The purpose of this document is to provide simplified, up-to-date, and readily accessible guidance for primary care medical providers related to the prevention, diagnosis, and management of hepatitis B virus (HBV) infection, including hepatocellular carcinoma surveillance.

About the HBV Primary Care Workgroup
This guidance was developed by the Hepatitis B Primary Care Workgroup, a multidisciplinary panel of national experts in the field of viral hepatitis B, including representation from hepatology, infectious diseases, pharmacy, primary care, public health, and other national organizations. The workgroup was organized by the National Taskforce on Hepatitis B in partnership with the San Francisco Hep B Free — Bay Area and Project ECHO™ and did not receive any outside funding.

Collaboration with University of Washington
This guidance was produced in collaboration with the University of Washington’s National Hepatitis Training Center (HTC). The UW HTC will host and feature the most current version of these guidelines on the free Hepatitis B Online website (hepatitisB.uw.edu). The UW HTC is funded by the Centers for Disease Control and Prevention (CDC).

Chronic Hepatitis B Testing and Management Algorithm

Screen for chronic hepatitis B virus (HBV) infection with:
> Hepatitis B surface antigen (HBsAg), and
> Hepatitis B surface antibody (anti-HBs), and
> Hepatitis B core antibody (anti-HBc): Total or IgG

If pregnant, see Perinatal HBV Management (page 8)
If treatment candidate, see Preferred HBV Antiviral Treatment (page 6)

If susceptible to HBV as indicated by anti-HBc(−) & anti-HBs(−), vaccinate
If prior HBV infection as indicated by anti-HBc(+), counsel on HBV reactivation risk

1 Do not include anti-HBc IgM in HBV screening panel unless suspect acute HBV.
# Hepatitis B Virus (HBV) Serology Interpretation and Management

<table>
<thead>
<tr>
<th>HBsAg</th>
<th>Anti-HBc (Total or IgG)</th>
<th>Anti-HBs</th>
<th>Interpretation</th>
<th>Management</th>
</tr>
</thead>
</table>
| +     | +                       | −/+     | Current infection | > See *Evaluation, Counseling, Management, Treatment, and HCC Surveillance* (pages 4, 5, 6, 7)  
> Refer household and sexual contacts for HBV screening; if susceptible, vaccinate |
| −     | +                       | +       | Prior infection with immune control | > No transmission risk; HBV dormant in liver  
> Reactivation risk if on immunosuppressive medications |
| −     | +                       | −       | Prior infection or occult infection¹ | > If immunocompetent², counsel as prior infection above  
> Reactivation risk if on immunosuppressive medications  
> If immunocompromised, check HBV DNA for occult infection¹ |
| −     | −                       | +       | Immune from prior vaccination | Protected for life. No need for booster vaccine |
| −     | −                       | −       | Susceptible | VACCINATE³ |

¹ Occult HBV infection is defined by the presence of detectable HBV DNA in persons who are negative for HBsAg. Patients with occult HBV infection should be managed similarly to those with current infection, but note that most have very low HBV DNA levels and do not need HBV treatment.

² Consider HBV vaccination for persons with no known risk factors or persons not from an area of intermediate or high endemicity as this may represent a false-positive anti-HBc result. The rate of false positive anti-HBc is less than 2 per 1,000 tests using current assays.

³ For “susceptible” persons considered at high risk for HBV who previously received a complete vaccine series without follow-up serologic testing, acceptable management options include (a) give a booster vaccine dose followed by serologic testing 1 to 2 months later, with completion of a full vaccine series if the post-booster anti-HBs test remains negative or (b) give full vaccine series followed by post-vaccination serologic testing 1 to 2 months after the last vaccine dose.

