regulatory History**

- Approved by NRC in early 2013
  - Written directive required
  - Physicians approved for any beta or photon emitter with energy less than 15keV under 10CFR 35.390 or 10CFR 35.396 can be authorized to treat
- Was temporarily unavailable in October 2014 due to particles found in solution
- November 6, 2014 production resumed
- Originally manufactured only in Norway
- December 22, 2014 Cardinal Health announced they will build a manufacturing site in Indianapolis
Indications

- Castrate resistant prostate cancer
- Symptomatic bone metastasis
- No visceral metastasis
- Administered post chemotherapy
- Concomitant treatment with chemotherapy in phase III clinical trials
Protocols

- 50 kBq (1.35µCi) per Kg body weight
- Given at 4 week intervals for 6 injections
- Absolute neutrophil count (ANC) ≥ 1.5x10^9/L
- Platelet count ≥ 100 x 10^9 /L
- Hemoglobin ≥ 10g/dL
- Subsequent injections:
  - ANC ≥ 1.0 x 10^9 /L and platelet ≥ 50 x 10^9 /L
- Patient well hydrated
- Good I.V. as tested with saline drip, injections etc.
- AU must be present.
- Typical post treatment precautions
- Alpha emitter: family concerns not as acute compared to I-131.
Reimbursement (1/1/15)

- CPT A9606 - $120.65/µCi (No longer per dose)
  - NDC #50419-0208-01
- CPT 79101 – $ 276.82 Radiation iv therapy
- Bayer’s standard dose is 162µCi at reference date
  - WAC at $18,439 / vial or $113.82/µCi
- Can order specific, individual dose (µCi/kg)
- Get approval and authorization from private payers before proceeding
- Update charge master!!
Rubidium -82 (CardioGen-82)

- Strontium -82 (Sr-82) and unavoidable Sr-85 decays into Rb-82
  - Sr-82 25 day $\frac{1}{2}$ life
  - Rb-82 75 seconds
- Saline eluted through generator column exchanging Na+ ions for Rb-82+ ions
- Controlled Rb-82 infusion delivered to patient
- As generator ages (replaced every 28 days) Sr-82 and Sr-85 occurs.
• Sr-82 and 85 detected at US border in 2011 causing a 1 year recall
• Generators were reintroduced with a more stringent training and oversight process
• Manufacturing delays coupled with interruptions of the supply of Sr-82, caused decreased and sometimes no generator shipments (3 months)
Training of Users

• Each user must undergo 3 trainings in order to be allowed to receive generator.
  • Recertified each year by vendor.
  • Sites are encouraged to have a minimum of 3 trained
• QC Training: On site by Bracco apps specialist
• Monitor Program Training: On site or WEBX
• EDC (computer) training
  • User must past test and requirements before they are issued a pass word to use system.
  • QC data and other info entered which allows system to issue alerts and detect system expiration.
## Threshold/Expiration Limits

<table>
<thead>
<tr>
<th>Criteria</th>
<th>μCi Sr-82/mCi Rb-82</th>
<th>μCi Sr-85/mCi Rb-82</th>
<th>Total Elution Volume (Liters)*</th>
<th>Days Post Generator Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threshold</td>
<td>0.002</td>
<td>0.02</td>
<td>14</td>
<td>NA</td>
</tr>
<tr>
<td>Expiry</td>
<td>0.01</td>
<td>0.1</td>
<td>17</td>
<td>42</td>
</tr>
</tbody>
</table>

*The Total Elution Volume is defined as the total amount of Sodium Chloride Injection USP that has passed through the generator column which includes the total elution volumes for daily column wash, daily calibration, Sr-82/Sr-85 levels and the daily total volume for patient + waste.*
Rb-82 Operational Considerations

