“Into the Lion’s Den”
My Experience with Third Party Payers and Molecular Diagnostics

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Disclaimers/Disclosures

- I am a full-time employee of Invitae Corporation, a genetic testing company, from whom I receive salary and stock options
- Although the opinions expressed here are based on my experience working at Invitae, the opinions are my own and do not necessarily reflect those of Invitae

Anecdotes as Data

“The plural of anecdote is data”

- Raymond Wolfinger , Stanford Graduate Seminar (1969-1970)

“The plural of anecdote is not data”

- Bernstein, I. S. Metaphor, cognitive belief, and science. Behavioral and Brain Sciences 11:247-24 (1988).

Third Party Payers are NOT Monolithic
Each payer creates its own policies

- Medicare
- Large Private Payers (United, Aetna)
- The many “Blues”, large and small; some were acquired and belong to a large umbrella but still retain some autonomy, some are independent
- State Medicaid, managed Medicaid
- Etc. etc. etc.

MolDX does not dictate to most Insurers

But it does wield much influence

When it comes to Molecular Genetic Testing Many (?Most) Payers Play “Follow-the-Leader”

- MolDX – reviews evidence concerning whether to cover genetic tests – Directed by Dr. Elaine Jeter
- MolDX grew out of the work of Palmetto GBA, a subsidiary of Blue Cross Blue Shield of South Carolina. Palmetto is an AB Medicare Administrative Contractor (MAC).

When it comes to Molecular Genetic Testing Many (?Most) Payers Play “Follow-the-Leader”

- Noridian took over Jurisdiction 1 AB MAC region— California, Nevada, Hawaii, and the Pacific Territories
- MolDX program continues to be supported in jurisdiction 1 and has been added to Palmetto GBA’s Jurisdiction 11 contract (South Carolina, North Carolina, Virginia, and West Virginia).
- Other MACs may look to MolDX but they make their own Local Coverage Decisions (LCD)
- Many Private Insurers look to MolDX for guidance
- But remember: Medicare only covers affected individuals and not relatives at risk

MolDX and the new Code for Hereditary Breast and Ovarian Cancer by NGS

When applying for Local Coverage Decision

- Analytical Validity Data
- Clinical Interpretation concordance within and between labs (using Clinvar)
- Clinical Utility

Preliminary Pricing: $622 while paying >$2000 for old BRCA1/2 code

Complex Dynamic Among Concerned Parties

Patients and Providers

- Driven by Personal Utility concerns
- Looking to get their tests paid for

Payers

- Driven by Clinical Utility concerns
- Looking for utilization management
- Concerned about downstream costs engendered by testing

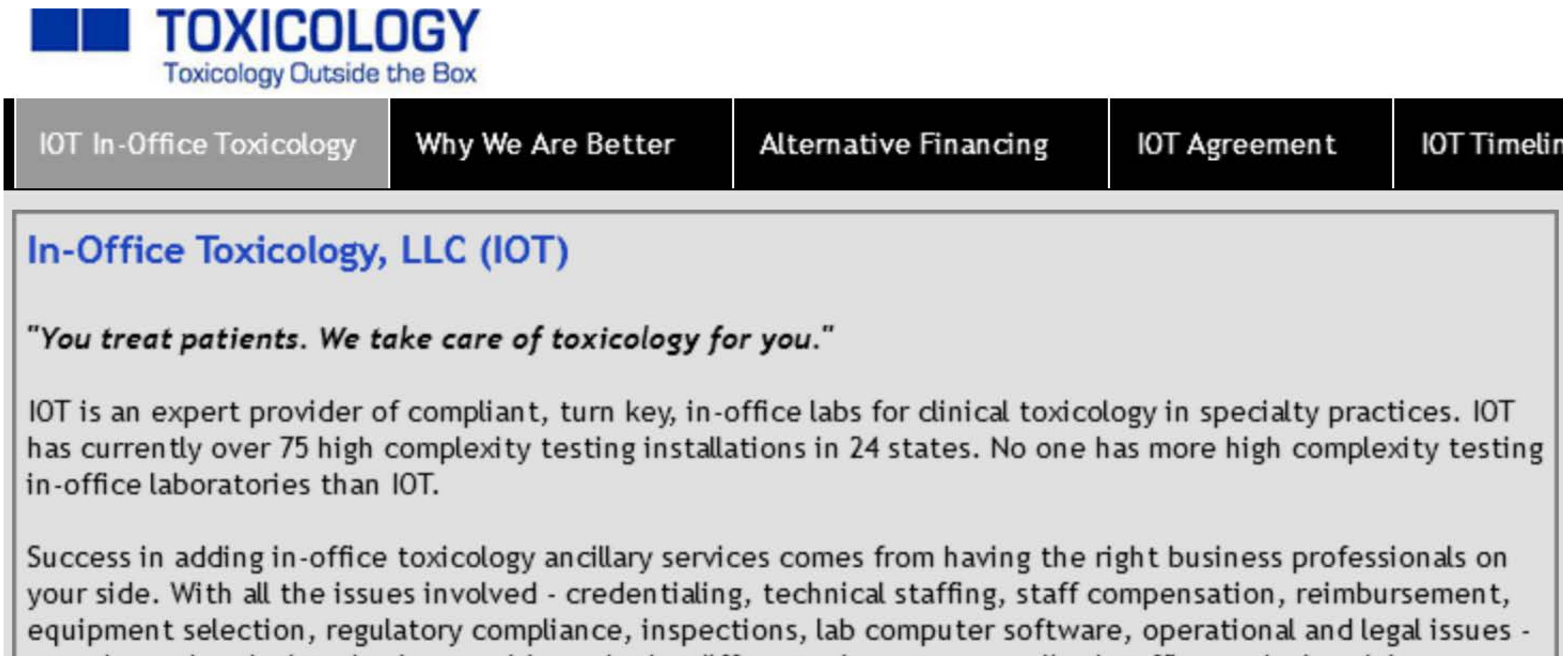
Lab

- Keep the lights on
- Get into contract with Payers
- Keep customers happy

Insurers' Previous Experience with Testing

Staggering under Code Stacking Burned by Drug Testing

The Toxicology Boom



Even More Complex Dynamic: Example of LDLR mutation testing and PCSK9 Inhibitors

Patients and Providers and Advocates

- Driven by Personal Utility concerns
- Looking to get their tests paid for

Payers

- Want genetic testing that will limit use of expensive therapies

Lab

- Keep the lights on
- Get into contract with Payers
- Keep customers happy

Drug Companies

- Don't want genetic testing that will limit use of expensive therapies

Summary

- Obtaining 3rd party payer coverage for genetic testing is a chaotic and fragmented process
- Some payers understand the field, others are clueless
- There is a theoretical bar of showing true clinical utility for the individual patient (alters management) but this bar is arbitrarily and haphazardly applied or disregarded by different payers
- Many payers are “fighting the last war” and worrying about panel testing because of code stacking in the past.
- Utilization management is a mantra but its implementation is rigid, bureaucratic, and contributes unnecessarily to increased health care costs