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## Post-Vaccination Serologic Testing

Assessment of the response to HBV vaccination with a post-vaccination serologic test of anti-HBs between 1 and 2 months after the final dose of vaccine should be obtained in all of the following adult groups at high risk for HBV:

> Health care personnel and public safety workers  
> Sexual and household contacts of HBsAg(+) persons  
> Hemodialysis patients  
> Persons who inject drugs  
> Persons with HIV and other immunocompromising conditions
## Initial Evaluation of the HBsAg(+) Patient

<table>
<thead>
<tr>
<th>History/Examination</th>
<th>Routine Laboratory Tests</th>
<th>Serology/Virology</th>
<th>Imaging/Staging Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Symptoms/signs of cirrhosis</td>
<td>□ CBC comprehensive</td>
<td>□ HBeAg/anti-HBe</td>
<td>□ Abdominal ultrasound</td>
</tr>
<tr>
<td>□ Alcohol and metabolic risk factors</td>
<td>□ Comprehensive metabolic panel including:</td>
<td>□ HBV DNA</td>
<td>□ Elastography (e.g. FibroScan)</td>
</tr>
<tr>
<td>□ Family history of hepatocellular carcinoma (HCC)</td>
<td>□ AST/ALT</td>
<td>□ Anti-HAV (total or IgG) to determine need for vaccination if none documented</td>
<td>or Serum fibrosis assessment¹ (e.g. APRI, FibroSure, FIB-4)</td>
</tr>
<tr>
<td>□ Hepatitis A vaccination status</td>
<td>□ Total bilirubin</td>
<td>□ Anti-HCV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Alkaline phosphatase</td>
<td>□ Anti-HDV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Albumin</td>
<td>□ Anti-HIV</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Creatinine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ INR</td>
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</tr>
</tbody>
</table>

1 APRI and FIB-4 scores can be calculated using platelet count and AST and ALT from routine labs. Calculators with score interpretation are available. See Hepatitis B Online APRI calculator and FIB-4 calculator. FibroSure and FibroTest are commercially available blood tests that can be ordered as well.

## Counseling of the HBsAg(+) Patient

1. Give a plan for follow-up care. Patients will need regular (minimum every 6 months) follow-up and monitoring for disease progression.
2. Educate and counsel on the long-term implications of chronic HBV infection (e.g., cirrhosis and hepatocellular carcinoma).
3. Advise patient to inform all current and future medical providers of their HBsAg-positive status, especially if they ever need treatment for cancer or any immunologic condition such as rheumatoid arthritis or other immune disorders.
4. Counsel to avoid or limit alcohol use.
5. Advise to optimize body weight and address metabolic complications, including control of diabetes and dyslipidemia (to prevent concurrent development of metabolic syndrome and fatty liver).
6. Provide education on how to prevent transmission of HBV to others.

### Persons with chronic HBV:

<table>
<thead>
<tr>
<th>Should:</th>
<th>Use condoms to prevent HBV transmission during sexual intercourse with partners who are susceptible to HBV infection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ Verify that sexual contacts, household contacts, family members, or injection partners are screened and vaccinated</td>
<td></td>
</tr>
<tr>
<td>▶ Cover open cuts and scratches</td>
<td></td>
</tr>
<tr>
<td>▶ Clean blood spills with diluted bleach (1:10)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Should NOT:</th>
<th>Share toothbrushes, razors, nail clippers, or earrings</th>
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</thead>
<tbody>
<tr>
<td>▶ Share injection equipment</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Can:</th>
<th>Share glucose testing equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>▶ Share food and utensils, or kiss others</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Can:</th>
<th>Pursue educational or career opportunities without limitations, including work as a health care professional</th>
</tr>
</thead>
</table>
# Management of the HBsAg(+) Patient

<table>
<thead>
<tr>
<th>Cirrhosis</th>
<th>HBV DNA (IU/mL)</th>
<th>ALT (U/L)</th>
<th>Management</th>
</tr>
</thead>
</table>
| YES       | Any             | Any       | > TREAT with antiviral medication (page 6)  
> Monitor HBV DNA and ALT every 6 months  
> Refer to specialist for screening endoscopy and, if needed, for other cirrhosis-related complications  
> HCC surveillance, including in persons who become HBsAg(-) (page 7)  
> All patients with decompensated cirrhosis should be promptly referred to a hepatologist |

| Elevated³ | >2,000          | > Monitor HBV DNA and ALT every 6 months  
> Monitor HBeAg and anti-HBe every 6 months in patients who are HBeAg+ at time of treatment initiation to evaluate for seroconversion from HBeAg(+)/anti-HBe(-) to HBeAg(-)/anti-HBe(+)  
> Check HBsAg annually if/when HBeAg negative |

| NO        | Normal          | > Monitor HBV DNA and ALT every 6 months  
> Liver fibrosis assessment every 2 to 3 years |

| Elevated³ | ≤2,000          | > Evaluate other etiologies for elevated ALT  
> Monitor HBV DNA and ALT every 6 months |

| Normal    | > Monitor HBV DNA and ALT every 6 months and HBsAg every 1 year for seroclearance |

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1 In contrast to other HBV guidelines that have incorporated HBeAg status into treatment initiation decisions for non-cirrhotic HBsAg(+) patients, this guidance for primary care providers uses only HBV DNA and ALT to determine initial treatment indication in non-cirrhotic HBsAg(+) patients.