- Receive a new generator every 28 days (unless Sr breakthrough occurs)
- Fixed price of approximately $36K. The more patients, the less the unit cost
  - $16.98/pt for tubing
- Fast patient throughput is possible (45 minutes for a R/S pharmacological study)
- Can take up to 1.5 hours to QC generator every morning.
<table>
<thead>
<tr>
<th>Studies</th>
<th>Description</th>
<th>CPT</th>
<th>2015 National APC Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>S</td>
<td>Myocardial PET, perfusion, single study at rest and stress</td>
<td>78491</td>
<td>$1,286.23</td>
</tr>
<tr>
<td>S</td>
<td>Myocardial PET perfusion multiple study rest and stress</td>
<td>78492</td>
<td>$1,286.23</td>
</tr>
<tr>
<td>Q1</td>
<td>Cardiovascular stress test, exercise or pharmacological</td>
<td>93017</td>
<td>$238.04 ***</td>
</tr>
<tr>
<td>N</td>
<td>Rb-82/per dose</td>
<td>A9555</td>
<td>Packaged into APC</td>
</tr>
<tr>
<td>N</td>
<td>(Adenosine scan)</td>
<td>J0151</td>
<td>Packaged into APC</td>
</tr>
<tr>
<td>N</td>
<td>Regadenoson (Lexiscan)</td>
<td>J2785</td>
<td>Packaged into APC rate</td>
</tr>
</tbody>
</table>

N = Items and services packaged into APC Rate
Q1 = Packaged APC payment if billed on same date of services with an S, T or V status if not, paid separately.
S = Procedure or services not discounted when multiples
Rb-82 MPI: Not a Lost Leader

- Assumes 2 techs and 1 stress test supervisor (NP, PA)
- Schedule 1.5 hours for QC testing
- Schedule patients every 45 minutes for 8/day

- **Net revenue:** $2,572,000
  - 2000 pts/year
- **Salary:** $364,000
  - $50/tech; $75/LP)
- **Benefits:** $120,120
  - 33%
- **Generators** $432,000
- **Tubing:** $ 33,960
- **Other supplies:** $6,000
  - $3.00/pt.
- **R&M:** $200,000
  - 10% of purchase price
- **Total expenses:** $976,444
MIBI vs. 82-Rb

SPECT MPI with Mibi

PET MPI with 82-Rb
Amyloid Imaging

- Florbetapir
- Flutemetamol
- Florbetaben

**New research focus on Tau imaging**
- Beta Amyloid levels plateau but Tau increases.
# Amyloid Imaging

<table>
<thead>
<tr>
<th></th>
<th>Florbetapir</th>
<th>Flutemetamol</th>
<th>Florbetaben</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prototype</strong></td>
<td>$^{18}F$-18 (109.77 min 1/2 life)</td>
<td>$^{18}F$-18 (109.77 min 1/2 life)</td>
<td>$^{18}F$-18 (109.77 min 1/2 life)</td>
</tr>
<tr>
<td><strong>Target</strong></td>
<td>Amyloid Beta Peptide</td>
<td>Amyloid Beta Peptide</td>
<td>Amyloid Beta Peptide</td>
</tr>
<tr>
<td><strong>Mechanism for Retention</strong></td>
<td>Binds to beta amyloid plaque</td>
<td>Binds to beta amyloid plaque</td>
<td>Binds to beta amyloid plaque</td>
</tr>
<tr>
<td><strong>Availability</strong></td>
<td>FDA approval, 2012</td>
<td>FDA approval, 2013</td>
<td>FDA approval 2014</td>
</tr>
<tr>
<td><strong>Trade Name</strong></td>
<td>Amyvid</td>
<td>Vizamyl</td>
<td>Neuraceq</td>
</tr>
<tr>
<td><strong>Distributor</strong></td>
<td>Lily</td>
<td>G.E.</td>
<td>Piramal Imaging</td>
</tr>
<tr>
<td><strong>Amount injected</strong></td>
<td>370 MBq (10 mCi)</td>
<td>185 MBq (5 mCi)</td>
<td>300 MBq (8.0 mCi)</td>
</tr>
<tr>
<td><strong>Images Acquired</strong></td>
<td>30-50 min post inj</td>
<td>90 min post inj</td>
<td>45-130 min post inj</td>
</tr>
<tr>
<td><strong>CPT Code and NDC #</strong></td>
<td>A9586 / No NDC#</td>
<td>A9599</td>
<td>A9599</td>
</tr>
<tr>
<td></td>
<td>NDC# 17156-067-10 (10 ml)</td>
<td>NDC# 17156-067-30 (30 ml)</td>
<td>NDC# 54828-001-30</td>
</tr>
</tbody>
</table>
Regulatory and Reimbursement Environment for AD Imaging Agents