2 Patients should be considered to have decompensated cirrhosis and promptly referred to a hepatologist if any of the following are present: jaundice, ascites, variceal hemorrhage, hepatic encephalopathy, or a Child-Turcotte-Pugh (CTP) score ≥7 (see Hepatitis B Online CTP calculator).

3 Elevated ALT defined as >25 U/L in females and >35 U/L in males that is persistent for at least 3 to 6 months.

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### Assessing Treatment Response and Endpoints for Antiviral Discontinuation

After initiation of HBV antiviral, recheck HBV DNA every 3 months until undetectable, then every 6 months once undetectable. If the patient does not achieve undetectable HBV DNA after 1 year of antiviral therapy and the HBV DNA levels are not downtrending, obtain expert consultation or refer to a specialist.

> Persons with cirrhosis: Do not stop antiviral treatment, unless guided by expert consultation.

> Persons without cirrhosis and HBeAg(+) at baseline: Patients with persistent undetectable HBV DNA, normal ALT, and persistent HBeAg(-) and anti-HBe(+) 1 year after HBeAg seroconversion [from HBeAg(+)/anti-HBe(-) to HBeAg(-)/anti-HBe(+)] may trial off antiviral treatment.

> Persons without cirrhosis and HBeAg(-) at baseline: Continue antiviral treatment until HBsAg clearance.
### Preferred Antiviral Treatment of the HBsAg(+) Patient

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adult dose</th>
<th>Pregnancy category¹</th>
<th>Side effects</th>
<th>Monitoring on treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entecavir (Baraclude)</td>
<td>Standard: 0.5 mg by mouth daily</td>
<td>Formerly FDA category C</td>
<td>Headache, fatigue, dizziness, nausea reported in ≥3%</td>
<td>Adjust dose with CrCl &lt;50 mL/min</td>
</tr>
<tr>
<td></td>
<td>Decompenated liver disease: 1 mg by mouth daily</td>
<td>Limited pregnancy exposure, pregnancy exposure registry available</td>
<td>Post-marketing surveillance include infrequent reports of:</td>
<td>Avoid in pregnant patients</td>
</tr>
<tr>
<td></td>
<td>Take 2 hours before or after food</td>
<td>Insufficient human data to assess risk of major birth defects</td>
<td>&gt; lactic acidosis</td>
<td>Avoid in patients with prior exposure to lamivudine or known lamivudine resistance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No adverse effects observed in animal studies</td>
<td>&gt; severe hepatomegaly</td>
<td>Lactic acid levels if clinical concern</td>
</tr>
<tr>
<td>Tenofovir disoproxil fumarate (TDF) Viread</td>
<td>300 mg by mouth daily</td>
<td>Formerly FDA category B</td>
<td>Nausea (9%)</td>
<td>Adjust dose with CrCl &lt;50 mL/min</td>
</tr>
<tr>
<td></td>
<td>Take without regard to food</td>
<td>Pregnancy exposure registry available</td>
<td>Post-marketing surveillance include infrequent reports of:</td>
<td>Serum creatinine at baseline; if at risk for renal impairment, serum creatinine and phosphorus, and urine glucose and protein at least annually</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Extensive data from pregnant women with HIV or HBV infections indicate no increase in pregnancy complications or major birth defects</td>
<td>&gt; nephropathy</td>
<td>Consider bone density study at baseline and during treatment in persons with history of fracture or risks for osteopenia</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; Fanconi syndrome</td>
<td>Lactic acid levels if clinical concern</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; osteomalacia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>&gt; lactic acidosis</td>
<td></td>
</tr>
<tr>
<td>Tenofovir alafenamide (TAF) Vemldy</td>
<td>25 mg by mouth daily</td>
<td>No human data in pregnancy</td>
<td>Headache (12%)</td>
<td>Avoid with CrCl &lt;15 mL/min if not receiving hemodialysis</td>
</tr>
<tr>
<td></td>
<td>Take with food</td>
<td>No adverse effects observed in animal studies</td>
<td>Lactic acidosis/ severe hepatomegaly with steatosis is a warning for tenofovir AF due to rare reports with use of tenofovir DF</td>
<td>Dose after HD in those on HD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>If at risk for renal impairment, serum creatinine and phosphorus, and urine glucose and protein as clinically indicated.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lactic acid levels if clinical concern</td>
</tr>
</tbody>
</table>

¹ In 2015, the US FDA replaced the pregnancy risk designation by letters A, B, C, D, and X with more specific language on pregnancy and lactation. This new labeling is being phased in gradually and, to date, only tenofovir alafenamide includes these additional data.

² Decompensated liver disease defined as Child-Turcotte-Pugh (CTP) ≥7 (see Hepatitis B Online CTP calculator).
Hepatocellular Carcinoma (HCC) Surveillance

Indications for HCC Surveillance
Persons with chronic HBV at increased risk for hepatocellular carcinoma (HCC) who require routine surveillance include:

- All persons with cirrhosis, including persons who become HBsAg(-)
- The following populations, even in the absence of cirrhosis:
  - Asian or black/African\(^1\) males older than 40 years of age
  - Asian females older than 50 years of age
  - Persons with a family history of HCC
  - Persons with hepatitis D virus coinfection

Recommended HCC Surveillance Method
HCC surveillance should be performed in the primary care setting with liver ultrasound with or without serum alpha-fetoprotein (AFP)\(^2\) every 6 months. More frequent monitoring or other imaging modalities such as computed tomography (CT) or magnetic resonance imaging (MRI), with and without contrast, may be indicated to further evaluate new liver lesions.

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\(^1\) More recent African immigrants may be at increased risk for HCC and some experts begin HCC surveillance at age <40 years.

\(^2\) Wait at least 6 months after pregnancy before using AFP for HCC surveillance.
Screen for HBV during each pregnancy\(^1\)

**HBsAg(+)\(^2\)**

Screen all household and sexual contacts for HBV

See Initial Evaluation, Counseling, Management, and Treatment of the HBsAg(+) Patient (pages 4, 5, 6)

**If treatment indicated for active HBV**, start TDF and continue until stopping criteria met\(^3\)

**If not on HBV treatment**, recheck HBV DNA at 26 to 28 weeks gestation age to determine MTCT risk

- HBV DNA \(\leq 200,000\) IU/mL: Low risk for MTCT, no HBV antiviral indicated
- HBV DNA \(> 200,000\) IU/mL: High risk for MTCT, start TDF between 28 to 32 weeks

**Stop TDF at time of birth and monitor for ALT flares at least every 3 months for 6 months**

**ALL infants of HBsAg(-) women should:**
- Receive birth dose HBV vaccine within 24 hours of birth

**ALL infants of HBsAg(+) women should:**
- Receive birth dose HBV vaccine and HBIG within 12 hours of birth
- Complete HBV vaccine series on schedule\(^5\)
- Receive a post-vaccination serology test at 9 to 12 months of age with HBsAg and anti-HBs to assess for mother-to-child transmission and confirm immunity

**HBV and Breastfeeding**

All HBsAg(+) mothers, including those on TDF, should be educated on the value and safety of breastfeeding and that HBV is not transmitted through breastmilk.

Breastfeeding mothers with cracked nipples should practice proper nipple care and be informed that HBV vaccination and HBIG will protect against transmission from such blood exposures.

1. All pregnant women should be screened for HBV (with HBsAg at minimum) during each pregnancy, regardless of prior HBV screening results. For complete HBV profile, add anti-HBs to determine immunity and anti-HBc IgG or total for evidence of prior infection.
2. All HBsAg(+) mothers should be educated on the importance of regular follow-up during and after the pregnancy so that appropriate HBV monitoring can occur.
3. Engerix-B and Recombivax-HB are safe to give at any time during pregnancy. Due to insufficient data, Heplisav-B vaccine is not recommended during pregnancy.
4. If an HBsAg(+) woman is already on antiviral therapy when she becomes pregnant, the antiviral regimen should immediately be switched to tenofovir disoproxil fumarate (if she is not already taking this medication).
5. For infants weighing less than 2,000 grams, the birth dose does not count toward the vaccine series and the infant should receive another HBV vaccine one month after birth.
Selected References