- FDA approval does NOT mean CMS approval
- FDA and CMS are two entirely different agencies, with different mission and goals
- FDA approves: Has it met efficacy (does it work like it is supposed to) and is it safe?
- CMS approves: can it demonstrate improved changes in outcomes and patient management?
  - Sometimes they are at cross purposes as is the case with AD imaging agents.
- May 1, SNMMI sent a compelling letter to CMS asking for distinct codes for all three
CMS Limited Coverage

- PET Beta Amyloid Imaging is promising in two scenarios
  - Can exclude AD in difficult clinical situations (AD vs. fronto-temporal lobe dementia)
  - Enrich clinical trials for AD drug treatments
- Will cover 1 PET scan/pt through a coverage with evidence development (CED) in clinical studies
  - CMS approves site
    - University of Kansas Medical School
    - UCLA
- In the past, Lily has supplied vouchers for dose.
Dopamine Transporter Imaging
I-123 Ioflupane (DaTScan)

- Detects degeneration of the dopaminergic nigro-striatal pathway
- Separates essential tremor from presynaptic Parkinsonian syndrome
- Concentrates in the dopamine transporters (DaT)
- DaT concentrations are low in Parkinson’s Disease and in Lewy Body Dementia
- DaT concentrations are usually normal in AD disease
Distribution of I-123 Ioflupane

Normal

Abnormal
Patient Prep and Protocol

- Med Rec essential (cocaine, amphetamines, ephedrine, phentermine, etc. decreasing binding to DaT
  - false positives possible
- Block thyroid 1 hr. pre injection
- Single dose 3-5 mCi delivered over 20 sec followed by saline push
- Scan 3-6 hrs. post injection
  - Each site should decide on a time for standardization in interpretations.
• Is a controlled substance (cocaine)
  – AU: DEA license **with address of isotope delivery site**
• Only ships T-F
  – Must cancel 48 business hours in advance by noon CST
• Dose is expensive. Rigorous scheduling/screening process. Consider charging for no shows
• CMS and privates reimburse but I-123 Ioflupane is bundled into APC.
  – A9584 and 78607
  – **Always** obtain pre-authorizations for private patients
• **ALWAYS** list A9584 on bill with a corresponding charge.
  – Allows true cost to be determined by CMS although 2 years behind.
Lung Agents

• In early 2014 the cost went up…
  – MAA vial 2158% more!!
  – MAA dose 933% more!
  – DTPA vial 748% more!
  – DTPA dose 209% More!
• Single supplier so market can not dictate price
• Update charge master with higher prices and always list on bill
• Never split a unit dose up. This is a serious violation
Lung Agents (Con’t.)

- Consider switching to PYP for aerosol
  - Off label but so is DTPA
  - Longer pulmonary retention with pyp compared to DTPA
  - Absorbed dose is > with pyp (0.33 rads/mCi to 0.10 rads/mCi with DTPA)

- Xe-133 is NOT going away: Lantheus and Cardinal distribution contract.
CCK Alternatives

• Consider using Ensure Plus instead of CCK.
  – Techs at our hospital can not give adjunctives so had to wait for a nurse.
    • Ensure Not a medication (yet!)
  – Wait at least 30 minutes post drink to image
  – Even though we have CCK now, we selectively use this
  – It’s cheaper
You Are Not in this Alone

- SNNMI has formed multiple task forces and meets regularly with:
  - White House to secure a reliable **and** national supply of Mo-99
    - NRU open until 2018!!!!
  - FDA to educate about differences between radioactive and non-radioactive meds so that our regulations are not nonsensical
  - FDA to create a more efficient and timely radio pharm approval
  - CMS to establish a more appropriate reimbursement scheme for radiopharmaceuticals
  - Third Party payers to educate, advise, and review policies as regards to Nuclear Medicine
  - DEA to eliminate requirement that DaTscan is a schedule II drug
WHERE THERE IS LIFE, THERE IS HOPE

STEPHEN HAWKING