**HBV Primary Care Workgroup Members***

**HBV GUIDANCE CO-CHAIRS**
Amy S. Tang, MD  
Karla Thornton, MD, MPH

**HEPATOLOGY**
Eric W. Chak, MD, MPH  
Assistant Professor of Medicine  
Division of Gastroenterology and Hepatology  
UC Davis Comprehensive Cancer Center  
Robert G. Gish, MD  
Medical Director  
Hepatitis B Foundation  
Anna S. Lok, MD  
Alice Lohrman Andrews Research Professor of Hepatology  
Professor of Internal Medicine  
Director of Clinical Hepatology  
Assistant Dean for Clinical Research  
University of Michigan Medical School  
Brian J. McMahon, MD  
Medical and Research Director, Liver Disease and Viral Hepatitis Program  
Alaska Native Medical Center  
Lewis R. Roberts, MB, ChB, PhD  
Peter and Frances Georgeson Professor of Gastroenterology Cancer Research  
Division of Gastroenterology and Hepatology  
Mayo Clinic  
Norah A. Terrault, MD, MPH  
Professor of Medicine  
Chief, Division of Gastroenterology and Liver  
Keck School of Medicine, University of Southern California

**INFECTIOUS DISEASES**
Camilla S. Graham, MD, MPH  
Co-Director, Viral Hepatitis Center  
Beth Israel Deaconess Medical Center  
David H. Spach, MD  
Professor of Medicine  
Division of Infectious Diseases  
University of Washington  
Mark S. Sulkowski, MD  
Medical Director, Viral Hepatitis Center  
Professor of Medicine  
John Hopkins University and Medicine  
Karla Thornton, MD, MPH  
Professor, Division of Infectious Diseases  
Senior Associate Director, Project ECHO Viral Hepatitis Programs  
University of New Mexico Health Science Center

**PHARMACY**
Paulina Deming, Pharm D  
Associate Professor of Pharmacy Practice  
Assistant Director, Project ECHO Viral Hepatitis Programs  
University of New Mexico Health Science Center

**PRIMARY CARE**
Richard Andrews, MD, MPH  
Co-Chair, National Taskforce on Hepatitis B  
Viral Hepatitis Director  
HOPE Clinic, Houston, TX  
Amy S. Tang, MD  
Co-Chair, National Taskforce on Hepatitis B  
Director of Immigrant Health  
North East Medical Services, San Francisco, CA  
Grace Wang, MD, MPH  
Family Physician  
International Community Health Services  
Su Wang, MD, MPH  
Medical Director, Center for Asian Health  
Saint Barnabas Medical Center  
President-Elect, World Hepatitis Alliance

**PUBLIC HEALTH**
Moon S. Chen Jr., PhD, MPH  
Professor and Associate Director for Population Sciences and Community Outreach/Engagement  
UC Davis Comprehensive Cancer Center  
Chari Cohen, DrPH, MPH  
Senior Vice President  
Hepatitis B Foundation  
Stuart Fong, MD  
Governing Counsel Chair  
San Francisco Hep B Free – Bay Area  
Aaron M. Harris, MD, MPH  
Team Lead (Acting), Prevention Branch  
Division of Viral Hepatitis, Centers for Disease Control and Prevention  
Rita K. Kuwahara, MD, MIH  
Hepatitis B Policy Fellow  
Association of Asian Pacific Community Health Organizations (AAPCHO)  
Richard So, MPH, MPA  
Executive Director  
SF Hep B Free – Bay Area  
Ann Winters, MD  
Medical Director, Viral Hepatitis Program  
New York City Department of Health and Mental Hygiene

**Additional Workgroup Support from:**
Melanie Bird, PhD  
Clinical Policies Strategist  
American Academy of Family Physicians  
Jennifer Lim  
Data Manager  
South Central AIDS Education and Training Center (SCAETC)  
ECHO Institute  
University of New Mexico Health Sciences Center  
Amir Qaseem, MD, PhD  
Vice President, Clinical Policy and Center for Evidence Reviews  
American College of Physicians  
Amy Trang, PhD, M.Ed  
Administrator  
National Taskforce on Hepatitis B

* Committee participation in the HBV Primary Care Workgroup does not constitute organizational endorsement of the recommendations or conclusions.
Disclosures

The following workgroup members had no disclosures: Melanie Bird, PhD; Eric W. Chak, MD, MPH; Moon S. Chen Jr., PhD, MPH; Paulina Deming, PharmD; Stuart Fong, MD; Camilla S. Graham, MD, MPH; Aaron M. Harris, MD, MPH; Rita K. Kuwahara, MD, MIH; Jennifer Lim; Amir Qaseem, MD, PhD; Richard So, MPH, MPA; David H. Spach, MD; Karla Thornton, MD, MPH; Amy Trang, PhD, M.Ed; Grace Wang, MD, MPH.

<table>
<thead>
<tr>
<th>Workgroup Member Name</th>
<th>Research Grant or Research Support</th>
<th>Speakers Bureaus/ Honoraria</th>
<th>Consultant/ Advisory Board</th>
<th>Stock Shareholder (directly purchased)</th>
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</thead>
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<tr>
<td>Robert G. Gish, MD</td>
<td>Gilead Sciences</td>
<td>AbbVie, Bayer Pharmaceuticals, Bristol-Meyers Squibb, Dova Pharmaceuticals, Eisai, Gilead Sciences, Intercept Pharmaceuticals</td>
<td>See footnote 1</td>
<td>Athenaex, Cocrystal Pharma, Ribosciences, Triact Therapeutics See footnote 2</td>
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<tr>
<td>Anna S. Lok, MD</td>
<td>Assembly Biosciences, Bristol-Meyers Squibb, Gilead Sciences, TARGET PharmaSolutions</td>
<td>CLEAR, Gilead Sciences, GlaxoSmithKline, Huahui, Roche, Spring Bank Pharmaceuticals, TARGET PharmaSolutions, Viravaxx</td>
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<td>ARIAD Pharmaceuticals, Exact Sciences, Gilead Sciences, RedHill Diagnistics, Exact Sciences, Bristol-Meyers Squibb, Gilead Sciences, Janssen, Medimmune, Merck. in the last two years, Dr. Robert G. Gish has been a consultant or an advisor to: Abbvive, Access Biologicals, Alexion Pharmaceuticals, Arrowhead Pharmaceuticals, Bayer Pharmaceuticals, Biocollections Worldwide, Bristol-Meyers Squibb, Eiger BioPharmaceuticals, Eisai, ENYO Pharma, eStudySite, Fujifilm/Wako, Gilead Sciences, HepaTx, HepQua, Intercept Pharmaceuticals, Ionis Pharmaceuticals, Janssen, Laboratory for Advanced Medicine, Lilly, Merck, Salix Pharmaceuticals, Shionogi, Quest Diagnostics,Trimaran Pharma, Viking Therapeutics.</td>
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<td>NYC Hep B Coalition Advisory Board, PRIME</td>
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1 Dr. Robert G. Gish’s current activity with scientific or clinical advisory boards: Abbott, Abbvie, Arrowhead Pharmaceuticals, Bayer Pharmaceuticals, Dova Pharmaceuticals, Eiger BioPharmaceuticals, ENYO Pharma, Hatch Biofund, HepQuant, Intercept Pharmaceuticals, Janssen, Medimmune, Merck. In the last two years, Dr. Robert G. Gish has been a consultant or an advisor to: Abbvive, Access Biologicals, Alexion Pharmaceuticals, Arrowhead Pharmaceuticals, Bayer Pharmaceuticals, Biocollections Worldwide, Bristol-Meyers Squibb, Eiger BioPharmaceuticals, Eisai, ENYO Pharma, eStudySite, Fujifilm/Wako, Gilead Sciences, HepaTx, HepQuant, Intercept Pharmaceuticals, Ionis Pharmaceuticals, Janssen, Laboratory for Advanced Medicine, Lilly, Merck, Salix Pharmaceuticals, Shionogi, Quest Diagnostics, Trimaran Pharma, Viking Therapeutics.

2 Dr. Robert G. Gish’s stock options: Arrowhead Pharmaceuticals, Athenex, Eiger BioPharmaceuticals, HepQuant

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